arthrosurface	Clinical Evaluation Report Update

Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) Update

AS-001, AS-001B, AS-001C, AS-001H, AS-001HA and AS-004 CER

October 07, 2021

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Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) Clinical Evaluation Report: Update

Disclaimer

The findings and conclusions are considered to be an accurate representation of the available scientific (or other) information. The use of company or product name(s) is for identification only and does not constitute endorsement or recommendations for use.

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Revision History

Date	Description
Feb 7, 2017	Update to HemiCAP Total Shoulder Resurfacing System CER dated May 1, 2016 to align with requirements of Rev 4 of MEDDEV 2.7.1.
October 18, 2019	Update to HemiCAP Total Shoulder Resurfacing System CER dated February 7, 2017 to include all Arthrosurface shoulder systems, new device safety related information from Arthrosurface database and/or newly published data from clinical literature.
July 31, 2020	Revised to meet requirements of TGA's Clinical Evidence Guidelines for Medical Devices Version 1.0 and for EU submission for CE marking of OVOMotion.
August 27, 2020	Minor typo and formatting edits (to the above recent revision) for TGA submission.
December 14, 2020	Revised to include estimated date of next update, and to include data from post-market clinical study in section 5.3.1
October 07, 2021	Updated to include Appendix G for TGA response to query on application for device approval in Australia

Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) Clinical Evaluation Report: Update

Executive Summary

This report update was prepared to evaluate the performance and safety of the Arthrosurface Shoulder Arthroplasty Systems, i.e., HemiCAP Shoulder, OVO, OVOMotion and GRS (Glenoid Resurfacing System), manufactured by Arthrosurface, Inc., based on a review of clinical data. The evaluation was conducted in accordance with Arthrosurface procedure (AS 91-07 Clinical Evaluation Report Development) and *MEDDEV 2.7.1 Rev. 4, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC.*

The Clinical Evaluation of Arthrosurface Shoulder Arthroplasty Systems evaluated the compliance of the Product with the Essential Requirements (ER) in accordance with MEDDEV 2.7.1. The following Essential Requirements were specifically addressed:

- ER1: Various clinical evaluation data sources (including a Literature Review) were evaluated to identify any new clinical safety risks associated with the intended use that were not already addressed by the risk analysis of the Arthrosurface Shoulder Arthroplasty Systems.
- ER3: A Literature Review of clinical data from comparable devices was conducted to demonstrate that the devices resulted in clinical outcomes that met the intended use of Arthrosurface Shoulder Arthroplasty Systems.
- ER4: A Literature Review of clinical data from comparable devices was conducted to evaluate the long-term safety and function of the devices.
- ER6: Various clinical evaluation data sources and the Arthrosurface Shoulder Arthroplasty Systems' risk analysis were reviewed to demonstrate that any undesirable side-effects were acceptable when weighed against the devices' performance (Risk/Benefit analysis).

For hemiarthroplasty, the HemiCAP Shoulder, OVO and OVOMotion are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. For total shoulder arthroplasty, the OVO, OVOMotion and GRS are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. All implant devices are single-use implants intended to be used with bone cement.

Clinical data from technical journals and databases maintained by regulators were used to establish the performance and safety of this category of devices (considering all manufacturers). The HemiCAP Shoulder, OVO, OVOMotion and GRS are FDA cleared for use in the U.S. Product complaints specific to these implant systems were collected from both regulator databases and the Arthrosurface complaints management system.

Clinical data associated with hemi or total shoulder arthroplasty, in general, were evaluated to assess safety and performance of this category of medical devices.

The evaluation of clinical data related to these issues supports the continued safety and performance of the Arthrosurface Shoulder Arthroplasty Systems for the stated indications for use.

The assessment of the safety of the Arthrosurface Shoulder Arthroplasty Systems was based on a review of information provided by Arthrosurface (i.e., complaint data, risk management file, and accompanying documents) and safety databases maintained by regulators.

The risks associated with the Arthroplasty Shoulder Arthroplasty Systems appear to be comparable to risks associated with similar devices, and frequency of complaints and revisions is low. The Risk Management Reports for these systems identify that the overall residual risk for these devices was found to be acceptable.

The evidence supports the continued performance and safety of the Arthrosurface Shoulder Arthroplasty Systems. No evidence was found that would suggest that the device would not perform as expected, or not be safe for use for its intended performance.

The next update to this CER is estimated to commence in March 2022, with the updated report planned to be documented by June 2022.

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Appendices:

Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) Clinical Evaluation Report: Update

1. Introduction

This clinical evaluation update of the Arthrosurface Shoulder Arthroplasty Systems manufactured by Arthrosurface, Inc., is based on a review of clinical data. The evaluation was conducted in accordance with the Arthrosurface, Inc. procedure *AS 91-07 Clinical Evaluation Report Development* and MEDDEV 2.7.1 Rev. 4, June 2016: *Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC.*

NOTE: The previous CER update entitled HemiCAP Total Shoulder Resurfacing System dated February 7, 2017 included only the OVO/GRS Total Shoulder Arthroplasty System. The present update considers all of the Arthrosurface, Inc. Shoulder Arthroplasty Systems, i.e., the HemiCAP Shoulder, OVO, OVOMotion and GRS. The HemiCAP Shoulder, OVO and OVOMotion are indicated for hemiarthroplasty, and the OVO or OVOMotion in combination with the GRS are also indicated for total shoulder arthroplasty.

The body of this report contains a summary of the results of this evaluation. As appropriate, relevant information provided by Arthrosurface has been incorporated into this report. Detailed information and clinical data summaries generated during the course of this evaluation are included in the report appendices.

2. Scope of the Clinical Evaluation

2.1. Product Description

Device Description and Mechanism of Action

Arthrosurface Shoulder Arthroplasty Systems – Overview

The Arthrosurface Shoulder Arthroplasty Systems addressed in this Clinical Evaluation Report comprise:

- HemiCAP Shoulder Hemiarthroplasty System
- OVO Hemiarthroplasty or Total (with GRS) Arthroplasty System
- OVOMotion Hemiarthroplasty or Total (with GRS) Arthroplasty System
- GRS Total Arthroplasty System (with OVO or OVOMotion)

The Arthrosurface Shoulder Arthroplasty Systems are comprised of the following components:

- HemiCAP Shoulder Articular Components (FIG 1)
- HemiCAP Shoulder Taper Post Components (FIG 1)

FIG 1: HemiCAP Shoulder Articular Components with Taper Post Components

- OVO Articular Components (FIG 2)
- OVOMotion Articular Components (FIG 2)
- OVO/OVOMotion Taper Post Component (FIG 2)

FIG 2: OVO (L) and OVOMotion Articular Components with OVO/OVOMotion Taper Post Component

- GRS Articular Components (FIG 3)

FIG 3: GRS Articular Components (L: Single/Partial Component; R: Double/Full Component)

- Instrumentation Kits (for the HemiCAP Shoulder, OVO, OVOMotion and GRS systems)

Instructions for the safe use of the Arthrosurface Shoulder Arthroplasty Systems are provided in the *HemiCAP Shoulder Hemiarthroplasty System (PN 3001-2000, 3001-2002), OVO Shoulder Arthroplasty System (PN 3001-2020, 3001-2021, 3001-2022), OVOMotion Shoulder Arthroplasty System (PN 3001-2023)* and *GRS Shoulder Arthroplasty System (PN 3001-2010)*. These IFUs provide a description of the systems and their components, a list of materials, indications for use, contraindications, warnings, precautions, possible adverse effects, and a description of the sterilization method. The various instrument kit IFU's for these systems are provided via PN's 0020-0010, 0020-0016 and 0020-0017.

The Technique Guides – *HemiCAP Shoulder Hemiarthroplasty (PN 3001-3000, 3001-3007, 3001-3012), OVO/GRS Shoulder Arthroplasty (PN 3001-3009) and OVO/OVOMotion/GRS Shoulder Arthroplasty (PN 3001-3013)* provide guidance for the conduct of the Arthrosurface Shoulder Arthroplasty Systems. (The Technique Guides are included in Appendix C.)

Arthrosurface Shoulder Arthroplasty Systems – Description

The Arthrosurface Shoulder Arthroplasty Systems provide a surgical method for the treatment of localized cartilage lesions and defects, and partial or total arthritis in the shoulder joint. These systems are comprised of four elements; a three-dimensional mapping technology, a set of instruments to map and prepare the damaged area, cobalt-chrome and titanium humeral implants, and ultrahigh molecular weight polyethylene (UHMWPE) glenoid implants (for use with OVO and OVOMotion only). The systems precisely align the surface of the implant to the contours of the patient's articular cartilage surface, thus filling the defect and restoring a smooth and continuous articular surface in case of the HemiCAP shoulder hemiarthroplasty or replacing the entire cartilage of the humerus in case of a OVO/OVOMotion shoulder hemiarthroplasty, or along with a part of the glenoid cartilage in case of a total shoulder arthroplasty in combination with the GRS. These systems have been developed to be utilized via minimally disruptive surgical techniques and are to be used with their respective instrument kits for proper application.

The stemless articular implants are available in several sizes and surface curvatures, are designed to allow for a minimum amount of bone and soft tissue resection and offer a variety of offset sizes for the treating physician to select from at the time of surgery allowing a high degree of precision and flexibility in sizing and fitting the articular components to the existing anatomy.

The HemiCAP Shoulder Articular Components comprise of 37 anatomically matched symmetrical and asymmetrical implant convexities. The HemiCAP is available in four diameters, 25 mm, 30 mm, 35 mm and 40 mm, and multiple offsets ranging from 2.5 mm x 2.5 mm to 5.0 mm x 5.0 mm (for the 25 mm), 4.5 mm x 4.5 mm to 7.0 mm x 7.0 mm (for the 30 mm), 6 mm x 6 mm to 9.0 mm x 10.0 mm (for the 35 mm) and 8.0 mm x 8.0 mm to 12.0 mm x 12.0 mm (for the 40 mm). A 9/12.5 mm x 35 mm taper post is used with the 25 mm and 30 mm articular components, a 10/13.5 mm x 31 mm taper post is used with the 35 mm articular components; a 10/13.7 mm x 32 mm taper post is used with the 40 mm articular components for fixation.

The stemless HemiCAP shoulder articular components are designed to minimize bone resection, providing replacement of a focal cartilage lesion with a contiguous, lubricious articulating surface so as to negate the need for removal of the entire articular surface of the native humeral head.

The OVO and OVOMotion Articular Components are available in multiple diameters and offset sizes ranging from 46 mm x 42 mm to 58 mm x 54 mm. A 12/15.6 mm x 32 mm Taper Post is used with these articular components for fixation.

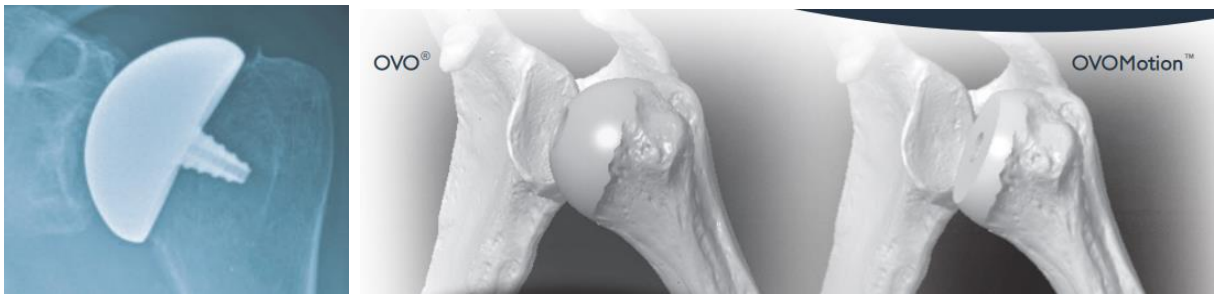

FIG 4: OVO component *in situ* (R); humeral head preparation for OVO & OVOMotion components (L)

The OVO and OVOMotion components do not require removal of the entire native humeral head; the level of bone resection for the two systems is demonstrated in FIG 4, with respective placement of the implants, optimizing the orientation of the implant in terms of height and version, shown in FIG 4 (OVO) and FIG 5 (OVOMotion). The OVOMotion component design includes an epiphyseal crown (FIG 5). This change was made

to allow additional bone removal from the humeral head for easy visualization and access to the glenoid surface for utilization of the GRS implants. The crown supports the base of the OVOMotion articular component, providing biomechanical support for adequate humeral head fixation (refer to Section 2.5).

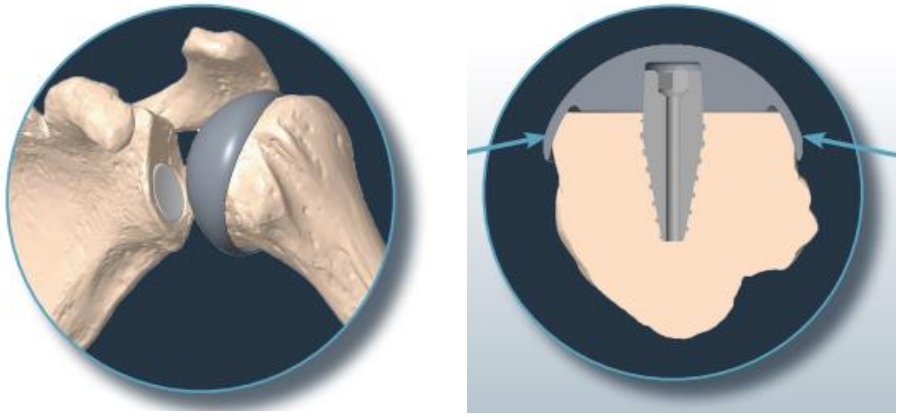

FIG 5: OVOMotion & GRS (R); cross-section showing epiphyseal crown (L)

The HemiCAP Shoulder, OVO and OVOMotion articular resurfacing component and taper post component mate together via a Morse taper interlock to provide stable and immobile fixation of the implant and stress bearing-contact at the bone/prosthetic interface.

The inlay glenoid GRS Articular Components are intended to interface and articulate with the humeral OVO or OVOMotion components when both articular surfaces of the joint are affected. The glenoid component is designed to minimize the risk of rocking-horse phenomenon and so risk of component loosening or failure. The GRS components are available in a two sizes 19 mm x 20 mm (single or partial glenoid component) and 20 mm x 25 mm (double or full component) (FIG 3 & 6), each having two offsets of 1.0 mm and 1.5 mm. The bone-contacting surface of the GRS articular components are designed to have industry standard peg and keel features with multiple insets, rings and slots for a strong and stable integration with bone cement at the bone-cement-implant interface.

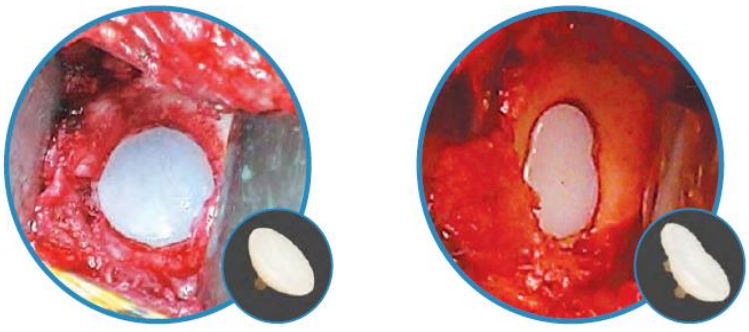

FIG 6: Single (R) & full (L) GRS *in situ*

The two sizes and two offsets optimize matching of the GRS component with the curvature of the glenoid and the extent of the glenoid cartilage damage; the GRS articulates with the correctly sized OVO or OVOMotion humeral component, as illustrated below (FIG 7).

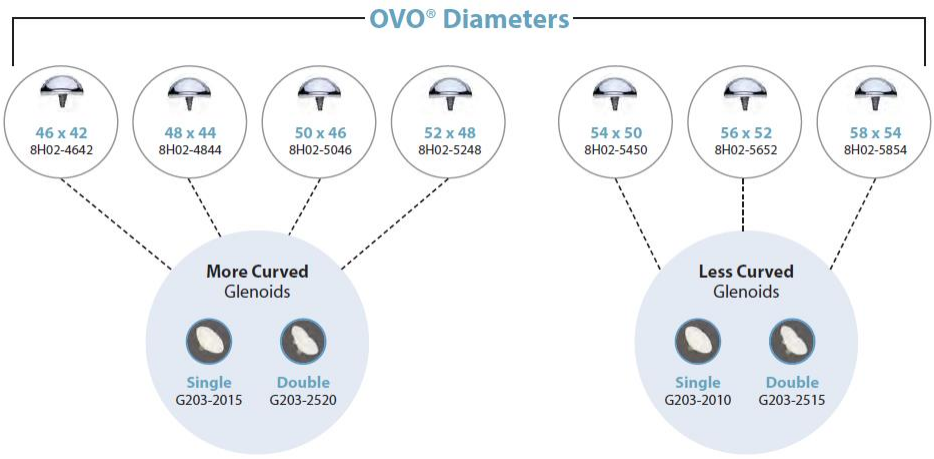

FIG 7: Matching OVO/OVOMotion Implant Diameters to the appropriate Glenoid (GRS) component

The Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) are single-use implants intended to be used with bone cement.

Materials and Biocompatibility

The Arthrosurface Shoulder Arthroplasty Systems implant components are manufactured from the following materials:

- HemiCAP Shoulder, OVO and OVOMotion Articular Components: Cobalt-Chromium-Molybdenum alloy (Co-Cr-Mo) per ASTM F799 and ASTM F1537. These have a bone contacting surface that is coated with a spray-applied CP Titanium (CP Ti) coating, a polished articular bearing surface, and a distal male or female Morse taper.
- HemiCAP Shoulder, OVO and OVOMotion Taper Posts: Titanium alloy (Ti-6Al-4V) per ASTM F136. These fixation components are cylindrical threaded stems that have a tapering major and minor diameter, a full-length cannulation, and a proximal male or female Morse taper.
- GRS Articular Components: Ultra High Molecular Weight Polyethylene (UHMWPE) per ASTM F648.

Per *ISO 10993-1:2016 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*, Arthrosurface Shoulder Arthroplasty Systems implant components are classified as Body Contact, Implant, Tissue/Bone, Contact Duration Permanent (> 30 days).

Materials used in the Arthrosurface Shoulder Arthroplasty Systems are the same as those used in previously cleared and commercially available orthopedic products. The composition of materials used in the device has been commonly used in other orthopedic implantable devices and as such, the biological effects of these are commonly accepted and have exhibited biocompatibility during multiple decades of use. Reference the Biological Evaluation File for the Arthrosurface Shoulder Arthroplasty Systems for biocompatibility testing and/or rationale related information.

Safety (including but not limited to sterilization)

The HemiCAP Shoulder, OVO and OVOMotion Articular Components and Taper Post Components are provided gamma sterilized (^{60}Co) to a Sterility Assurance Level (SAL) of 10^{-6}, selecting and substantiating a radiation dose of 25 – 40 kGy by the VDmax 25 method per ISO 11137-1.

The GRS Articular Components are STERRAD gas plasma sterilized to a Sterility Assurance Level (SAL) of 10^{-6} by the Overkill Sterilization Method per ISO 14937:2009. Reference the sterilization validation report in the sterilization binder for details of the sterilization specifications, methods and parameters.

Reprocessing

The Arthrosurface Shoulder Arthroplasty Systems implants are not reprocessed.

Accessories/Instruments

The following instrumentation is used with the Arthrosurface Shoulder Arthroplasty Systems:

- Instrument Kit, HemiCAP Shoulder, 25 mm/30 mm (non-sterile) (PN 6000-3000)
- Instrument Kit, HemiCAP Shoulder, 35 mm (non-sterile) (PN 8000-3000)
- Instrument Kit, HemiCAP Shoulder, 40 mm (non-sterile) (PN 8000-4000)
- Instrument Kit, OVO (non-sterile) (PN 8000-5000)
- Instrument Kit, OVOMotion (non-sterile) (PN 8000-5100)
- 2.5 mm Guide Pin for HemiCAP Shoulder 35 mm/40 mm/OVO/OVOMotion (sterile) (PN 8007-1200)
- 2.5 mm Guide Pin for HemiCAP Shoulder 35 mm/40 mm/OVO/OVOMotion (non-sterile) (PN 8007-1205)
- 2.0 mm Guide Pin for HemiCAP Shoulder 25 mm/30 mm (sterile) (PN 6007-1200)
- 2.0 mm Guide Pin for HemiCAP Shoulder 25 mm/30 mm (non-sterile) (PN 6007-1205)
- GRS Instrument Kit Inferior (sterile, disposable) (PN G000-0100)
- GRS Instrument Kit Superior (sterile, disposable) (PN G000-0200)
- GRS 15 mm Reamer Pack (sterile, disposable) (PN G000-0300)
- 2.0 mm Guide Pin for GRS (sterile) (PN G007-1400)

Expected Benefits

Following successful implantation of the Arthrosurface Shoulder Arthroplasty Systems implants in a patient population consistent with the approved indications for use statement, the patient(s) should experience the following:

A. Substantial reduction in pain
B. Significant improvement in functional range of motion (i.e. forward flexion, abduction and external rotation)

in comparison to their preoperative status. These comprise the two primary performance outcomes claimed by Arthrosurface, Inc., for the Arthrosurface Shoulder Arthroplasty Systems addressed in this CER.

The overall patient satisfaction scores and implant survivorship rate for the Arthrosurface Shoulder Arthroplasty Systems are expected to be in agreement with data published in the clinical and scientific peer-reviewed literature.

2.2. Product History

US FDA 510(k) Clearances:

- K173964 OVOMotion Shoulder Arthroplasty System (04/18/2018)
- K142942 HemiCAP Humeral Head XL (HHXL i.e., OVO) Articular Resurfacing System (12/19/2014)
- K091196 GRS Glenoid Resurfacing System (10/27/2009)
- K023096 HemiCAP Humeral Head (Shoulder) Resurfacing System (04/10/2003)

EU NB CE Approvals:

- N° 9455 rev.7 Shoulder Resurfacing Implant and Fixation Components (HemiCAP Shoulder and OVO)
- N° 34530 rev.3 Total Shoulder Prosthesis (OVO, OVOMotion and GRS)
- N° 34531 rev.5 Total Shoulder Prosthesis (OVO, OVOMotion and GRS)

Health Canada Approvals:

- License #67702 HemiCAP Shoulder Resurfacing System (issued 03/09/2005)
- License #90933 HemiCAP OVO Resurfacing System (issued 03/21/2013)
- License #96718 HemiCAP Glenoid Resurfacing System (issued 03/29/2016)

The Australian TGA ARTG Inclusion for HemiCAP Shoulder (ARTG ID 112709) was cancelled in 2015 due to reclassification of the device from Class IIb to III in Australia; the reclassification was not in place in Europe at that time.

The supply history of the Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) is included in Appendix E.

2.3. Intended Uses/Indications for Use

Intended Application of the Device:

• HemiCAP Shoulder Articular Components	Single Use Implants
• HemiCAP Shoulder Taper Post Components	Single Use Implants
• OVO Articular Components	Single Use Implants
• OVOMotion Articular Components	Single Use Implants
• OVO/OVOMotion Taper Post Component	Single Use Implants
• GRS Articular Components	Single Use Implants
• Sterile, Disposable Instruments	Single Use Instruments
• Instrumentation Kits	Reusable

Indications for Use:

For Hemiarthroplasty

The HemiCAP Shoulder, OVO and OVOMotion are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable.

For Total Shoulder Arthroplasty

The OVO, OVOMotion and GRS are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. All implant devices are a single use implants intended to be used with bone cement.

Patient Population, Contraindications, Warnings and Precautions, and Possible Adverse Events:

Patient selection factors to be considered include:

1. Need to obtain pain relief and improve function.
2. Patient age as a potential for early-age-revision of total joint arthroplasty.

3. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.
4. Failure of previous conservative treatment options in correcting deformity and achieving pain relief.

Contraindications

Absolute contraindications include:

1. Defects that are not localized.
2. Defects that are located on joint surfaces that are discontinuous.
3. Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis.
4. Patients that have a known sensitivity to Cobalt-Chrome alloys or UHMWPE polymers (GRS only) typically used in prosthetic devices.
5. Significant bone loss or erosion of the anterior, posterior, or vault of the glenoid that would compromise implant fixation (GRS only).

Relative contraindications include:

1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions.
2. Metabolic disorders which may impair the formation or healing of bone.
3. Infections at remote sites which may spread to the implant site.
4. Rapid joint destruction or bone resorption visible on roentgenogram.
5. Chronic instability or deficient soft tissues and other support structures.
6. Vascular or muscular insufficiency.

Warnings

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device (except GRS). Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned and mated with taper in Taper Post. Visually confirm distal tip of contact probe is making contact on articular surfaces and free from any soft tissue structures to ensure accuracy. Use light pressure on contact probe to slightly indent articular surface at each measurement point, ensuring that the selected implant will be flush or slightly recessed with the articular surface (HemiCAP Shoulder only).

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned. When placing implant, carefully trim articular cartilage debris or osteophytes around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues (OVO and OVOMotion only).

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues (HemiCAP Shoulder Only).

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues (GRS only).

Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to postoperative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

These implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Their safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions
These implants are intended to be fitted and installed with the associated instruments. Use of instruments from other systems may result in improper implant selection, fitting and placement, which could result in implant failure or poor clinical outcome. The instruments should be regularly inspected for any signs of wear or damage.

Surgeon or Physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

Possible Adverse Events

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between the implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surface.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.
13. Embolism.

2.4. Intended Therapeutic and/or Diagnostic Indications and Claims

Arthrosurface, Inc. makes no additional claims beyond those contained in the intended uses and indications for use.

2.5. Changes to the Device since the Last Evaluation

Since the February 2017 CER, the OVOMotion Shoulder Arthroplasty System had been added to the Arthrosurface Shoulder Arthroplasty Systems. The OVOMotion system included new articular components that are same as the OVO articular components with only one change, i.e. the addition of a planar shelf on the underside of the components. This change was made to allow additional bone removal from the humeral head for easy visualization and access to the glenoid surface for utilization of the GRS implants. The same taper post fixation component is used for the OVO and OVOMotion articular components. A new OVOMotion instrument kit was also designed for site preparation and delivery of these new components. Both OVO and OVOMotion systems are substantially equivalent based on their intended use and technological characteristics. This was used as the basis of getting FDA 510(k) clearance for the OVOMotion system, which was received in April of 2018, and for getting CE certification, which was received in May of 2021. This CER update includes a safety and performance evaluation of all Arthrosurface Shoulder Arthroplasty Systems, including the recently added OVOMotion system.

2.6. Description of Post-Market Surveillance Program

Post market surveillance activities are conducted according to AS 91-09 Product Vigilance & Post Market Surveillance procedure. Activities include but are not limited to:

- Monitoring complaint reports.
- Maintaining summary of clinical activity, including post market clinical studies, white papers, other publications, etc., (post market & clinical activity binders).
- Periodic audio conferences with surgeons for direct feedback on clinical and product use.
- Post-market project meetings and design reviews.

3. Clinical Background, Current Knowledge, State of the Art

3.1. Relevant Medical Fields/Conditions

Relevant conditions include painful and/or severely disabled shoulder joints resulting post-trauma, or associated with degenerative disease or from avascular necrosis. The humeral head (“ball”) fits into the glenoid (“socket”) in the shoulder. Both are covered with cartilage, which eases the movement. Conditions such as injury or arthritis wear down cartilage, resulting in bone-on-bone interaction, causing stiffness, grinding, pain, loss of motion and/or lessened function. Pain may be severe enough to occur even while resting.

3.2. Relevant Treatment Options, Benefits/Risks

Table 1 provides a summary of medical (non-surgical) options available to treat patients suffering from painful and/or severely disabled shoulder joints resulting post-trauma, from degenerative disease or from avascular necrosis. The table provides a brief description of the medical options, and the benefits (i.e. advantages) and risks (i.e. disadvantages) of each option. The “Comments” section describes known limitations of the medical option, and the acceptability of undesirable side effects and other risks.

Table 1. Current treatment options for osteoarthritis of the shoulder joint

Medical Option	Description	Benefits	Risks	Comments
HA injection	3 weekly series 5 weekly series	Pain relief Reduce inflammation Lubricates the joint Benefits can be seen as long as 4-6 months Restores the normal articular homoeostasis	Local reaction	Can be expensive Multiple treatment series are possible
Corticosteroid injection	Normally injected with Lidocaine	Pain relief Most effective up to 4 weeks	Local reaction Potential damage to the collagen matrix of tendons and ligaments-destructive cartilage changes Flare up within 24 hours	Best for rotator cuff tendinopathy and adhesive capsulitis No more than 3-4 injections in one joint in one year
Physical therapy	Exercises tailored to specific needs of patient	Maintain muscle strength for greater stability of joint thereby reducing stress on the joint Keep range of motion Improve mood and reduce anxiety Prevent muscle, ligament and tendon atrophy Prevent joint stiffness	None identified	Should be started before the development of atrophy or contracture Should be under the direction of a Physiotherapist to avoid damage from over-exercising
NSAIDs	For moderate to severe pain relief	Anti-inflammatory Pain relief Reduce swelling Readily available Inexpensive	Gastrointestinal irritation- pain and/or ulcer Bleeding disorder Renal irritation or dysfunction Hepatotoxic CV events HBP elevation	Not well tolerated in elderly patients
Medications: analgesics acetaminophen	For mild to moderate pain relief	Temporary relief of pain Readily available Inexpensive Few side effects	Excessive doses can be hepatotoxic - the FDA recommends no more than 4,000 mg of acetaminophen per day to avoid liver toxicity	650 to 1,000 mg of acetaminophen up to four times per day to relieve osteoarthritis symptoms
Narcotics, opioids, tramadol	For severe pain relief	Pain relief	Nausea Vomiting Constipation	Can cause dependence/addiction Only recommended if not responded to NSAIDs or acetaminophen

Medical Option	Description	Benefits	Risks	Comments
	Can be short acting (3-4 hours) or long-acting (12-24 hours)		Risk of falls in the elderly	Should be carefully monitored
Topical NSAIDs	Apply directly to skin Options: Capsaicin to block pain signals, Lidocaine for local anesthetic, Counterirritants to distract from pain or Salicylates for anti-inflammatory benefits	Safety and tolerability Readily available Inexpensive	Can enter blood stream Can interact with other medications Can cause burning on skin	The primary ingredients in these creams are usually counterirritants, such as wintergreen and eucalyptus, which stimulate the nerve endings and distract the brain from joint pain. Can be used in conjunction with other treatments
Glucosamine and Chondroitin	Over the counter pills taken daily Most effective when used with physical therapy	Moderate pain relief over placebo Slows cartilage breakdown Anti-inflammatory	Not FDA approved	Interacts with the cartilage Complementary treatment
Humeral Head Resurfacing	For early stage treatment of localized or non-localized arthritis of the humeral head only	Pain relief Safe and effective Improved ROM Minimally disruptive Less bone removal than traditional or reverse shoulder arthroplasty implants Option to convert to TSA/RTSA in future Same level of pre-operative activity possible	Requires surgery May not provide adequate pain relief May require revision surgery Disease may progress or advance Implant failure or rejection	Primarily for young and active patients who have localized cartilage loss and want to continue with their pre-operative activity levels. Can be easily revised in case it fails or disease advances. Leaves the glenoid as is.
Stemless Total Shoulder Arthroplasty	For treatment of non-localized arthritis of the shoulder joint with generally intact subchondral bone	Pain relief Safe and effective Improved ROM Minimally disruptive Less bone removal than traditional or reverse shoulder arthroplasty implants Option to convert to TSA/RTSA in future	Requires surgery May not provide adequate pain relief May require revision surgery Implant failure or rejection	Primarily for young and active patients who have articular cartilage damage of the humeral head and glenoid and want to continue with their pre-operative activity levels. Can be easily revised in case it fails.

Medical Option	Description	Benefits	Risks	Comments
		Same level of pre-operative activity possible		
Traditional Shoulder Arthroplasty	For standard treatment of shoulder arthritis	Pain relief Safe and effective Improved ROM Option to convert to RTSA in future	Requires surgery May not provide adequate pain relief May require revision surgery Fewer revision options Excessive bone removal compared to stemless options Implant failure or rejection	Requires more bone removal than stemless options but is tried and tested over multiple decades of use with successful results. Does require intact rotator cuff for successful outcomes.
Reverse Shoulder Arthroplasty	For treatment of shoulder arthritis in cases with deficient rotator cuff	Pain relief Allows basic functions with ability to perform activities of daily living	Requires surgery May not provide adequate pain relief May require revision surgery Reduced ROM with lack of ability to regain pre-operative levels of activity Revisions option limited to another RTSA Excessive bone removal compared to stemless options Implant failure or rejection	Last option in shoulder arthroplasty and is reserved for severe cases in elderly patients with a deficient rotator cuff. Provides adequate pain relief but limits the ROM. Once it fails, salvage with a repeat surgery is the only option.

Discussion

The use of non-operative treatment in shoulder joint osteoarthritis has been well accepted in the literature. Several regimens have been described with good success; however, their longevity may be limited.

The full spectrum of conservative care should be considered before surgical options are utilized, particularly for patients with mild-to-moderate osteoarthritis (OA) or when pain and functional limitations are modest despite more advanced radiographic changes (Chillemi 2013).

The most effective conservative treatment for shoulder osteoarthritis is a combination of modalities that are customized to the patient rather than a single drug or nonsurgical option (Iannotti 2005). Medications (NSAIDs, analgesics, opioids, etc.) and hyaluronic acid injections (HA, Corticosteroids (CS)) have been the mainstay of treatments for OA of the shoulder (Hinton 2001, Silverstein 2007). Analgesics and NSAIDs can be less effective and the side effects less well tolerated especially in the elderly patient (Blaine 2008, Singh 1998a, 1998b). Intraarticular injections can reduce pain and inflammation while lubricating the joint. Colen, et al. compared injections of HA to Phosphate Buffered Saline (PBS) and found an improvement from baseline for pain and function with both treatments. The improvements seen with HA injections however were significant with an effect size of 2 and superior to PBS injections, which had an effect size of 1.5 (Colen 2014). Merolla, et al. compared HA injections to CS injections and found that HA injections reduced pain for up to 6 months while improvement from the CS injections lasted only 1 month (Merolla 2011).

Combined, these non-operative modalities provide symptomatic relief for patients with shoulder osteoarthritis, however, symptoms may return, and the longevity of conservative measures may be limited. Surgical treatment of shoulder arthritis is primarily centered around patients who are refractory to conservative treatment and require a surgical intervention. However, physician evaluation is required to determine the appropriateness of replacement, including when humeral head replacement alone or with glenoid replacement, is appropriate. Shoulder arthroplasty may be specialized to meet the patient need, and results in pain elimination and return of the range of motion, strength and function.

Avascular osteonecrosis (AVN) treatment is based on the clinical symptoms, the stage and size of the area of necrosis. The early stages can be successfully treated with conservative care. There is a paucity of studies on AVN of the shoulder; however, there have been a number of clinical studies of conservative treatment published in other joints, particularly the hip.

Claben, et al. presented a study that treated 108 patients with 136 osteonecrosis of different joints (including the hip, knee and ankle), etiology and severity with Vasoactive prostaglandin analogue iloprost (PGI2). Early studies using this therapy have shown good results (Aigen 2001, 2002; Jager 2008, 2009, 2011; Disch 2005). At 49 months, Claben, et al. reported a 74.8% significant improvement in symptoms of their patients, however 25.2% of patients reported similar symptoms or worsening of their symptoms after therapy. Other nonsurgical therapies include various pharmacological approaches such as the use of lipid-lowering agents, anticoagulants and bisphosphonates, hyperbaric oxygen, electrical stimulation and capacitance coupling. (Disch 2005, Agarwala 2002,2005; Desai 2005, Meizer 2005). Camporesi, et al. used hyperbaric oxygen to treat their patients. After 20 treatments, they reported significant pain reduction and range of motion improvement, which was sustained for 7 years. They also observed substantial radiographic healing in 78% of their patients.

The use of surgery for treatment of osteoarthritis of the shoulder is also well established and published in the literature, with safety and efficacy profiles of different implant designs studied in detail. Historically, traditional shoulder arthroplasty has involved the use of stemmed implants similar to those used for hip arthroplasty. In the past two decades, other innovative shoulder implants have been introduced, with successful use in patients of all ages. A reverse shoulder arthroplasty, as the name suggests, reverses the ball and socket configuration with the humeral head being converted to a socket and the glenoid being converted to a ball. Patients with deficient rotator cuff muscles benefit from this design as it modifies the deltoid muscles moment arm, enabling it to become the primary muscle group controlling the shoulder's range of motion. This procedure should be reserved for the elderly because if it fails, the revision options are extremely limited, if any.

In contrast, a shoulder hemiarthroplasty implant is aimed at replacing a part of or the complete articular surface of the humeral head. The HemiCAP Shoulder and OVO/OVOMotion implants fall under this category. In a hemiarthroplasty, as the name suggests, only one side of the joint is resurfaced or replaced; the native glenoid in these cases is not resurfaced or replaced.

A stemless shoulder arthroplasty involves the use of both humeral head and glenoid options in which the humeral head implant is fixed within the subchondral bone. The OVO/OVOMotion implants used in conjunction with the GRS fall in this category of implants.

Both these latter implant categories are advantageous in that they provide pain relief and enable the patient to resume close to normal levels of activity, while being minimally disruptive to the bone stock and surrounding soft tissues. They optimize revision options since minimal bone stock is removed to seat the implants on the humeral side of the joint. Options to convert these to a traditional or reverse shoulder arthroplasty are, therefore, maintained in case a revision is required for unresolved symptoms or disease progression.

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Risks associated with shoulder implantation surgery are similar to those of knee and hip replacement, the latter which are conducted more frequently than shoulder arthroplasty.

3.3. Unmet medical need

Unmet medical need is defined as a condition for which, currently, there exists no satisfactory treatment. In patients with a painful and/or severely disabled shoulder joint resulting from post-traumatic degenerative disease or avascular necrosis, and in whom non-surgical alternatives may be insufficient or do not provide sustained relief, surgical intervention may be described as satisfying the unmet medical need. Surgical intervention with the Arthrosurface Shoulder Systems provides an effective surgical treatment for patients requiring resurfacing or reconstruction of the shoulder joint, providing the option for either hemi- or total arthroplasty. As described above, the Arthrosurface Shoulder Systems provide a clinically effective surgical treatment in terms of pain relief and re-establishment of joint mobility. The surgical implantation technique and implant design necessitate minimal disruption to the bone stock and surrounding soft tissues of the shoulder joint , thereby optimizing future revision options including total shoulder arthroplasty should revision be required.

4. Applicable Standards, Guidance Documents; Professional Guidelines

- ASTM F799-19 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)
- ASTM F1537-20 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
- ASTM F136-13 (2021)e1 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
- ASTM F648-21 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
- ISO 11137-1:2006 (A1:2013) Radiation - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- ISO 11137-2:2013 Radiation - Part 2: Establishing the Sterilization Dose
- ISO 14971:2019 Medical devices -- Application of risk management to medical devices (R2010)
- ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- MEDDEV 2.7.1 Rev. 4, June 2016 Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC.
- American Academy of Orthopaedic Surgeons: The Treatment of Glenohumeral Joint Osteoarthritis Guideline And Evidence Report, 2009
    - Total shoulder arthroplasty and hemiarthroplasty are options when treating patients with glenohumeral joint osteoarthritis.
        - Strength of Recommendation: Limited. A Limited recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.
        - Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as Limited and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

- We suggest total shoulder arthroplasty over hemiarthroplasty when treating patients with glenohumeral joint osteoarthritis.
  - Strength of Recommendation: Moderate. A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.
  - Implications: Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.

5. Identification and Appraisal of Clinical Data

The Medical Device Directive 93/47/EEC Annex X requires that the safety and performance of medical devices be supported by clinical evidence drawn from either the literature, from in-house clinical trials, or both. This report reviews published literature, risk analysis and post-market reports on similar devices in the same product category, including, where available, clinical data for the device(s) under consideration.

5.1. Demonstration of Equivalence

Demonstration of equivalence to resurfacing, stemless shoulder systems currently marketed was evaluated using clinical data. Clinical, technical and biologic characteristics were taken into consideration. A description of the equivalence of devices identified in the Literature Search Methodology and Results section, or referenced in the Product Risks and Complaints section, is included in more detail in the following sections: Section 5.4, and Appendices B & D.

The comparator devices identified as substantially equivalent (i.e. similar marketed devices) comprise the following systems; a comparison of device component images, humeral and glenoid implant sizes is included in Table 5a in Appendix B. A comparison of the Arthrosurface OVO and OVOMotion devices is provided in Table 5b. A head-to-head comparison of the Arthrosurface HemiCAP, OVO, OVOMotion and GRS vs the individual comparator systems is included in Table 5c in Appendix B:

- Tornier Aequalis Resurfacing Head & Tornier Aequalis PerForm Glenoid System
- Zimmer Biomet Copeland Mark-3 Resurfacing Head
- Zimmer Biomet TESS Shoulder System
- Zimmer Biomet Stemless Comprehensive Implant System
- DePuy Global CAP Resurfacing Humeral Head & Global Advantage Glenoid Solutions component
- Synthes EPOCA Resurfacing Head & Glenoid
- Smith & Nephew Promos Resurfacing System
- Arthrex Eclipse Stemless Shoulder Prosthesis & VaultLock Glenoid

5.2. Context of the Evaluation and Choice of Clinical Data Types

The evaluation of the performance and safety of the Arthrosurface Shoulder Arthroplasty Systems focused on the following types of clinical data:

Clinical data provided by Arthrosurface, Inc.:

- Summary of product complaints
- Accompanying documentation (i.e., information for use, technique guide, etc.)

Clinical data from external sources:

- Clinical literature
- Regulator safety databases (recalls, alerts, adverse event complaints)

Usability Data

- Not applicable to this update.

Animal Study Data (if done in place of clinical data)

An animal study was conducted in goats using the HemiCAP Knee (Focal Condyle) Resurfacing System as part of the design and development of the HemiCAP Project. The results of that study were published in the Journal of Orthopaedic Research (Kirker-Head, Carl A., et al. "Safety of, and biological and functional response to, a novel metallic implant for the management of focal full-thickness cartilage defects: Preliminary assessment in an animal model out to 1 year." Journal of orthopaedic research 24.5 (2006): 1095-1108). This study concluded the following: "We were able to derive useful preliminary data pertaining to the safety of the implant and the functional and biological response to its use. The potential value of the implant as a clinical management tool is implied. All six goats retained excellent range of motion in the operated joint and clinical outcomes were very good. Our data imply the safety, biocompatibility, and functionality of the implant." These animal study data are applicable to the HemiCAP Shoulder Hemiarthroplasty System since the HemiCAP Shoulder System is intended to treat articular focal defects, albeit of the humeral head, using the same design elements, materials and technique.

5.3. Clinical Data Summary

This evaluation of clinical data was conducted to assess the performance and safety of the Arthrosurface Shoulder Arthroplasty Systems. Clinical data from manufacturer's own clinical investigations (if any), technical journals and databases maintained by individual jurisdiction regulators, e.g. USA, UK, Australia, were used to establish the performance and safety of this category of devices (considering all manufacturers). Product complaints specific to the HemiCAP Shoulder, OVO, OVOMotion and GRS were obtained from Arthrosurface, Inc.'s device history documentation and adverse events reported for these systems and similar devices were collected from regulator databases.

Studies from scientific journals were appraised based on suitability/relevance and data contribution criteria. Evaluations of clinical, technical, and biological relevance were reviewed. The authors' expertise in the field, the technology, and medical practice using devices for shoulder arthroplasty were examined. This review supported the assessment of the safety and efficacy of the Arthrosurface Shoulder Arthroplasty Systems. Data appraisal was conducted per the *MEDDEV 2.7.1, rev 4, Guidelines on Medical Devices, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC, 2016.* The objective of this clinical evaluation of the Arthrosurface Shoulder Arthroplasty Systems was to answer three questions:

1. Does the device achieve its intended performance?
2. Is the device safe for its intended purpose?
3. Has the risk management process:
    - eliminated or reduced risks as far as reasonably possible;
    - taken adequate measures to mitigate risks that cannot be eliminated; and
    - informed users of residual risks?

5.3.1. Clinical Investigations Conducted by Arthrosurface

As part of the device approval process for the OVO Total Shoulder Prosthesis, Arthrosurface conducted a post-market clinical study in accordance with protocol number AS-CE-TSA-01 dated September 28, 2018, and published the final post-market clinical study report dated November 14, 2019, which was submitted as part of the design dossier for approval of this device (report attached as addendum to Appendix D).

This post-market clinical study was conducted to evaluate the continued safety and efficacy of the OVO device at a minimum follow-up of two years. A total of n = 80 total shoulder procedures with the OVO and GRS devices were studies. Thirty nine procedures were performed on the left shoulder and 41 on the right. The primary indication for surgery was glenohumeral arthritis or avascular necrosis in all patients. On average, patients were assessed at a mean of 44.1 months (range 24-84 months). At the time of last follow-up, all subjects had retained their original OVO and GRS implant components and no component failure modes were observed in this study leading to device removal or revision. Post-operative pain was assessed using a pain scale from zero (no pain) to 10 (worst pain). At last follow-up, the average pain score was 1.1 (range 0-8). Range of motion measurements included forward elevation and external rotation. On average, patients achieved 158.7 degrees of forward elevation (range 11-180 degrees) and 61.5 degrees of external rotation (range 20-90 degrees). As noted in the literature review section for data published on other similar devices, these end points were comparable, or even better from both a safety and efficacy perspective. As noted in section 2.1, Expected Benefits above, these two primary performance outcomes claimed by Arthrosurface, Inc., were successfully achieved for its OVO and GRS total shoulder arthroplasty system. By extension, this is also applicable to the OVOMotion device given the similarity and substantial equivalence established in this document between these two devices.

The report of this post-market clinical study concluded that “The Arthrosurface Total Shoulder System is safe and effective for continued marketing and has acceptable risks levels as per documented risk management and as compared to other marketed shoulder implants used in the treatment of glenohumeral arthritis.” Therefore, this data, along with the data published in the literature for similar devices, continues to support the use of Arthrosurface, Inc.’s shoulder arthroplasty system’s implants for safe and effective clinical use.

5.3.2. Clinical Evaluations of Equivalent Devices (Literature Search Results)

The clinical evaluation of equivalent devices (i.e., similar marketed devices identified as substantially equivalent to the Arthrosurface Shoulder Arthroplasty Systems) was based on the review of relevant articles from the medical literature. The results of this evaluation were intended to provide a broad understanding of the performance and safety of shoulder arthroplasty devices (hemi and total). Studies were screened for clinical relevance to the intended use, resulting in the final articles included in this literature evaluation. The evaluation focused on 20 published studies published in medical journals that may or may not be peer reviewed.

5.3.3. Data selection process

An evaluation was performed of the obtainable, relevant scientific literature relating to safety, performance, design characteristics and intended purpose of shoulder arthroplasty devices (hemi and total). Data were taken from scientific publications of technologically equivalent devices. To be considered equivalent, the devices were assessed to have similarity with regard to the clinical, technical and biological parameters with special attention to the intended use, performance and materials.
Equivalence means:

- ***Clinical***: used for the same clinical condition or purpose at the same site in the body, in similar; have similar relevant critical performance according to expected clinical effect for specific intended use.
- ***Technical***: used under similar conditions of use; have similar specifications and properties; be of similar design; use similar deployment methods (if relevant); have similar principles of operation.
- ***Biological***: use the same materials in contact with the same human tissues or body fluids.

Evaluation of data quality

Each study was evaluated according to study design. Data in studies were evaluated for clinical, technical, and biological significance. The inclusion of journal articles to be evaluated was based on the scope, method and results of clinical studies. Further, studies were evaluated based on scientific principles and Good Clinical Practices. The author's assessment of study results had to be objective and methodologically sound. The quality of an assessed journal article includes, but is not limited to, consideration of the adequacy of disclosure of the methods used, the adequacy of data disclosure (including reporting adverse events and outcomes; description of prognostic factors; and disclosure of results that the study was originally intended to generate), validity of the authors' conclusions, and potential author conflict of interests.

Discussion

Clinical data associated with shoulder arthroplasty devices (hemi and total) were evaluated to assess safety and performance of this category of medical devices. This report provides a summary of the results from the literature regarding these aspects of device safety and performance, and a summary of adverse events known and/or reported by the authors.

5.3.4. Conclusion

These data generated in this report support the continued safety and performance of the Arthrosurface Shoulder Arthroplasty Systems for the stated indications for use statements, as demonstrated in the sections that follow.

5.4. Evaluation of Product Safety Data

The assessment of the safety of the Arthrosurface Shoulder Systems was based on a review of adverse event data collected as part of the clinical literature assessment and data from the following additional sources:

- Arthrosurface Complaint Data (2011 to 2019)
- Arthrosurface Implant Revision History (2004 onwards)
- Arthrosurface Reportable Events
- Arthrosurface Risk Management Reports for all its Shoulder Systems and Related Risk Management File Documents
- FDA MAUDE database of Medical Device Reports (MDRs) and FDA Recall database for product codes: HSD (Prosthesis, shoulder, hemi-, humeral, metallic uncemented) and KWS (Prosthesis, shoulder, semi-constrained, metal/polymer cemented).
- UK Medicines & Healthcare products Regulatory Agency (MHRA): Alerts and Recalls for Drugs and Medical Devices
- Australia Therapeutic Goods Administrations (TGA) Alerts
- Health Canada – Recall and Alerts

5.4.1. Anticipated Adverse Events

As identified in the product information for use, adverse events/hazards associated with use of the shoulder arthroplasty devices include:

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between the implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surface.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.
13. Embolism.

5.4.2. Arthrosurface Complaint Data (2011 to 2019)

Product distribution for the HemiCAP Shoulder began in Q1 of 2004, GRS began in Q2 of 2011, OVO began in Q3 of 2011 and OVOMotion began in Q2 of 2018.

Sales for the HemiCAP Shoulder, OVO, OVOMotion and GRS implants as of September 2019 are as follows:

HemiCAP Shoulder			
Year	**US**	**International**	**Total**
2011	531	76	607
2012	409	66	475
2013	356	61	417
2014	304	55	359
2015	261	1	262
2016	230	24	254
2017	212	30	242
2018	206	10	216
2019 (through Sep)	155	15	170
Total	**2664**	**338**	**3002**

OVO, OVOMotion and GRS			
Year	**US**	**International**	**Total**
2011	235	5	240
2012	740	46	786
2013	888	36	924
2014	1133	10	1143

OVO, OVOMotion and GRS			
Year	**US**	**International**	**Total**
2015	1118	35	1153
2016	1267	47	1314
2017	1433	14	1447
2018	1433	38	1471
2019 (Sept)	1412	37	1449
Total	**9659**	**268**	**9927**

The following table summarizes the complaints received by Arthrosurface related to the Arthrosurface Shoulder Systems and includes a calculation of complaint rates for each year based on the number of units distributed during that same calendar year. (Note: Distributed product may not have been used in the same calendar year that it was distributed. Therefore, the results provide a rough estimate of complaint rates for each calendar year).

Complaint Type	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total	Rate
Damaged Glenoid Reamer	3	1	3	0	0	3	1	0	0	11	0.085
Glenoid Reamers blocking guide Pin to pass through (Manufacturing defect)	1	0	0	0	0	0	0	0	0	1	0.008
Damaged Peg Drill	1	1	2	0	1	0	1	1	0	6	0.046
Periprosthetic Fracture	0	1	0	0	0	0	0	0	0	1	0.008
Implant Loosened	0	0	0	0	1	0	0	1	1	3	0.023
Pain/ Swelling/ LROM	0	0	0	0	2	0	1	0	0	3	0.023
OVO Drill Bit Damaged	0	1	0	0	0	0	0	0	1	2	0.015
Shoulder twist drill damaged	0	0	0	0	0	1	0	0	0	1	0.008
Expired Implant	0	0	1	0	0	0	0	0	0	1	0.008
Kink on Suction Tubing	0	0	0	0	0	0	0	0	1	1	0.008

Complaint Type	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total	Rate
Wrong Pouch Label	0	0	0	0	0	0	0	1	0	1	0.008
Bent Instruments	0	0	1	0	1	3	1	0	0	6	0.046
Implant Packaging warped	0	0	0	0	0	0	1	0	0	1	0.008
Implant fit recessed	0	0	0	0	0	0	1	0	0	1	0.008
Incompatible taper post used	0	0	0	0	0	1	0	0	0	1	0.008
Guide Pin Fused with Trial	0	0	0	1	0	1	0	0	0	2	0.015
OVO template mismarked	0	0	0	0	1	1	0	0	0	2	0.015
Revision Driver Broken	0	0	0	0	3	0	0	0	0	3	0.023
Total Complaints	**5**	**3**	**7**	**1**	**9**	**10**	**6**	**3**	**3**	**47**	**0.003**
Distributed Units	**847**	**1261**	**1341**	**1502**	**1415**	**1568**	**1689**	**1687**	**1619**	**12929**	N/A
Complaint Rate	**0.59**	**0.23**	**0.52**	**0.06**	**0.63**	**0.63**	**0.35**	**0.17**	**0.18**	**0.36**	**0.003**

Of the 47 complaints, 40 were associated with surgical tools (e.g. damaged reamers and drills). Seven complaints were associated with the implant: Loosening (3), Pain/ Loss of Range of Motion (3) and a periprosthetic fracture (1).

5.4.3. Implant Revision History

Arthrosurface, Inc. maintains records of all implant revisions. The information about these revisions is provided by surgeons involved in the original implantation procedure. If a revision was conducted by a surgeon who was not involved in the original procedure, (i.e. if the patient moved or selected a new surgeon), it is unlikely that the surgeon would communicate the procedure to Arthrosurface, Inc., and the revision history would not be recorded. Therefore, the reported revision rate is expected to be lower than the actual rate.

The Arthrosurface records identify that a total of 131 revisions have been performed since 2004 for the implants of the Arthrosurface Shoulder Arthroplasty Systems. The implant revision rate for these implants since 2004 is as follows:

- 1.2% for the HemiCAP Shoulder Implants
- 0.3% for the OVO Implants

- 0.4% for the GRS Implants

These numbers are well below the revision rates listed in national registries and currently published literature on the use of these types of shoulder implants. For example, the Australian Orthopaedic Association National Joint Replacement Registry reported a revision burden of 8.7% for shoulder replacements in 2018 (AOANJRR 2019 Report).

A detailed analysis of reported revisions is provided below for the period 2004 to July 2020:

CAUSES	HemiCAP Shoulder	OVO	OVOMotion	GRS
IRPS	32	3		1
DAOAC	28	3		
DSTSS	9	2		3
IL	1			7
PIRD	1		1	1
IN	4			2
TE	16	2		1
OL	1			
UNK	13			
Total Revisions	**105**	**10**	**1**	**15**

IRPS: Incomplete Resolution of Symptoms
DAOAC: Damage to Adjacent or Opposite Articular Cartilage
DSTSS: Damage to Surrounding Soft-Tissue Support Structures
IL: Implant Loosening
PIRD: Patient Injury Related Damage
IN: Infection
TE: Technical Error
OL: Osteolysis
UNK: Unknown

No specific trends could be identified for the OVO, OVOMotion and GRS implant revisions. For the HemiCAP Shoulder implant revisions, ~50% of implant revisions were due to incomplete resolution of symptoms (IRPS) or damage to adjacent or opposite articular cartilage (DAOAC).

DURATION	HemiCAP Shoulder	OVO	OVOMotion	GRS
≤ 24 Months	47	4		12
> 24 Months	40	5		3
UNK	18	1	1	
Total Revisions	**105**	**10**	**1**	**15**

For HemiCAP Shoulder and OVO implants the revisions were evenly split between implant durations of less than equal to 24 months and greater than 24 months. For GRS, 80% revisions occurred within the first 2 years of implantation.

COUNTRY	HemiCAP Shoulder	OVO	OVOMotion	GRS
USA	101	10	1	15
GERMANY	3			
ITALY	1			
Total Revisions	**105**	**10**	**1**	**15**

Most of the revisions reported for these devices were from those implanted in US patients as would be expected since 88% of Arthrosurface Shoulder Systems have been supplied within the USA.

5.4.4. Arthrosurface, Inc.'s Reportable Events (2011 to 2019)

Of the 47 complaints identified above, 14 were reportable to the US FDA. Those reports are summarized below.

Event Date	Event Description	Result
10/25/2012	Persistent pain in left shoulder that progressively increased with time. Patient has difficulty with daily activities and has been not been able to work. Revised to a total shoulder arthroplasty.	Discussion with the surgeon led to the finding that disease had progressed on the glenoid side of the joint, which was the cause of ongoing pain. As a result, a total shoulder arthroplasty was necessary. There were no issues or failures related to the use of the shoulder hemicap device.
11/16/2011	After implantation of shoulder hemicap device, the surgeon forcefully manipulated the shoulder joint past it's range of motion limits, resulting in fracture of the proximal humeral shaft. This (fda medwatch form 3500a) is now being filed in accordance with the findings on form 483 (observations), received during our fda inspection held in (b)(6) 2015.	The surgeon was able to successfully implant the shoulder hemicap device and was happy with the fit and final placement of the same. While evaluating the range of motion, he forcefully attempted to dislocate the joint, which caused the fracture of the promixal humeral shaft. The shoulder hemicap device components were removed and the patient was converted to a stemmed total shoulder device. No further issues have been reported by the user or the patient.
02/04/2016	Patient contacted arthrosurface via website and asked to recommend a surgeon who he is planning to consult regarding on-going issues with his shoulder. The patient has a shoulder hemicap implanted and he believes that his surgery was botched. He reported that he had been waiting to get a call back from his original treating surgeon since 2 weeks. On following up with his initial complaint, patient seems concerned about the range of motion with the implant at the end of 10th week after surgery. Reports that he has about 10 degree active flexion as well as abduction. On passive stretching his shoulder pops, cracks and will lock into place. His pt is unable to manipulate his shoulder the way he needs to because of this.	The radiographs provided by the patient were reviewed by arthrosurface clinical staff and there are no signs of loosening of the implant, the implant is still intact. The patient had a post-op ct scan done which showed a bone spur (osteophyte) that explains his concerns for limited range of motion (rom). The patient also had concerns regarding cracking and locking of the shoulder for which he met with another physician for second opinion. The second physician expressed that patient has a too advanced stage of arthritis for which osteophyte cannot be removed. Currently, patient has initiated and continuing treatment with the second physician. Patient was asked what his plans with the second physician are. No response was received. Based on the information provided by patient and the second opinion, it is evident that no arthrosurface components contributed to the reported issues. The complaint is considered closed.
01/01/2014	Arthrosurface received a legal notice on (b)(6) 2018 from (b)(6) the notice states that their client received an ovo implant around (b)(6) 2014. On (b)(6) 2017, the patient was revised as the ovo implant came loose. They also state	An ovo case recorded with subject taper post component lot (75ad2205) could not be located for (b)(6) 2014 (per complainant's information). To date, no complaints pertaining to pain or loosening have been reported for this lot. The dhrs of the incoming as

Event Date	Event Description	Result
	patient is now in pain due to arthrosurface hemicap resurfacing system.	well as final inspection lots were reviewed. The material certs, qips indicate that the parts were built to specification. There were no rejects or scrapped parts from this lot. Note that the taper post lot in question was part of a voluntray recall (recall # z-1114-2015) inititade due to regulatory concerns but not due to any complaints, safety or efficacy concerns. However, the device is currently active in the eu and other ous markets with safety and efficacy data on file. The exact reason for patient's pain could not be concluded due to insufficient information provided by the complainant. As such, the reason for loosening is unknown as the device components have not been returned for investigation. The patient has been revised in (b)(6) 2017 and all arthrosurface components have since been explanted. Any further information received regarding this complaint will be reported through supplemental mdrs as required.
05/10/2019	On 05/10/19, arthrosurface received a voluntary fda medwatch report filed by a patient. Per the report, the patient received arthrosurface glenoid implant in 2018. Following the initial surgery, patient underwent 3 additional surgeries later in the year due to ongoing complications which involved pus formation and loosening of the glenoid component. The patient was concerned since the arthrosurface device loosened within less than 6 months of implantation. At the time of this report, the patient is scheduled for revision to a reverse shoulder implant of unknown manufacturer.	Reported event was unable to be confirmed due to limited information. Root cause was unable to be determined as the necessary information to adequately investigate the reported event was not provided. No sterility, packaging or manufacturing related issues were noted per lot dhr review. No other complaints concerning a serious injury or a device malfunction were reported from this device lot. If any further information is found which would change or alter any conclusions or information, a supplemental mdr will be filed accordingly. Arthrosurface will continue to monitor for trends. Multiple mdr reports were filed for this event, please see associated reports: 3004154314-2019-00002 and 3004154314-2019-00003.
02/01/2012	Peri-prosthetic fracture after glenoid implantation. Pt complained of pain post-surgery and x-ray showed posterior glenoid fracture and migration of implant. Discussion with revising surgeon indicated that arthrosurface hemicap shoulder and glenoid implants were removed without incident and converted to a standard stemmed hemi and glenoid. Dr. Herring stated that the excessive posterior placement of the glenoid implant left insufficient bone for a stable glenoid. Dr. Herring was satisfied with the outcome of the case and stated it was not a product issue, but surgeon technique. X-rays, photographs and images on file.	Successful outcome and conversion to total shoulder.

Event Date	Event Description	Result
04/29/2013	The peg drill tip broke and was separated from the shaft during surgery. It was retrieved from the patient and discarded by the surgeon. This mdr (fda medwatch form 3500a) is now being filed in accordance with the findings on form 483 (observations), received during our fda inspection held in 10/2015.	The broken peg drill was not returned and thus not available for the evaluation. Therefore, it is not known as to what caused the drill to break. Another peg drill was available to complete the procedure. There was no harm to the user or patient and the case was completed uneventfully.
06/10/2013	The peg drill tip broke and was separated from the shaft during surgery. This issue occured in a total of three drills in the same case. All of those were retrieved from the patient and discarded by the surgeon. This mdr (fda medwatch form 3500a) is now being filed in accordance with the findings on form 483 (observations), received during our fda inspection held in 10/2015.	The peg drills were returned and evaluated by the engineering department. It is not known as to what caused the drill to break. The surgeon used an awl to complete the procedure. There was no harm to the user or patient and the case was completed uneventfully.
08/11/2015	The patient's glenoid implant was reported loosened. The initial surgery date was (b)(6) 2014.	The exact cause for loosening of glenoid component in the patient is unknown. Arthrosurface was notified that the implant was removed and revised to a total shoulder implant of another manufacturer on 08/11/2015. There are not enough details to investigate since the patient was revised and the components were discarded. Following are the dates that belong to glenoid components removed from the patient. Part # 8h02-5248-w lot # 75ad0813 mfg dt: 01/20/2014 exp. Dt: 01/31/2021. Part # 8156-0032-w lot # 75ed0517 mfg dt: 05/14/2014 exp. Dt: 05/31/2019. Note: the event was initially reported to arthrosurface as a revision and was not documented as a customer complaint. After a recent review of the revision form by a quality personnel, the case was perceived as a customer complaint and reportable on 12/07/2015. All the supporting information will be documented in the complaint file as a part of arthrosurface quality system.
03/13/2017	It was reported that a paddle reamer was broken during a glenoid surgery. There was no harm or injury to the user or to the patient. The surgeon used a readily available second glenoid kit and finished the surgery without issues.	It was learned that the paddle reamer hit the metal retractor during the surgery. The surgeon had difficulty accessing the site and hence the interference between the instruments. During the second attempt, the surgeon made sure that he had good exposure to the site and used the reamer from the additional kit. The surgery was completed without incident.
02/20/2017	It was reported that a peg drill from a glenoid reamer kit was broken during a shoulder surgery. The surgeon used a peg drill from another glenoid reamer kit readily available to complete the case.	There was no harm to the patient or to the user as a result of the reported issue. The exact reason for the failure of peg drill is unknown since the device was discarded after surgery and not available for evaluation. As a part of the investigation, the manufacturing records (incoming and final inspection)

Event Date	Event Description	Result
		were reviewed and no issues noted. Review of peg drill lot (incoming) showed compliance to functional specifications. Poor exposure or access to the operating site may have resulted in interference of the device with other surgical instruments. The surgical history of the lot has been reviewed and no other complaints have been received as of the date of this report. The complaint is considered closed at this time.
06/12/2017	The patient called into arthrosurface customer service department to report pain in his shoulder. The patient has been implanted with arthrosurface glenoid components in (b)(6) 2016. The patient currently feels that catching on overhead motion was possibly related to implant.	Arthrosurface has very limited information regarding the patient's clinical history and his experience with implanted components. It is undetermined if arthrosurface implants caused or contributed to any pain. The patient has scheduled an appointment with the operating physician to inform of his on-going issues. A supplemental mdr will be filed to report additional information from the patient following consultation with his physician.
03/30/2018	It was reported that a peg drill from the glenoid instrument kit was broken during a surgery.	The surgeon used another drill kit readily available with the rep to finish the case and outcome was not affected. The reason for the breaking of the reported peg drill is unknown. The root cause is unable to be determined as the instrument is not returned for investigation. Review of the dhr indicates that all units of lot(s) in question were built to specification. No non-conformances, rejects or reworks relative to the issue were noted. Review of previously logged complaints indicated broken peg drills due to poor exposure of the implant site, application of excessive force or interference with other surgical instruments during the procedure. No other issues or complaints were reported from this lot. The failure mode has been identified and addressed in the risk binder. We will continue to monitor.
06/28/2018	Response to: tell us what and how it happened. Please find docs and timeline listed below. Original surgery: partial shoulder replacement, (b)(6) 2018. Physical therapy begins within 2 weeks of surgery and lasts until late (b)(6) 2018. Had very good range of motion and strength with one exception: i could not sustain a direct load to shoulder. Condition appeared from the beginning and never improved; it is believed that this was the indicator that the glenoid component had dislodged very early on, within a month or less. Second surgery: (b)(6) 2018, to determine cause of drainage from suture line in shoulder; the previous incision was completely reopened and probed to the capsule. Several suture abscesses where forming by remaining vicryl suture that hadn't finished spitting. No evidence of sinus tract formation, deep space infection, or involvement of the joint capsule. Late (b)(6) 2018: topical abscess in suture line begins to form; visit dr (b)(6) twice in december before surgery on (b)(6). Dr confused as to why my condition persisted after the complete cleaning from previous surgery. Third surgery: (b)(6) 2018. No capsular infection/bacteria found; loose component detected. Dr (b)(6) at this time stated he believed the component had loosened due to bacteria breaking the bond of the cement to the bone and/or component. He said this process takes a long time to occur. Dr (b)(6) later agreed that no bacteria was found or cultured from the capsule and because there was no wear on the component a	

Event Date	Event Description	Result
	failure was possible. Fourth surgery: (b)(6) 2019; removal of loose prosthetic and implant of medicated space due to protocol for possible capsular infection. No infection/bacteria found. Infectious disease dr (b)(6) 2019; six weeks of twice a day anti-biotic infusion (90 min each) for suspected infection/bacteria. Never found or confirmed. Fifth surgery scheduled for (b)(6) 2019: reverse shoulder. After visiting with the four drs: (b)(6) - first surgeon, (b)(6) - physical therapist, (b)(6) - infectious decease, (b)(6) - second surgeon, the component was discovered loose less than 6 months after implantation, but after close review of the physical therapy documents by dr (b)(6). It was determined that the device had probably loosened soon after implantation. Because the arthrosurface 8156-0032 has already been the subject of a recall by the fda, i wanted to bring it to your attention. I do not have the financial ability to legally pursue this matter, but i was hoping by reporting it, i might help someone else. All - 0200s allogen xlarge, 2ml. On (b)(6) 2019: left shoulder allogen.	

In summary, the above identified complaint analyses did not indicate any trends in device failure and did not identify any potential device failures that have not been previously identified and addressed, as indicated within the Arthrosurface risk management file for the shoulder implant systems.

5.4.5. FDA MAUDE Database

The US FDA maintains Medical Device Reports (MDRs) in the Manufacturer and User Facility Device Experience (MAUDE) database. The database can be searched using a variety of parameters including "product code". Two product codes are relevant to the Arthrosurface Shoulder Arthroplasty Systems are:

- HSD - Prosthesis, shoulder, hemi-, humeral, metallic uncemented
- KWS - Prosthesis, shoulder, semi-constrained, metal/polymer cemented

A large number of MDRs have been reported for both product codes. The database allows for searches based on the "Event Type". The most severe event in the database is "death". No deaths related to HSD or KWS products have been reported since 2011. For the majority of these reports, the report identified "insufficient information", "device dislodged or dislocated" or "adverse event without identified device or use problem" so not allowing identification or analysis of the underlying problem.. Given the large number of reports, they could not be reviewed individually in detail. Instead, the Total Product Lifecycle (TPLC) Report feature was used to identify the top "Device Problems" associated with both product codes. These are identified in the tables below:

Device Problem	Number of HSD Reports
Insufficient Information	954
Device Dislodged or Dislocated	616
Adverse Event Without Identified Device or Use Problem	298
Appropriate Term/Code Not Available	166
Break	150
Loss of Osseointegration	150
Fracture	140
Migration or Expulsion of Device	96
Disassembly	84
Naturally Worn	73
Unstable	58
Fitting Problem	56

Device Problem	Number of HSD Reports
Loss of or Failure to Bond	54
Malposition of device	42
Failure To Adhere Or Bond	39
Loose or Intermittent Connection	38
Difficult to Insert	37
Detachment Of Device Component	32
Difficult to Remove	25
Detachment of Device or device Component	24
Loosening of Implant Not Related to Bone-Ingrowth	22
Inadequacy of Device Shape and/or Size	18
Mechanical Jam	14
Material Erosion	14
Migration	11
Metal Shedding Debris	10
Device-Device Incompatibility	10
Material Deformation	10
Positioning Problem	9
Connection Problem	9
Osseointegration Problem	9
Device Operates Differently Than Expected	9
Misconnection	8
Noise, Audible	8
Material Separation	8
Mechanical Problem	7
Failure to Osseointegrate	7
Component Missing	7
Defective Component	6
Packaging Problem	6
Device Markings / Labelling Problem	6
Separation Problem	5
Tear, Rip or Hole in Device Packaging	5
Compatibility Problem	5
Bent	5
Unintended System Motion	5
Failure to Advance	4
Device Slipped	4
Device remains implanted	4
Component Incompatible	3
Implant, removal of	3
Misassembled	3
Use of Device Problem	3
Unknown (for use when the device problem is not known)	3

Device Problem	Number of HSD Reports
Explanted	3
Device Abrasion From Instrument Or Another Object	2
Difficult or Delayed Positioning	2
Dislocated	2
Defective Device	2
Crack	2
Dull, Blunt	2
Scratched Material	2
Unsealed Device Packaging	2
Material Fragmentation	2
Incomplete or Missing Packaging	2
Separation Failure	2
Loose	2
Unintended Movement	1
Device Misassembled During Manufacturing / Shipping	1
Incorrect Device Or Component Shipped	1
Peeled / Delaminated	1
Off-Label Use	1
Plate	1
Out-Of-Box Failure	1
Manufacturing, Packaging or Shipping Problem	1
Entrapment of Device	1
Failure to Disconnect	1
Disconnection	1
Thread	1
Split	1
Torn Material	1
Difficult To Position	1
Pitted	1
Material Disintegration	1
Device Operational Issue	1
Patient-Device Incompatibility	1
Electronic Property Issue	1
Decoupling	1
Contamination / decontamination Problem	1
Delivered as Unsterile Product	1
Delamination	1
Particulates	1
Screw	1
Deformation Due to Compressive Stress	1
Tip	1
Incorrect Measurement	1
Total	**3448**

Device Problem	Number of KWS Reports
Insufficient Information	1118
Adverse Event Without Identified Device or Use Problem	906
Device Dislodged or Dislocated	682
Fracture	227
Migration or Expulsion of Device	189
Unstable	164
Difficult to Insert	126
Loss of Osseointegration	124
Naturally Worn	122
Loss of or Failure to Bond	108
Appropriate Term/Code Not Available	103
Break	91
Loosening of Implant Not Related to Bone-Ingrowth	89
Loose or Intermittent Connection	71
Disassembly	63
Detachment of Device or device Component	62
Device Operates Differently Than Expected	48
Mechanical Problem	40
Detachment Of Device Component	40
Malposition of device	39
Migration	35
Fitting Problem	32
Missing Value Reason	30
Bent	30
Noise, Audible	28
Inadequacy of Device Shape and/or Size	27
Device Slipped	23
Material Integrity Problem	23
Material Separation	21
Device-Device Incompatibility	20
Difficult To Position	20
Material Erosion	20
Screw	20
Material Deformation	18
Device Damaged by Another Device	15
Positioning Problem	14
Device Contaminated during manufacture or shipping	13
Disconnection	12
Packaging Problem	12
Osseointegration Problem	12
Failure To Adhere Or Bond	11
No Apparent Adverse Event	10

Device Problem	Number of KWS Reports
Unintended System Motion	10
Device Issue	10
Mechanical Jam	9
Positioning Failure	9
Scratched Material	8
Use of Device Problem	8
Device Difficult to Setup or Prepare	7
Degraded	7
Improper or Incorrect Procedure or Method	7
Difficult to Remove	7
Patient-Device Incompatibility	7
Failure to Osseointegrate	6
Device Abrasion From Instrument Or Another Object	6
Cuff	6
Dull, Blunt	6
Failure to Align	6
Torn Material	6
Plate	6
Material Fragmentation	5
Unsealed Device Packaging	5
Unintended Movement	5
Connection Problem	5
Material Twisted / Bent	5
Human-Device Interface Problem	5
Pitted	4
Component Missing	4
Component or Accessory Incompatibility	4
Defective Device	4
Separation Problem	3
Crack	3
Material Distortion	3
Device Packaging Compromised	3
Patient Device Interaction Problem	3
Separation Failure	3
Physical Resistance / Sticking	3
Metal Shedding Debris	3
Delivered as Unsterile Product	3
Device Operational Issue	3
Guidewire	3
Corroded	3
Compatibility Problem	2
Failure to Advance	2
Device Inoperable	2

Device Problem	Number of KWS Reports
Tear, Rip or Hole in Device Packaging	2
Defective Component	2
Material Disintegration	2
Device Reprocessing Problem	2
Tip	2
Unintended Collision	2
Device Contamination with Chemical or Other Material	2
Loose	2
Off-Label Use	2
Incomplete or Missing Packaging	2
Difficult to Advance	2
Component Falling	2
Entrapment of Device	2
Implant, removal of	2
Adapter (Adaptor)	1
Total	**5106**

Note: The MAUDE database does not identify the number of procedures performed, so it is not possible to determine the frequency of occurrence from these data. Additionally, the product codes HSD and KWS are also used for Standard Stemmed Shoulder Arthroplasty Systems and Reverse Shoulder Arthroplasty Systems, which are fundamentally different compared to the Arthrosurface Shoulder Arthroplasty Systems which are essentially stemless designs. The number of complaints related to the devices under consideration is difficult to ascertain based on the shear volume of data made available on the FDA's website under the same umbrella of HSD and KWS product codes. Therefore, not all of these reported adverse events may be applicable to the Arthrosurface Shoulder Arthroplasty Systems, and the reader is directed to review the results of the clinical literature search that identifies adverse events that are more specific to the devices under consideration. In summary, the above analyses did not raise any device failure risk that has not been identified in the development and risk analysis process of the Arthrosurface Shoulder Arthroplasty Systems.

5.4.6. FDA Recall Database

The US FDA's MAUDE database also identifies reported recalls by product code. For HSD, there were seven Class II and one Class III recalls reported since 2011. During that same timeframe, there were 19 Class II recalls for KWS. These recalls are summarized in the table below:

For HSD:

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
02/02/2019	Ascension Orthopedics, Inc	Vendor change control	The product was packaged with the Instructions for Use for a different product (Ascension First Choice DRUJ System Partial Ulnar Head Implant).
07/17/2018	Fx Solutions	Package design/selection	Breach in the external blister of certain lots of Humelock Offset Head 50 X 20 and Centered Head 50 X 19.
03/13/2018	Zimmer Biomet, Inc.	Under Investigation by firm	Zimmer Biomet is conducting a medical device recall for two lots of Comprehensive Humeral

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
			stems. The lots were commingled during the manufacturing process and were etched with incorrect lot numbers. The size difference between the two stem sizes is 1.1 inches. It is visually recognizable by the user that the box label does not match the contents of the box.
03/01/2018	DePuy Orthopaedics, Inc.	Nonconforming Material/Component	The affected lots are being recalled because the epiphysis may not assemble to the stem, which may cause a surgical delay.
09/02/2015	Limacorporate S.P.A	Nonconforming Material/Component	The dimensions of the mating features of the recalled products are out of specification causing the device to be difficult to assemble.
02/12/2015	Arthrosurface, Inc.	No Marketing Application	Fully threaded Taper Post Fixation components not cleared for marketing in the US with current indications.
07/10/2013	Zimmer, Inc.	Packaging process control	The firm is initiating a removal of one lot of the Bigliani/Flatow Humeral Provisional Stem (00-4301-012-17, lot 62283991) as the stems manufactured under the lot are 14mm x 170mm devices incorrectly etched and packaged as 12mm x 170mm devices.
04/17/2013	Synvasive Technology Inc	Packaging change control	Biomet part # 506076, lot 928182 was received from Synvasive Technology containing the incorrect blade.

For KWS:

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
03/01/2019	Zimmer Biomet, Inc.	Packaging process control	The product was potentially being packaged without a taper adapter.
03/28/2018	Encore Medical, Lp	Device Design	It was discovered during a surgery that the design of the radius at the base of the pegs of the Anatomic Glenoid Trial (Part Numbers: 804-07-380, 804-07-420, 804-07-460, 804-07-500, and 804-07-540) is much larger on the trails than on the implants.
03/01/2018	DePuy Orthopaedics, Inc.	Nonconforming Material/Component	The affected lots are being recalled because the epiphysis may not assemble to the stem, which may cause a surgical delay.
02/27/2018	DePuy Orthopaedics, Inc.	Employee error	The screw in specific lots of the GLOBAL UNITE Anatomic Body and GLOBAL UNITE Fracture Body was inverted during assembly to the body, which will cause the humeral stem to sit proud and may cause surgical delays.
01/18/2018	Exactech, Inc.	Under Investigation by firm	Potentially mislabeled.
06/01/2017	Zimmer Biomet, Inc.	Under Investigation by firm	Zimmer Biomet is conducting a voluntary recall for a single lot of the Modular Hybrid Glenoid Base Large for the Comprehensive Shoulder System after it was determined that two pieces from the lot were moved to finished goods and shipped despite having an open Non-

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
			Conformance Report (NCR). The NCR indicated that one piece from the lot had scratches and the other non-confirming threads.
03/27/2017	Zimmer Biomet, Inc.	Process design	Endotoxin levels higher than process maximum limits were discovered in the identified polyethylene components.
12/03/2016	Tornier, Inc	Component design/selection	Tornier is conducting a recall on Aequalis Fx2 (implant parts and instrument trays) due to reports of dislocations of the poly insert and the stem.
06/16/2016	Zimmer Gmbh	Device Design	In some cases it has been difficult or not possible to disassemble the adjusted Dome Centric from the AS Humeral Rasp after initial positioning of the AS Humeral Trial Head which resulted in the whole construct of the Dome Centric with the still assembled AS Humeral Rasp taken out of the humeral canal. This could cause a delay in surgery time or the surgeon could decide to close the wound without finishing the surgery, increasing the infection risk or second use of anesthesia necessary.
05/25/2016	Limacorporate S.P.A	Component design/selection	Complaints of intra-operative breakage of the glenosphere impactors/extractors.
08/10/2015	Stryker Howmedica Osteonics Corp.	Process control	A package labeled as Part #5901-S-4818, Lot MAC7C14, standard humeral head trial, contained part # 5901-E-4818 Lot MAC7C14, offset humeral head trial.
04/20/2015	Exactech, Inc.	Labeling mix-ups	Incorrectly packaged. Outer and inner labeling may incorrectly identify the size of the enclosed device.
02/24/2015	Biomet, Inc.	Process control	The taper adaptor is missing from the packaging, which may result in a delay in surgery greater than 30 minutes.
11/08/2014	Integra LifeSciences Corp.	Nonconforming Material/Component	A single lot of left and a single lot of right Reverse Shoulder System cutting templates were manufactured incorrectly. Specifically, the threaded handle has been welded backwards on the template resulting in the cutting angle being the reverse of what it should be.
01/09/2013	Biomet, Inc.	Nonconforming Material/Component	Biomet is recalling Part Number PT-113950 PT Hybrid Glenoid Post, following an investigation which identified that the male thread of the post may be oversized. This oversized condition can vary in degree and may lead to the following three events: 1) If the PT Hybrid Glenoid Post is not fully seated into the Hybrid Base and the implant construct is implanted, then a gap of 1-3 mm will be prese
11/06/2012	Zimmer, Inc.	Error in labeling	Zimmer Inc., is initiating a correction to the patient labels of products manufactured before

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
			March 2010 by the Zimmer GmbH production site in Winterthur, Switzerland, after receiving four complaints of a discrepancy between product patient labels and product labels with respect to the reference and lot numbers of the product. While the information printed on the product label is correct, the info
07/31/2012	Exactech, Inc.	Labeling False and Misleading	Exactech, Inc. initiated a recall of Equinoxe Replicator Plates, Equinoxe Locking Screws, Equinoxe Compression Screw Kits, Equinoxe Fracture Adapter Tray Screws, and Octane-C Intervertebral fusion devices due to the firm determining that the device labeling identifies the affected parts as having a ten year shelf life; however, the packaging configuration that was used it qualified to a five year
07/06/2011	Encore Medical, Lp	Nonconforming Material/Component	The device has the potential to not appropriately mate with the humeral stem.
06/09/2011	Biomet, Inc.	Employee error	The firm is initiating this recall following an investigation which identified the rare possibility that certain units of Comprehensive Reverse Shoulder Humeral Trays may contain a locking ring that is incorrectly assembled.

Note: Similar to the Adverse Events reported on the FDA's MAUDE Database, the recalls listed for the product codes HSD and KWS are also inclusive of Stemmed Shoulder Arthroplasty Systems and Reverse Shoulder Arthroplasty Systems, the findings of which are not applicable to the Arthrosurface Shoulder Arthroplasty Systems. However, as stated in the previous section, it is not pragmatic to review in detail all the information made available on the FDA's website, and to be comprehensive, all the findings are reported herein with the aim of being inclusive rather than exclusive of the all potential issues related to the broader category of shoulder implants. It is of note that none of the reported recalls indicates or involves any fundamental issues with the performance of shoulder arthroplasty systems nor indicates any major safety issues related to shoulder implants. The recalls resulted from isolated issues with specific lots of a specific implant or system, i.e. supporting the overall safety of the devices and that the benefits outweigh the potential risks that may arise when these devices are used as intended.

5.4.7. MHRA MDAs

The UK's MHRA maintains a database of Medical Device Alerts (MDAs) at: https://www.gov.uk/drug-device-alerts

Two results were returned for search term "Shoulder" for the alert type "Medical Device Alert" and medical specialty "Orthopaedics". These are listed below:

1. Comprehensive Reverse Titanium Shoulder Tray (specific lots) - risk of device fracture
2. Shoulder system: Comprehensive Nano Humeral Components – increased risk of revision when used in reverse configuration

Neither of these alerts is applicable to the Arthrosurface Shoulder Arthroplasty Systems since these were issued specifically for reverse shoulder arthroplasty systems.

5.4.8. TGA Alerts

Australia's TGA maintains a database of Medical Device Alerts (MDAs) at: https://www.tga.gov.au/all-alerts

Five results were returned for a search on the term "Shoulder". These are listed below:

1. Affinis Fracture ceramic head (used in shoulder replacements) (24 December 2014)
   It has been identified that there is a risk of disconnection of components of the implant from each other due to inadequate fixation during surgery.
2. Glenosphere Orientation Guide - Instrument used to implant Delta XTEND Reverse Shoulder System (7 June 2013)
   It has been identified that, in the affected lot, an arrow etched onto the instrument is located on the wrong side of the device. This etching error could lead to incorrect placement of the glenosphere and consequently a number of potential complications.
3. PyroTitan humeral resurfacing arthroplasty - used in shoulder replacements (12 August 2013)
   It has been identified that there is potential for PyroTitan humeral resurfacing arthroplasty devices to break after being implanted. If this occurs, revision surgery will be necessary.
4. SMR L2 Metal Back Glenoid Component (used in shoulder replacements) (30 October 2012)
   The TGA contacted Lima Orthopaedics Australia, whose subsequent investigations revealed that under certain conditions, for example: rotator cuff failure or patient trauma, the SM L2 Metal Back Glenoid Component's polyethylene liner could become detached from the glenoid component, and that this had increased the revision rate of the SMR. As a result, the SMR L2 Metal Back Glenoid Component has been discontinued
5. VAIOS Total Shoulder Replacement System (21 October 2015)
   Information published by the Australian Orthopaedic Association's National Joint Replacement Registry (link is external) (AOANJRR) indicated that, to December 2013, the VAIOS Total Shoulder Replacement System had a revision rate at two years of 17.6%. The comparable revision rate at two years for all other total conventional shoulder implants was 5.5%.

Four of these five alerts are not applicable to the Arthrosurface Shoulder Arthroplasty Systems as these were issued specifically for stemmed or reverse shoulder arthroplasty systems. Alert #3 is applicable, and the potential adverse event noted in this alert is "implant fracture" or "breakage". This is identified as one of the adverse events for the Arthrosurface Shoulder Arthroplasty Systems, and the users have been notified of the same through the IFU document which is provided with the implants.

5.4.9. Health Canada – Recalls and Alerts

Health Canada maintains a database of Medical Device Recalls and Alerts at:
http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php

The search of the Health Canada recall and alerts database returned 91 results for the search term "Shoulder". Seven of these 91 could be considered to be applicable to the Arthrosurface Shoulder Arthroplasty Systems. Two were related to instrument failures, i.e. guide pin fracture and rasp malfunction, two to packaging related issues and three to labeling errors. None were implant related adverse events.

5.4.10. Risk-Benefit Analysis

The assessment of product risks by Arthrosurface is documented in the Risk Management Plan and Reports for:

1) AS-001, Rev 1 – HemiCAP Shoulder 25/30 mm;
2) AS-001C, Rev 1 – HemiCAP Shoulder 35 mm;
3) AS-001D, Rev 1 – HemiCAP Shoulder 40 mm;
4) AS-001H, Rev 1 – OVO;
5) AS-004, Rev 1 – GRS, and
6) AS-001HA, Rev 1 – OVOMotion.

The reports identify that all identified risks have been assessed and that "the medical benefits of the Arthrosurface Shoulder Arthroplasty Systems outweigh the overall residual risk inherent to this product."

There are ten design FMEAs relevant to the Arthrosurface Shoulder Arthroplasty Systems (referenced here as D1 to D10):

- D1: HemiCAP Shoulder 25/30 mm Articular Component Rev. 2
- D2: HemiCAP Shoulder 25/30 mm Taper Post
- D3: HemiCAP Shoulder 35 mm Articular Component Rev. 2
- D4: HemiCAP Shoulder 35 mm Taper Post Rev. 2
- D5: HemiCAP Shoulder 40 mm Articular Component Rev. 2
- D6: HemiCAP Shoulder 40 mm Taper Post
- D7: OVO Articular Component Rev. 2
- D8: OVO/OVOMotion Taper Post Rev. 2
- D9: GRS Articular Component Rev. 3
- D10: OVOMotion Articular Component Rev. 2

Arthrosurface has also established process FMEAs that address risks related to the manufacturing process. Relevant process FMEAs (referenced here as P1 to P6) are:

- P1: Assembly and Bonding of Instruments Rev. 1
- P2: Cleaning of Implantable Components Rev. 1
- P3: Coating of Implantable Components Rev. 1
- P4: Laser Marking of Articular Components Rev. 1
- P5: Ultrasonic Bonding of Thermoplastic to Metal Assemblies Rev. 1
- P6: Packaging and Labeling of the CAP System for Shipment Rev. 1

There are four accompanying documents relevant to the Arthrosurface Shoulder Arthroplasty Systems:

- IFU1: 3001-2010 - GRS Shoulder Arthroplasty System
- IFU2: 3001-2020/21/22 - OVO Shoulder Arthroplasty System
- IFU3: 3001-2000/02 - HemiCAP Shoulder Hemiarthroplasty System
- IFU4: 0020-0010/16/17 - Instrument Kit
- IFU5: 3001-3023 - OVOMotion Shoulder Arthroplasty System

The following table identifies the types of hazards identified as part of this review (i.e., from Arthrosurface, Inc.'s data, public databases, and clinical literature) and identifies whether the hazard is addressed in the risk documentation and/or the accompanying documentation.

Ref	Hazard	Risk Reference	IFU
1	Damaged/Broken Instrument	n/a	IFU4: Inspect for signs of wear or damage

2	Nonconforming Instrument	P1 (addressed throughout the document)	n/a
3	Broken/Fractured/ Detached Implant	D1(2B, 2F) D2(1A,1D) D3(2B, 2F) D4(1A,1D) D5(2B, 2F) D6(1A,1D) D7(2B, 2F) D8(1A,1D) D9(10B, 10C, 10D) D10(2B, 2F)	IFU1, 2,3 and 5: Possible Adverse Effects
4	Nonconforming Implant	P2 to P5 (addressed throughout documents)	n/a
5	Poor Implant Fixation	D1(2F) D2(1C, 1H) D3(2F) D4(1C, 1H) D5(2F) D6(1C, 1H) D7(2F) D8(1C, 1H) D9(10D) D10(F)	IFU1, 2, 3 and 5: Warning and Precautions
6	Periprosthetic Fracture	D1(2B, 2C) D2(1A, 1D, 1E, 1F) D3(2B, 2C) D4(1A, 1D, 1E, 1F) D5(2B, 2C) D6(1A, 1D, 1E, 1F) D7(2B, 2C) D8(1A, 1D, 1E, 1F) D9(10I) D10(2B, 2C)	IFU1, 2, 3 and 5: Possible Adverse Effects
7	Implantation/ Alignment/ Disassembly Problems	D1(2A, 2E, 2G, 2H) D2(1B, 1G, 1I) D3(2A, 2E, 2G, 2H) D4(1B, 1G, 1I) D5(2A, 2E, 2G, 2H) D6(1B, 1G, 1I) D7(2A, 2E, 2G, 2H) D8(1B, 1G, 1I) D9(10A) D10(2A, 2E, 2G, 2H)	IFU1, 2, 3 and 5: Warning and Precautions
8	Normal Wear	D1(2D) D2(1F) D3(2D) D4(1F)	IFU1, 2, 3 and 5: Possible Adverse Effects

		D5(2D) D6(1F) D7(2D) D8(1F) D9(1F) D10(2D)	
9	Packaging Issues	D8(1L) D9(10H) P6 (addressed throughout document)	n/a
10	Labeling Issues	P6 (addressed throughout document)	n/a
11	Process Control/ Human Error	P1 to P6 (addressed throughout documents)	n/a
12	Contamination/ Infection	D8(1K) D9(10F)	IFU1, 2, 3 and 5: Sterility

The nature and extent of the expected benefits following application of the Arthrosurface shoulder implants is listed in Section 2.1. These benefits are experienced by the patients receiving the subject device or similar marketed devices as is evident from the comprehensive review of the literature detailed in Appendix B.

The data provided support that, following implantation, these devices result in reduced pain, improved range of motion and improved functional outcomes that were evaluated using numerous clinical scoring methods. This was evident for both short-term, i.e. less than 1 year and long-term, i.e. > 10 years, periods. The literature also reflected that there are risks associated with the use of such devices, with the most common reported being the need for revision surgery due to a lack of resolution of pre-operative symptoms. As previously detailed in the benefit/risk analysis in Section 3, shoulder resurfacing and stemless shoulder arthroplasty implants are less disruptive implant procedures than total or reverse shoulder arthroplasty involving stemmed implants yet afford the patients the same level of pain relief with an increased probability of achieving pre-operative levels of functional activity, while also allowing easy revision to traditional or reverse shoulder arthroplasty options where such a need arises subsequently. The benefit of achieving pain-free, pre-operative levels of activity outweighs the risks associated with the use of stemless resurfacing, hemi- or total arthroplasty implants; the predominant risk being the need for a revision surgery frequently due to progression of the disease within the shoulder joint.

The risk management file has identified risk mitigation strategies that have been implemented to address device safety and operational related issues, which have been documented in the labeling that is presented to the user along with the product. These risks, together with generally accepted risks associated with any surgery, concur with the risks identified in the published literature as is evident from Table 6 in Appendix B.

In summary, the benefits of using the Arthrosurface shoulder resurfacing and stemless shoulder implants outweigh the generally accepted risks presented with the use of such devices for a period of up to 10 years. A risk/benefit analysis shows that the Arthrosurface devices are clinically effective when used as intended offering soft-tissue sparing and minimal bone resection , and are associated with a pre-identified risk profile associated with this group of stemless shoulder resurfacing and arthroplasty devices and

orthopedic surgery in general. The devices provide a surgery option that can be revised should the need arise due, for example, to disease progression.

5.4.11. Conclusion

The risk management process has identified and assessed hazards that are associated with similar devices. All hazards identified in this review are considered in the relevant risk management file documents, and are addressed in risk documents or information for use. The residual risk associated with these hazards has been determined to be acceptable by the Arthrosurface risk management team.

Of the 47 complaints received by Arthrosurface in relation to the Arthrosurface Shoulder Arthroplasty Systems which are the subject of this report, 40 were associated with surgical tools (e.g. damaged reamers and drills). Seven complaints were associated with the implant: Loosening (3), Pain/ Loss of Range of Motion (3) and a periprosthetic fracture (1).

The risks associated with the Arthrosurface Shoulder Arthroplasty Systems appear to be comparable to risks associated with substantially equivalent comparator stemless orthopedic shoulder devices; the frequency of complaints and revisions is low.

6. Clinical Evaluation Conclusion

Based on this evaluation of clinical data, the Arthrosurface Shoulder Arthroplasty Systems considered in this report achieve their intended performance and are safe for use as intended. Specifically, this evaluation has identified that the Arthrosurface Shoulder Arthroplasty Systems comply with the Essential Requirements (Annex I sections 1, 3, 4 and 6 of the MDD) as demonstrated by the following elements of this evaluation:

- Acceptability of the risk/benefit profile
    - As an established surgical procedure, there is sufficient clinical study data and no relevant clinical trials were identified during the literature search period.
    - The clinical data evaluated as part of this report support the continued safety and performance of the Arthrosurface Shoulder Arthroplasty Systems for the stated Indications for Use.
    - The American Academy of Orthopaedic Surgeons: The Treatment of Glenohumeral Joint Osteoarthritis Guideline and Evidence Report, 2009 provides a “moderate” recommendation for total shoulder arthroplasty over hemiarthroplasty when treating patients with glenohumeral joint osteoarthritis. [Note: A Moderate recommendation means that the benefits exceed the potential harm, but the strength of the supporting evidence is not as strong.]
- Adequacy of the information materials
    - Information for Use and the Technique Guide provide adequate information to users.
    - As appropriate, residual risks are communicated to users in documents supplied with the devices.
- Suitability of the device and adequacy of claims/intended purpose
    - The intended purpose and claims for the device are identified in sections 2.3 and 2.4 of this report. The clinical data support the use of the Arthrosurface Shoulder Arthroplasty Systems for these purposes.
- Adequacy of clinical data, IFUs and risk management documentation
    - The risks associated with the Arthrosurface Shoulder Arthroplasty Systems appear to be comparable to risks associated with similar devices, and frequency of complaints and revisions is low.
- Consistency between these documents and the current knowledge/ the state of the art

  - There is consistency between the documents and the current knowledge about shoulder arthroplasty. In patient populations for which non-surgical treatment is not effective, shoulder arthroplasty is considered state of the art in appropriate patient populations. The state of the art of the implants used continues to evolve.
- Any residual risks or uncertainties
  - As appropriate, residual risks are communicated to users in documents supplied with the devices.
  - No evidence was found that indicates that a Post Market Clinical Follow-up (PMCF) study is required.

In conclusion, the clinical evidence presented and reviewed above and in the supporting Appendices was found acceptable and met the applicable Essential Requirements and specifications. The clinical evidence supports the safety and performance of the Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO OVOMotion and GRS) when used as intended in primary resurfacing, hemi or total shoulder arthroplasty, and the risks associated with the use of the devices are acceptable when weighed against the benefits to the patient.

The next update to this CER is estimated to commence in March 2022, with the updated report planned to be documented by June 2022.

Appendix A: List of Evaluators

Author & Clinical Evaluator: Nikhil T. Jawrani, M.S.
Mr. Jawrani is a Biomedical Engineer with over 10 years of research and product development experience in the orthopaedic medical device industry. He has published more than ten articles in peer reviewed scientific and clinical journals, has more than five patent applications to his credit and has been a project lead on over eight new product development projects. He has supported the development of clinical evaluation and literature search reports for all Arthrosurface, Inc.'s medical devices.

Product Safety and Risk Analysis Evaluator: Dawn J. Wilson
Mrs. Wilson has over 25 years of experience developing and accessing Quality Management Systems and leading process improvement and risk management programs. She has assisted in the development of risk analyses systems and has supported the development of multiple clinical evaluation reports. She is also the lead regulatory personnel who oversees all of Arthrosurface, Inc.'s regulatory compliances worldwide.

Independent Reviewer Clinical User & Expert: Anthony Miniaci, MD
Dr. Miniaci of the Cleveland Clinic, Cleveland, Ohio has over 25 years of experience in shoulder arthroplasty. He has extensive experience in shoulder resurfacing and replacement with both the existing HemiCAP, OVO, and OVOMotion shoulder implants as well as competitive commercial shoulder arthroplasty devices. He now has more than 100 patients implanted with the HemiCAP and OVO who have reached the 5-year post-operative milestone. He has been involved in product development activities for all of Arthrosurface, Inc.'s shoulder implant products and understands the system design and clinical needs requirements. Dr. Miniaci's CV is included in Appendix F.

Arthrosurface Shoulder Arthroplasty Systems (HemiCAP Shoulder, OVO, OVOMotion and GRS) Clinical Evaluation Report: Update

Appendix B: Literature Search Methodology and Results

1. Background

Device name/model:

- Arthrosurface Shoulder Arthroplasty Systems:
  - HemiCAP Shoulder Hemiarthroplasty System
  - OVO Hemiarthroplasty or Total (with GRS) Arthroplasty System
  - OVOMotion Hemiarthroplasty or Total (with GRS) Arthroplasty System
  - GRS Total Arthroplasty System (with OVO or OVOMotion)

The critical review of the literature for the intended patient population in order to assess the benefit/risk profiles are tabulated and summarized herein.

Arthrosurface has conducted previous literature reviews and updates, with the most recent being 02/07/2017. The present search was dated from 11/01/2016 to 09/30/2019, continuing where it was left-off. Note: this specific update was done in July 2020 to meet the CER reporting requirements of the TGA, and in anticipation of filing a CE marking application for the OVOMotion device in the EU. A new article was published on the OVO and GRS implants in this period and has been assigned File #354 and included in this analysis.

A technical comparison of the Arthrosurface Shoulder Arthroplasty Systems and the devices described in the literature is included in Table 5a in Section 2.4 within this Appendix.

2. Methods

The data search, review of the journal articles, appraisal for relevance and appraisal of data contribution was performed in September 2019, for the period 11/01/2016 to 09/30/2019 for this CER update by Nikhil T. Jawrani, M.S., Partner at Jawrani MedTECH Consulting, LLP.

2.1. Search coverage

Original publications were identified through searches in PubMed using the text words and the Medical Subject Headings (MeSH) database described in Table 1. The search was limited to humans and was not limited exclusively to clinical trials.

Literature sources also included journal references lists and web searches; Cochrane Reviews; www.clinicaltrials.gov, and other sources.

It is not always known if a journal article is peer reviewed. Therefore, all relevant articles are reviewed and assessed based on their inherent quality. A journal article obtained from a known peer-reviewed journal does not preclude the same level of quality assessment.

2.2. Database search details

To identify published studies to support this clinical evaluation, a search of the National Library of Medicine (NLM) using PubMed, Cochrane Reviews, and www.clinicaltrials.gov was conducted. The NLM search terms (key words) used and the Boolean logic relationships applied are provided in Table 1, along with the results (i.e., the number of hits) for each line in the search strategy. These results were reviewed, and candidate articles exported to text files (including abstracts), and the abstracts further reviewed.

Table 1. Search Details

Filters activated: Publication date from 2016/11/01 to 2019/09/30, Humans, English.	Number Identified	Articles selected	Abstract reviewed and determined to be potentially relevant; obtain article	Obtainable articles	Articles included in the review
PubMed shoulder resurfacing OR humeral head resurfacing OR total shoulder resurfacing OR inset glenoid OR biomet copeland OR tornier aequalis	68	133	59	59	19
PubMed "total shoulder arthroplasty" NOT (reverse OR uncemented OR hemiarthroplasty OR cadaver)	285				
PubMed hemicap shoulder (done in June 2020 for search period of 2019/09/30 to 2020/06/30)	1	1	1	1	1
Cochrane Review Summaries shoulder	7	None Relevant			
www.clinicaltrials.gov with results total shoulder arthroplasty total shoulder resurfacing glenoid shoulder replacement	13 0 1 2	2	2	0	0
BioMed Central ISRCTN registry total shoulder arthroplasty total shoulder resurfacing glenoid shoulder replacement	0 0 2 3	None Relevant			

Limitations

Articles eliminated from effectiveness consideration:

- Anecdotal experience; case reports; small case series (except as described for Arthrosurface devices)
- Quality of data for assessment insufficient for assessment

Method to Identify Potential Data Duplication

Full text articles reviewed were assessed by author, study site and date of study to identify potential data duplication.

Literature Excluded:

Potentially relevant articles were selected. Articles eliminated from consideration included, but were not necessarily limited to:

- Articles not available in English
- Different indications for use
- Studies with sample sizes less than 10 patients (except as described for Arthrosurface devices)
- Biomechanical, computational model, *in vitro* or cadaver studies
- Stemmed shoulder arthroplasty studies
- Reverse shoulder arthroplasty studies
- Studies on radiographic results only
- Studies evaluating patient specific implants or 3d printed implants
- Robotic or computer assisted arthroplasty studies
- Studies evaluating custom instrumentations or patient specific instrumentation
- Studies with no mention of implant brand, manufacturing company and/or type
- Studies including comparison to a different procedure or technique

The abstracts were selected and reviewed for relevance. Potentially relevant articles were identified and where available, were obtained. Upon receipt of candidate journal articles, articles were thoroughly read and similarly eliminated from consideration based on the above exclusion criteria. Some articles that were not selected for final review were nonetheless assessed to review adverse events/report of complications for shoulder arthroplasties.

Literature Selected for Review

A total of 20 full content available articles were reviewed and assessed according to the criteria described in Tables 2 and 3, below. The full list of journal articles reviewed and identified as potentially relevant (including abstracts), and full articles obtained for review assessment are included as Appendix D.

Literature Containing Data Generated and Held by Arthrosurface

No data described in the literature were generated by Arthrosurface. A data collection plan ensuring data integrity and an analysis plan for analyzing data are not applicable.

2.3. Clinical Literature Appraisal

The selected literature was appraised in accordance with the criteria provided in Tables 2 and 3, below. Each of the studies was appraised to have sufficient relevance and quality for inclusion in the clinical literature evaluation. The results are summarized in Table 4.

Table 2. Appraisal Criteria for Relevance

	Data Contribution Criteria	Description	Category
1	Appropriate device	Were the data generated from the device in question?	1 Same device 2 Equivalent device 3 Other or unclear device
2	Use	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	1 Same use 2 Minor deviation 3 Major deviation
3	Population, disease, condition	Were the data generated for the same Indication for Use (patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	1 Applicable 2 Limited 3 Different population
4	Outcome measures; endpoints	Do the outcome measures or endpoints reported reflect the intended performance of the device?	1 Yes 2 No
5	Follow-up; report of hazards	Is the duration of follow-up long adequate to assess duration of treatment effects and identify complications or adverse events?	1 Follow-up > 2 years 2 Follow-up ≤ 2 years (short term) 3 Unknown
6	Statistical significance	Has a statistical analysis been provided and is it appropriate?	1 Yes 2 No
7	Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	1 Yes 2 No
		Was the benefit compared to any hazards identified?	1 Yes 2 No

Table 3. Appraisal Criteria for Quality of Data Contribution

	Data Contribution Criteria	Description	Category
8	Data source	Was the study design appropriate?	1 Yes (clinical trial) 2 Limited (other design) 3 No (case report/series)
		Was there a comparator or control?	1 Yes 2 No
		Was there a sample size calculation?	1 Yes 2 No
9	Quality for assessment	Do the reports or collations of data contain sufficient information to be able to undertake an adequate assessment?	1 High quality 2 Some deficiencies 3 Major deficiencies

Table 4. Clinical Investigation Journal Article Assessment

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
16	Ranalletta et al	2019	1	1	1 N=9	1 CS[1] ASES[2] ROM[3]	1 Mean = 44 months; 24 months minimum	1	1/2	2/1/2 2-Prospective Case Series 1-Comparison to pre-op baseline 2-N/A	2
26	Camus et al	2018	2	1	1 N=35	1 CS RO[4]	2 Mean = 20±6 months	1	1/2	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	2
31	Ibrahim et al	2018	2	1	1 N=14	1 OSS[5] CMS[6] VAS[7] ROM	1 Mean = 10.4 years; range: 5.8 to 13.9 years	1	1/2	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
35	Ingoe et al	2018	2	1	1 N=87	1 OSS Quick DASH[8] IS[9]	1 Mean = 5.4±2.5 years; range = 0.9 to 10 years	2	2/2	2/2/2 2-Retrospective 2-None 2-N/A	3
39	Maier et al	2018	2	1	1	1	1	1	1/2	2/1/2	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
					N=34	CS ROM IS	Mean = 33 months; range = 5 to 68 months			2-Retrospective 1-Comparison to pre-op baseline 2-N/A	
42	Bulhoff et al	2018	2	1	1 N=50 (sports: 42; non-sports: 8)	1 Custom Questionnaire	1 Mean = 5.5 years; range = 2.5 to 12 years	2	2/2	2/2/2 2-Retrospective 2-None 2-N/A	3
44	Verstraelen et al	2017	2	1	1 N=33	1 CMS NRS[10] SST[11] DASH EQ-5D[12]	1 Mean = 7.2 years; range = 5.7 to 9.3 years	2	2/2	2/2/2 2-Retrospective 2-None 2-N/A	3
47	Werner et al	2017	2	1	1 N=38	1 CS ROM PS[13]	1 Mean = 66.3 months; range = 24 to 168 months	1	1/1	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
52	Bessette et al	2017	1	1	1 N=16	1 SF-12[14] MSS[15] PSS[16]	1 Mean = 36.9 months; range = 25 to 56/53 months	1	1/1	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
57	Geervliet et al	2017	2	1	1 N=48	1 CS SST SF-12	1 Mean = 6.4 years; range = 5.1 to 7.9 years	1	1/1	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	2
60	Soudy et al	2017	2	1	1 N=105	1 CS SST RO DASH	1 Mean = 56 months; range = 24 to 120 months	1	1/1	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
64	Glanzmann et al	2017	2 and 3 N=37 Stemmed TSA N=37 Resurfacing TSA	1	1 N=74 total	1 CMS RO SPADI[17] Quick DASH	2 Up To 24 months	1	1/1	2/1/2 2-Observational 1-Comparison to pre-op baseline 2-N/A	2
123	Bulhoff et al	2019	2	1	1 N=38	1 CS ROM RO PS	1 Mean = 37.1 months; range = 24 to 72 months	1	1/1	2/1/2 2-Unknown 1-Comparison to pre-op baseline 2-N/A	2
195	Beck et al	2018	2	1	1 N=31	1 IS RO	1	1	1/1	2/1/2 2-Retrospective	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
						VAS Quick DASH CS	Mean = 94.7±11.3 months			1-Comparison to pre-op baseline 2-N/A	
199 *	Sayed-Noor et al	2018	2	1	1 N=63	1 Quick DASH ROM Muscle Strength	2 Up to 1 year	1	1/2	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	2
214 *	Kadum et al	2018	2	1	1 N=63	1 VAS Quick DASH	2 Up to 1 year	1	1/2	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	2
251	Spranz et al	2017	2 and 3 N=13 Stemmed TSA N=12 Stemless TSA	1	1 N=25 total	1 CS ROM	1 Stemmed Mean = 6.3±2.4 years Stemless Mean = 4.3±1.1 years	1	2/1	2/1/2 2- Unknown 1-Comparison to stemmed design 2-N/A	2
331	Kooistra et al	2017	2 and 3 N=28 Stemmed TSA N=20	1	1 N=49 total	1 CS RO SST OSS	1 Minimum 2 years	1	2/1	2/1/2 2- Prospective 1-Comparison to stemmed design and	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
			Stemless TSA			DASH				pre-op baseline 2-N/A	
335	Uschok et al	2017	2 and 3 N=20 Stemmed TSA N=20 Stemless TSA	1	1 N=40 total	1 CS RO	1 Minimum 2 years	1	1(vs pre-op) 2(vs stemmed)/1	1/1/2 1- Prospective Randomized Trial 1-Comparison to stemmed design and pre-op baseline 2-N/A	2
354	Egger et al	2019	1	1	1 N=31	1 ROM RO VAS PSS	1 Mean = 42.6 months; range = 24 to 74 months	1	1/1	2/1/2 2- Retrospective 1-Comparison to pre-op baseline and between different glenoid types 2-N/A	1

[1]CS: Constant Score [2]ASES: American Shoulder and Elbow Surgeons Shoulder Score [3]ROM: Range of Motion [4]RO: Radiographic Outcome [5]OSS: Oxford Shoulder Score [6]CMS: Constant-Murley Score [7]VAS: Visual Analog Score [8]Quick DASH: Disabilities of the Arm, Shoulder and Hand Score [9]IS: Implant Survival [10]NRS: Numerous Rating Scale [11]SST: Simple Shoulder Test [12]EQ-5d: EuroQol-5D [13]PS: Patient Satisfaction [14]SF-12: Short Form Health Survey [15]MSS: Musculoskeletal System Score [16]PSS: Penn Shoulder Score [17]SPADI: Shoulder Pain and Disability Index * These two articles report data on the same patient group; however, different outcomes are studied and reported in each article.

2.4. Discussion

Deviations from the Literature Search Protocol

There were no deviations from the literature search protocol.

Current Knowledge/ State of the Art

Current Knowledge, State of the Art is discussed in Section 3.0 of the CER.

Hemi and total shoulder arthroplasty are accepted treatments for specific patient populations, and/or when non-surgical treatment is not successful, or relief is not sustained.

As accepted treatment, comparison to baseline studies may be acceptable.

Weaknesses of the Studies

Weaknesses of the studies considered the following:

- Weaknesses of study identified by author
- Author conclusion that additional studies are required
- Omission of:
  - the methods used
  - the identity of products used
  - numbers of patients exposed
  - definition of the clinical outcomes
  - all the results the clinical study or investigation planned to investigate
  - confidence intervals; statistical significance (i.e. descriptive statistics only)
- Numbers too small for statistical significance
- Improper statistical methods
- Lack of adequate comparator or controls
- Subjective endpoints
- Endpoints influenced by natural fluctuations
- Effectiveness studies where subjects are likely to take or receive co-interventions
- Other factors – outcomes affected by variability in the population studied, the disease, user skills, availability of follow-up; use of prophylactic medication
- Significant differences between publications
- Inappropriate use of external or historic data
- If conclusion is supported by the data (i.e. misinterpretation by author)
- Statistical significance versus clinical relevance

Contribution and Weight (quality of evidence) of Journal Articles to the Conclusion

Only patient populations with applicable conditions were included in the assessment. The contribution/weight of assessed study articles included (but was not necessarily limited to):

- Controlled trials with randomization and blinding (higher weight than other clinical study types)
- Adequate documentation of condition
- Sample size calculations or rationale for sample size assessment
- *A priori* identification of outcome measures and criteria
- Statistical analysis used and statistical significance level identified

- Description of statistical significance and how it translates to clinical significance
- Appearance of post-study sub-population analysis not originally identified (i.e. appearance of data dredging)
- Author conclusion supported by the data
- Identification of other weaknesses of the study (i.e. bias)

Clinical contribution and weight were assessed (but not necessarily limited to) review of patient populations, treatment regimen, definition of outcome measures and follow-up, description of clinically meaningful outcome measures, statistical and clinical significance, size of treatment effect, and evidence of adverse events.

Study contribution and weight was assessed (but not necessarily limited to) review of the robustness of the study design (including randomization and blinding; use of controls), sample size, consideration of potential bias or confounding, a priori definitions success/failure and populations to be analyzed, adequate follow-up period, statistical analysis used, and whether data supported the conclusion.

Good quality of evidence of the strength of a studies contribution is defined as the appropriate patient populations and use, well-conducted robust studies with well-defined *a priori* success or failure criteria, and adequate statistical and clinical significance.

Fair quality of evidence of the strength of a studies contribution is defined as sufficient evidence to have some determination of a health outcome effect, but the strength of the evidence is limited by the limitations of the studies, or generalizability to a general population.

Limited quality of evidence of the strength of a studies contribution is defined as lack of sufficient data to assess the effect due to study limitations adequately, population limitations, lack of adequate description of analysis of data collection; poor results or failure to meet success criteria, etc.

The overall conclusion of the study contributions to evidence of safety is described considering the cumulative number of patients assessed and quality of data provided by the authors. An overall conclusion of the study contributions to evidence of performance is also described in the Conclusion using these general criteria.

Study Summaries: Performance; Strength of the Evidence; Benefit

The studies are summarized below including limitations, study contribution and weight, and quality and strength of the evidence.

File 16:

Ranalletta et al: "Results of partial resurfacing of humeral head in patients with avascular necrosis"
(Note: Article is in Spanish but was selected because it reports outcomes for the current device under consideration)

Summary: The aim of this study was to report the short-term results and complications of partial humeral head resurfacing (HemiCAP) in patients treated by avascular necrosis. Nine patients who underwent partial resurfacing of humeral head were evaluated. The mean follow-up was 44 months (minimum 24 months). The average age was 47 years (range 32-57 years).

Results: The patients had a significant improvement in functional scores and mobility between the pre-operative and last follow-up control. The Constant score improved from 35 to 79 points ($P < .001$), ASES score improved from 31 to 76 points ($P < .001$), forward flexion and external rotation improved from 101 to

150◦(P < .001), and from 24 to 45◦(P < .001), respectively. One patient presented symptomatic glenoid wear during follow-up, requiring revision surgery.

Conclusion: The authors conclude that in patients treated by avascular necrosis, the partial resurfacing of humeral head (using HemiCAP) demonstrated a significant improvement in functional scores and mobility with an average follow-up of 44 months.

Weakness of the Study: This study was in the Spanish language but was included as it was for the HemiCAP device under consideration. The number of patients was very small, but the follow-up period was longer than 2 years with good outcomes.

Quality for Assessment: Outcome measure endpoints appear appropriate. The English language abstract of this study was well described with adequate details; however, the study had a relatively small sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this prospective case series contribute to the body of evidence of this treatment using the Arthrosurface HemiCAP Shoulder. The weight of the evidence is fair quality.

File 26:

Camus et al: "Total shoulder prosthesis with humeral resurfacing: Impact on lateral offset and short-term clinical consequences"

Summary: The objectives of this study were to assess changes in overall lateral offset and their potential short-term clinical consequences after combined humeral resurfacing and glenoid replacement with the Tornier Aequalis Resurfacing Head and Aequalis PerForm glenoid implants. Combined humeral resurfacing and glenoid replacement induces a large increase in overall lateral offset, resulting in short-term clinical consequences. The primary outcome measure was the change in lateral offset between radiographs obtained pre-operatively and 3 months post-operatively. The functional outcome assessed using the Constant score was compared between the groups with a lateral offset change <10 mm vs. ≥10 mm. A total of 35 shoulder arthroplasties with humeral resurfacing were performed in 32 patients with a mean age of 72.1 years (range, 55–86 years). Mean follow-up was 20 ± 6 months (range, 12–31 months).

Results: Overall lateral offset was significantly greater post-operatively than pre-operatively (14 ± 6 mm vs. 5 ± 7 mm, p < 0.0001), the mean difference being 8 mm (range, 2–20 mm). Post-operative range of motion was better in the group with an overall lateral offset ≥10 mm (p = 0.0016). The mean weighted pre-operative Constant score was 37 ± 11 (range, 13–54). At last follow-up, the mean Constant score was 68 ± 7 (range 40–80) and the mean weighted Constant score was 91 ± 9 (range, 60–100). All evaluated clinical parameters were significantly improved compared to their pre-operative values.

Conclusion: Combined humeral resurfacing and glenoid replacement markedly increases overall lateral offset. This increase is not associated with adverse effects on short-term function and may improve post-operative motion range. However, greater lateral offset elevates the loads on the glenoid implant, which may increase the risk of glenoid implant loosening and rotator cuff tearing. Close radiological monitoring is therefore imperative.

Weakness of the Study: The authors list the following: "Our study has several limitations. The sample size is small. The clinical and radiological outcomes were assessed only in the short term, and follow-up duration varied across patients. Follow-up was too short for an assessment of glenoid implant loosening, which plays a major role in total shoulder arthroplasty survival. There was no control group. Measurement bias due to the use of plain radiographs, which are difficult to standardize, cannot be ruled out. However, bias in humeral measurements related to external or internal rotation of the humerus has been reported to induce less than 10% of error. Furthermore, intra-observer reproducibility of radiographic measurements, although poorer compared to CT measurements, seems nevertheless sufficient to support the validity of our findings."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were not identified and there was no discussion of the benefits compared to hazards. Follow-up was also short-term.

Quality for Assessment: Outcome measure endpoints although limited, appear appropriate. This was a fairly described prospective study, albeit with a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this prospective study contribute to the body of evidence of this treatment. The weight of the evidence is fair quality.

File 31:

Ibrahim et al: "Resurfacing hemiarthroplasty of the shoulder for patients with juvenile idiopathic arthritis"

Summary: The aim of this study was to report the outcomes of resurfacing hemiarthroplasty (RHA) using the Zimmer Biomet Copeland Mark-3 implants in a cohort of patients with juvenile idiopathic arthritis (JIA) affecting the shoulder joint. Fourteen uncemented RHA procedures were performed for 11 consecutive patients who required surgery because of JIA. Mean age at surgery was 36.4 years. Mean clinical follow-up was 10.4 years (range, 5.8-13.9 years). A significant humeral head defect (up to 40% surface area) was found in 5 shoulders and filled with autograft from the distal clavicle or femoral head allograft.

Results: At latest follow-up, no patient required revision. There was excellent relief from pain. The mean Oxford Shoulder Score and Constant-Murley Score improved significantly. No shoulder had a poor outcome, and 6 had a very good or excellent outcome. Worse outcome was associated with an intraoperative finding of significant humeral head erosion. Two shoulders required early arthroscopic subacromial decompression, but there were no other reoperations. There were no instances of radiographic implant loosening or proximal migration. Painless glenoid erosion was seen in 5 shoulders but was not associated with worse outcome. All patients reported their shoulder was extremely painful before surgery. The mean preoperative pain score was 9.0 of 10 (range, 7-10 points). At the latest follow-up, 8 of 14 shoulders were pain free, and the remainder experienced only mild pain (mean, 0.64 points; range, 0-3 points; $P < .001$).

Conclusion: Copeland surface RHA is a safe and effective intervention that significantly improves pain, range of motion, and function in the midterm for patients with end-stage arthritis of the shoulder due to JIA. The outcome is at least equivalent to that of stemmed hemiarthroplasty, with the added benefits of bone conservation, easier revision, and mitigation of periprosthetic fracture.

Weakness of the Study: The authors list the following: "This study is limited by the small number of patients and lack of a control group with unoperated-on shoulders. The methodologic design is retrospective and therefore prone to bias, but the outcome data were collected at the time of patient consultation by observers independent of the operating surgeon. The same prosthesis was used throughout, and validated scoring methods were applied. Cross-sectional imaging was not performed before surgery for any of our patients because it did not change our surgical management. We do acknowledge that with the advent of stemless prostheses, some patients may be suitable for glenoid implantation without the need for a stemmed humeral implant. Another indication may be to assess humeral head erosion if a stemmed prosthesis is not available on the shelf. Cross-sectional imaging would also be useful in the postoperative period to assess glenoid erosion but was not available in this study. The lack of standardization of plain radiographs and, therefore, lack of precision in measurement of glenoid erosion is a weakness of the radiographic follow-up. However, the immediate postoperative and latest postoperative radiographs were at least comparable, allowing a broad assessment of glenoid erosion to be made."

Statistical and clinical significance of the results were discussed in this study for different outcome scores; however, the study was not designed with *a priori* acceptance criteria, which is due to the

retrospective nature of this study. Postoperative complications were noted, but there was limited discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study, albeit with a small sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment in the young patient population. This is very much applicable to the current devices under consideration. However, due to the small sample size, the weight of the evidence is fair quality.

File 35:

Ingoe et al: "Seven-year survival analysis of the Global CAP (Conservative Anatomic Prosthesis) shoulder resurfacing"

Summary: This article presents a survival analysis of the DePuy Global CAP hemi-resurfacing implanted by multiple surgeons with up to 10 years of follow-up. Two survival analyses were performed; first, where failure was defined as component exchange and, second, where failure was defined as re-operation for any reason. Postoperative functional outcome was quantified using the Quick Disability Arm Hand and Shoulder Score (Quick DASH) and Oxford Shoulder Score (OSS). Eighty-seven Global CAPs were implanted in 75 patients. The mean (SD) follow-up was 5.4 years (2.5 years) (range 0.9 years to 10 years).

Results: Five patients had revision surgery and three patients underwent a reoperation for any reason. Survival at year 7 with component exchange as the endpoint was 80% and survival with re-operation for any reason as the end point was 62%. The mean OSS and Quick DASH were 35 and 27.6, respectively.

Conclusion: The Global CAP has similar survivorship in the short to medium term and produces similar clinical outcomes compared to other shoulder resurfacings. The Global CAP prosthesis has a similar survival to registry data but lower survival against the CRSA III at the principle site. It has a higher early revision rate compared to conventional shoulder arthroplasties, which may be a result of both the ease of revision and implant-related factors.

Weakness of the Study: The authors list the following: "The results from the 2015 NJR have shown the first PROMS data, with an average OSS for a resurfacing postoperatively at 6 months of 34, which is comparable to our results. An OSS of 35 or more is often present in the asymptomatic population. The OSS and Quick DASH did show a previously undescribed bimodal distribution of functional outcomes. This may occur because a single binary factor, such as rotator cuff tendinopathy or no rotator cuff tendinopathy, leads to either good or poor function. We cannot currently reliably predict this, and no statistically significant difference was found between age, sex or prosthesis type for OSS or Quick DASH. It is beyond the scope of the present study to identify reasons for this bimodal distribution beyond these variables. However, the reasons for such a distribution of scores need to be explored in future studies."

No statistical or clinical significance of the results were discussed in this study, and it was not designed with a priori acceptance criteria, which is due to the retrospective nature of this study. Hazards were listed but there was no discussion of benefits compared to hazards. A major shortcoming was the lack of comparison with either a baseline or another device.

Quality for Assessment: This was a well described study for the stated aim, with appropriate analysis of the implant survival outcomes; however, there was a lack of preoperative outcome score data for comparison with the corresponding postoperative scores that were measured. Since this was a study of implant survival with a large sample size and a moderate follow-up period, the article is considered to be of fair quality for assessment.

Conflict of interest: The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: AR and his department have received educational grants from DePuy Ltd and JRI Ltd. Both these are outside the published work. The other authors declare that they have no conflicts of interest.

Contribution and weight of the evidence: Although limited in nature, the results of this implant survival study contribute to the body of evidence of this treatment modality consistent for the current devices under consideration. The weight of the evidence is fair quality.

File 39:

Maier et al: "Cementless humeral head resurfacing for degenerative glenohumeral osteoarthritis fails at a high rate"

Summary: The aim of the study was to examine clinical and radiographic results of a cementless humeral surface implant and to evaluate prognostic parameters for implant failure. 34 shoulders were examined preoperatively and after a mean 2.7 years. Radiographic parameters, Constant scores (CS) and complications were recorded. 20 women and 14 men were included with a mean age of 63.7 (±11.2). The mean duration follow-up was 33 months [range, 5 to 68 months] for the clinical and radiographical follow-up. The implants used were Biomet Copeland in 10 cases, Synthes EPOCA RH in 21 cases and Tornier Aequalis RH in 3 cases.

Results: Eight patients (24%) had an implant revision for secondary glenoid erosion after a mean duration of 22.9 months with the earliest being after 8 months and latest after 68 months. They all received a stemmed total shoulder prosthesis (Tornier Aequalis shaft and glenoid) as replacement for the CUP hemi prosthesis. No revisions were performed for aseptic loosening, or trauma. The mean Constant score improved from 27 points (range, 10 to 49 points) preoperatively to 51 points (range, 10 to 83 points) 2.7 years postoperatively ($p < 0.0001$), and, adjusted by age and sex, from 36% (range, 14% to 61%) to 69% (range, 14% to 123%) ($p < 0.0001$). Significant differences were also found in terms of pain relief, activity, mobility, shoulder flexion, abduction, and external and internal rotation ($p < 0.05$).

Conclusion: The study shows a high revision rate (24%) after surface replacement arthroplasties. There was a correlation between the revisions and the surgery conditioned LGHO changes, a lower preoperative CS, decreased preoperative LGHO and heights as well as a higher preoperative CCD.

Weakness of the Study: The authors list the following: "The current study has its limitations. The number of cases was relatively small, and we used three different types of implants for cementless surface replacement. Furthermore, there is no radiological analysis in the axial plane, hence limiting the evaluation of the resurfacing. As Jia et al. showed, using a 3-D computed tomography would be more reproducible than plain radiography assessment. Nevertheless, postoperative x-ray imaging of patients undergoing shoulder replacement is a central component of clinical follow-up, why we used it in the present study."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were not identified and there was no discussion of the benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints although limited, appear appropriate. This was a fairly described study, albeit with a relatively moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment while reporting a high revision rate but in a moderate sample size. The weight of the evidence is thus of fair quality.

File 42:

Bulhoff et al: "Getting back in the game after humeral head resurfacing"

Summary: The aim of this investigation was to analyze whether patients undergoing humeral head resurfacing (HHR) surgery are able to successfully return to their sports and occupation afterwards. Fifty patients treated with CUP (HHR) arthroplasty were included. Two groups were built: Patients who have participated in sports less than 5 years prior surgery (Group 1: n=42 (84%)) and patients who have never participated in sports (Group 2: n=8 (16%)). Evaluation was based on a questionnaire asking for types of sports, frequency, time to return to sports and work as well as limitations in work life. Mean age at the time of surgery was 58.6 (36–84) years in Group 1 and 65 (56–75) years in Group 2. Mean time follow-up was 5.5 years (2.5–12) years. The implants used were Biomet Copeland RH and Synthes EPOCA RH.

Results: Twenty-seven (64%) patients in Group 1 participated in sports right before surgery. Twenty-one patients (50%) returned to sports after surgery. The returning rate was 78%. Seven (17%) patients in Group 1 stated that the reason they underwent shoulder replacement surgery was to continue to participate in sports. Swimming and skiing were two of the most favorable sports. Two (4%) patients had to change their profession due to surgery. Most of the patients were retired at follow-up.

Conclusion: Most of the active patients undergoing HHR surgery are successfully able to return to their sports activities after surgery. Patients employed were able to return to their occupation after surgery. Many patients were already retired at the time of follow up.

Weakness of the Study: The authors list the following: "Our study has some limitations: we did not evaluate the clinical or radiographic outcome of the patients included, and this was a questionnaire-based investigation. However, the high rate of return, particularly the ability of the majority of patients to return to activities performed prior to surgery within 12 months, leads us to assume that the clinical outcome is satisfactory, especially considering that many of the sports activities include the upper extremity and the affected shoulder. Prospective trials with clinical and radiographic follow-up are needed to verify the findings of our study."

No clinical or radiographic outcomes, or implant survival were reported in this study. Only a custom questionnaire was created to obtain sports related information. There was no statistical and clinical significance described in this study, and there was no pre-operative data available. Sample size and follow-up were moderate and medium-term, respectively. Hazards were not identified and there was no discussion of benefits compared to hazards. There were no comparisons available.

Quality for Assessment: Outcome measure endpoints missing from this study. Sample size was moderate, and the scope of this study was limited to sports outcomes only. The article is of limited quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study have a limited contribution to the body of evidence of this treatment. The weight of the evidence is limited to make any judgments.

File 44:

Verstraelen et al: "Clinical and radiological results 7 years after Copeland shoulder resurfacing arthroplasty in patients with primary glenohumeral osteoarthritis: an independent multicenter retrospective study"

Summary: The aim of this multicenter cohort study was to evaluate the midterm outcomes and survival after cementless stemless resurfacing arthroplasty (CSRA) using the Biomet Copeland Mark-3 implants in a series of 33 shoulders in 27 patients with primary osteoarthritis. Clinical outcome assessment included: Constant– Murley score (CMS); Simple Shoulder Test (SST); Disability of Arm, Shoulder, Hand (DASH); EuroQol-5D (EQ-5D) utility scores; Numerous Rating Scale (NRS) for pain. Radiographs were assessed by two independent observers for oversizing, radiolucency, glenohumeral subluxation, glenoid erosion and subsidence. Correlations between the clinical and radiological outcomes were calculated. Complications were registered, and revision and survival rates were

calculated. Mean age at time of surgery and mean follow-up time were, respectively, 67.7 (range 50.2–85.1) and 7.2 years (range 5.7–9.3 years).

Results: Means (SD) for CMS, age- and gender- adjusted CMS, SST, DASH and EQ-5D utility scores were: 56.4 (20.2), 76.5 (25.0), 54.0 (29.8), 37.6 (23.3) and 0.8 (0.1), respectively. NRS for pain was 2.0 and 3.8, respectively, in rest and during activities. Radiographic assessment of the CSRAs showed oversizing in 54.5%; radiolucency in 18.2%; superior glenohumeral subluxation in 33.3%; glenoid erosion in 45.5%; and subsidence in 3.0%. Perioperative complications did not occur. Revision surgery was performed in one patient (3.0%).

Conclusion: Despite a high percentage of lost to follow-up, CSRA seems to result in good clinical outcomes after a mean follow-up of 7.2 years. Noteworthy is that substantial radiological abnormalities were found. On the other hand, there was no correlation between the poor radiological findings and the clinical outcome.

Weakness of the Study: The authors list the following: "There are some limitations applicable to this study, which are mostly due to its retrospective design. The lack of preoperative data is an important limitation. On the other hand, all patients had primary end-stage glenohumeral OA with a severely impaired shoulder function and received prolonged conservative treatments for at least 1 year, as mentioned in our inclusion criteria. We tried to deal with this limitation by including questions about the preoperative state of the patients. This study shows the midterm results in a homogeneous study population. This was achieved by excluding patients with any other diagnosis than primary glenohumeral OA. Having this homogenous population allowed us to provide a better guidance for orthopaedic surgeons dealing with this patient group. Another limitation is the high percentage of lost to follow-up (37%). However, this is partially (10 CSRAs, 23%) due to the fact that we excluded patients with a large incompleteness of the questionnaires. Therefore, we could include them in the analyses, but we do know that they were satisfied with the result of the CSRA. As far as we know, this is the first study to report midterm results regarding disabilities in daily living and quality of live after CSRA. In our opinion, this is one of the most important outcomes measures in the perception of patients."

No statistical and clinical significance was described in this study as there were no comparative data available from either a baseline or another device. Hazards were noted but there was no discussion of benefits compared to the hazards. The study sample size was moderate, and the follow-up was long term. This was a retrospective study that could have been very useful were there any baseline or other data to compare to for gauging the clinical significance.

Quality for Assessment: Outcome measure endpoints were numerous, well defined and appear appropriate, but there were no pre-operative data available for comparison. This was a fairly described study, with a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this long-term retrospective study contribute to the body of evidence of this treatment with numerous outcome measures noted post-operatively. However, the lack of any pre-operative or comparative data make the weight of the evidence fair quality.

File 47:

Werner et al: "Progressive glenoid bone loss caused by erosion in humeral head resurfacing"

Summary: The aim of this study was to determine the development of glenoid erosion following shoulder resurfacing using a new measurement technique and detect potential prognostic factors. The authors performed a retrospective analysis on 38 shoulders undergoing humeral head resurfacing with a mean follow-up of 65.4 ± 43 months using the Biomet Copeland Mark-3 implant in 27 cases and the Tornier Aequalis RH implant in 11 cases. Clinical and radiographic evaluation followed a standardized protocol including pre- and postoperative Constant score, active range of motion, and X-rays in true anteroposterior view. Three independent observers performed measurements of glenoid erosion.

Results: The study reports good interobserver reliability for glenoid erosion measurements (intraclass correlation coefficient [ICC] 0.74–0.78). Progressive glenoid erosion was present in all cases, averaging 5.5 ± 3.9mmat more than 5 years' follow-up. Male patients demonstrated increased glenoid bone loss within the first 5 years ($p < 0.04$). The mean Constant score improved to 55.4 ± 23.6 points at the latest follow-up. Younger age was correlated to increased functional outcome. Revision rate due to painful glenoid erosion was 37%. The mean Constant score improved from 17.7 points (range 2–59 points) preoperatively to 55.4 points (range 14–98 points, $p < 0.001$) at the latest follow-up. The adjusted Constant score improved from 20.2% (range 2.2–64.1%) to 66.5% (range 20–103.3%, $p < 0.001$). Mean active anterior elevationimprovedfrom88.6° (range 10–160°) to 121.1° (range 45–170°, $p < 0.001$), abduction increased from 71.7° (range 10–160°) to106.1° (range 30–170°, $p<0.001$) at the latest follow-up. External rotation improved from10° (range 0–30°) to an average of 27.3° (range 0–70°, $p < 0.001$) postoperatively. At time of the most recent follow-up, 8 patients were very satisfied and 13 were satisfied with the operation, while 17 patients rated the outcome as fair or disappointed.
Conclusion: Glenoid erosion can be routinely expected in patients undergoing humeral head resurfacing. Painful glenoid erosion leads to deterioration in functional outcome and necessitates revision surgery in a high percentage of cases.
Weakness of the Study: The authors list the following: "The limitations of this study on cementless humeral head resurfacing are the limited number of patients operated for various etiologies and the retrospective character. We did not perform a priori power analysis; therefore, the lack of correlation between parameters might be related to the lack of power. However, we present long-term results of a single-surgeon series. Further studies are needed to develop strategies to reduce glenoid erosion especially in young patients."
While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were identified and there was discussion of the benefits compared to hazards for resurfacing procedures. Sample size was moderate, and follow-up was medium-term.
Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study, albeit with a moderate sample size. The article was of fair quality for assessment.
Conflict of interest: B.S.Werner and F.Gohlke declare to be under consultancy contracts with Wright/Tornier. J. Stehle, A. Abdelkawi, P. Plumhoff, and R. Hudek declare that they have no competing interests.
Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment in light of complications associated with glenoid erosion. The weight of the evidence is fair quality.

File 52:

Bessette et al: "Partial Resurfacing for Humeral Head Defects Associated with Recurrent Shoulder Instability"
Summary: This study retrospectively reviewed a cohort of patients with recurrent or locked anterior and posterior instability who underwent partial prosthetic humeral head resurfacing for significant Hill-Sachs and reverse Hill-Sachs lesions using the Arthrosurface HemiCAP Shoulder Resurfacing implants. At an average of 36.4 months after the index procedure, 16 patients were contacted by mail and telephone. Of the study group, 13 patients underwent partial resurfacing for anterior instability and 3 patients underwent partial resurfacing for posterior instability. Mean age at the time of the surgery was 32.3 years (range, 17-49 years) for the anterior instability cohort, with average follow-up of 36.9 months (range, 25-56 months).
Results: No patient had a repeat dislocation. In addition, 77% of patients in the anterior instability cohort and all of the patients in the posterior instability cohort returned to their full preinjury activity

level. For the anterior instability cohort, significant improvements from preoperatively to final follow-up occurred for mean Musculoskeletal Review of System score (4.54, P<.0001) and Short Form-12 physical component score (9.52, P=.002). For the combined cohort, the Penn Shoulder Score improved by 36.4 points (P=.059). This study showed the effectiveness of partial humeral head resurfacing for preventing redislocation for patients with significant Hill-Sachs and reverse Hill-Sachs lesions. Of these 13 patients, 11 had regained full range of motion and 2 reported mild restrictions. In 1 case, loss of range of motion was attributed to stiffness, and the other was caused by a sensation of instability. In addition, 10 patients (77%) reported full return to activities compared with preinjury activity levels, including waterskiing, squash, snowboarding, college-level ice hockey, rugby, and rock climbing. For the posterior instability cohort, all 3 patients reported no sensation of instability despite arm positioning. In addition, all 3 had full return to shoulder range of motion and returned to preinjury activity levels All 16 patients had both pre- and postoperative Review of Musculoskeletal System scores available for analysis. For the anterior instability group, 1 patient did not have preoperative SF-12 physical component scores available, but SF-12 physical component scores were available for all other patients. For the anterior instability cohort, mean Review of Musculoskeletal System score improved from 7.69 preoperatively to 3.15 postoperatively (P=.003). For patients with posterior instability, mean Review of Musculoskeletal System score improved from 5.33 to 0.66 (P=.37). The SF-12 physical component scores improved from 39.9 to 49.4 (P=.01) for the anterior instability group and from 32.7 to 51.0 (P=.18) for the posterior instability group. Changes in Penn Shoulder Scores were calculated only for patients who had pre- and postoperative data available for comparison.

Conclusion: Significant bone defects of the humeral head present a challenging clinical problem for the treatment of shoulder instability. This study reports the follow-up of a cohort of patients treated with partial resurfacing and its success at preventing recurrent instability, with a low rate of complications and satisfactory outcomes for motion and activity levels.

Weakness of the Study: The authors list the following: “The study cohort included a heterogeneous patient population treated with various combinations of procedures. Humeral defects that require surgical treatment are rare and often are seen in the setting of coexisting glenoid and capsulolabral deficiency. Although it would be ideal to study the effect of partial resurfacing in isolation with a more homogeneous population, it would be difficult to report on a significant number of patients without compromising adequate treatment of all risk factors for recurrent instability. The limited numbers of patients included in this study made useful multivariate analysis impossible. Although the primary outcome was recurrent instability, more complete capture of patient-reported outcome scores would provide a more accurate description of patient perceptions and function after surgery. A 38% rate of patients reporting a sense of apprehension in certain positions is high and could be considered a failure for those patients, even though no subsequent dislocations occurred.”

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. Hazards were noted, and there was discussion of benefits compared to hazards for this patient group, i.e. with partial defects of the articular surface. The sample size was small and follow-up was short term.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study, albeit with a small sample size and short-term follow-up. The article was of fair quality for assessment.

Conflict of interest: Drs Bessette, Frisch, Kodali, and Jones have no relevant financial relationships to disclose. Dr Miniaci is a paid consultant for Arthrosurface, receives royalties from Arthrosurface and Zimmer, and holds patents with Arthrosurface and Zimmer.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the Arthrosurface HemiCAP devices under consideration, and acknowledge that this device might offer an interim solution. Progression of OA is acknowledged by the

manufacturer, which is a potential hazard, but allows the treating physician to maintain the shoulder in its native condition by replacing only the damaged articular region. The weight of the evidence is fair quality.

File 57:

Geervliet et al: "Outcome and revision rate of uncemented glenohumeral resurfacing (C.A.P.) after 5–8 years"

Summary: This study reports the mid-term results of the DePuy Global C.A.P. uncemented resurfacing shoulder prosthesis. 48 humeral cementless resurfacing prostheses in 46 patients were performed. All patients were diagnosed with primary glenohumeral osteoarthritis. Patients were contacted for review; the Constant Score, visual analog pain scale, Dutch Simple Shoulder Test, SF-12 scores and physical examination were assessed both preoperatively and yearly postoperatively. Complications and revision surgery were documented. Radiographs were evaluated for component size, offset, inclination, height, loosening and subluxation. Forty-six patients (12 males) with a mean age of 72 years old (range 59–89) were included.

Results: At a mean 6.4-year follow-up (range 5–8), the Constant Score, visual analog pain scale and the Dutch Simple Shoulder Test scores improved significantly ($p < 0.05$) from baseline. Three patients were lost to follow-up. One patient died and two patients were not able to attend the follow-up appointments, due to other health-related issues. Eleven patients (23%) had a revision operation. The mean Constant score (corrected for gender and age) improved from points 47 ± 18, preoperatively to 83 ± 22 points at follow-up ($p < 0.001$). The mean Dutch Simple Shoulder Test (DSST) improved from 20 ± 21 points, preoperatively to 67 ± 30 points at follow-up ($p < 0.001$). The pain score, according to the visual analog scale (VAS), decreased from 66 ± 19, preoperatively to 29 ± 28 points at follow-up ($p < 0.001$). The SF-12, divided in a mental and a physical score, the mean SF-12 mental score improved from 49 ± 12 points preoperatively, to 51 ± 8 points at follow-up ($p = 0.45$). The mean SF-12 physical score improved from 35 ± 8 points preoperatively, to 39 ± 11 points at follow-up ($p = 0.05$).

Conclusion: The most important findings of this study of the Global C.A.P. shoulder resurfacing arthroplasty were an increase of range of motion, a reduction of pain complaints, but a concerning high rate of revision after midterm follow-up. The mid-term of the global C.A.P. resurfacing prosthesis are in line with other studies with a concerning revision rate of 23%.

Weakness of the Study: The authors list the following: "The conclusions of this study have to be drawn in the light of some limitations. Although the patients were enrolled prospectively in a computerized database, there was no control group treated with a stemmed implant or a resurfacing prosthesis with a glenoid component as a TSP. The reported study group was small but nonetheless comparable to other published studies of shoulder resurfacing. Our revision rate (23%) was higher compared to the rate reported by Levy at al. They reported a revision rate of 14% in the resurfacing shoulder replacement after 10 years follow-up. In contrast to the series reported by Streubel et al., our patients had satisfactory results after revision surgery."

Clinical and statistical significance of the results was discussed in detail in this study; however, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. Postoperative complications were noted and there was good discussion of benefits compared to hazards with these stemless device designs.

Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study, with a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: The original CAP study was funded by a grant (Spaarne Gasthuis #116347 and Alrijne Hospital #221090) from DePuy/Synthes, Warsaw, IN, USA, which participated in the study design and data management. The implant used in this study was not provided free of charge. The study sponsors had no role in the in the collection, analysis, interpretation of data, in the writing of the manuscript, and in the decision to submit the manuscript for publication. Dr Van Noort is a key

opinion leader for Johnson and Johnson. Cornelis Visser: Dr Visser is a key opinion leader for Johnson and Johnson.

Contribution and weight of the evidence: The results of this medium-term prospective study contribute to the body of evidence of this treatment but mention the fact that these designs may provide an interim solution while maintaining future surgical options for the patients, if required. The weight of the evidence is fair quality.

File 60:

Soudy et al: "Results and limitations of humeral head resurfacing: 105 cases at a mean follow-up of 5 years"

Summary: The objective of this study was to assess clinical and computed-tomography (CT) outcomes at least 2 years after humeral head resurfacing to treat concentric glenohumeral osteoarthritis. Humeral head resurfacing provides similar outcomes to those achieved with stemmed humeral head implants. This single-center retrospective study included 40 Biomet Copeland and 65 Tornier Aequalis humeral resurfacing heads implanted between 2004 and 2012. Mean patient age at diagnosis was 64 years. The diagnoses were osteoarthritis with an intact (68%) or torn (21%) rotator cuff, avascular necrosis (5%), osteoarthritis complicating chronic instability (3%), post-traumatic osteoarthritis (2%), and chronic inflammatory joint disease (1%). Validated clinical scores, radiographs, and CT before surgery and at last follow-up were compared.

Results: During the mean follow-up of 56 months, complications occurred in 24 implants. Revision surgery with reverse shoulder replacement was required in 18 cases, after a mean of 43.6 months, to treat glenoid wear or a rotator cuff tear. At last follow-up, for the implants that did not require revision surgery, the mean Constant score was 64/100. The implants had a mean varus of 5° and mean retroversion of −13.3°. The mean increase in glenoid cavity depth was 2.4 mm. Mean increases in medial and lateral humeral offset were 1.9 mm and 2.7 mm, respectively. Pre-operative factors significantly associated with failure were rotator cuff tear ($P = 0.017$) and glenoid erosion ($P = 0.001$).

Conclusion: This study reports a high failure rate related to glenoid wear or progressive rotator-cuff impairment, although CT showed no evidence of implant malposition or overstuffing. Previous studies of stemmed humeral head implants showed better outcomes. Given the low medium-term prosthesis survival rate, the authors now reserve humeral head resurfacing for concentric osteoarthritis without glenoid erosions or rotator cuff damage. The low medium-term survival rate of humeral head resurfacing implants in this study was ascribable to pre-operative glenoid wear and to rotator cuff tears. In the authors' opinion, despite the scrupulous operative technique and implant positioning, the resurfacing implant caused excessive lateral humeral offset responsible for rotator cuff stress and glenoid wear. The major adverse effect of pre-operative glenoid wear explains the difference in outcomes between the two implant models and illustrates the limitations of humeral head resurfacing.

Weakness of the Study: The authors list the following: "The limitations of our study are related to the retrospective design and absence of anatomic evaluation of the rotator cuff, which was evaluated indirectly based on the radiographic acromio-humeral interval. The number of patients with each diagnosis was too small for an evaluation of potential associations between diagnosis and implant survival. The large number of surgeons may have affected the reproducibility of the resurfacing procedure."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described. Hazards were identified and there was some discussion of benefits compared to hazards for this implant versus traditional stemmed implants.

Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study with a large sample size using two different stemless designs, each having a medium-term follow-up. The article was of good quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment for stemless designs as it relates to clinical outcomes with a known complication of glenoid erosion that may reduce implant survival rate. The weight of the evidence is good quality.

File 64:

Glanzmann et al: "Radiological and functional 24-month outcomes of resurfacing versus stemmed anatomic total shoulder arthroplasty"

Summary: This study compared clinical and radiographic outcomes of patients undergoing resurfacing total shoulder arthroplasty (TSA; Smith & Nephew Promos Resurfacing System) with those treated with a stemmed TSA. Patients with primary osteoarthritis who underwent humeral resurfacing (RES) or stemmed (STA) TSA were identified for a retrospective observational analysis. Standard radiographs and clinical/patient-rated assessments were made up to 24 months post-surgery. Implant revisions were assessed. Patients were frequency-matched in a 1:1 (RES:STA) ratio based on gender and age, and compared with regard to operation time and shoulder function (Constant, SPADI and Quick DASH scores). Mixed models with statistical adjustments were applied. 44 RES and 137 STA operations were performed in 157 patients.

Results: One and two revisions were recorded in the RES and STA group, respectively. The final matched cohort included a total of 69 patients and 37 operations per treatment group. Resurfacing TSA was 17 min shorter (95%CI: 5–28) compared to the stemmed procedure ($p = 0.005$). RES and STA patients showed significant functional improvement six months post-implantation, yet all measured scores did not differ between the groups at 2 years ($p \geq 0.131$). The status of static centering of the humeral head, acromio-humeral distance, and a lack of signs of implant loosening were also similar between treatments. The mean baseline Constant, qDASH and SPADI scores were similar between patient groups and significantly improved after implantation ($p < 0.001$). After adjusting for gender and age, there were no significant differences between the three functional scores for RES and STA patients up to 24 months after primary implantation ($p \geq 0.131$). Both groups had similar radiographic outcomes regarding static centering of the humeral head in the AP view. At the last follow-up, the mean acromio-humeral distance for the RES and STA cohorts was 11.9 mm (SD 3.0) and 12.6 mm (SD 3.5), respectively ($p = 0.357$). There were no signs of implant loosening such as component migration or radiolucency lines greater than 2 mm in both groups. At 24 months post-surgery, 89 % RES and 95 % STA patients reported that they would undergo the same operation again. One STA patient opted against having the same implantation again, and the remainder were undecided.

Conclusion: Similar 24-month post-operative radiological and functional outcome is achieved by RES and STA patients, even with a shorter RES surgery time. Larger cohorts and longer follow-up are required to better assess implant survival.

Weakness of the Study: The authors list the following: "Several limitations of this study are acknowledged. This is an analysis of register data with an observational design. Patients were not randomized to either of the TSA groups. This resulted in baseline imbalances, notably regarding age and arthritis severity, since early resurfacing implantation was performed in younger patients at our clinic. Despite the matching process in our patient selection, some level of residual confounding cannot be excluded. The sample size is small and does not offer sufficient analytical power for some outcome parameters such as the comparison of revision rates. Nevertheless, a power of 82% was achieved to detect a difference of 10 points in the Constant score at the two-year follow-up. Our pre-operative classification of glenoid wear was based on axillary radiographs in conjunction with Walch's criteria that were initially described for CT scans. Radiographic analysis also did not include glenoid version and tilt. Finally, our follow-up was limited to 24 months, which is suboptimal to detect differences in terms of survival and revision rates."

Statistical and clinical significance of the results were discussed in this study for different outcome scores; however, the study was not designed with *a priori* acceptance criteria, which is due to the

retrospective nature of this study. Postoperative complications were noted, and there was discussion of benefits of stemless designs compared to hazards related to stemmed designs.

Quality for Assessment: This was a well described study, with appropriate homogeneity of the groups, a moderate sample size but short-term follow-up. Statistical analysis is appropriate and described in great detail. The article was of good quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using stemless designs when compared to stemmed designs. The weight of the evidence is good quality based on the presentation and discussion of the data and findings.

File 123:

Bulhoff et al: "Mid-term results with an anatomic stemless shoulder prosthesis in patients with primary osteoarthritis"

Summary: The introduction of a stemless prosthesis in shoulder arthroplasty represents a novel design whereby the proximal humerus is restored anatomically, while leaving the diaphysis of the humerus untouched. The aim of this study was to present the mid-term results of total evolutive shoulder system (TESS; Biomet), a stemless shoulder prosthesis. The study included 38 consecutive patients (18 men and 20 women; mean age: 66 years; range: 55-81 years) treated with shoulder arthroplasty between 2009 and 2011 with TESS for primary glenohumeral arthritis. Total shoulder arthroplasty (TSA) was performed in 28 cases (74%), hemi shoulder arthroplasty (HSA) in 10 (26%). Constant score, active range of motion, patient satisfaction rate, and radiological assessment were analyzed. Mean time of follow-up was 37 months.

Results: Constant score improved from 21.8 points (28.6 adjusted for age) preoperatively to 74.1 points (86.6 adjusted for age) postoperatively. Active range of motion increased significantly from the pre- to postoperative status. Eighty-nine percent were very satisfied or satisfied with shoulder replacement surgery. One cemented glenoid was revised due to aseptic loosening. None of the components were found to be loose at the final follow-up. No signs of stress shielding were seen. Patients were also asked about their satisfaction with surgery at final follow-up. A total of 26 patients (70%) were very satisfied with their shoulder replacement surgery, seven patients (19%) were satisfied, and four (11%) were not or were less satisfied with surgery.

Conclusion: The present study showed good mid-term results, both clinically and radiographically, with a stemless shoulder arthroplasty design. Long-term results are needed to confirm these results.

Weakness of the Study: The authors list the following: "The present study also has its limitations. The follow-up is not long enough to see whether this type of prosthesis can withstand classic shoulder arthroplasty. We do not know whether loosening of the humeral component or stress shielding might lead to problems or whether revision surgery may be necessary. Long-term results are needed to clarify these questions."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described. Hazards were identified and there was some discussion of benefits compared to hazards for this implant versus traditional stemmed implants.

Quality for Assessment: Outcome measure endpoints are well described and analyzed, and appear to be appropriate. This was a well described study, albeit with a moderate sample size and short-term follow-up (in contrast to the authors' claim of mid-term). The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this study contribute to the body of evidence of this treatment as it relates to stemless shoulder arthroplasty devices. The weight of the evidence is fair quality.

File 195:

Beck et al: "Long-term survivorship of stemless anatomical shoulder replacement"

Summary: The aim of this study was to evaluate long-term results of stemless anatomical TSA. Between 2006 and 2009, 51 shoulders in 46 patients were resurfaced using the Biomet Total Evolutive Shoulder System (TESS). Thirty-one shoulders in 26 patients who were aged 66.7 ± 10.0 (range 34–82) years were available for review at a mean follow-up of 94.7 ± 11.3 (76–124) months.
Results: The implant survival rate was 93.5% at eight years. The overall revision rate of the TESS implant was 9.7%. Radiolucent lines were found on the glenoid side of the TESS arthroplasty in 90.9% of the cases. All stemless humeral corolla implants showed solid fixation at follow-up. Clinical scores significantly improved at long-term follow-up (VAS from 8.1 ± 0.9 to 1.0 ± 1.2, $p < 0.001$; Quick-DASH from 67.9 ± 13.5 to 18.7 ± 16.5, $p < 0.001$ and Constant score from 14.7 ± 6.1 to 68.8 ± 13.2, $p < 0.001$).
Conclusion: With the numbers given and with regard to the follow-up described herein, the results of arthroplasty with this type of implant seem to be comparable with the anatomic long-stem implants. However, comparative studies with a longer follow-up are required in order to reach a scientific final conclusion.
Weakness of the Study: The authors list the following: "Our study has some limitations; our investigation is a single-center retrospective study. It has to be mentioned that seven patients could only be assessed by telephone interview as they were unable to attend. Therefore, these shoulders were not available for radiographic follow-up. We report on long term results, nevertheless, the stemless implant has to be the subject of further investigation since stemmed implants still represent the 'gold standard' with regard to implant survival rates over ten years."
Statistical and clinical significance of the results were discussed in this study for different outcome scores; however, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. The main aim of the study was to determine implant survival. Postoperative complications were noted, and there was some discussion of benefits compared to hazards.
Quality for Assessment: This was a well described study for the stated aim, with appropriate analysis of the survival outcomes, as well as different clinical scores. The sample size was moderate and the follow-up was long-term. The article was of good quality for assessment.
Conflict of interest: None reported.
Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment as it relates to implant survival rate and clinical outcome measures. The weight of the evidence is good quality.

File 199:

Sayed-Noor et al: "Fatty infiltration and muscle atrophy of the rotator cuff in stemless total shoulder arthroplasty: a prospective cohort study"
Summary: The influence of preoperative rotator cuff fatty infiltration (FI) and muscle atrophy (MA) on the postoperative outcome of total shoulder arthroplasty (TSA) has only rarely been investigated and reported in the literature. This study hypothesized that more FI and MA would be associated with a worse postoperative functional outcome. This prospective cohort study included 63 patients (31 female and 32 male patients; mean age, 71 years [range, 53-89 years; standard deviation, 7 years]) with primary osteoarthritis of the shoulder operated on with anatomic stemless TSA. Preoperatively and at 3 months and 1 year after the operation, the functional outcome (QuickDASH [short version of Disabilities of the Arm, Shoulder and Hand questionnaire] score) and range of motion (ROM) (goniometer) and strength (dynamometer) for abduction at the scapular plane and for external rotation were measured. The degree of preoperative FI and MA was evaluated using computed tomography scans. All patients received the Zimmer Biomet Stemless Comprehensive implants.
Results: The authors report clinically and statistically significant improvements in functional outcome, strength, and ROM at both 3 months and 1 year of follow-up compared with those preoperatively. The Pearson correlation coefficient (r) showed significant correlations between preoperative

supraspinatus and infraspinatus FI and MA and preoperative and 1-year postoperative shoulder abduction and external rotation strength but not ROM. However, there was no influence of the rotator cuff FI and MA on the functional outcome after TSA.

Conclusion: This prospective cohort study demonstrated a significant correlation between rotator cuff FI and MA and strength but not ROM of the shoulder joint. However, it did not show any influence of the rotator cuff FI and MA on functional outcome after TSA. These findings would help orthopedic surgeons in their management when treating shoulder OA patients in whom TSA is planned. It would be very useful to perform the same study with a longer follow-up in the future.

Weakness of the Study: The authors list the following: "We realize that this study has limitations and its results should be interpreted with some caution. First, we evaluated the functional outcome with only 1 score, the QuickDASH. The QuickDASH has some disadvantages such as floor and ceiling effects, which could mask small differences among patients. This score, however, is widely used and well validated in Sweden, and this allows us to compare our results with those of other authors. Second, we did not include an evaluation of the FI and MA degree at the 1-year follow-up as in the study of Lapner et al. This could have added important information about the natural histories of FI and MA and their influence on outcome. Unfortunately, we did not include this part in our study protocol. Third, the radiologic evaluation of FI and MA on CT was conducted by 1 observer, an orthopedic surgeon with an interest in the shoulder and with good experience in shoulder joint radiology. When making the radiologic measurements, the observer was blinded to the clinical results of the patients. No interobserver and intraobserver reliability measures were conducted, which could jeopardize the accuracy of the obtained measurements. However, such reliability measures have partly been reported in the literature."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were not identified and there was no discussion of the benefits compared to hazards. Follow-up was also very short-term.

Quality for Assessment: Outcome measure endpoints although limited, appear appropriate. This was a fairly described study, albeit with a relatively short-time frame but a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this prospective study contribute to the body of evidence of this treatment for a specific observation related to fatty infiltration and muscle atrophy as it relates to clinical outcomes. The focus was more on the prior and, therefore, the weight of the evidence is of limited quality.

File 214:

Kadum et al: "Higher preoperative sensitivity to pain and pain at rest are associated with worse functional outcome after stemless total shoulder arthroplasty"

Summary: The aims of this study were to investigate any possible relationship between a preoperative sensitivity to pain and the degree of pain at rest and on exertion with postoperative function in patients who underwent stemless total shoulder arthroplasty (TSA) using the Zimmer Biomet Stemless Comprehensive implants. 63 patients who underwent stemless TSA and were available for evaluation one year postoperatively. There were 31 women and 32 men; their mean age was 71 years (53 to 89). The pain threshold, which was measured using a Pain Matcher (PM) unit, the degree of pain (visual analogue scale at rest and on exertion, and function using the short version of the Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH), were recorded preoperatively, as well as three and 12 months postoperatively.

Results: The study reports an inverse relationship between both the preoperative PM threshold and pain (VAS) at rest and the 12-month postoperative QuickDASH score (Pearson correlation coefficient (r) ≥ 0.4, $p < 0.05$). A linear regression analysis showed that the preoperative PM threshold on the

affected side and preoperative pain (VAS) at rest were the only factors associated with the QuickDASH score at 12 months.

Conclusion: These findings indicate the importance of central sensitization in the restoration of function after TSA. Further studies are required to investigate whether extra analgesia and rehabilitation could influence the outcome in at risk patients.

Weakness of the Study: The authors list the following: "The study has limitations. First, we cannot discount the influence of parameters that were not included, such as body mass index (BMI), the duration of symptoms of OA, the perioperative analgesic consumption, and the psychosocial status, on the results. Second, there was no control group of healthy non-hospitalized, nonorthopaedic subjects. We compared our results with those of healthy Swedish subjects included in the study of Lund et al. Third, the QuickDASH functional and pain (VAS) scores have some disadvantages, such as being rather subjective, and could have floor and ceiling effects, which might mask small differences among patients. These scores, however, are widely used and well validated in Sweden, and their use allows us to compare our results with others. A score such as the Constant–Murley score36 would have been a good alternative but it unfortunately has not been validated in the Swedish language."

While statistical and clinical significance was achieved, no a priori acceptance criteria was described, and the description of this data was limited to a single outcome score. Hazards were not identified and there was no discussion of the benefits compared to hazards. Follow-up was also very short-term.

Quality for Assessment: Outcome measure endpoints, although limited, appear appropriate. This was a fairly described study, albeit with a relatively short-time frame but a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this prospective study contribute to the body of evidence of this treatment for a specific observation related to clinical outcomes based on pain sensitivity of a patient. The weight of the evidence is of fair quality.

File 251:

Spranz et al: "Functional midterm follow-up comparison of stemless total shoulder prostheses versus conventional stemmed anatomic shoulder prostheses using a 3D-motion-analysis"

Summary: The aim of this study was to compare the functional midterm outcome of stemless shoulder prostheses with standard anatomical stemmed shoulder prostheses and to show that the STEMLESS results are comparable to the STEMMED with respect to active maximum range of shoulder motion (ROM) and Constant score (CS). Seventeen patients underwent total shoulder arthroplasty (TSA) in 25 shoulder joints. Stemless TSA was performed in 12 shoulder joints (group STEMLESS using the Biomet TESS implants), third-generation stemmed TSA in 13 shoulder joints (group STEMMED). Functional results were documented using the CS. 3D-motion-analysis using the Heidelberg upper extremity model (HUX) was conducted to measure active maximum (ROM).

Results: The group STEMLESS achieved a CS of 67.9 (SD 12.0) points and the group STEMMED of 70.2 (SD 5.8 points) without significant difference between the groups (p = 0.925). The maximum ROM of the group STEMLESS, ascertained by 3-D-motion-analysis, was in forward flexion 125.5° (SD 17.2°), in extension 49.4° (SD 13.8°), in abduction 126.2° (SD 28.5°) and in external rotation 40.3° (SD 13.9°). The maximum ROM of the group STEMMED, also ascertained by 3-D-motion analysis, was in forward flexion 135.0° (SD 16.8°), in extension 47.2° (SD 11.5°), in abduction 136.3° (SD 24.2°) and in external rotation 40.1° (SD 12.2°). The maximum ROM of the STEMLESS group was lower in forward flexion and abduction, higher in extension and almost identical in external rotation. But there was no significant difference (forward flexion p = 0.174, extension p = 0.470, abduction p = 0.345, external rotation p = 0.978).

Conclusion: Both types of shoulder prostheses achieve similar results for active ROM and CS in the midterm follow-up.

Weakness of the Study: The authors list the following: "One limitation of our study was the short duration of our follow-up. Our assessment with a mean follow-up of 4.3 years in the TESS group was too short to detect possible differences in the survivorship of stemless TSA. Further investigations would be necessary to determine the long-term performance of this kind of prosthesis. Another limitation was that some patients included in this study were treated and examined on both sides while others only were treated unilaterally. Although the results can be regarded as the results of independent surgical treatments, patient factors such as postoperative training motivation and compliance, pain perception, handedness and others possibly have an impact on the overall outcome that may influence both shoulders and thus violate the assumption of independence of statistical testing."

Statistical and clinical significance were achieved with an *a priori* acceptance criterion that the results of the stemless design should be similar to that of a stemmed design. The description of these data was limited to a single outcome score. Hazards were identified and there was limited discussion of the benefits compared to hazards. Follow-up was medium-term but different between the two groups and the sample size was small.

Quality for Assessment: Outcome measure endpoints although limited, appear appropriate. This was a fairly described study, albeit with a relatively small sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this comparative study contribute to the body of evidence of this treatment when compared to a stemmed TSA. The weight of the evidence is fair quality.

File 331:

Kooistra et al: "Comparative study of total shoulder arthroplasty versus total shoulder surface replacement for glenohumeral osteoarthritis with minimum 2-year follow-up"

Summary: Compared with total shoulder arthroplasty (TSA), total shoulder surface replacement (TSSR) may offer the advantage of preservation of bone stock and shorter surgical time, possibly at the expense of glenoid component positioning and increasing lateral glenohumeral offset. This study hypothesized that in patients treated for osteoarthritis with a sufficient rotator cuff, TSA and TSSR patients have comparable functional outcome, glenoid component version, and lateral glenohumeral offset. This was a retrospective cohort study with a minimum of 2 years of follow-up. Patients in the TSA and TSSR groups received a cemented, curved, keeled, all-poly glenoid component. A cemented anatomical humeral stem was used in TSA. TSSR involved a humeral surface replacement (i.e. Tornier Aequalis Resurfacing Head). Patients were assessed for functional outcome. Radiographs were assessed for radiolucent lines. Glenoid component position and lateral glenohumeral offset were assessed using computed tomography images.

Results: After 29 and 34 months of mean follow-up, respectively, TSA (n = 29) and TSSR (n = 20) groups showed similar median adjusted Constant Scores (84% vs. 88%), Oxford Shoulder Scores (44 vs. 44), Disabilities of the Arm, Shoulder and Hand scores (22 vs. 15), and Dutch Simple Shoulder Test scores (10 vs. 11). Glenoid components showed similar radiolucent line counts (median, 0 vs. 0), similar anteversion angles (mean, 0° vs. 2°), and similar preoperative to postoperative increases in lateral glenohumeral offset (mean, 4 vs. 5 mm). One intraoperative glenoid fracture occurred in the TSSR group.

Conclusion: The present study showed that TSSR patients have comparable 2-year functional outcome and comparable glenoid component positioning compared with TSA. Also, similar offset was noted between groups. The current data show that both procedures are acceptable solutions for shoulder replacement in patients with osteoarthritis.

Weakness of the Study: The authors list the following: "Our study is mainly limited by its retrospective design and a small sample size. The short-term follow-up presented may be too short to draw firm conclusions. Case series with longer follow-up have found 98% and 100% 5-year survival for TSA

compared with 63% and 78% 10-year survival for TSSR. However, this is currently the longest comparative follow-up for TSA and TSSR that we are aware of. Although we realize that glenoid component loosening may take longer than 2-years of follow-up, there were no differences in glenoid RLL scores in this study yet. Therefore, we expect from our data that the loosening pattern on long-term will not substantially differ. The retrospective design has introduced some biases. First, although the 2 surgeons used similar operative techniques, the TSA group was operated only by 1 of them; therefore, it is possible that a difference in surgeon experience has biased the comparison. Second, patient selection to undergo TSA or TSSR was not randomized but was dependent on the time frame in which the patient presented to the surgeon: from 2006 to 2008, patients underwent TSA, and from 2009 to 2012, patients underwent TSSR. As a result, there are probably unknown prognostic variables with unequal distribution across the groups. In addition, 3-dimensional reconstruction CT scans could provide more valid measurement of glenoid component position than the 2-dimensional CT scan slices that were used in our study because the influence of coronal scapular rotation on glenoid version measurement is not accounted for. However, our measurements showed excellent interobserver agreement (ICC, 0.94). Lateral offset measurement may have been inaccurate because there is no consensus on the optimal measurement. Although CT measurement of lateral offset is more reliable than a radiographic measurement, we believe that measuring along the scapular plane is of major importance because capsular and cuff tension run along this direction. Another limitation is that these CT-based measurements have not been investigated in shoulder arthroplasty patients and merit separate validation studies."

Statistical and clinical significance was achieved with an *a priori* acceptance criterion that the results of the stemless design should be similar to that of a stemmed design. Hazards were identified and there was discussion of the benefits compared to hazards. Follow-up was short-term, and sample size was moderate and different in each group.

Quality for Assessment: Outcome measure endpoints are well described and appear appropriate. This was a fairly described study, albeit with a small sample size and short-term follow-up. The article was of fair quality for assessment.

Conflict of interest: W. Jaap Willems is a consultant for Tornier and Smith and Nephew. Derek F.P. van Deurzen has received research funding (protocol number 0908-T-RESURF-RM) from Tornier, a designer and manufacturer of orthopedic surgical products related to the subject of this work. The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this comparative study contribute to the body of evidence of this treatment when compared to a stemmed TSA. The weight of the evidence is fair quality.

File 335:

Uschok et al: "Is the stemless humeral head replacement clinically and radiographically a secure equivalent to standard stem humeral head replacement in the long-term follow-up? A prospective randomized trial"

Summary: Stemless humeral head replacement represents a young generation of shoulder arthroplasty. This study evaluated the differences of a stemless design compared with the fourth-generation standard stemmed design. Total shoulder arthroplasty was performed in 20 patients with a stemless shoulder prosthesis (group 1; using the Arthrex Eclipse implants) and in 20 patients with a standard stem humeral head replacement (group 2; using the Arthrex Univers-II implants). Twenty-nine patients were examined clinically and radiographically at a minimum follow-up of 2 years and a minimum follow-up of 5 years. Functional results were assessed using the age- and gender-related Constant Score (CS). The radiographic analysis used native x-rays in 3 planes.

Results: The postoperative CS improved significantly in both groups, with no significant difference between the minimum of 2-year and 5-year follow-up. The difference in the CS, its subcategories, and active range of motion between the implant groups was not significant. A significant difference was observed in the radiographic analysis for the zone adjacent to the humeral calcar, with a lower bone mineral density in 41% of group 2 and in 0% in group 1. Radiolucent lines were statistically more frequent in group 2. No statistical differences were observed between the implant groups for the change of the inclination angle, the medial offset, and the lateral offset. The functional outcome obtained in this series after humeral head replacement using a stemless humeral head implant, with a significant improvement of the CS from 54 preoperatively to 73 at the minimum of 5-year follow-up, was comparable to the results after shoulder arthroplasty using a stemmed fourth-generation shoulder prosthesis, with an increase of the CS from 26 preoperatively to 70 postoperatively. Comparison of the subcategories of the CS between the Eclipse group and the Univers II group found no significant differences. The analysis of the active range of motion showed a statistically significant improvement for flexion, abduction, and external rotation, without a difference between both groups.
Conclusion: Both implants showed a consistently good functional outcome at the minimum of a 5-year follow-up, without significant improvement compared with the 2-year follow-up functional outcome. Both kinds of humeral implants achieved an anatomic reconstruction of the humeral head geometry in the coronal plane. The stemless implants did not show increased radiographic signs of prosthetic loosening. A reduction in bone density was increasingly observed below the trunnion as well as at the lateral shaft with the standard stem implant but seems to have no effect on the functional outcome.
Weakness of the Study: None reported by the study authors. Statistical and clinical significance were achieved, but no *a priori* acceptance criteria were defined. The follow-up period was not clearly defined and seemed to be different for different groups for different data sets. Hazards were identified but there was no discussion of the benefits compared to hazards. Follow-up was short and medium-term and sample size was small in each group. Not all patients were available for follow-up at the different timepoints described in the study, which made it difficult to analyze and evaluate the outcomes.
Quality for Assessment: Outcome measure endpoints are limited and not very well described. This was a fairly described study, with a small sample size and short to medium-term follow-up. The article was of limited quality for assessment.
Conflict of interest: Peter Habermeyer receives patent fees for the Eclipse prosthesis from Arthrex Inc. Sven Lichtenberg is a consultant of Arthrex Inc. The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.
Contribution and weight of the evidence: The results of this prospective randomized trial contribute to the body of evidence of this treatment comparing stemless versus stemmed designs for TSA. However, there is lack of clarity on the follow-up times and corresponding data sets as presented, making it difficult to arrive at a conclusion. Therefore, the weight of the evidence is of limited quality.

File 354:

Egger et al: "Total shoulder arthroplasty with nonspherical humeral head and inlay glenoid replacement: clinical results comparing concentric and nonconcentric glenoid stages in primary shoulder arthritis"
Summary: This study examined the results of the Arthrosurface OVO and GRS in glenoids at different stages of disease progress. It was hypothesized that there would be no statistically significant difference in outcomes between Levine concentric (Walch A) and Levine nonconcentric (Walch B) glenoids treated for primary glenohumeral arthritis using nonspherical humeral head and inlay glenoid replacement. This retrospective case series included 31 shoulders in 29 patients (25 male, 4 female), with an average age of 58.5 years. Outcomes included the Penn Shoulder Score (PSS), visual

analog scale for pain (VAS-Pain), range of motion, radiographic analysis, and complications. Inclusion criteria were primary glenohumeral arthritis, intact rotator cuff, and no prior open shoulder surgeries. Mean follow-up was 42.6 months (range, 24-74 months). The study included 7 concentric and 24 nonconcentric glenoids. The preoperative diagnosis for all shoulders was OA with a grade 4 Kellgren Lawrence (KL) stage in 25 shoulders (80.6%), grade 3 in 5 shoulders (16.1%), and grade 2 in 1 shoulder (3.2%). The mean follow-up was 42.6 months (24-74 months).

Results: The patients' ASA gradings were as follows: ASA 1 (n = 4, 12.9%), ASA 2 (n = 20, 64.5%), and ASA 3 (n = 3, 9.7%). The ASA grading was not available for 4 patients (12.9%). Clinical outcomes at the last follow-up (PSS, VAS-Pain, FF, ER) were also tested across ASA Classifications, sex, and preoperative KL grade, resulting again in the same distribution across both sexes, and all 3 ASA and KL OA grades ($P > .05$ for all tests). Clinical outcomes of the 2 glenoid component sizes showed the same distribution in all variables, except for FF (20 mm, n = 21, median FF 170˚; 25 mm, n = 10, median FF 160˚). Comparison of preoperative with postoperative range of motion showed a significant improvement in FF by 52.3˚ (from 114.6˚ to 167.3˚) and ER by 37.2˚ (from 16.2˚ to 56.6˚) ($P < .001$). At the last follow-up, the mean PSS Pain was 25.8 ± 4.7, PSS Function was 52.7 ± 6.9, PSS Satisfaction was 8.4 ± 2.2, PSS-T was 87.0 ± 12.6, and VAS Pain was 0.9 ± 1.2. Preoperative scores were available for 16 shoulders (51.6%) (15 male and 1 female), with an average age of 56.4 years (range, 42-69 years). The mean VAS-Pain score improved from 6.4 to 1.0, and the mean Penn Total Score more than doubled from preoperative levels. The individual improvement in PSS-T (range, 14.0-85.9) indicated that all patients with baseline scores surpassed the PSS MCID (11.4 scale points) and minimal detectable change (12.1 scale points) thresholds for TSA. The maximal possible improvement in the Penn Total Score showed that all patients surpassed the MCID of >30% and 94% achieved a significant clinical benefit of >50% improvement. Outcomes comparison showed no statistically significant differences in PSS domains including Pain ($P = .92$), Function ($P = .98$), Satisfaction ($P = .89$), and Total ($P = .98$); forward flexion ($P = .78$); external rotation ($P = .64$); and VAS-Pain ($P = 0.12$). At the last follow-up, the mean PSS Pain was 25.3/30, Function 52.7/60, Satisfaction 8.4/10, and Total 87.0/100. The mean forward flexion was 167.3˚, external rotation 56.6˚, and VAS-Pain 0.9. There were no signs of periprosthetic fracture, component loosening, osteolysis, and hardware failure, and no revisions or 90-day rehospitalizations were required. One patient was prophylactically treated with oral antibiotics for a history of prior infection and 1 patient required a later open biceps tenodesis after a traumatic proximal biceps rupture postoperatively.

Conclusion: Nonspherical shoulder arthroplasty with inlay glenoid replacement demonstrated excellent clinical benefits for both concentric and nonconcentric glenoids. The technique appears to be a promising option for glenohumeral arthritis even in the presence of posterior glenoid erosion. Initial results show that nonspherical HH resurfacing combined with inlay glenoid replacement is a viable outpatient technique for primary GH arthritis across patients with concentric and eccentric glenoid morphology. The results in both groups suggest that this total shoulder construct may be considered a reasonable alternative to treating shoulder arthritis even in the presence of posterior bone erosion and subluxation. We feel that both the HH design and the inlay component contribute to these results. Meaningful and SCBs included excellent functional results and pain relief, high patient satisfaction, and low risk in patients with and without preoperative glenoid erosion. No 90-day rehospitalization was required, and no implant failures were noted at a mean follow-up of 42.6 months. Further research with larger cohorts and longer follow-up is warranted, as this technique provides a unique option for primary GH OA.

Weakness of the Study: The authors list the following: “The weaknesses in our study include those that are inherent to all retrospective investigations and are related to the clinical documentation, radiographic imaging, cohort size determination, and follow-up. Clinical outcomes were lacking Penn baseline outcomes scores in approximately half of our cohort. Before 2014, preoperative PSS scores were not available for inclusion in this retrospective study. Since then, PSS metrics have been included

in our questionnaire and database for routine assessment of all shoulder procedures. Radiographic imaging followed a standard clinical protocol and lacked in control of precise beam orientation a prospective study could have achieved; hence axillary preoperative and postoperative comparison of humeral subluxation in the AP plane was not feasible. The variability in radiographic angles may have also influenced imaging assessment. The inlay glenoid component used in this study lacks a metal marker that makes the radiographic visualization more challenging. However, our positive clinical results, combined with strong basic science evidence, support the stability of the inlay glenoid and offset this limitation. Establishing a prospective radiographic assessment protocol to ensure consistent Grashey views and axillary projections that include the full length of the scapula would have been beneficial in tracking periprosthetic radiolucency with varying degrees of glenoid retroversion. Future studies with preoperative computed tomography imaging would provide further insight into the effects of glenoid retroversion on patient-reported outcomes, complications, and radiographic fixation strength on mid- and long-term follow-up. The overall cohort size in our study was relatively small, thereby weakening subgroup analysis. Therefore, we opted to primarily use the binary Levine glenoid classification and incorporated the original Walch classification rather than the 2016 update by Bercik et al, which included additional B3 and D stages that require 3-dimensional imaging. The retrospective study was limited to last follow-up comparison for the primary endpoint and follow-up was short term. This cohort will continue to be followed and longer term clinical and radiographic results will need to be evaluated to confirm implant stability and longevity. Future studies should explore prospective data to reconfirm and augment the risks and benefits of this technique."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. However, the study was designed with a hypothesis that was successfully tested. Hazards were noted, and there was discussion of benefits compared to hazards, focusing on the benefits of a stemless shoulder arthroplasty over traditional stemmed shoulder arthroplasty for patients even with posterior glenoid erosion. The sample size was moderate and follow-up was mid-term.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study with a moderate small sample size and mid-term follow-up. The article was of good quality for assessment.

Conflict of interest: Anthony Miniaci received consulting fees and royalties from Arthrosurface related to intellectual property related to the subject of this work. All the other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the current devices under consideration, i.e. OVO and GRS. No device failure or revision was reported at mid-term follow-up, and complications were also limited to only one patient that were not related to the device safety or efficacy. A sub-group analysis showed significant improvement to pre-operative scores, which also met the MICD criteria. A comparison of ROM and functional scores with published results of other stemless designs showed that the OVO/GRS performed better than most devices, while also having no device-related complications. The weight of the evidence is good quality.

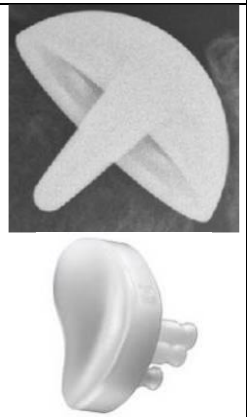
Device Comparison

The available specifications of the devices cited in the studies are described in Tables 5a and 5b. A comparison of the parameters, when available is included.

Extraction of information from the journal articles is difficult as 1) even when a manufacturers' device is specified, the model/design of a device may not be, and 2) sizing and/or exact material specification of the implant components used is never mentioned or discussed.

As it applies to a comparison to the Arthrosurface devices, the comparator devices are either a one-piece construct or two-piece constructs with different fixation designs. There are technical differences in the number and type of fixation features for the humeral and/or glenoid components. Additionally, the Arthrosurface devices are also available in smaller sizes (HemiCAP Shoulder) that provide partial coverage of the humeral head, compared to the comparator devices that only offer a large size to cover the entire humeral head (similar to the OVO/OVOMotion implants) to replace the entire surface of the humeral head. These differences may potentially affect the clinical properties of the construct but are considered technically equivalent as the intended use is the replacement of diseased or arthritic portion of the glenohumeral joint's articular surfaces. Thus, the assessment of the cited comparator devices generally supports the performance and safety of the Arthrosurface Shoulder Arthroplasty devices for the same indications for use as these devices.

Table 5a – Graphic & Dimensional Comparison of Arthrosurface vs Similar Marketed Devices

Company	Arthrosurface	Arthrosurface	Arthrex	Zimmer Biomet	DePuy	Smith & Nephew	Tornier	Synthes
Device	HemiCAP Total Shoulder	OVO/OVOMotion & GRS	Eclipse Stemless Shoulder Prosthesis & VaultLock Glenoid	Copeland Mark-3; TESS; Stemless Comprehensive Implants	Global CAP CTA Head; Global Advantage Glenoid Solutions component	Promos Resurfacing Prosthesis	Aequalis Resurfacing Head Aequalis PerForm Glenoid System	EPOCA RH Cup & Glenoid
Image								

Company	Arthrosurface	Arthrosurface	Arthrex	Zimmer Biomet	DePuy	Smith & Nephew	Tornier	Synthes
Device	HemiCAP Total Shoulder	OVO/OVOMotion & GRS	Eclipse Stemless Shoulder Prosthesis & VaultLock Glenoid	Copeland Mark-3; TESS; Stemless Comprehensive Implants	Global CAP CTA Head; Global Advantage Glenoid Solutions component	Promos Resurfacing Prosthesis	Aequalis Resurfacing Head Aequalis PerForm Glenoid System	EPOCA RH Cup & Glenoid
								
Humeral Implant Sizes	Ø 25 mm, 30 mm, 35 mm and 40 mm in multiple curvatures	Ø 46 mm x 42 mm to 58 mm x 54 mm in increments of 4 mm	Ø 37 mm to 55 mm	Ø 38 mm to 56 mm	Ø 40 mm to 56 mm	Not Available	Ø 37 mm to 54 mm	Ø 40 mm to 58 mm
Glenoid Implant Sizes	Not Applicable	19 mm x 20 mm and 20 mm x 25 mm in multiple curvatures	S, M and L	Ø 40 mm to 57 mm Articular Surface	Ø 40 mm to 56 mm	Not Available	S, M, L and XL	Ø 40 mm to 58 mm

Table 5b – Comparison of Arthrosurface OVO vs OVOMotion Device

Device Manufacturer & Name Attributes Compared	Arthrosurface OVO Shoulder Arthroplasty System	Arthrosurface OVOMotion Shoulder Arthroplasty System	Comparison between OVO and OVOMotion
Indications for Use/ Intended Use (Physical and Clinical Attributes)	OVO: For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement. GRS: For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implants intended to be used with bone cement.	OVOMotion: For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty. Both humeral and glenoid components of the OVOMotion Shoulder Arthroplasty System are intended for cemented use only. GRS: For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implants intended to be used with bone cement.	The physical application and clinical attributes of the OVO and OVOMotion shoulder arthroplasty systems are the exact same, in that these implant systems are both to be used for hemiarthroplasty or total shoulder arthroplasty of the humeral head and/or glenoid, respectively. Both implants are used for the same clinical conditions at the same site in the body and have the same relevant performance according to expected clinical effect for specific intended use.
Design (Technological Attribute)	Humeral: two-piece design with a threaded taper post design that interlocks with the head via a Morse taper interlock, available in multiple	Humeral: two-piece design with a threaded taper post design that interlocks with the head via a Morse taper interlock, available in multiple	The technological attributes of the OVO and OVOMotion implants are the exact same except for one minor difference. The undersurface of the OVOMotion articular component has a shelf that was included in

	sizes ranging from Ø 46 mm x 42 mm to 58 mm x 54 mm in increments of 4 mm Glenoid: one-piece pegged/keeled design available in two sizes ranging from 19 mm x 20 mm and 20 mm x 25 mm in multiple curvatures	sizes ranging from Ø 46 mm x 42 mm to 58 mm x 54 mm in increments of 4 mm Glenoid: one-piece pegged/keeled design available in two sizes ranging from 19 mm x 20 mm and 20 mm x 25 mm in multiple curvatures	the design to allow for slightly more reaming of the humeral head bone, thus allowing for better visualization of the glenoid surface for implantation of the GRS implant component. All other design attributes are the exact same in that both implants are used under same conditions of use, have same specifications and properties, use the same deployment methods and have the same principles of operation. Comparative pre-clinical bench testing conducted between the OVO and OVOMotion implants revealed that these implants are substantially equivalent and that the OVOMotion implants function safely and effectively as desired (Reference RIH Test Reports UO-17-104, UO-14-120B and UO-11-059).
Materials (Biological and Chemical Attributes)	Humeral: Co-Cr Alloy with Cp Ti Spray and Ti Alloy Glenoid: UHMWPE	Humeral: Co-Cr Alloy with Cp Ti Spray and Ti Alloy Glenoid: UHMWPE	There is no difference in the biological and chemical attributes of these two implant systems in that these use the exact same materials that are in contact with the exact same human tissues.

Table 5c. Device Comparison Arthrosurface Shoulder Arthroplasty Systems & Similar Marketed Devices

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
Arthrosurface HemiCAP Shoulder OVO with GRS (File #16, #52 and #354)	Y	For Hemiarthroplasty The HemiCAP Shoulder, OVO and OVOMotion are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. For Total Shoulder Arthroplasty The OVO, OVOMotion and GRS are indicated for use for the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator	N/A	Humeral: two-piece design with a threaded taper post design that interlocks with the head via a Morse taper interlock, available in multiple sizes Glenoid: one-piece pegged/keeled design available in multiple sizes	N/A	Humeral: Co-Cr Alloy with Cp Ti Spray and Ti Alloy Glenoid: UHMWPE	N/A

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
		cuff should be intact or reconstructable. All implant devices are a single use implants intended to be used with bone cement.					
Tornier Aequalis Resurfacing Head Aequalis PerForm (File #26, #39, #47, #60 and #331)	Y	The AEQUALIS™ Resurfacing Humeral Head is indicated as a total or hemi shoulder joint replacement where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable. The replacement of the joint with this device is indicated to relieve severe pain or significant disability caused by degenerative pathologies: osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, and primary and secondary necrosis of the humeral head. The resurfacing implant is intended for uncemented use only. The glenoid component is for cemented use only.	The clinical use is similar in that both devices are indicated for arthroplasty of the shoulder joint. The only difference is with regards to the HemiCAP Shoulder implants in which the amount of the articular defect replaced does not cover the entire surface of the humeral head. The OVO/OVOMotion for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS replaces the entire shoulder joint as do the Tornier devices. The difference for the smaller sizes of the HemiCAP Shoulder is not expected to result in a different outcome, and the clinical data for the Tornier device is applicable because the Arthrosurface device is clinically intended for a subset of the same treatment population. The	Humeral: one-piece design with tapered, tri-fin, press-fit fixation peg design available in multiple sizes Glenoid: one-piece keeled or pegged design available in multiple sizes	The Arthrosurface humeral implant is a two-piece Morse taper fixation design with a threaded fixation compared to a tri-fin, press-fit fixation design. The Arthrosurface two-piece design allows for better instrument control and accuracy of component placement, which should lead to better outcomes compared to the one-piece Tornier design. The glenoid implants are both one-piece designs with peg/keel and cemented fixation. Therefore, these differences are at least not expected to result in a different clinical outcome than	Humeral: Co-Cr Alloy with Cp Ti Spray and/or HA Coating Glenoid: UHMWPE	The materials used for both the Arthrosurface and Tornier devices are the same, with the prior using CPTi Spray/Ti-6Al-4V for its fixation component and the latter adding HA for cementless fixation. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use. As a result, the clinical outcome is expected to remain consistent with the current state of the knowledge.

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
			Tornier humeral implant is for cementless use only compared to the Arthrosurface humeral implant that is for cemented use. The data are applicable as the Tornier's cementless use is a worst-case scenario that may not present with the fixation strength that is provided with any cemented device.		what is currently published.		
	In summary, the aforementioned differences between the Arthrosurface and Tornier devices are not expected to result in different clinical outcomes compared to the currently published data. These differences also do not raise any new concerns of additional risks or adverse events for the Arthrosurface devices. This is confirmed by the similarities of the risks acknowledged (for the Arthrosurface devices – reference IFU's) and the risks published (for the Tornier devices) as seen in Table 6.						
Zimmer Biomet Copeland Mark-3 Zimmer Biomet TESS Zimmer Biomet Stemless Comprehensive Implants (File #31, #39, #42, #44, #47,	Y	Indicated for the following conditions where the humeral head and neck are of sufficient bone stock and there is presence of an intact or reconstructable rotator cuff, which is necessary for proper functioning and dislocation resistance: 1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. 2. Rheumatoid arthritis	The clinical use is similar in that both devices are indicated for arthroplasty of the shoulder joint. The only difference is with regards to the HemiCAP Shoulder implants in which the amount of the articular defect replaced does not cover the entire surface of the humeral head. The OVO/OVOMotion for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS replaces the entire shoulder joint same as the Zimmer	Copeland: one-piece design with tapered, four-fin, press-fit fixation peg design available in multiple sizes TESS and Comprehensive: Two-piece Morse taper design with fixation	The Arthrosurface humeral implant is a two-piece Morse taper fixation design with a threaded fixation compared to a four-fin, press-fit fixation design of the Copeland and corolla design of the TESS/Comprehensive. The Arthrosurface two-piece design allows for better instrument control and accuracy of component	Humeral: Co-Cr Alloy with Cp Ti Spray and/or HA Coating Glenoid: UHMWPE with Titanium metal backed design having axillary screws	The materials used for both the Arthrosurface and Zimmer Biomet devices are the same, with the prior using CPTi Spray/Ti-6Al-4V for its fixation component and the latter adding HA for cementless fixation. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use. As a result, the clinical outcome is

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
#60, #123, #195, #199, #214 and #251)		3. Correction of functional deformity 4. Reconstructable rotator cuff 5. Treatment of fractures of the humeral head 6. Traumatic arthritis Implants with Interlok/hydroxyapatite are cleared for uncemented applications. Implants with MacroBond and MacroBond coating with hydroxyapatite are cleared for cemented and uncemented applications; however, cement should only be applied to the surfaces that do not contain hydroxyapatite coating (i.e. stem).	Biomet devices. The difference for the smaller sizes of the HemiCAP Shoulder is not expected to result in a different outcome, and the clinical data for the Zimmer Biomet device is applicable because the Arthrosurface device is clinically intended for a subset of the same treatment population. The Zimmer Biomet humeral implant is for both cemented and cementless use only compared to the Arthrosurface humeral implant that is for cemented use. The data are applicable as the Zimmer Biomet's cementless use is a worst-case scenario that may not present with the fixation strength that is provided with any cemented device.	component having four/six finned/fanned corolla design, available in multiple sizes Glenoid: one-piece pegged design or two piece metal-polyethylene design with axillary screw fixation, available in multiple sizes	placement, which should lead to better outcomes compared to the one-piece Zimmer Biomet design and similar outcomes to the TESS/Comprehensive designs. The one-piece glenoid designs have peg/keel cemented fixation designs. The Zimmer Biomet's two-piece glenoid with metal backed screw fixation design is relatively new with lesser clinical use and published data available. As such, these differences are at least not expected to result in a different clinical outcome than what is currently published.		expected to remain consistent with the current state of the knowledge.
	In summary, the aforementioned differences between the Arthrosurface and Zimmer Biomet devices are not expected to result in different clinical outcomes compared to the currently published data. These differences also do not raise any new concerns of additional risks or adverse events for the Arthrosurface devices. This is confirmed by the similarities of the risks acknowledged (for the Arthrosurface devices – reference IFU's) and the risks published (for the Zimmer Biomet devices) as seen in Table 6.						
DePuy Global CAP	Y	Patients disabled by arthritic pain from either non-	The clinical use is similar in that both devices are	Humeral:	The Arthrosurface humeral implant is a	Humeral:	The materials used for both the Arthrosurface

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
(File #35 and #57)		inflammatory or inflammatory degenerative joint disease (i.e. rheumatoid arthritis, osteoarthritis and avascular necrosis). • Mild or moderate deformity of the humeral head. • Fractures of the humeral head. • Post-traumatic arthritis. Glenoid component is indicate for use in total shoulder arthroplasty in cemented application.	indicated for arthroplasty of the shoulder joint. The only difference is with regards to the HemiCAP Shoulder implants in which the amount of the articular defect replaced does not cover the entire surface of the humeral head. The OVO/OVOMotion for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS replaces the entire shoulder joint same as the DePuy devices. The difference for the smaller sizes of the HemiCAP Shoulder is not expected to result in a different outcome, and the clinical data for the DePuy device is applicable because the Arthrosurface device is clinically intended for a subset of the same treatment population. The DePuy's HA coated humeral implant is for cementless use only compared to the Arthrosurface humeral implant that is for cemented use. The data are applicable as the DePuy's	one-piece design with tapered, four-fin, press-fit fixation peg design available in multiple sizes Glenoid: one-piece keeled or pegged design available in multiple sizes	two-piece Morse taper fixation design with a threaded fixation compared to a four-fin, press-fit fixation design. The Arthrosurface two-piece design allows for better instrument control and accuracy of component placement, which should lead to better outcomes compared to the one-piece DePuy design. The glenoid implants are both one-piece designs with peg/keel and cemented fixation. Therefore, these differences are at least not expected to result in a different clinical outcome than what is currently published.	Co-Cr Alloy with Cp Ti Spray and/or HA Coating Glenoid: UHMWPE	and DePuy devices are the same, with the prior using CPTi Spray/Ti-6Al-4V for its fixation component and the latter adding HA for cementless fixation. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use. As a result, the clinical outcome is expected to remain consistent with the current state of the knowledge.

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
			cementless use is a worst-case scenario that may not present with the fixation strength that is provided with any cemented device.				
	An extensive cadaveric mechanical test was conducted between the Arthrosurface and DePuy devices to determine the fixation strength and micromotion in a comparative study. The data showed that the Arthrosurface device's fixation was superior to that of the DePuy's device in both static and cyclic test conditions. In summary, the aforementioned differences between the Arthrosurface and DePuy devices are not expected to result in different clinical outcomes compared to the currently published data. These differences also do not raise any new concerns of additional risks or adverse events for the Arthrosurface devices. This is confirmed by the similarities of the risks acknowledged (for the Arthrosurface devices – reference IFU's) and the risks published (for the DePuy devices) as seen in Table 6.						
Synthes EPOCA RH Cup (File #39)	Y	Advanced joint destruction resulting from degenerative, posttraumatic, rheumatoid arthritis, tumors and other conditions	The clinical use is similar in that both devices are indicated for arthroplasty of the shoulder joint, with the Synthes device having much broader indications. The only difference is with regards to the HemiCAP Shoulder implants in which the amount of the articular defect replaced does not cover the entire surface of the humeral head. The OVO/OVOMotion for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS replaces the entire shoulder joint same as the Synthes devices. The difference for the smaller sizes of the HemiCAP Shoulder is not	Humeral: one-piece design with cylindrical shell, grooved, press-fit design available in multiple sizes Glenoid: one-piece keeled or pegged design available in multiple sizes with or without metal backed coating	The Arthrosurface humeral implant is a two-piece Morse taper fixation design with a threaded fixation compared to a cylindrical shell, grooved, press-fit fixation design. The Arthrosurface two-piece design allows for better instrument control and accuracy of component placement, which should lead to better outcomes compared to the one-piece Synthes design. The glenoid implants are both one-piece designs with peg/keel	Humeral: Stainless Steel with or without TiNB coating Glenoid: UHMWPE with our without titanium spray coating	The materials used for both the Arthrosurface and Synthes devices are different (glenoid is same), with the prior using CPTi Spray/Ti-6Al-4V for its fixation component and the latter being SS. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use, with SS being less common in current application. As a result, the clinical outcome is expected to remain consistent

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
			expected to result in a different outcome, and the clinical data for the Synthes device is applicable because the Arthrosurface device is clinically intended for a subset of the same treatment population.		and cemented fixation. Synthes also has cementless metal backed glenoid that is not commonly used. Therefore, these differences are at least not expected to result in a different clinical outcome than what is currently published.		with the current state of the knowledge.
	The humeral component design and materials are different between the two devices. The SS material used for the Synthes device is not common in currently marketed other devices as observed in this table. In summary, the aforementioned differences between the Arthrosurface and Synthes devices could result in different clinical outcomes compared to the currently published data for the Synthes device. However, these differences also do not raise any new concerns of additional risks or adverse events for the Arthrosurface devices as its materials and design matches more closely with the other competitive devices in the market. This is also confirmed by the similarities of the risks acknowledged (for the Arthrosurface devices – reference IFU's) and the risks published (for the Synthes and other devices) as seen in Table 6.						
Smith & Nephew Promos Resurfacing Prosthesis (File #64)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Information from publicly searchable domains (e.g. www.google.com; S&N's website) has not revealed any brochures or technique guides related to the device that was the subject of this article. As a result, it was not possible to make any of these comparisons and conclude the applicability of the published data. However, from the article itself it can be gathered that the data are generally applicable to the Arthrosurface devices because of the similar indications for use. The published safety and performance data for this device are also similar to the data published for other devices.						
Arthrex Eclipse Stemless Shoulder Prosthesis (File #335)	Y	The Arthrex Eclipse Shoulder Prosthesis is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis. The humeral component is fixated with a hollow screw	The clinical use is similar in that both devices are indicated for arthroplasty of the shoulder joint. The only difference is with regards to the HemiCAP Shoulder implants in which the amount of the articular	Humeral: three-piece design with a trunnion and caged screw design that interlock with the head via a	The Arthrosurface humeral implant is a two-piece Morse taper fixation design with a threaded fixation compared to three-piece trunnion and cage screw	Humeral: Co-Cr Alloy with Cp Ti Spray and/or HA Coating and Ti alloy cage screw	The materials used for both the Arthrosurface and Arthrex devices are the same, with the prior using CPTi Spray/Ti-6Al-4V for its fixation component and the latter adding

Device Manufacturer & Name (Ref. Article)	CE Marked (Y/N/ Un-known)	Indications for Use/ Intended Use (Clinical Application)	Clinical Comparison to Arthrosurface Device	Design/ Technical Characteristics	Technical Comparison to Arthrosurface Device	Materials (Biological Properties)	Biological Comparison to Arthrosurface Device
		and the glenoid components are intended for cemented fixation in the joint and must only be used with appropriate bone cement	defect replaced does not cover the entire surface of the humeral head. The OVO/OVOMotion for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS replaces the entire shoulder joint same as the Arthrex devices. The difference for the smaller sizes of the HemiCAP Shoulder is not expected to result in a different outcome, and the clinical data for the Arthrex device is applicable because the Arthrosurface device is clinically intended for a subset of the same treatment population.	Morse taper interlock, available in multiple sizes Glenoid: one-piece keeled or pegged design available in multiple sizes or a metal backed design also available in multiple sizes	fixation design. Both designs are similar allowing for better instrument control and accuracy of component placement, which should lead to better outcomes compared to the one-piece designs of other systems. The glenoid implants are both one-piece designs with peg/keel and cemented fixation with Arthrex having a metal backed glenoid design. Therefore, these differences are not expected to result in a different clinical outcome than what is currently published in the literature.	Glenoid: UHMWPE with or without metal backed Ti alloy	HA for cementless fixation. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use. As a result, the clinical outcome is expected to remain consistent with the current state of the knowledge.
	The Arthrosurface and Arthrex devices with their threaded fixation and Morse taper interlock design features are very similar in design and application. Therefore, the aforementioned differences between the Arthrosurface and Arthrex devices are not expected to result in different clinical outcomes compared to the currently published data. The minor differences between these designs do not raise any new concerns of additional risks or adverse events for the Arthrosurface devices. This is confirmed by the similarities of the risks acknowledged (for the Arthrosurface devices – reference IFU's) and the risks published (for the Arthrex devices) as seen in Table 6.						

Clinical Trial Databases

Two clinical trials were identified from the databases, but the data presentation format made it difficult to extract information for thorough review and analysis.

Safety

Table 6 summarizes the adverse event/hazards/complications reported/cited in the studies reviewed as well as additional reports of adverse events/hazards from the published literature. Note that additional literature articles that were relevant from a complication/adverse events perspective were identified during the literature search and filtration process. Upon review of those articles, it was observed that the unexpected or reported side effects or adverse events or complications listed in those were similar to the ones listed and identified in the table below for the final selected articles. No additional AE's were observed in those non-selected studies.

Table 6. Adverse events/hazards

File	Author	Device	Unexpected or reported side effects or adverse events or complications	Included in Arthrosurface Instructions for Use?
16	Ranalletta et al	Arthrosurface HemiCAP Shoulder	symptomatic glenoid wear; revision surgery	Yes
26	Camus et al	Tornier Aequalis Resurfacing Head Aequalis PerForm	soft tissue tear with shoulder dislocation; revision surgery	Yes
31	Ibrahim et al	Zimmer Biomet Copeland Mark-3	revision surgery; impingement syndrome	Yes
35	Ingoe et al	DePuy Global CAP	revision surgery; implant replacement; soft-tissue failure; glenoid erosion; ongoing pain	Yes
39	Maier et al	Zimmer Biomet Copeland Synthes EPOCA RH Cup Tornier Aequalis Resurfacing Head	revision surgery; glenoid erosion	Yes
42	Bulhoff et al	Zimmer Biomet Copeland	humeral stem fissure; superficial wound infection	Yes
44	Verstraelen et al	Zimmer Biomet Copeland Mark-3	glenoid erosion; subluxation; subsidence; revision surgery; periprosthetic fracture	Yes
47	Werner et al	Zimmer Biomet Copeland Mark-3 Tornier Aequalis Resurfacing Head	Revision surgery; ongoing pain; glenoid erosion; dislocation	Yes
52	Bessette et al	Arthrosurface HemiCAP Shoulder	Stiffness; loss of ROM; instability; revision surgery; soft tissue tear; clavicle fracture	Yes
57	Geervliet et al	DePuy Global CAP	Revision surgery; migration; soft tissue failure; glenoid erosion; infection;	Yes

File	Author	Device	Unexpected or reported side effects or adverse events or complications	Included in Arthrosurface Instructions for Use?
			ongoing pain; poor function; arthrofibrosis	
60	Soudy et al	Zimmer Biomet Copeland Mark-3 Tornier Aequalis Resurfacing Head	Revision surgery; glenoid erosion; soft tissue tear; superficial wound infection; adhesive capsulitis	Yes
64	Glanzmann et al	Smith & Nephew Promos Resurfacing Prosthesis	Revision surgery; soft tissue tear; malrotation; infection	Yes
123	Bulhoff et al	Zimmer Biomet TESS	Revision surgery; implant loosening; glenoid perforation	Yes
195	Beck et al	Zimmer Biomet TESS	Implant disassembly; revision surgery; soft tissue failure; displacement; implant loosening; periprosthetic fracture	Yes
199	Sayed-Noor et al	Zimmer Biomet Stemless Comprehensive Implants	None reported	N/A
214	Kadum et al	Zimmer Biomet Stemless Comprehensive Implants	None reported	N/A
251	Spranz et al	Zimmer Biomet TESS	None reported	N/A
331	Kooistra et al	Tornier Aequalis Resurfacing Head	Glenoid fracture	Yes
335	Uschok et al	Arthrex Eclipse Stemless Shoulder Prosthesis	Reduced bone density; migration; implant loosening; revision surgery; soft tissue failure; bone fracture	Yes
354	Egger et al	Arthrosurface OVO & GRS	soft tissue injury caused by post-operative trauma	Yes

Note: A general warning statement has been included in the IFU's that covers the AE's from this list, which are applicable to any orthopaedic surgery in general.

Training

NA – This document is an update.

Engineering Usability

NA - This document is an update.

Product Literature and Operator Manuals

The Instructions for Use and Surgical Technique manuals are appropriate and include description of the intended purpose, handling instructions, warnings, precautions and contraindications, and are in line with the clinical evaluation. The risk associated with adverse events/hazards is assessed in risk documents. Residual risks are communicated in the product literature based upon the results of that risk assessment.

2.5. Conclusion

The evidence supports the continued performance and safety of the Arthrosurface Shoulder Arthroplasty Systems. No evidence was found that would suggest that the device would not perform as expected, nor not be safe for its intended use.

Appendix C and Appendix D are maintained separately

Appendix E: Arthrosurface Shoulder Arthroplasty Systems Supply History

Product	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020 YTD	Totals	Year First Shipped
USA (Includes Puerto Rico)																			
Shoulder	38	264	450	613	763	765	681	592	437	378	348	257	217	201	192	180	83	**6459**	2004
OVO	0	0	0	0	0	0	0	155	512	615	735	724	792	780	730	501	190	**5734**	2011
OVOM	0	0	0	0	0	0	0	0	0	0	0	0	0	0	99	600	325	**1024**	2018
Glenoid	0	0	0	0	0	0	0	75	214	300	386	388	461	474	592	838	421	**4149**	2011
Canada																			
Shoulder	32	51	63	30	15	-60	29	39	0	22	16	13	4	7	0	8	3	**272**	2004
OVO	0	0	0	0	0	0	0	0	8	26	18	10	4	0	2	6	0	**74**	2012
Glenoid	0	0	0	0	0	0	0	0	2	0	2	4	15	7	11	7	0	**48**	2012
EU (Includes UK)																			
Shoulder	30	69	467	104	51	63	-79	41	3	32	18	-50	-8	0	6	16	1	**764**	2004
OVO	0	0	0	0	0	0	0	13	12	1	14	5	3	1	28	25	10	**112**	2011
Glenoid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	17	18	7	**42**	2018
Australia																			
Shoulder	20	56	106	21	31	13	12	234	10	-29	18	7	1	2	-5	-3	-1	**493**	2004
OVO	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	**1**	2016
Glenoid	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	**1**	2016
New Zealand																			
Shoulder	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	4	12	**18**	2017
OVO	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	N/A
Glenoid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	N/A
Africa																			
Shoulder	0	45	24	39	4	0	21	-23	-20	19	1	0	2	2	0	2	0	**116**	2005
OVO	0	0	0	0	0	0	0	0	12	4	3	1	6	1	2	0	0	**29**	2012
Glenoid	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	0	**8**	2012
South America																			
Shoulder	0	11	243	18	28	48	13	3	114	28	-104	0	2	0	0	0	0	**404**	2005
OVO	0	0	0	0	0	0	0	0	44	0	-32	14	6	0	0	0	0	**32**	2012
Glenoid	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	**8**	2015
Asia																			
Shoulder	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	N/A
OVO	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	N/A
Glenoid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	N/A
Totals	**120**	**496**	**1353**	**825**	**892**	**829**	**677**	**1129**	**1356**	**1396**	**1423**	**1381**	**1507**	**1476**	**1675**	**2202**	**1051**	**19,788**	

Product	Total Sales
HemiCAP Shoulder	8526
OVO	5982
OVOMotion (OVOM)	1024
Glenoid (GRS)	4256

NOTE: Numbers shown in red show units which have been returned for reasons of supply chain or expired implants.

NOTE: 2020 units supplied YTD (June 2020)

NOTE: Units supplied to Australia were supplied under the Special Access Scheme/prior to reclassification to Class III, etc.

Appendix F: Dr. Anthony Miniaci's *Curriculum Vitae (maintained separately)*

Appendix G: Device Comparison, Literature Review & Post-Market Data per TGA's CEG

For the ongoing device application with TGA, the subject device is only the OVO/GRS, and not the HemiCAP Shoulder and the OVOMotion devices that have previously been covered by this CER. The OVO/GRS is the sole device covered by Appendix G, which has been documented in response to TGA's requirement to "Select a single device/system for the purposes of demonstrating equivalence".

The aforegoing clinical evaluation report for the HemiCAP Shoulder, OVO, OVOMotion and GRS had considered multiple comparator devices to establish the safety and effectiveness of these devices marketed by the manufacturer in various jurisdictions including the US and EU (see Appendix B). The data presented on the comparator devices, along with the available data presented for the manufacturer's own devices, formed the basis for approval of the manufacturer's devices in the EU via CE certification. The multiple comparator devices were selected in the CER based on the guidance identified below:

EU regulations in MEDDEV 2.7/1 revision 4 (in Appendix A on page 33 of 65 under footnote #14) explicitly states the following:

"Evaluators may wish to refer to several devices that are equivalent. In such a situation, equivalence of every single device to the device under evaluation should be fully investigated, demonstrated, and described in the clinical evaluation report."

However, in order to satisfy the clinical evaluation requirements as part of the device approval process per Australia's TGA requirements, the manufacturer has now selected Zimmer Biomet's Copeland Shoulder Arthroplasty System (hereafter referred to as the 'Copeland device') as the single comparator device to provide sufficient clinical evidence that demonstrates the safety and effectiveness of the subject device, i.e., the OVO/GRS.

The manufacturer also notes that for US FDA's 510(k) clearance, the Copeland device served as the substantially equivalent predicate device for the subject OVO device.

The manufacturer has extracted all relevant information for the Copeland device from the main body of the CER as well as from Appendix B to include in this Appendix G, along with additional data and information as they relate to device safety and performance. Specifically, the following relevant and updated information is provided herein: Device Comparison, Literature Review and Post-Market Data.

I: Device Comparison

To establish substantial equivalence between the manufacturer's subject OVO/GRS device and the comparator Copeland device, the following device comparative table is provided (note: the same information has been provided to the US FDA and EU regulators in the past for the subject device's clearance and approval in those jurisdictions, respectively):

Device	Subject Device	Comparator Device	Comparison
Manufacturer	Arthrosurface	Zimmer Biomet	N/A
Trade Name	OVO/GRS	Copeland	N/A
Images			N/A
Indications for Use/ Intended Use (Physical and Clinical Attributes)	For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.	Indicated for the following conditions where the humeral head and neck are of sufficient bone stock and there is presence of an intact or reconstructable rotator cuff, which is necessary for proper functioning and dislocation resistance: 1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis. 2. Rheumatoid arthritis 3. Correction of functional deformity 4. Reconstructable rotator cuff 5. Treatment of fractures of the humeral head 6. Traumatic arthritis Implants with Interlok/hydroxyapatite are cleared for uncemented applications. Implants with MacroBond and MacroBond coating with hydroxyapatite are cleared for cemented and uncemented applications; however, cement should only be applied to the surfaces that do not contain hydroxyapatite coating (i.e., stem).	The physical application and clinical attributes of the subject and comparator devices are equivalent, in that these implant systems are intended to be used for hemiarthroplasty or total shoulder arthroplasty of the humeral head and/or glenoid, respectively. The OVO alone for hemiarthroplasty or total shoulder arthroplasty in combination with the GRS to replace the entire shoulder joint, same as that for the comparator devices' humeral and glenoid components, respectively. The Copeland humeral implant is for both cemented and cementless use compared to the Arthrosurface humeral implant that is for cemented use only. The Copeland cementless use data are also applicable to this review as it represents a worst-case scenario given that the fixation strength provided with any cemented device is

Device	Subject Device	Comparator Device	Comparison
			generally demonstrated to be superior. Based on this comparison, the manufacturer concludes that the subject and comparator devices are substantially equivalent, and that the data available for the comparator device is applicable to the subject device.
Design (Technological Attributes)	Humeral Design: modular two-piece design with a threaded taper post fixation that interlocks with the head via a Morse taper interlock Humeral Sizes: available in seven sizes ranging from Ø 46 mm x 42 mm to 58 mm x 54 mm in increments of 4 mm Glenoid Design: one-piece pegged/keeled design (one to two pegs) Glenoid Sizes: available in two sizes ranging from 19 mm x 20 mm and 20 mm x 25 mm in multiple curvatures corresponding with the humeral component sizes (reference Section 2.1)	Humeral Design: one-piece design with a fluted (to act as cement mantle) and tapered fixation post Humeral Sizes: available in eight sizes ranging from Ø 38 mm to 56 mm Glenoid Design: one-piece pegged/keeled design (one to three pegs) Glenoid Sizes: Available in four sizes from S0 to S3 having articular surface curvatures from Ø 40 mm to 57 mm	Note: the technical differences between the subject and comparator devices are explained in further detail following this table under headings titled “Design & Development”, where it is shown how the minor differences in the design of the subject device are incorporated to result in similar, if not better, clinical results as it relates to device safety and performance.
Materials (Biological and Chemical Attributes)	Humeral Materials: Co-Cr Alloy (articular component) with Cp Ti Spray (bone contacting surface) and Ti-6Al-4V Alloy (bone contacting fixation component) Glenoid Material: UHMWPE	Humeral Materials: Co-Cr Alloy (articular component) with Cp Ti Spray and/or HA Coating (bone contacting surface) Glenoid Material: UHMWPE	The materials used for both the subject and comparator devices are similar, with the prior using CP Ti Spray/Ti-6Al-4V for its fixation component and the latter adding HA for cementless fixation. Since the subject device is modular in design, its fixation component is composed of Ti-6Al-4V, which is the most common material of choice for subchondral/IM bone fixation in all joint arthroplasty procedures. All of these materials have excellent history of clinical use for shoulder arthroplasty for multiple decades of use. Based on this comparison,

Device	Subject Device	Comparator Device	Comparison
			the manufacturer concludes that the subject and comparator devices are substantially equivalent, and that the data available for the comparator device is applicable to the subject device.

Design & Development – Copeland Implants

Several articles identified in the literature search and review section below describe in detail the design and development of the Copeland implants, including its progression from Mark I to Mark III designs. The 2004 article by Levy et al., (Reference File #461 in Attachment G2) describes the following:

"The first implant (Mark 1 prosthesis [3M, UK]) consisted of a central pegged humeral component that was secured initially with a screw from the lateral side of the proximal humerus together with an all polyethylene glenoid secured by a cementless finned peg. It was soon observed that the screw was unnecessary, and its use was abandoned.

The Mark 2 prosthesis (Zimmer, Swindon, UK) was introduced in 1990; it added a metal backing to the glenoid component and a fluted taper fit peg to both components.

For the mark 3 prosthesis (Biomet Merck, Swindon, UK), hydroxyapatite coating was added, and this has been in use since 1993.

There are 3 sizes of humeral component, all with a 24.5-mm radius but a different skirt cut of the sphere. There are 2 sizes (small and standard) of cementless metal-backed conforming glenoid components. The Copeland glenoid component radius of curvature matches the Neer glenoid component, and they are interchangeable, to preserve flexibility in case revision will be necessary, avoiding the need for obligatory replacement of all components.

The indications for surface replacement arthroplasty are the same as for any other type of shoulder replacement and include pain and disability arising from the glenohumeral joint arthritis as a result of primary and secondary osteoarthritis, rheumatoid arthritis and other inflammatory arthritides, posttraumatic arthritis, avascular necrosis, instability arthropathy, glenohumeral deformity with secondary arthritis, and rotator cuff tear arthropathy.

In all patients presenting for possible shoulder replacement, surface replacement arthroplasty is considered. Only patients with severe bone loss with no surface to replace, acute fractures, and nonunion of fractures are judged to require a stemmed prostheses. Up to 40% of humeral head bone loss would be regarded suitable for CSRA; stemmed prosthesis should be considered when more extensive bone loss is present."

It is important to note that based on the latest information available from the company's marketing materials, the implant sizes and size ranges seem to have been modified with additional sizes being made available in recent years (File #424/#432 also note that a design modification was made in 2011/2010, i.e., much later than the Mark III design was introduced; See Attachment G2). The device comparison made herein relies on the most recently available information sourced from the company's website and/or other available resources over the internet.

Design & Development – OVO/GRS Implants

As noted in the device comparative table above, compared to the Copeland device, the subject device design incorporates minor improvement features that were made based on the available scientific literature as it relates to the shoulder joint. These are described in further detail below:

Humeral Design:
Both subject and comparator devices' humeral designs have a resurfacing (hollow undersurface of implant) design philosophy that limits the amount of bone resection from the native humeral head. In both devices, fixation is achieved in the subchondral bone with either a tapered/threaded design (subject device) or a tapered/fluted design (comparator device).

The available sizes of the humeral head implants range from Ø 38 mm to Ø 56 mm for the comparator device and from Ø 46 mm x Ø 42 mm to Ø 58 mm x Ø 54 mm for the subject device, both available in 4 mm increments. From a sizing perspective, there is an overlap between the two designs with the comparator device having a smaller size, akin to the manufacturer's HemiCAP Shoulder implant sizes that are available in much smaller sizes (from Ø 25 mm to Ø 40 mm), which are intended for treatment of focal lesions.

While the comparator device has a spherical shape with a uniform radii of surface curvature in both planes based on the implant size (e.g., the Ø 46 mm size has a radius of surface curvature 23 mm in both SI and AP planes), the subject device's humeral head shape is ovoid, having a 2 mm offset in radii of curvatures between the SI and AP values (e.g., the Ø 46 mm x Ø 42 mm size has radii of surface curvatures 23 mm and 21 mm in the SI and AP planes, respectively). Multiple decades of scientific research on shoulder joint anatomy has shown that the native humeral head is not a sphere, being rather ovoid in shape. Based on this research evidence, the manufacturer chose to design an ovoid shaped humeral head to better replicate the shoulder joint anatomy and biomechanics following implantation. The details of this research are effectively summarized in the Clinical Monograph document PN 0020-0109 Rev. C (Reference Attachment G1).

With regards to monobloc (comparator device) versus modular (subject device) designs, throughout the history of development of joint arthroplasty devices, researchers, designers, and developers have moved away from single-piece/monobloc constructs to multiple-piece/modular constructs owing to the advantages of the latter (as also referenced in File #428; See Attachment G2). In the present scenario, there are multiple advantages presented by the subject device owing to its modular design. First, a separate fixation component allows the use of Ti-6Al-4V alloy as the material of choice, compared to the Copeland device in which the entire single piece is made of Co-Cr alloy. Multiple decades of research advocates that the fixation component of joint arthroplasty devices should be made using titanium and its alloys as their modulus of elasticity is half that of Co-Cr and SS based materials. The latter can lead to stress shielding and implant fixation related problems over years of use in vivo. Second, with the monobloc design of the comparator device, the surgeon is unable to control the precise depth of device placement as the tapered and fluted design of the fixation post acts as a piston, which upon impaction provides little to no control over its depth of seating in the native humeral head. In contrast, the subject device design incorporates a modular design that uses a threaded fixation post that allows for an extremely precise placement of the fixation component followed by placement of the humeral head component (following

in vivo implant assembly via the Morse taper, the device essentially functions as a monobloc design) down to the sub-millimeter level. In addition, the subject device system deploys several depth gauging features throughout the technique to ensure that the subject implant restores the native position/height of the humerus. This is not the case for the comparator device, which can lead to ineffective reconstruction of the native joint anatomy, and thus clinical use issues (as noted in the articles in Files #424, #432, #435; See Attachment G2).

Moreover, the manufacturer has multiple decades of experience with its threaded taper post fixation design that has been deployed across multiple joint arthroplasty devices (shoulder, knee, wrist, toe), with an extremely low number of reports of device failures related to its fixation characteristics. None of the articles published in peer reviewed literature for the manufacturer's shoulder devices report any issues or failures related to this aspect of the device's design. Lastly, it has been reported in literature that bone-implant micromotion beyond a certain threshold has negative implications for long term implant fixation and stability (as also noted in File #424; See Attachment G2). To understand this aspect of the devices' design, a cadaveric micromotion test series between the subject device design and comparator device design was conducted. It was observed that the subject threaded taper post implant design reduced the bone-implant interface micromotion by ≥ 3X compared to a tapered/fluted implant design (Reference Attachment G1 for Mechanical Test Monograph document PN 0020-0113 Rev. A along with RIH Test Report #UO-15-008 for full test report; note: the comparator device used was the DePuy Global CAP, which has the exact same monobloc design as that of the Copeland device including the same implant material and tapered/fluted fixation design, as also noted in File #424; See Attachment G2).

Glenoid Design:

Both subject and comparator devices' glenoid implants are manufactured from UHMWPE and rely on cemented fixation with peg/keel design features that are standard in the industry for most glenoid implants.

Most published literature on shoulder arthroplasty outcomes notes that it is usually the glenoid side of the shoulder implant that is the cause of device failure. This is owing to multiple factors, which the subject device's design aims to improve upon.

As stated above, it is of note that failures resulting due to the glenoid component are almost always the cause of overall device related failure in shoulder arthroplasty cases (as also noted in File #461; See Attachment G2). Most glenoid designs, including that of the comparator device, are onlay, i.e., sitting on top of or proud with respect to the surface of the glenoid bone. This design is prone to mechanical rocking as the humeral head moves across its surface during ROM activities (especially edge loading), thus leading to loosening and failure over time (often referred to as the rocking-horse failure). This is eliminated with the subject device design, which is inlay in nature, meaning, the entire implant is embedded in the glenoid bone such that the outermost edges of the implant are flush or sub-flush with the surrounding native glenoid bone. With this design, the rocking-horse type device failure is significantly minimized, if not completely eliminated. This has been proved via extensive mechanical testing. These tests formed the bases of device clearance for this implant with the US FDA, and subsequently its approval in the EU. The details of another cadaver study to understand the rocking-horse effect were published in the article "A comparison of onlay versus inlay glenoid component loosening in total shoulder arthroplasty" (Reference Article in Attachment G1). This article concluded that "The inlay glenoid implant exhibited biomechanical

characteristics favoring stability and decreased loosening compared with the onlay glenoid implant in this cadaveric model". None of the inlay glenoid components in this study exhibited gross loosening. While the manufacturer has noted cases of glenoid failure with its subject device, the number of failures reported is extremely low compared to those for other devices. Secondly, while the onlay glenoid designs tend to lateralize the shoulder joint, thus altering the joint biomechanics, that is not the case with the inlay design of the subject device, which maintains the native humeral head and glenoid anatomies along with their respective native heights and relative positions. This is noted to have beneficial clinical use implications as noted in the aforementioned published literature for such designs, as well as in the manufacturer's Case Study Monograph document PN 0025-0014 Rev. C (Reference Attachment G1).

Note: The overall surgical technique for both the subject and comparator devices are equivalent, with both requiring the same exposure and preparation of the shoulder joint. In summary, the technique steps for both devices involve measuring, reaming, and drilling steps for preparation of the humeral head and glenoid bones for placement of the implant components using orthopaedic delivery instruments such as screw drivers and impactors. As noted above, the subject device and its associated instrumentation are designed for improved accuracy of bone preparation and implant placement, to better replicate the native shoulder joint anatomy. As a result, the benefits and risks related to shoulder surgery for the subject and comparator devices are equivalent, with the subject device expected to result in superior outcomes based on the design improvements as noted above.

Overall Device Comparative Summary

Based on the information presented above, the manufacturer summarizes the following important aspects of the subject device:

The humeral design:

- maintains anatomic geometry without altering height, version, inclination angle or joint volume
- minimizes blood loss
- preserves bone
- minimizes overstuffing with its unique ovoid shape
- reduces risk of periprosthetic fracture and allows uncomplicated conversion to primary stemmed shoulder arthroplasty
- minimizes eccentric loading on the glenoid

The glenoid design:

- matches native glenoid surface
- preserves peripheral glenoid bone
- prevents joint lateralization
- minimizes rocking horse effect
- avoids bone grafting for Type C glenoid

In 2015, renowned surgeon users of the subject device, in collaboration with the manufacturer, published a white paper titled "Stemless Shoulder Inlay Arthroplasty Basic Science and Clinical Review" (document PN 0020-0100 Rev. D; Reference Attachment G1). This article concluded that compared to existing shoulder arthroplasty procedures, the subject device avoids technical challenges encountered in restoring the humeral head surface with a low-profile inlay implant. Component shapes are based on scientific

evidence to maximize the anatomic fit for each patient. Joint biomechanics are maintained, which may have positive effects on implant survivorship, patient recovery and function. Multiple component sizes and shapes provide a pathology specific surface restoration. Preservation of bone stock and healthy cartilage support the concept as a primary arthroplasty procedure.

Therefore, the manufacturer concludes that the aforementioned minor and incrementally improved design differences incorporated in the subject device are expected to result in equivalent or better clinical outcomes compared to the currently available data for the comparator device. Design changes have been made to the OVO/GRS to improve clinical outcomes by mitigating risks observed with the comparator device. The technical design changes are, therefore, expected to result in at least improved safety outcomes (i.e., reduced risks of adverse events, complications, or device related failures), which may result in improved functional outcomes as well.

These differences also do not raise any new concerns of additional risks or adverse events for the subject device and are rather designed to minimize shortcomings of the comparator device's design by incorporating additional safety features that allow for improved device fixation and anatomical fit. This is also confirmed by the similarities of the risks acknowledged for the subject device and the comparator devices (see adverse events/hazards table in literature review table below) and the post-market surveillance data provided for the subject device in the main body of the CER.

II: Literature Review

A detailed literature review and analysis was previously presented in Appendix B of this CER, considering multiple comparator devices in accordance with MEDDEV 2.7.1 rev. 4. Information presented below is extracted from Appendix B and is specific to the subject device and the aforementioned single comparator device. Note: the literature search methods and processes are the same and are not presented herein to minimize redundancy. Only relevant details and results are included in this section. Reference Appendix B for full details.

A critical review of the literature for the intended patient population in order to assess the benefit/risk profiles are tabulated and summarized herein for the subject device and comparator device.

Arthrosurface has conducted previous literature reviews and updates, with the most recent being 12/14/2020. The present search presents literature data from the period of 01/01/1961 to 08/31/2021. Note: this specific update was done in September 2021 to meet the clinical evaluation requirements of the TGA.

The table below presents updated literature search results specific to this literature review conducted for the on-going subject device approval application with the TGA and considers only the subject device (OVO/GRS) and comparator device (Copeland).

Literature Database Search Details – Updated in September 2021 (as relevant for on-going TGA application)

Databases, Search Terms and Search Dates Filters Activated: Humans, English.	Number Identified	Articles selected	Abstract reviewed and determined to be potentially relevant; obtain article	Obtainable articles	Articles included in the review
PubMed hemicap shoulder (done in September 2021 for search period of 2020/07/01 to 2021/08/31)	2	41	28	28	19
PubMed (biomet OR zimmer OR Copeland) AND shoulder arthroplasty (done in September 2021 for search period of 2019/09/30 to 2021/08/31)	52				
PubMed copeland shoulder (done in September 2021 for search period of 1961/01/01 to 2021/09/23)	80				
Relevant Articles from Last CER Revision dated 12.14.2020 (from Table 1 in Appendix B)	382	136	62	60	7

A total of 26 full content available articles were reviewed and assessed according to the criteria described in Tables 2 and 3 in Appendix B. The full list of journal articles reviewed and identified as potentially relevant (including abstracts), and full articles obtained for review assessment are included as Appendix D (for prior searches conducted and document as part of the last CER revision) and as Attachment G2 as relevant for this specific search conducted in September 2021 as part of the update for the on-going device approval process with the TGA.

Clinical Investigation Journal Article Assessment

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
31	Ibrahim et al	2018	2	1	1 N=14	1 OSS CMS VAS ROM	1 Mean = 10.4 years; range: 5.8 to 13.9 years	1	1/2	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
39	Maier et al	2018	2	1	1 N=34	1 CS ROM IS	1 Mean = 33 months; range = 5 to 68 months	1	1/2	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
42	Bulhoff et al	2018	2	1	1 N=50 (sports: 42; non-sports: 8)	1 Custom Questionnaire	1 Mean = 5.5 years; range = 2.5 to 12 years	2	2/2	2/2/2 2-Retrospective 2-None 2-N/A	3
44	Verstraelen et al	2017	2	1	1 N=33	1 CMS NRS SST DASH EQ-5D	1 Mean = 7.2 years; range = 5.7 to 9.3 years	2	2/2	2/2/2 2-Retrospective 2-None 2-N/A	3
47	Werner et al	2017	2	1	1 N=38	1 CS	1	1	1/1	2/1/2	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
						ROM PS	Mean = 66.3 months; range = 24 to 168 months			2-Retrospective 1-Comparison to pre-op baseline 2-N/A	
60	Soudy et al	2017	2	1	1 N=105	1 CS SST RO DASH	1 Mean = 56 months; range = 24 to 120 months	1	1/1	2/1/2 2-Retrospective 1-Comparison to pre-op baseline 2-N/A	2
354	Egger et al	2019	1	1	1 N=31	1 ROM RO VAS PSS	1 Mean = 42.6 months; range = 24 to 74 months	1	1/1	2/1/2 2-Retrospective 1-Comparison to pre-op baseline and between different glenoid types 2-N/A	1
361	Yalcin et al	2021	1	1	1 N=17	1 VR-12 RO KJOC PSS	1 Mean = 37.8 months; range = 14 to 63 months	1	1/2	2/1/1 2-Prospective case series 1-Comparison to pre-op baseline 1- n=17 yields statistically significant	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
										power of 80% at α=0.05	
412	Dekker AP et al	2020	2	1	1 N=266	1 OSS CMS VAS	1 Mean = 6 years; range = 2 to 15 years	1	1/1	2/1/2 2-Retrospective 1-Comparison within sub-groups 2-N/A	1
418	Rai P et al	2015	2	1	1 N=46	1 OSS SF-12	1 Mean = 12 years; range = 3 to 18 years	1	1/2	2/1/2 2-Retrospective 1-Comparison within sub-groups 2-N/A	2
419	Al-Hadithy N et al	2015	2	1	1 N=41	1 OSS CS ROM PS	1 Mean = 5.1 years; up to 7.6 years	1	1/1	2/1/2 2-Retrospective 1-Comparison within sub-groups 2-N/A	2
422	Levy O et al	2014	2	1	1 N=42	1 CS SANE PS/SSV	1 Mean = 14.5 years; range = 10 to 25 years	1	1/1	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	1
424 #	Mechlenburg I et al	2014	2	1	1	1	2	1	1/1	1/1/1	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
					N=13/18 (Copeland/Global CAP)	CS WOOS RO	Up to 2 years			1-Randomised Control Trial 1-Comparison to pre-op baseline; between 2 devices 1- n=30 required per group for statistically significant power of 80% at α=0.05; but study power at 76% based on available data	
425	Jerosch J et al	2014	2	1	1 N=14	1 CS RO ROM	1 28 months	1	1/1	2/1/2 2-Prospective 1-Comparison to pre-op baseline 2-N/A	2
427	Hwang N et al	2014	2	1	1 N=73	1 OSS PS RO	1 Mean = 72 months; range = 9 to 121 months	2	2/2	2/2/2 2-Unknown 2-N/A 2-N/A	3
428	Alizadehkhaiyat O et al	2013	2	1	1 N=102	1 OSS CS	1 Mean = 4 years;	2	2/1	3/2/2 2-Observational	3

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
						SF-12 VAS PS RO	range = 2 to 9 years			Study/Case Series 2-Subgroup analysis only 2-N/A	
432	Mechlenburg I et al	2013	2	1	1 N=71	1 RO WOOS	2 6 months	1	1/2	2/1/2 2-Unknown 1-Comparison to pre-op baseline 2-N/A	2
434	Al-Hadithy N et al	2012	2	1	1 N=50	1 OSS CS RO	1 Mean = 4.2 years; range = 2 to 8 years	1	1/1	2/1/2 2-Retrospective 2- Comparison to pre-op baseline 2-N/A	2
435 #	Stilling M et al	2012	2	1	1 N=11/10 (Copeland/Global CAP)	1 CS WOOS RO	2 Up to 6 months	1	1/2	1/1/2 1-Randomised Control Trial 1-Comparison to pre-op baseline; between 2 devices 2-N/A	2
436	Deladerrière JY et al	2012	2	1	1 N=32/10 (Copeland/Aequalis)	2 Anatomical CT Study	2 Mean = 18 months; range = 2.6	1	2/1	2/1/2 1-Retrospective	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
							to 57 months			1-Comparison to pre-op baseline 2-N/A	
448	Mullett H et al	2007	2	1	1 N=21	1 CS ROM	1 Mean = 4.5 years; range = 2.1 to 9.3 years	2	1/1	2/1/2 2-Prospective 2- Comparison to pre-op baseline 2-N/A	3
457	Thomas SR et al	2005	2	1	1 N=48	1 CS ROM	1 Mean = 34.2 months; range = 24 to 63 months	1	1/1	2/1/2 2-Unknown 2- Comparison to pre-op baseline; sub-group analysis 2-N/A	2
458	Thomas SR et al	2005	2	1	1 N=39	1 CS/CMS ROM RO	1 Mean = 38 months; range = 24 to 72 months	1	1/1	2/1/2 2-Prospective 2- Comparison to pre-op baseline 2-N/A	2
461	Levy O et al	2004	2	1	1 N=69 (TSA: 39; HA: 30)	1 CS PS RO ROM	1 TSA: Mean = 7.6 years; range = 4 to 13 years HA:	2	1/1	2/1/2 2-Unknown 2- Comparison to pre-op baseline 2-N/A	2

File	Author	Date	1) Appropriate Device	2) Use	3) Population, disease/condition	4) Outcome; endpoints*	5) Follow-up; hazards	6) Statistical significance	7) Clinical significance	8) Data source	9) Quality for Assessment
							Mean = 4.4 years; range = 2 to 6.5 years				
462	Levy O et al	2004	2	1	1 N=75 (TSA: 42; HA: 33)	1 CS PS RO ROM	1 Mean = 6.5 years; range = 2 to 16 years	2	1/1	2/1/2 2- Retrospective 2- Comparison to pre-op baseline; TSA vs HA 2-N/A	2
476	Levy O et al	2001	2	1	1 N=98	1 CS PS RO ROM	1 Mean = 6.8 years; range = 5 to 10 years	1	1/1	2/1/2 2-Unknown 2- Comparison to pre-op baseline 2-N/A	2

CS: Constant Score; ROM: Range of Motion; RO: Radiographic Outcome; OSS: Oxford Shoulder Score; CMS: Constant-Murley Score; VAS: Visual Analog Score; Quick DASH: Disabilities of the Arm, Shoulder and Hand Score; IS: Implant Survival; NRS: Numerous Rating Scale; SST: Simple Shoulder Test; EQ-5d: EuroQol-5D; PS: Patient Satisfaction; SF-12: Short Form Health Survey; PSS: Penn Shoulder Score; VR-12: 12-Item Veterans RAND Health Survey; KJOC: Kerlan-Jobe Orthopaedic Clinic; SANE: Single Assessment Numeric Evaluation; SSV: Subjective Shoulder Value; WOOS: Western Ontario Osteoarthritis of the Shoulder Index; #Both of these articles are from the same Randomized Control Trial, reporting the same set of data on the same patient groups, albeit at different follow-up time points; File #435 is the older version that reported data at 6-months whereas File #424 is the more recent version reporting data at 2-years with slightly more number of patients.

The studies available on the subject and comparator devices are summarized below including data on the devices' safety and performance, study limitations, study contribution and weight, and quality and strength of the evidence presented.

File 31:

Ibrahim et al: "Resurfacing hemiarthroplasty of the shoulder for patients with juvenile idiopathic arthritis"

Summary: The aim of this study was to report the outcomes of resurfacing hemiarthroplasty (RHA) using the Zimmer Biomet **Copeland Mark-3** implants in a cohort of patients with juvenile idiopathic arthritis (JIA) affecting the shoulder joint. Fourteen uncemented RHA procedures were performed for 11 consecutive patients who required surgery because of JIA. Mean age at surgery was 36.4 years. Mean clinical follow-up was 10.4 years (range, 5.8-13.9 years). A significant humeral head defect (up to 40% surface area) was found in 5 shoulders and filled with autograft from the distal clavicle or femoral head allograft.

Results: At latest follow-up, no patient required revision. There was excellent relief from pain. The mean Oxford Shoulder Score and Constant-Murley Score improved significantly. No shoulder had a poor outcome, and 6 had a very good or excellent outcome. Worse outcome was associated with an intraoperative finding of significant humeral head erosion. Two shoulders required early arthroscopic subacromial decompression, but there were no other reoperations. There were no instances of radiographic implant loosening or proximal migration. Painless glenoid erosion was seen in 5 shoulders but was not associated with worse outcome. All patients reported their shoulder was extremely painful before surgery. The mean preoperative pain score was 9.0 of 10 (range, 7-10 points). At the latest follow-up, 8 of 14 shoulders were pain free, and the remainder experienced only mild pain (mean, 0.64 points; range, 0-3 points; $P < .001$).

Conclusion: Copeland surface RHA is a safe and effective intervention that significantly improves pain, range of motion, and function in the midterm for patients with end-stage arthritis of the shoulder due to JIA. The outcome is at least equivalent to that of stemmed hemiarthroplasty, with the added benefits of bone conservation, easier revision, and mitigation of periprosthetic fracture.

Weakness of the Study: The authors list the following: "This study is limited by the small number of patients and lack of a control group with unoperated-on shoulders. The methodologic design is retrospective and therefore prone to bias, but the outcome data were collected at the time of patient consultation by observers independent of the operating surgeon. The same prosthesis was used throughout, and validated scoring methods were applied. Cross-sectional imaging was not performed before surgery for any of our patients because it did not change our surgical management. We do acknowledge that with the advent of stemless prostheses, some patients may be suitable for glenoid implantation without the need for a stemmed humeral implant. Another indication may be to assess humeral head erosion if a stemmed prosthesis is not available on the shelf. Cross-sectional imaging would also be useful in the postoperative period to assess glenoid erosion but was not available in this study. The lack of standardization of plain radiographs and, therefore, lack of precision in measurement of glenoid erosion is a weakness of the radiographic follow-up. However, the immediate postoperative and latest postoperative radiographs were at least comparable, allowing a broad assessment of glenoid erosion to be made."

Statistical and clinical significance of the results were discussed in this study for different outcome scores; however, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. Postoperative complications were noted, but there was limited discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study, albeit with a small sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment in the young patient population. This is very much applicable to the current devices under consideration. However, due to the small sample size, the weight of the evidence is fair quality.

File 39:

Maier et al: "Cementless humeral head resurfacing for degenerative glenohumeral osteoarthritis fails at a high rate"

Summary: The aim of the study was to examine clinical and radiographic results of a cementless humeral surface implant and to evaluate prognostic parameters for implant failure. 34 shoulders were examined preoperatively and after a mean 2.7 years. Radiographic parameters, Constant scores (CS) and complications were recorded. 20 women and 14 men were included with a mean age of 63.7 (±11.2). The mean duration follow-up was 33 months [range, 5 to 68 months] for the clinical and radiographical follow-up. The implants used were Biomet **Copeland** in 10 cases, Synthes EPOCA RH in 21 cases and Tornier Aequalis RH in 3 cases.

Results: Eight patients (24%) had an implant revision for secondary glenoid erosion after a mean duration of 22.9 months with the earliest being after 8 months and latest after 68 months. They all received a stemmed total shoulder prosthesis (Tornier Aequalis shaft and glenoid) as replacement for the CUP hemi prosthesis. No revisions were performed for aseptic loosening, or trauma. The mean Constant score improved from 27 points (range, 10 to 49 points) preoperatively to 51 points (range, 10 to 83 points) 2.7 years postoperatively ($p < 0.0001$), and, adjusted by age and sex, from 36% (range, 14% to 61%) to 69% (range, 14% to 123%) ($p < 0.0001$). Significant differences were also found in terms of pain relief, activity, mobility, shoulder flexion, abduction, and external and internal rotation ($p < 0.05$).

Conclusion: The study shows a high revision rate (24%) after surface replacement arthroplasties. There was a correlation between the revisions and the surgery conditioned LGHO changes, a lower preoperative CS, decreased preoperative LGHO and heights as well as a higher preoperative CCD.

Weakness of the Study: The authors list the following: "The current study has its limitations. The number of cases was relatively small, and we used three different types of implants for cementless surface replacement. Furthermore, there is no radiological analysis in the axial plane, hence limiting the evaluation of the resurfacing. As Jia et al. showed, using a 3-D computed tomography would be more reproducible than plain radiography assessment. Nevertheless, postoperative x-ray imaging of patients undergoing shoulder replacement is a central component of clinical follow-up, why we used it in the present study."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were not identified and there was no discussion of the benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints although limited, appear appropriate. This was a fairly described study, albeit with a relatively moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment while reporting a high revision rate but in a moderate sample size. The weight of the evidence is thus of fair quality.

File 42:

Bulhoff et al: "Getting back in the game after humeral head resurfacing"

Summary: The aim of this investigation was to analyze whether patients undergoing humeral head resurfacing (HHR) surgery are able to successfully return to their sports and occupation afterwards. Fifty patients treated with CUP (HHR) arthroplasty were included. Two groups were built: Patients

who have participated in sports less than 5 years prior surgery (Group 1: n=42 (84%)) and patients who have never participated in sports (Group 2: n=8 (16%)). Evaluation was based on a questionnaire asking for types of sports, frequency, time to return to sports and work as well as limitations in work life. Mean age at the time of surgery was 58.6 (36–84) years in Group 1 and 65 (56–75) years in Group 2. Mean time follow-up was 5.5 years (2.5–12) years. The implants used were Biomet **Copeland** RH and Synthes EPOCA RH.

Results: Twenty-seven (64%) patients in Group 1 participated in sports right before surgery. Twenty-one patients (50%) returned to sports after surgery. The returning rate was 78%. Seven (17%) patients in Group 1 stated that the reason they underwent shoulder replacement surgery was to continue to participate in sports. Swimming and skiing were two of the most favorable sports. Two (4%) patients had to change their profession due to surgery. Most of the patients were retired at follow-up.

Conclusion: Most of the active patients undergoing HHR surgery are successfully able to return to their sports activities after surgery. Patients employed were able to return to their occupation after surgery. Many patients were already retired at the time of follow up.

Weakness of the Study: The authors list the following: "Our study has some limitations: we did not evaluate the clinical or radiographic outcome of the patients included, and this was a questionnaire-based investigation. However, the high rate of return, particularly the ability of the majority of patients to return to activities performed prior to surgery within 12 months, leads us to assume that the clinical outcome is satisfactory, especially considering that many of the sports activities include the upper extremity and the affected shoulder. Prospective trials with clinical and radiographic follow-up are needed to verify the findings of our study."

No clinical or radiographic outcomes, or implant survival were reported in this study. Only a custom questionnaire was created to obtain sports related information. There was no statistical and clinical significance described in this study, and there was no pre-operative data available. Sample size and follow-up were moderate and medium-term, respectively. Hazards were not identified and there was no discussion of benefits compared to hazards. There were no comparisons available.

Quality for Assessment: Outcome measure endpoints missing from this study. Sample size was moderate, and the scope of this study was limited to sports outcomes only. The article is of limited quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study have a limited contribution to the body of evidence of this treatment. The weight of the evidence is limited to make any judgments.

File 44:

Verstraelen et al: "Clinical and radiological results 7 years after Copeland shoulder resurfacing arthroplasty in patients with primary glenohumeral osteoarthritis: an independent multicenter retrospective study"

Summary: The aim of this multicenter cohort study was to evaluate the midterm outcomes and survival after cementless stemless resurfacing arthroplasty (CSRA) using the Biomet **Copeland Mark-3** implants in a series of 33 shoulders in 27 patients with primary osteoarthritis. Clinical outcome assessment included: Constant– Murley score (CMS); Simple Shoulder Test (SST); Disability of Arm, Shoulder, Hand (DASH); EuroQol-5D (EQ-5D) utility scores; Numerous Rating Scale (NRS) for pain. Radiographs were assessed by two independent observers for oversizing, radiolucency, glenohumeral subluxation, glenoid erosion and subsidence. Correlations between the clinical and radiological outcomes were calculated. Complications were registered, and revision and survival rates were calculated. Mean age at time of surgery and mean follow-up time were, respectively, 67.7 (range 50.2–85.1) and 7.2 years (range 5.7–9.3 years).

Results: Means (SD) for CMS, age- and gender- adjusted CMS, SST, DASH and EQ-5D utility scores were: 56.4 (20.2), 76.5 (25.0), 54.0 (29.8), 37.6 (23.3) and 0.8 (0.1), respectively. NRS for pain was 2.0

and 3.8, respectively, in rest and during activities. Radiographic assessment of the CSRAs showed oversizing in 54.5%; radiolucency in 18.2%; superior glenohumeral subluxation in 33.3%; glenoid erosion in 45.5%; and subsidence in 3.0%. Perioperative complications did not occur. Revision surgery was performed in one patient (3.0%).

Conclusion: Despite a high percentage of lost to follow-up, CSRA seems to result in good clinical outcomes after a mean follow-up of 7.2 years. Noteworthy is that substantial radiological abnormalities were found. On the other hand, there was no correlation between the poor radiological findings and the clinical outcome.

Weakness of the Study: The authors list the following: "There are some limitations applicable to this study, which are mostly due to its retrospective design. The lack of preoperative data is an important limitation. On the other hand, all patients had primary end-stage glenohumeral OA with a severely impaired shoulder function and received prolonged conservative treatments for at least 1 year, as mentioned in our inclusion criteria. We tried to deal with this limitation by including questions about the preoperative state of the patients. This study shows the midterm results in a homogeneous study population. This was achieved by excluding patients with any other diagnosis than primary glenohumeral OA. Having this homogenous population allowed us to provide a better guidance for orthopaedic surgeons dealing with this patient group. Another limitation is the high percentage of lost to follow-up (37%). However, this is partially (10 CSRAs, 23%) due to the fact that we excluded patients with a large incompleteness of the questionnaires. Therefore, we could include them in the analyses, but we do know that they were satisfied with the result of the CSRA. As far as we know, this is the first study to report midterm results regarding disabilities in daily living and quality of live after CSRA. In our opinion, this is one of the most important outcomes measures in the perception of patients."

No statistical and clinical significance was described in this study as there were no comparative data available from either a baseline or another device. Hazards were noted but there was no discussion of benefits compared to the hazards. The study sample size was moderate, and the follow-up was long term. This was a retrospective study that could have been very useful were there any baseline or other data to compare to for gauging the clinical significance.

Quality for Assessment: Outcome measure endpoints were numerous, well defined and appear appropriate, but there were no pre-operative data available for comparison. This was a fairly described study, with a moderate sample size. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this long-term retrospective study contribute to the body of evidence of this treatment with numerous outcome measures noted post-operatively. However, the lack of any pre-operative or comparative data make the weight of the evidence fair quality.

File 47:

Werner et al: "Progressive glenoid bone loss caused by erosion in humeral head resurfacing"

Summary: The aim of this study was to determine the development of glenoid erosion following shoulder resurfacing using a new measurement technique and detect potential prognostic factors. The authors performed a retrospective analysis on 38 shoulders undergoing humeral head resurfacing with a mean follow-up of 65.4 ± 43 months using the Biomet **Copeland Mark-3** implant in 27 cases and the Tornier Aequalis RH implant in 11 cases. Clinical and radiographic evaluation followed a standardized protocol including pre- and postoperative Constant score, active range of motion, and X-rays in true anteroposterior view. Three independent observers performed measurements of glenoid erosion.

Results: The study reports good interobserver reliability for glenoid erosion measurements (intraclass correlation coefficient [ICC] 0.74–0.78). Progressive glenoid erosion was present in all cases, averaging 5.5 ± 3.9mmat more than 5 years' follow-up. Male patients demonstrated increased glenoid bone loss within the first 5 years ($p < 0.04$). The mean Constant score improved to 55.4 ± 23.6 points at the

latest follow-up. Younger age was correlated to increased functional outcome. Revision rate due to painful glenoid erosion was 37%. The mean Constant score improved from 17.7 points (range 2–59 points) preoperatively to 55.4 points (range 14–98 points, $p < 0.001$) at the latest follow-up. The adjusted Constant score improved from 20.2% (range 2.2–64.1%) to 66.5% (range 20–103.3%, $p < 0.001$). Mean active anterior elevationimprovedfrom88.6° (range 10–160°) to 121.1° (range 45–170°, $p < 0.001$), abduction increased from 71.7° (range 10–160°) to106.1° (range 30–170°, $p<0.001$) at the latest follow-up. External rotation improved from10° (range 0–30°) to an average of 27.3° (range 0–70°, $p < 0.001$) postoperatively. At time of the most recent follow-up, 8 patients were very satisfied and 13 were satisfied with the operation, while 17 patients rated the outcome as fair or disappointed.
Conclusion: Glenoid erosion can be routinely expected in patients undergoing humeral head resurfacing. Painful glenoid erosion leads to deterioration in functional outcome and necessitates revision surgery in a high percentage of cases.
Weakness of the Study: The authors list the following: "The limitations of this study on cementless humeral head resurfacing are the limited number of patients operated for various etiologies and the retrospective character. We did not perform a priori power analysis; therefore, the lack of correlation between parameters might be related to the lack of power. However, we present long-term results of a single-surgeon series. Further studies are needed to develop strategies to reduce glenoid erosion especially in young patients."
While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described, and the description of these data was limited to a single outcome score. Hazards were identified and there was discussion of the benefits compared to hazards for resurfacing procedures. Sample size was moderate, and follow-up was medium-term.
Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study, albeit with a moderate sample size. The article was of fair quality for assessment.
Conflict of interest: B.S.Werner and F.Gohlke declare to be under consultancy contracts with Wright/Tornier. J. Stehle, A. Abdelkawi, P. Plumhoff, and R. Hudek declare that they have no competing interests.
Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment in light of complications associated with glenoid erosion. The weight of the evidence is fair quality.

File 60:

Soudy et al: "Results and limitations of humeral head resurfacing: 105 cases at a mean follow-up of 5 years"
Summary: The objective of this study was to assess clinical and computed-tomography (CT) outcomes at least 2 years after humeral head resurfacing to treat concentric glenohumeral osteoarthritis. Humeral head resurfacing provides similar outcomes to those achieved with stemmed humeral head implants. This single-center retrospective study included 40 Biomet **Copeland** and 65 Tornier Aequalis humeral resurfacing heads implanted between 2004 and 2012. Mean patient age at diagnosis was 64 years. The diagnoses were osteoarthritis with an intact (68%) or torn (21%) rotator cuff, avascular necrosis (5%), osteoarthritis complicating chronic instability (3%), post-traumatic osteoarthritis (2%), and chronic inflammatory joint disease (1%). Validated clinical scores, radiographs, and CT before surgery and at last follow-up were compared.
Results: During the mean follow-up of 56 months, complications occurred in 24 implants. Revision surgery with reverse shoulder replacement was required in 18 cases, after a mean of 43.6 months, to treat glenoid wear or a rotator cuff tear. At last follow-up, for the implants that did not require revision surgery, the mean Constant score was 64/100. The implants had a mean varus of 5° and mean retroversion of −13.3°. The mean increase in glenoid cavity depth was 2.4 mm. Mean increases in medial and lateral humeral offset

were 1.9 mm and 2.7 mm, respectively. Pre-operative factors significantly associated with failure were rotator cuff tear (P = 0.017) and glenoid erosion (P = 0.001).

Conclusion: This study reports a high failure rate related to glenoid wear or progressive rotator-cuff impairment, although CT showed no evidence of implant malposition or overstuffing. Previous studies of stemmed humeral head implants showed better outcomes. Given the low medium-term prosthesis survival rate, the authors now reserve humeral head resurfacing for concentric osteoarthritis without glenoid erosions or rotator cuff damage. The low medium-term survival rate of humeral head resurfacing implants in this study was ascribable to pre-operative glenoid wear and to rotator cuff tears. In the authors' opinion, despite the scrupulous operative technique and implant positioning, the resurfacing implant caused excessive lateral humeral offset responsible for rotator cuff stress and glenoid wear. The major adverse effect of pre-operative glenoid wear explains the difference in outcomes between the two implant models and illustrates the limitations of humeral head resurfacing.

Weakness of the Study: The authors list the following: "The limitations of our study are related to the retrospective design and absence of anatomic evaluation of the rotator cuff, which was evaluated indirectly based on the radiographic acromio-humeral interval. The number of patients with each diagnosis was too small for an evaluation of potential associations between diagnosis and implant survival. The large number of surgeons may have affected the reproducibility of the resurfacing procedure."

While statistical and clinical significance were achieved, no *a priori* acceptance criteria were described. Hazards were identified and there was some discussion of benefits compared to hazards for this implant versus traditional stemmed implants.

Quality for Assessment: Outcome measure endpoints are well described and analyzed and appear to be appropriate. This was a well described study with a large sample size using two different stemless designs, each having a medium-term follow-up. The article was of good quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment for resurfacing designs as it relates to clinical outcomes with a known complication of glenoid erosion that may reduce implant survival rate. The weight of the evidence is good quality.

File 354:

Egger et al: "Total shoulder arthroplasty with nonspherical humeral head and inlay glenoid replacement: clinical results comparing concentric and nonconcentric glenoid stages in primary shoulder arthritis"

Summary: This study examined the results of the Arthrosurface **OVO/GRS** in glenoids at different stages of disease progress. It was hypothesized that there would be no statistically significant difference in outcomes between Levine concentric (Walch A) and Levine nonconcentric (Walch B) glenoids treated for primary glenohumeral arthritis using nonspherical humeral head and inlay glenoid replacement. This retrospective case series included 31 shoulders in 29 patients (25 male, 4 female), with an average age of 58.5 years. Outcomes included the Penn Shoulder Score (PSS), visual analog scale for pain (VAS-Pain), range of motion, radiographic analysis, and complications. Inclusion criteria were primary glenohumeral arthritis, intact rotator cuff, and no prior open shoulder surgeries. Mean follow-up was 42.6 months (range, 24-74 months). The study included 7 concentric and 24 nonconcentric glenoids. The preoperative diagnosis for all shoulders was OA with a grade 4 Kellgren Lawrence (KL) stage in 25 shoulders (80.6%), grade 3 in 5 shoulders (16.1%), and grade 2 in 1 shoulder (3.2%). The mean follow-up was 42.6 months (24-74 months).

Results: The patients' ASA gradings were as follows: ASA 1 (n = 4, 12.9%), ASA 2 (n = 20, 64.5%), and ASA 3 (n = 3, 9.7%). The ASA grading was not available for 4 patients (12.9%). Clinical outcomes at the last follow-up (PSS, VAS-Pain, FF, ER) were also tested across ASA Classifications, sex, and preoperative KL grade, resulting again in the same distribution across both sexes, and all 3 ASA and KL OA grades

(P > .05 for all tests). Clinical outcomes of the 2 glenoid component sizes showed the same distribution in all variables, except for FF (20 mm, n = 21, median FF 170˚; 25 mm, n = 10, median FF 160˚). Comparison of preoperative with postoperative range of motion showed a significant improvement in FF by 52.3˚ (from 114.6˚ to 167.3˚) and ER by 37.2˚ (from 16.2˚ to 56.6˚) (P < .001). At the last follow-up, the mean PSS Pain was 25.8 ± 4.7, PSS Function was 52.7 ± 6.9, PSS Satisfaction was 8.4 ± 2.2, PSS-T was 87.0 ± 12.6, and VAS Pain was 0.9 ± 1.2. Preoperative scores were available for 16 shoulders (51.6%) (15 male and 1 female), with an average age of 56.4 years (range, 42-69 years). The mean VAS-Pain score improved from 6.4 to 1.0, and the mean Penn Total Score more than doubled from preoperative levels. The individual improvement in PSS-T (range, 14.0-85.9) indicated that all patients with baseline scores surpassed the PSS MCID (11.4 scale points) and minimal detectable change (12.1 scale points) thresholds for TSA. The maximal possible improvement in the Penn Total Score showed that all patients surpassed the MCID of >30% and 94% achieved a significant clinical benefit of >50% improvement. Outcomes comparison showed no statistically significant differences in PSS domains including Pain (P = .92), Function (P = .98), Satisfaction (P = .89), and Total (P = .98); forward flexion (P = .78); external rotation (P = .64); and VAS-Pain (P = 0.12). At the last follow-up, the mean PSS Pain was 25.3/30, Function 52.7/60, Satisfaction 8.4/10, and Total 87.0/100. The mean forward flexion was 167.3˚, external rotation 56.6˚, and VAS-Pain 0.9. There were no signs of periprosthetic fracture, component loosening, osteolysis, and hardware failure, and no revisions or 90-day rehospitalizations were required. One patient was prophylactically treated with oral antibiotics for a history of prior infection and 1 patient required a later open biceps tenodesis after a traumatic proximal biceps rupture postoperatively.

Conclusion: Nonspherical shoulder arthroplasty with inlay glenoid replacement demonstrated excellent clinical benefits for both concentric and nonconcentric glenoids. The technique appears to be a promising option for glenohumeral arthritis even in the presence of posterior glenoid erosion. Initial results show that nonspherical HH resurfacing combined with inlay glenoid replacement is a viable outpatient technique for primary GH arthritis across patients with concentric and eccentric glenoid morphology. The results in both groups suggest that this total shoulder construct may be considered a reasonable alternative to treating shoulder arthritis even in the presence of posterior bone erosion and subluxation. We feel that both the HH design and the inlay component contribute to these results. Meaningful and SCBs included excellent functional results and pain relief, high patient satisfaction, and low risk in patients with and without preoperative glenoid erosion. No 90-day rehospitalization was required, and no implant failures were noted at a mean follow-up of 42.6 months. Further research with larger cohorts and longer follow-up is warranted, as this technique provides a unique option for primary GH OA.

Weakness of the Study: The authors list the following: “The weaknesses in our study include those that are inherent to all retrospective investigations and are related to the clinical documentation, radiographic imaging, cohort size determination, and follow-up. Clinical outcomes were lacking Penn baseline outcomes scores in approximately half of our cohort. Before 2014, preoperative PSS scores were not available for inclusion in this retrospective study. Since then, PSS metrics have been included in our questionnaire and database for routine assessment of all shoulder procedures. Radiographic imaging followed a standard clinical protocol and lacked in control of precise beam orientation a prospective study could have achieved; hence axillary preoperative and postoperative comparison of humeral subluxation in the AP plane was not feasible. The variability in radiographic angles may have also influenced imaging assessment. The inlay glenoid component used in this study lacks a metal marker that makes the radiographic visualization more challenging. However, our positive clinical results, combined with strong basic science evidence, support the stability of the inlay glenoid and offset this limitation. Establishing a prospective radiographic assessment protocol to ensure consistent Grashey views and axillary projections that include the full length of the scapula would have been beneficial in tracking periprosthetic radiolucency with varying degrees of glenoid

retroversion. Future studies with preoperative computed tomography imaging would provide further insight into the effects of glenoid retroversion on patient-reported outcomes, complications, and radiographic fixation strength on mid- and long-term follow-up. The overall cohort size in our study was relatively small, thereby weakening subgroup analysis. Therefore, we opted to primarily use the binary Levine glenoid classification and incorporated the original Walch classification rather than the 2016 update by Bercik et al, which included additional B3 and D stages that require 3-dimensional imaging. The retrospective study was limited to last follow-up comparison for the primary endpoint and follow-up was short term. This cohort will continue to be followed and longer term clinical and radiographic results will need to be evaluated to confirm implant stability and longevity. Future studies should explore prospective data to reconfirm and augment the risks and benefits of this technique."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with *a priori* acceptance criteria, which is due to the retrospective nature of this study. However, the study was designed with a hypothesis that was successfully tested. Hazards were noted, and there was discussion of benefits compared to hazards, focusing on the benefits of a stemless shoulder arthroplasty over traditional stemmed shoulder arthroplasty for patients even with posterior glenoid erosion. The sample size was moderate and follow-up was mid-term.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study with a moderate small sample size and mid-term follow-up. The article was of good quality for assessment.

Conflict of interest: Anthony Miniaci received consulting fees and royalties from Arthrosurface related to intellectual property related to the subject of this work. All the other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the current devices under consideration, i.e., OVO and GRS. No device failure or revision was reported at mid-term follow-up, and complications were also limited to only one patient that were not related to the device safety or efficacy. A sub-group analysis showed significant improvement to pre-operative scores, which also met the MICD criteria. A comparison of ROM and functional scores with published results of other stemless designs showed that the OVO/GRS performed better than most devices, while also having no device-related complications. The weight of the evidence is good quality.

File 361:

Yaclin et al: Clinical and Radiographic Outcomes of Total Shoulder Arthroplasty With a Nonspherical Humeral Head and Inlay Glenoid in Elite Weight Lifters: A Prospective Case Series

Summary: Weight lifting after total shoulder arthroplasty (TSA) can place significant stresses on implants that could lead to instability, loosening, and increased wear. A TSA system with nonspherical humeral head resurfacing and inlay glenoid—which improves the biomechanics and thus reduces instability, wear, and potential loosening—may be able to tolerate repetitive loads from weight lifting. The purpose of this study was to determine return to heavy weight lifting, patient-reported outcomes, radiographic outcomes, and complication rates in a weight-lifting group of patients after anatomic TSA using a combination of **OVO/GRS**. The authors hypothesized that this patient cohort would have high rates of return to weight lifting, high patient reported shoulder function, and low rates of radiographic loosening or posterior humeral head subluxation. This study prospectively enrolled 16 weight lifters (mean ± SD age, 57.2 ± 7.8 years; 15 male) undergoing primary anatomic TSA (n = 17 shoulders, 1 staged bilateral) with nonspherical humeral head resurfacing and inlay glenoid replacement for glenohumeral osteoarthritis. Outcome measures included the rate of return to weight lifting, results of patient reported outcome measures (Penn Shoulder Score, Kerlan-Jobe

Orthopaedic Clinic, and 12-Item Veterans RAND Health Survey), radiographic outcomes, and complication rate. Follow-up was obtained on all patients at a mean of 38 months (range, 14-63 months).

Results: All patients returned to competitive weight lifting at 15.6 ± 6.9 weeks. Compared to the preoperative weight lifting level, at last follow-up patients reported performance at the following level: lighter weight, 1 (6%); same weight, 8 (50%); heavier weight, 7 (44%). Preoperative eccentric posterior glenoid wear was common (71% Walch B2 classification; 12/17), but posterior humeral subluxation improved at follow-up according to the Walch index (mean, 55.5% preoperative vs 48.5% postoperative; P < .001) and contact point ratio (mean, 63.9% preoperative vs 50.1% postoperative; P < .001). Pre- to postoperative improvements were seen in Penn Shoulder Score (44.3 vs 82.6; P < .001), Kerlan-Jobe Orthopaedic Clinic (50.6 vs 91.1; P < .001), and 12-Item Veterans RAND Health Survey physical component score but not mental component score. No signs of radiographic loosening were detected in follow-up images, nor were there any postoperative instability episodes or revision surgeries.

Conclusion: Glenohumeral arthritis in competitive weight lifters has been difficult to treat owing to high rates of posterior eccentric glenoid wear and significant concern in this population for further posterior subluxation and implant loosening as well as wear after TSA and return to weight lifting. However, in the current study, the authors demonstrate excellent early to midterm clinical and radiographic outcomes after TSA in competitive weight lifters using a nonspherical humeral head and inlay glenoid component. Rates of RTS and patient-reported shoulder function were excellent. Radiographically, the humeral head centralizes on the glenoid after surgery, and there is no evidence of instability or component loosening at a mean 38-month follow-up.

Weakness of the Study: The authors list the following: "First, we included a highly specific patient population who underwent TSA by a single surgeon. The outcomes of this study may not be extrapolated for other athletes. However, weight lifters are one of the groups of athletes who exercise with high loads that place the glenohumeral joint under great stress. In terms of radiological outcomes, computed tomography would provide more precise measurements than anteroposterior and axillary radiographs. To control this limitation, we utilized standardized radiographs in all patients. We did not report the amount of pre- and postoperative weight lifted and relied on patient self-report. We were also not able to compare outcomes with other TSA implant designs or HA. A short follow-up period and a small sample size were other limitations. A longer time would be needed to evaluate the secondary posterior subluxation after TSA, and it should be noted that concerns with wear are greater with longer follow-up."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria. However, the authors confirmed that the available sample size resulted in sufficient statistical power to detect significance in the difference, if any, and also, the study was designed with a hypothesis and that was successfully tested. No hazards were noted, and hence, there was no discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study albeit with a small sample size and mid-term follow-up. The article was of good quality for assessment.

Conflict of interest: One or more of the authors has declared the following potential conflict of interest or source of funding: M.S. has received educational support from Smith & Nephew. A.M. has received educational support from Arthrex; consulting fees from Amniox Medical, Trice Medical, Linvatec, and Arthrosurface; royalties from Arthrosurface and Zimmer Biomet Holdings; honoraria from Arthrosurface; and hospitality payments from DJO.

Contribution and weight of the evidence: The results of this prospective case series contribute to the body of evidence of this treatment using the current devices under consideration, i.e., the OVO and GRS. No device failure or revision was reported at mid-term follow-up, and no complications were observed. The

authors studied the device performance and safety in what is considered a worst-case patient cohort in terms of exposing the shoulder joint, and thus the device, to certain extremes of real-life shoulder physical performance characteristics by including only weight lifters. Both safety and performance were successfully evaluated and confirmed in this worst case clinical application of this device. The weight of the evidence is good quality.

File 412:

Dekker AP et al: 6-Year clinical results and survival of Copeland Resurfacing hemiarthroplasty of the shoulder in a consecutive series of 279 cases

Summary: The purpose of this study was to evaluate the medium term outcomes and survival of the Copeland resurfacing hemiarthroplasty (CRHA) and compare these for the major underlying pathologies in a consecutive series of patients at an independent centre. The authors hypothesize that patients undergoing CRHA for cuff tear arthropathy (CTA) have poorer survival. The **Copeland Mark III** hydroxyapatite coated prosthesis was used for all cases. A consecutive series of patients undergoing CRHA over 14 years was retrospectively analyzed with no exclusions. Patients had a minimum 2-year follow-up by an independent assessor. Functional outcome was assessed using the Oxford Shoulder Score (OSS) and Constant-Murley Score (CMS). Pain and satisfaction was assessed using a visual analogue score. 279 Consecutive CRHAs were implanted by 5 consultant surgeons in 242 patients. Thirty-seven patients had bilateral implants. 73 were male and 206 were female. The median age of patients at the time of surgery was 71. The indications for operation were primarily pain and loss of function. The underlying diagnosis included osteoarthritis (OA) in 228 shoulders, rheumatoid arthritis or other inflammatory arthropathy (RA) in 42 shoulders, rotator cuff tear arthropathy (CTA) in 22 shoulders and avascular necrosis (AVN) in 2 shoulders. The integrity of the rotator cuff was assessed clinically, radiologically, and intra-operatively. All patients with a full thickness tear of the rotator cuff tendon were included in the CTA group regardless of migration of the humeral head. A minimum 2-year postoperative follow-up was achieved in 266 consecutive cases. Mean follow up was 6.1 years.

Results: For the OA group, 5-year survival was 90%, 10-year survival was 83% and mean survival was 13.2 years (95% CI 12.5-13.9). The mean OSS was 35.0 and mean CMS 49.9. CRHA for CTA had significantly poorer ($p < 0.001$) 5-year survival (55%), 10-year survival (41%) and mean survival (5.9 years, 95% CI 4.7-7.2). Mean OSS was 23.6 and mean CMS 30.3, which was poorer than for OA ($p < 0.001$). A subgroup analysis of OA patients found significantly better survival ($p = 0.013$) in those aged over 65 years but no difference in functional outcome. Range of movement was also significantly better in the OA group; however, VAS for improvement and pain were no different. Patients with OA were more likely to have the surgery again (93%) than with CTA (75%). 45 patients underwent revision surgery. The indications were pain and stiffness secondary to glenoid erosion in 44 cases and aseptic loosening in one case. There were no revisions for infection or fracture. The revision implant was a reverse total shoulder replacement in 27 cases, stemmed hemiarthroplasty in 6 cases, anatomical total shoulder replacement in 12 cases.

Conclusion: CRHA remains a reasonable option for OA in patients with an intact rotator cuff and with sufficient bone stock, especially in those aged over 65 years. With poorer functional outcomes and survival, CRHA should not be offered in those with CTA. The authors note that in 2018, the National Joint Registry of the United Kingdom (NJR) reported a decline in the proportion of resurfacings (both total and partial) with resurfacing hemiarthroplasty accounting for only 3.3% of implants in 2017 as compared to 6.5% for stemmed HA and 2.5% for stemless HA. The indication in 76.1% was OA with 6.5% for CTA and the remainder for trauma, inflammatory arthropathy and AVN. The NJR has published 5-year survival rates for shoulder arthroplasty and shows a revision rate of 7.9% (6.6-9.6) for resurfacing as compared with 8.6% (5.9-12.6) for stemless HA and 5.9% (4.6-7.7) for stemmed HA. Data from the Norwegian Arthroplasty Register found 5-year survival of 94% for HA and 96% for

resurfacing HA. This study has demonstrated survival at 5 years of 90% and at 10 years of 83% for those implanted for OA of all ages. For patients aged over 65 years with CRHA implanted for OA, survival rates were improved with 100% 5-year survival and 99% 10-year survival with no significant differences in functional outcomes between this age group and the younger age group.

Weakness of the Study: The authors list the following: "Limitations of this study include that this was a retrospective review with no true control group and no randomization, making it prone to confounding factors and selection bias. Although an independent arthroplasty physiotherapist assessed most patients, some were seen by the treating surgeon, and this may introduce bias. The surgeon did not influence the completion of the OSS, however, which was recorded by the patient without assistance. Preoperative functional scores were not available for a significant proportion of patients therefore were not included as part of this study. Postoperative functional scores were only available for 69% of patients. This was because those patients without scores had been performed in our unit before the introduction of the arthroplasty physiotherapist and therefore scores had not been collected. Although patients had plain film radiographs performed at follow up these were not qualitatively analyzed and not presented in this study. Because of this, the severity of the glenoid arthrosis and glenoid type was not recorded which limits the generalizability of the data."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria and there was no sample size calculation. Also, there was only subgroup analysis of the data with no comparison to baseline data due to its retrospective design. However, the study was designed with a hypothesis and that was successfully tested. Hazards were noted, and there was some discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study with a large sample size and mid- to long-term follow-up. The article was of good quality for assessment.

Conflict of interest: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. While higher revision rate was noted, it was attributed to CTA patients. The authors note that device survival is much better for treatment of OA compared to CTA, with a 10-year survival rate of 99% being observed in the OA group of patients over the age of 65. The weight of the evidence is good quality.

File 418:

Rai P et al: Long-term follow-up of the Copeland mark III shoulder resurfacing hemi-arthroplasty

Summary: The purpose of this study was to evaluate the long-term outcome of the **Copeland Mark III** humeral resurfacing replacement. Ninety-five shoulder hemi-arthroplasties were performed in 85 patients. Oxford Shoulder Score (OSS) and short form 12 (SF-12) questionnaires were administered. At 12-year follow-up, 49 patients were alive.

Results: The mean overall satisfaction score was 1.5 (SD: 0.81), where 1 is very satisfied and 4 is very dissatisfied. The mean OSS was 35.2 (SD: 8.54; range: 17–48). The mean functional score was 24.3 and the mean pain score was 11.3. The scores were good for all pathologies except for rotator cuff disease, which had a mean OSS of 23. The OA group had a mean score of 35.8. The numbers in the individual groups were too small to provide statistical comparison; however, there was no significant difference between OA and non-OA groups ($p = 0.4$). The male sub-group had a mean OSS of 38.9 and the female sub-group had a mean OSS of 33.5. The difference was not statistically significant ($p = 0.11$). The mean SF-12 score was 83. The mean physical score was 33.2 and the mean mental score was 49.8. Overall, 88% were very satisfied with their shoulder outcome, with 88% able to do housework or gardening and 85% able to do recreational activities. There were three revision operations during the study

period. A Kaplan–Meier survival analysis was undertaken to estimate implant survivorship. It showed a 10-year survival of 97.5% (90.5–99.4, 95% CI), a 15-year survival of 95.0% (84.0–98.5, 95% CI) and an 18-year survival of 95.0% (84.0–98.5, 95% CI).

Conclusion: This study provides long-term follow-up of the mark III Copeland resurfacing hemi-arthroplasty, showing good results in an elderly population, with few complications and a low revision rate. While the authors note that they cannot comment on the use of the prosthesis in a young population, they do recommend it in an elderly patient group.

Weakness of the Study: The authors list the following: "the retrospective nature of the current study is likely to under-report transient and minor complications. Additional limitations of the current study may be considered to be the absence of radiological follow-up. However, usage of patient-reported outcome measures is of more relevance in an elderly population, since the primary concern in this demographic is patient satisfaction, pain relief, function, and requirement for further surgery. After a followup of 12 years, these patients are often resident in nursing homes with poor general health. Inviting them back for radiological and clinical assessment is often not feasible, and indeed can be difficult to justify. Such a problem has been noted by previous authors. If patients are satisfied with their prosthesis and quality-of-life, then the arthroplasty has served its purpose. With this rationale in mind, recording specific values for range of movement are of less value in these patients."

Statistical and clinical significance of the results were discussed in this study, it was not designed with a priori acceptance criteria and there was no sample size calculation due to its retrospective design. Additionally, there was no baseline data available for comparison and only subgroup comparisons were provided. While hazards were noted, there was no discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were limited to two scores but were well described and appear to be appropriate. This was a well described study with a long term follow-up albeit with a small sample size. The article was of fair quality for assessment.

Conflict of interest: The authors have none to declare.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. The authors note that the device performance is better in the elderly patients with OA as the primary diagnosis. This study reports an 18-year survival rate of 95%. The weight of the evidence is fair quality.

File 419:

Al-Hadithy N et al: Cementless surface replacement hemiarthroplasty for primary glenohumeral osteoarthritis: results of over 5-year follow-up in patients with or without rotator cuff deficiency

Summary: The **Mark III Copeland** Cementless surface replacement hemiarthroplasty (CSRHA) has been used since 1993 and consists of a pegged humeral component with hydroxyapatite coating and has been used successfully to treat primary glenohumeral osteoarthritis. Although few studies have described the outcomes of CSRHA in cuff tear arthropathy, none have evaluated its outcome in primary glenohumeral osteoarthritis with full-thickness degenerative tears of their rotator cuffs. Therefore, this study aimed to report the clinical and functional outcomes of the Mark III Copeland CSRHA in patients with primary glenohumeral osteoarthritis with intact and deficient rotator cuffs. 41 CSRHA were performed for glenohumeral osteoarthritis with intact rotator cuffs (n=21) and cuff-deficient shoulders (n=20). Patients were assessed using Oxford and Constant questionnaires, patient satisfaction, range of motion measurements and by radiography. Mean age and follow-up were 75 years and 5.1 years, respectively.

Results: Functional gains were significantly higher in patients with intact rotator cuffs compared to cuff-deficient shoulders, with Oxford Shoulder Score improving from 18° to 37.5° and 15° to 27° and forward flexion improved from 60° to 126° and 44° to 77° in each group, respectively. Two patients with deficient cuffs had deficient subscapularis tendons; one of which was dislocated anteriorly.

Patients with intact rotator cuff had significantly greater improvement in OSS and achieved greater range of movement at final follow-up compared to the cuff-deficient group (p=0.01). No significant differences in outcome where noted in patients who had ACJ resection compared to those who did not. There were no cases of aseptic loosening or progressive radiolucent lines. Re-operation was required in three patients.

Conclusion: Humeral head resurfacing hemiarthroplasty is a viable treatment option for glenohumeral osteoarthritis. In patients with deficient cuffs, functional gains are limited, and suggest that it should be considered in low demand patients where pain is the primary problem. The study authors have changed their practice to routinely perform an ultrasound scan to assess the state of the rotator cuff pre-operatively. They note that caution should be taken in patients with a deficient subscapularis as a result of the high risk of dislocation and other treatment options should be considered. Glenohumeral osteoarthritis with or without associated rotator cuff tears causes significant morbidity and loss of function. This study shows that good pain reduction can be achieved following CSRHA in patients with glenohumeral osteoarthritis, however with less consistent gains in range of motion and inferior results in the cuff-deficient shoulder. Although reverse shoulder arthroplasty provides a more consistent increase in range of motion in the cuff-deficient shoulder due to an increase in deltoid function, resurfacing arthroplasty has several key advantages including preservation of bone stock, independency of glenoid bone stock, a shorter, less technically demanding operation, and a lower complication rate. This study reports three re-operations with one patient requiring revision in the cuff-deficient group (<10%), which compares favorably with the quoted complication rates for reverse shoulder arthroplasty.

Weakness of the Study: The authors list the following: "The present study has several limitations. It is a retrospective review with no true control group and no randomization, making it prone to confounding factors and measurement bias. We minimized measurement bias by having three researchers who were independent to the index procedure assess outcomes. We also performed ACJ resections in just under half of the patients, almost equally in both groups, and although no significant difference was seen, it may have confounded the results."

Although statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria and there was no sample size calculation. This study was retrospective in nature with no baseline data that was collected to gage direct benefit provided by this device and associated treatment. Hazards were noted, and the authors did discuss benefits compared to hazards of resurfacing arthroplasties.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study albeit with a small sample size and mid-term follow-up. The article was of fair quality for assessment.

Conflict of interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The author(s) received no financial support for the research, authorship, and/or publication of this article.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. The authors note that the functional outcomes are negatively affected in patients with deficient cuff and other supportive shoulder joint soft-tissue structures. They note that this device is less disruptive compared to a reverse shoulder arthroplasty, which also has higher rates of revision compared to that observed in this study for the comparator device. The weight of the evidence is fair quality.

File 422:

Levy O et al: Surface replacement arthroplasty for glenohumeral arthropathy in patients aged younger than fifty years: results after a minimum ten-year follow-up

Summary: The aim of this study was to evaluate cementless surface replacement arthroplasty's (CSRA) long-term results for glenohumeral arthritis in patients aged younger than 50 years with more than 10 years of follow-up (range, 10-25 years). 54 consecutive CSRAs using the **Copeland** implant were performed in 49 patients (25 men, 24 women), with 5 patients undergoing bilateral procedures. Patients were aged younger than 50 years, with a mean age of 38.9 years (range, 22-50 years) at the time of surgery. Three patients (4 shoulders) died over time and 8 were lost to follow-up, leaving 38 patients (42 shoulders) with a mean follow-up of 14.5 years (range, 10-25 years). There were 17 TSAs with a metal-backed glenoid implant and 37 humeral head resurfacing with microfracture of the glenoid (humeral surface arthroplasty [HSA]). The indications were avascular necrosis, 16; rheumatoid arthritis, 20; instability arthropathy, 7; primary osteoarthritis, 5; fracture sequelae, 3; post-infection arthritis, 2; and psoriatic arthritis, 1.

Results: Patients had significant pain relief and increases in shoulder range of movement with shoulder resurfacing. The pain score improved from a mean of 0.8 preoperatively to a mean of 13.8 of 15 at the most recent follow-up. The mean pain score improved from 0 of 15 preoperatively to a mean of 14.0 of 15 at the most recent followup for TSA and improved from a mean of 1.25 of 15 preoperatively to a mean of 12.4 of 15 at the most recent follow-up for HSA. The improvements in pain scores were statistically significant ($P < .001$). The improvements in motion were as follows: mean improvement in active elevation of 38°, from 78° preoperatively to 116° (range 30°-180°) at the most recent follow-up for humeral head resurfacing (hemiarthroplasty with microfracture). The mean improvement in active elevation was 51°, from 42° preoperatively to 93° at the most recent follow-up for TSA. The mean improvement in active abduction was 53°, from 55° preoperatively to 108° (range 30°-180°) at the most recent follow-up for humeral head resurfacing (hemiarthroplasty with microfracture) and from 38° preoperatively to 81° for TSA. The mean external rotation improvement was 38, from 13 preoperatively to 51 at the most recent follow-up. Mean internal rotation improved from 13° (palm to buttock) preoperatively to 47° (range 30°-90°; palm to lumbar spine) at the most recent follow-up. The mean relative Constant score increased from 11.5% to 71.8% ($P <.0001$), and the mean patient satisfaction at final follow-up was 8.7 of 10. The mean relative Constant score for the humeral head resurfacing with microfracture of the glenoid improved to 77.7% compared with 58.1% for total resurfacing arthroplasty. Two required early arthrodesis due to instability and deep infection. Seven were revised to stemmed prosthesis: 1 for traumatic fracture and 1 for glenoid erosion 16 years after the index procedure. Five shoulders in 4 patients (4 rheumatoid arthritis, 1 avascular necrosis) were revised at 8 to 14 years after surgery for cuff failure and loosening. Three were revised to stemless reverse total shoulder arthroplasty due to rotator cuff failure at 23, 16, and 13 years after surgery. The Kaplan-Meier survival curve for patients aged 50 years or younger receiving shoulder resurfacing arthroplasty showed estimated revision-free survival rate at 11 years of 97% for humeral head resurfacing (HSA-hemiarthroplasty) compared with 71% for TSA, survival of 91% for HSA compared with 71% for TSA at 14 years, and 85% for HSA compared with 61% for TSA at 22 years after resurfacing. The authors believe that the increased polyethylene wear and loosening in their series was due to use of metal-backed glenoids.

Conclusion: CSRA provides good long-term functional results in the treatment of glenohumeral arthropathy in patients aged younger than 50 years. This improvement is maintained over more than 10 years after surgery, with high patient satisfaction (8.7 of 10). However, 10 shoulders (of 54) (18.5%) underwent revision arthroplasty. Resurfacing offers a valuable tool in treating young patients with glenohumeral arthritis, providing reasonably good long-term results in 81.6% of the patients, while allowing preservation of bone stock if the need for revision arises. All the revision arthroplasty options are preserved, including less invasive procedures.

Weakness of the Study: The authors list the following: "A limitation of our study is that we had no control group treated with stemmed arthroplasty (hemiarthroplasty or TSA) for comparison. However, we can compare our results with resurfacing arthroplasty to the published series with

stemmed arthroplasty. A few variables in our series must be accounted for: There were a variety of diagnoses (AVN, rheumatoid arthritis, instability arthropathy, primary osteoarthritis, fracture sequelae, postinfectious arthropathy, and psoriatic arthritis) with different rotator cuff and soft tissues conditions that may have affected the prognosis. However, these are the usual etiologies for which young patients need to have arthroplasty and can be compared with other series. Approximately one-third of the patients were treated with TSA and the other two-thirds were treated with HSA and microfracture. We have separated the results to describe each group separately. Approximately one-third of the HSAs were non-HA coated, whereas the other two-thirds were. This does not appear to be an important variable in the study. The integrity of the rotator cuff affects the outcome. This has been discussed."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria despite it being a prospective case series. There was no sample size calculation or hypothesis testing. Hazards were noted and there was discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study with a long-term follow-up up to 25 years, albeit with a small sample size. The article was of good quality for assessment.

Conflict of interest: Stephen Copeland receives royalties from Biomet as designing surgeon. None of the other authors, their immediate families, and any research foundations with which they are affiliated have received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this prospective case series contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes over the long-term. The authors note that the device performance is acceptable in patients younger than 50 years of age, and that the integrity of the rotator cuff affects the results. This study reports a 22-year survival rate of 85% when the device is used for hemiarthroplasty. The weight of the evidence is good quality.

File 424:

Mechlenburg I et al: Evaluation of periprosthetic bone mineral density and postoperative migration of humeral head resurfacing implants: two-year results of a randomized controlled clinical trial

Summary: In this study, implant migration, bone mineral density (BMD), length of glenohumeral offset (LGHO), and clinical results were compared for the **Copeland** and the Global C.A.P. humeral head resurfacing implants (HHRIs). The overall aim of this study was to compare the 2 different HHRIs radiologically and clinically in a randomized controlled trial with 2 years of follow-up. The primary outcome was migration assessed 2 years after surgery. Secondary outcome measures were periprosthetic BMD, length of glenohumeral offset (LGHO), and clinical outcome measured by questionnaires. The study randomly allocated 32 patients (13 women), mean age 63 years (range, 39-82 years), with shoulder osteoarthritis to a Copeland (n = 14) or Global C.A.P. (n = 18) HHRI. Patients were monitored for 2 years with radiostereometry, dual-energy X-ray absorptiometry, Constant Shoulder Score (CSS), and the Western Ontario Osteoarthritis of the Shoulder Index (WOOS). LGHO was measured preoperatively and 6 months postoperatively.

Results: At 2 years, total translation (TT) was 0.48 mm (standard deviation [SD], 0.21 mm) for the Copeland and 0.82 mm (SD, 0.46 mm) for the Global C.A.P. (P = .06). Five HHRI were revised, and in the interval before the last follow-up (revision or 2 years), TT of 0.58 mm (SD, 0.61 mm) for revised HHRI was higher (P < .02) than TT of 0.22 mm (SD, 0.17 mm) in non-revised HHRI. A comparison of TT at the last follow-up (revision or 2 years) found no difference between the HHRIs (P = .12). Periprosthetic BMD decreased initially but increased continuously after 6 months for both HHRIs. At 2 years, BMD was 48% higher around the Copeland HHRI (P < .005). The mean difference in LGHO was

significantly higher for the Copeland than for the Global C.A.P. HHRI (P < .02). Clinical results evaluated with CSS and WOOS improved over time for both implant groups (P < .01), with no differences between the groups. The clinical consequences of a postoperatively increased LGHO for the Copeland HHRI are unknown, and the clinical outcome scores in the Copeland group were comparable to the scores for the Global C.A.P group. Yet, the increased LGHO verifies a potential overstuffing problem with the Copeland HHRI caused by the reaming process that only takes 2 mm of the humeral surface, whereas the apical thickness of the implant is 4 mm. The manufacturer altered the design of the Copeland HHRI in 2011 to comply with clinical concerns of overstuffing.

Conclusion: Both implants had only little migration and good clinical results. Periprosthetic BMD and LGHO both increased for the Copeland HHRI more than for the Global C.A.P HHRI. The Copeland HHRI was associated with increased BMD but also enlarged LGHO. However, the rate of revisions was high, which should be considered when balancing benefits and harms of a HHRI. These 2-year results can be generalized to patients with shoulder osteoarthritis in whom implanting a glenoid component is not required.

Weakness of the Study: The authors list the following: "a limitation of the study is that we did not engage a blinded observer to assess the CSS in patients."

Statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria despite it being a RCT. While sample size calculation was made, the number of patients required in each group fell short of the enrolled numbers in this study. Despite the detailed analysis provided, the study was designed without a hypothesis. While hazards were noted, there was some discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints although adequate, were focused more on basic science measurements, but were well described and appear to be appropriate for the stated aim for this study. This was a well described study albeit with a small sample size and short-term follow-up. The article was of fair quality for assessment.

Conflict of interest: This study was financially supported by the Danish Rheumatism Association, The Aase and Ejnar Danielsen Foundation, The AP Møller Foundation, The Danish Medical Association, Cooperative organizations Humanitarian and Cultural Foundation, The Hede Nielsen Family Foundation, Jacob Madsen & Olga Madsen's Foundation, Protesekompagniet/DePuy Denmark, and Biomet Denmark. The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this RCT contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. While the device resulted in improved functional outcomes, the authors did note the high rate of revisions that could be attributed to overstuffing problems given its design and technique. The authors note that the device has since been modified by the manufacturer to avoid or minimize this issue. The weight of the evidence is fair quality.

File 425:

Jerosch J et al: Humeral resurfacing arthroplasty in combination with latissimus dorsi tendon transfer in patients with rotator cuff tear arthropathy and preserved subscapularis muscle function: preliminary report and short-term results

Summary: Humeral resurfacing arthroplasty represents an alternative option to hemiarthroplasty for treatment of cuff tear arthropathy (CTA), with the advantages as follows: suitability for relatively young and high-demand patients because of preservation of bone stock and no loss of length, less invasive surgery, shorter operation time, no risk of periprosthetic stem fractures, and revision surgery can be undertaken easily. In this study, the authors report on a combination of **Copeland** humeral resurfacing arthroplasty and latissimus dorsi tendon transfer as a treatment option for patients having CTA with preserved subscapularis muscle function. Three hypotheses were tested. First hypothesis

was that humeral resurfacing arthroplasty in combination with latissimus dorsi tendon transfer would improve the overall functional outcome in patients with CTA. Second hypothesis was that humeral resurfacing arthroplasty in combination with latissimus dorsi tendon transfer would improve specifically humeral external rotation. Third hypothesis was that humeral resurfacing arthroplasty in combination with latissimus dorsi tendon transfer would improve specifically abduction and shoulder elevation. This study was conducted as an observational prospective case series. Fourteen patients having CTA were included. Follow-up was carried out at the end of the 28th month for all patients. Constant Score was used for follow-up evaluation.

Results: The absolute Constant Score improved significantly (P<0.05) from 34 points preoperatively to 69 points postoperatively. The relative Constant Score improved significantly (P<0.05) from 42% preoperatively to 91% postoperatively. Follow-up evaluation of the range of motion showed that active shoulder elevation improved significantly (P<0.05) from a mean of 95° preoperatively (range: 28° - 155°), to a mean of 138° (range: 110° - 174°) postoperatively, while active abduction improved significantly (P<0.05) from a mean of 88° (range: 30° - 167°) preoperatively, to a mean of 147° (range: 80° - 172°) postoperatively. External rotation slightly improved (non-significantly P>0.05) from a mean of 16° (range: -10° - 36°) preoperatively to a mean of 22° (range: 0° - 53°). Subscores of the Constant Score as pain and power improved significantly postoperatively. Analysis of the external rotation revealed that no improvement of the external rotation in the adducted arm was detected, yet improvement of the external rotation LAG sign. The evaluation of the radiographic measurement parameters revealed a significant (P<0.05) increase in the HO and AHD postoperatively, while non-significant increase in the height of center of rotation and LGHO postoperatively. The average operation time was 68 min (range 50–85 min). Postoperative complications were seen in one patient who developed a temporary radial neuropathy that showed spontaneous recovery after 4 months postoperatively. In addition, another patient developed superficial wound infection which was treated successfully with antibiotics. In three patients, a reverse ball-and-socket arthroplasty had to be performed about 18 month postoperatively due to secondary anterior superior instability

Conclusion: Humeral resurfacing arthroplasty in combination with latissimus dorsi tendon transfer in patients having CTA with preserved subscapularis function has satisfactory short-term functional clinical outcomes. To the author's knowledge, this is the first study that reports on humeral resurfacing arthroplasty in combination with latissimus dorsi transfer for treatment of patients with CTA. In this study, the overall functional outcome (according to the results achieved from the Constant Score), shoulder elevation, and abduction improved significantly postoperatively proving the first and third hypothesis, while external rotation slightly improved postoperatively (not significantly) disproving the second hypothesis.

Weakness of the Study: The authors list the following: "Limitations of the current study are as follows: (1) the small number of patients, but CTA is not a common condition and (2) the follow-up period is not a long-term one."

Although statistical and clinical significance of the results were discussed in this study, the study was not designed with a priori acceptance criteria despite it being an observational prospective case series. Also, there was no sample size calculation or power analysis. Nonetheless, the study was designed to conduct hypothesis testing. While hazards were noted, there was some discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were limited to one clinical outcome and ROM/RO measures but were well described and appear to be appropriate. This was a well described study albeit with a very small sample size and short-term follow-up. The article was of fair quality for assessment.

Conflict of interest: The authors declare that they have no conflict of interest. Also, they have not received any payment or services from any third party for any aspect of the submitted work. Also, they have no financial relationships with any the entities described in the instructions. Also, the authors have no patents whether planned, pending, or issued broadly relevant to the work. Also, the

authors have no other relationships/conditions/circumstances that present a potential conflict of interest.

Contribution and weight of the evidence: The results of this observational prospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. Although the sample size is small, the authors note that the device performance can be improved in patients with CTA when a combination treatment of soft-tissue balancing is performed. The weight of the evidence is fair quality.

File 427:

Hwang N et al: Mid-term results of Copeland shoulder cementless surface replacement arthroplasty from an independent centre

Summary: This study reports clinical experience with the **Mark III Copeland** shoulder CSRA used as a hemiarthoplasty (HA) and determines whether glenoid microfracture affects the progression of glenoid erosion at mid-term follow-up. One-hundred-and-twelve CSRAs were performed in 101 patients. Eighty-three patients were alive at the median follow-up time of 72 months (range: 9 to 121 months; interquartile range 46 to 93 months). Assessment included an Oxford shoulder score (OSS), patient satisfaction score and plain radiographs. In total, 112 implants were inserted into 101 patients, of whom 11 patients underwent staged bilateral procedures. The median age at the time of surgery was 75 years (range: 41 years to 89 years; interquartile range (IQR) 63 years to 80 years) and the cohort consisted of 75 females and 26 males. The majority of cases were performed for primary osteoarthritis (OA) (86%). Other indications for CSRA included rheumatoid arthritis (RA) (n=8), chronic dislocation (n=4), avascular necrosis (AVN) (n=3) and rotator cuff arthropathy (RCA) in one case.

Results: The mean (range) OSS was 27 (7 to 48) and 64 of 73 (87.7%) patients were 'very satisfied' or 'satisfied' with their shoulder. Twenty-three (20.5%) shoulders had over 2 mm of glenoid erosion. Microfracture was performed in 43 of 112 shoulders (38.4%) and did not influence the progression of glenoid erosion. Further surgery was performed in 27 (24.1%) shoulders, including 15 revisions, eight arthrolyses and four subacromial decompressions. Revision to total shoulder arthroplasty was performed in 14 cases: 10 for glenoid erosion; one each for loosening, periprosthetic fracture, deep infection, and chronic pain. One was revised to reverse arthroplasty for chronic pain. The overall revision rate in this series was 13%. The survival of the primary prosthesis was 99% at one year and this declined to 88% and 82% at three years and five years, respectively. This compared to a patient survival of 100% at one year, 93% at three years and 84% at five years.

Conclusion: CSRA performed in an independent centre reproduces the functional outcomes reported by the designer. Glenoid erosion, however, was a common occurrence and the main cause of revision – microfracture did not influence its progression. Overall, this series demonstrates that acceptable outcomes can be obtained for most patients after the Mark III Copeland shoulder CSRA, although there may be a considerable risk of progressive glenoid erosion. Although this has not always translated to a definite need for revision surgery within the present study.

Weakness of the Study: The authors list the following: "The present study contains limitations in its methodology, including the use of the OSS to measure the functional outcome without preoperative scores for comparison. It is also difficult to compare with other studies because different outcome measures have been reported. This methodology did, however, enable us to follow-up this population 5 years to 9 years after primary surgery by postal questionnaire with a high response rate of 88% and we also had annual radiographs available until the last follow-up date."

No statistical and clinical significance of the results were presented or discussed in this study, and it study was not designed with a priori acceptance criteria or hypothesis statement(s). The study design was also unknown and is unclear from the article, with no comparative baseline or other comparative data sets available. Hazards were noted but there was no discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were limited to one score, patient satisfaction and radiographic outcomes, but were not well described and lack any statistical analysis or clinical evaluation of significance. This may be due to the unknown design of this study. This was a poorly described study albeit with a large sample size and mid- to long-term follow-up. The article was of limited quality for assessment.
Conflict of interest: None declared.
Contribution and weight of the evidence: Given the shortcomings of this study, the results of this study may or may not contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. While the authors note that the device resulted in improved functional outcomes, the statistical and clinical significance of these results is unknown. This study reports a 5-year survival rate of 82%. The weight of the evidence is limited in quality.

File 428:

Alizadehkhaiyat O et al: Outcome of Copeland shoulder resurfacing arthroplasty with a 4-year mean follow-up

Summary: This observational study (case series) reports experience in using the **Mark IV Copeland** prosthesis, which has a hydroxyapatite coating in order to promote biological and long-term fixation with bone in-growth. The report includes functional and radiological outcome in a consecutive series of CSRA procedures predominantly for the management of OA and RA of the glenohumeral joint. The correlations between various outcome parameters used in the study are also highlighted in order to provide directions into the selection of appropriate outcome assessment tools. The mean follow-up was 4 years. There were 62 females (60.8%) and 40 males (39.2%) including 9 bilateral shoulders reviewed. The mean age of patients was 66.5 years (range, 19-91). One-hundred two consecutive patients with osteoarthritis (OA-47.1%), rheumatoid arthritis (RA–40.2%), rotator cuff arthropathy (RCA–8.8%), and avascular necrosis (AVN–3.9%) underwent CSRA. The outcome assessment included pain and satisfaction, physical limitation, Oxford Shoulder score (OSS), Constant score (CS), and SF-12. Imaging was reviewed for glenoid morphology (Walch classification) and humeral head (HH) migration.

Results: Highest patient satisfaction and lowest pain levels were related to the primary pathology with AVN best followed by OA, RA, and with RCA having the poorest outcome. Comparing the two largest groups the CS was significantly higher in OA (61 ± 21.3) than RA (44 ± 20.5). OSS showed a significant correlation with CS and physical subscale of SF-12. Walch type A (67.6%) and HH migration (47%) were the commonest radiographic observations. OSS, CS, pain, and satisfaction were significantly different between migration and non-migration groups. The revision rate in this series was higher than usual rate (8%) reported in the literature.

Conclusion: The design of shoulder prostheses has evolved over time from a mono-block structure to the modular, and then to more anatomical prostheses aimed at restoring normal kinematics of the glenohumeral joint with regard to anatomic location and orientation of the humeral and glenoid joint surfaces. This series of 102 consecutive CSRA shows comparable results to previously published results. The best results were obtained in OA patients with average postoperative CS of 61. This was significantly higher than CS found for the RA group (44). Furthermore, improvements in OSS, satisfaction level, pain score, and SF-12 (both physical and mental subscales) all indicated a better outcome from the patients' perspective in the OA group compared to RA. The CSRA provided satisfactory functional outcome and pain relief in many patients, making it a viable alternative to conventional stemmed shoulder arthroplasty. These results showed a predictable relationship between outcome and pathology, with significantly better outcome in osteoarthritic patients compared to those with inflammatory arthritis. Cuff deficiency was a major reason for failure and revision. While imaging revealed a high rate of glenoid wear and HH migration, a strong correlation with key outcome variables was noted only for the HH migration. Joint application of OSS, CS, and SF-12 provided a good understanding of the CSRA outcome from both patient and clinician perspectives.

Weakness of the Study: The authors list the following: "Comparative studies with longer follow-ups are needed for better understanding of important factors contributing to the clinical results and survival rate of the CSRA."

There was no statistical analysis performed although the authors claim that the results presented in this study showed clinically significant improvements. This was an observational case series that was not designed with a priori acceptance criteria or hypothesis testing as there was no baseline data available for comparison. Only subgroup analysis was performed. There was no sample size calculation either as this study lacked any form of statistical analysis. Hazards were noted and there was some discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were numerous but lacked in description as it relates to statistical analysis, comparison, or clinical significance. This was a narratively well described study with a large sample size but mid-term follow-up. The article was of limited quality for assessment.

Conflict of interest: Professor Frostick received royalties and consultant payments from Biomet Company, which is related to the subject of this work. The other authors, their immediate families, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this observational case series study may or may not contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. Although the authors report that the device resulted in improved functional outcomes, the data presented lacks in statistical and clinical significance comparisons/discussions. The authors note that the device performance is affected in shoulders with a deficient cuff. The weight of the evidence is of limited quality.

File 432:

Mechlenburg I et al: The Copeland resurfacing humeral head implant does not restore humeral head anatomy. A retrospective study

Summary: This study notes that there has been concern that the **Copeland** RHHI leaves the shoulder joint overstuffed because the reaming process only removes 2 mm of the humeral surface, while the average thickness of the prosthesis is 4 mm. The design of the Copeland HHRI was in 2010 changed by the manufacturer (Copeland thin shell) to comply with concerns of overstuffing. The purpose of this study was (1) to evaluate the Length of the Gleno-Humeral Offset (LGHO) in a selected cohort of patients operated with a Copeland RHHI, (2) to assess the patient-reported quality of life and functional outcome measured by Western Ontario Osteoarthritis of the Shoulder Index (WOOS) in the cohort and in all Danish patients operated with the Copeland RHHI in the same time period and (3) to determine the number of revisions in the cohort and in the Danish population operated with the Copeland RHHI in the same time period. Pre- and postoperative radiographs were retrieved from 71 of 91 possible patients operated with a Copeland RHHI. The cohort consisted of 30 males and 41 females at a mean age of 61 (38–89) years. One radiologist measured the LGHO and performed double measurements. The WOOS score 1 year after surgery and the number of revisions from all patients operated with a Copeland RHHI in Denmark was requested from the Danish Shoulder Arthroplasty Registry.

Results: The mean LGHO increased from 4.99 ± 0.53 cm before surgery to mean 5.39 ± 0.58 cm after surgery, ($p<0.001$). In the two hospitals LGHO was 4.96 and 5.08 cm preoperative and 5.39 and 5.40 cm postoperative. 95 % limits of agreement for measurements of LGHO were ± 0.11 cm indicating a high intra-tester reliability of the method. No systematic variation between the first and second measurement was found, the difference being -0.01 (95 % CI -0.03 to 0.01). One year after surgery, the WOOS score was mean 67 (20–100) for the cohort and mean 64 (5–100) for all patients operated with a Copeland RHHI in Denmark in the same period of time. Two to five years later, the WOOS score for the cohort was mean 66 (7–100). One to five years after RHHI, 13 of 71 implants (14 %) in the

cohort were revised, eight due to persistent pain. In those cases, overstuffing of the shoulder joint was suspected to cause the pain. One patient had the RHHI revised due rotator cuff problems, one due to glenoid attrition, one had a technically failed primary operation, one due to luxation and one due to infection in shoulder joint.

Conclusion: The authors evaluated the LGHO in a selected cohort of patients operated with a Copeland RHHI and found the mean LGHO to be significantly 4 mm wider after surgery compared to before. The measurements were precise with a high intratester reliability. The design of the RHHI is sought to recreate the normal anatomic relationships and contours of the humeral head but the authors consider the Copeland RHHI to potentially overstuff the shoulder joint caused by the reaming process that removes only 2 mm of the humeral surface while the average thickness of the prosthesis is 4 mm. Due to these design parameters, the RHHI may result in overstuffing and pain when the shoulder capsule is tight. There may be differences in the laxity of the joint capsule between patients so that some patients can adapt to the added offset with the Copeland RHHI while others cannot. The problem the surgeons experienced when using the Copeland RHHI was that the reamer for the Copeland RHHI did not allow the surgeon to ream the humeral head smaller. Then, the surgeon had the option of using an implant with a small diameter which resulted in an implant that looked like a ''hat'' put on the humeral head. Or the surgeon could use an implant that fitted the diameter of the humeral head but ended up with overstuffing the joint. Recently, the design of the Copeland HHRI was altered by the manufacturer to comply with concerns of overstuffing. In conclusion, the LGHO was significantly increased after Copeland RHHI and the high rate of revisions points to a problem with overstuffing associated with this prosthesis design. The design of the Copeland HHRI has been changed by the manufacturer to comply with the concerns of overstuffing and therefore this version of the Copeland HHRI will not be further used. Shoulder surgeons should be aware of potential overstuffing when they see a patient with persistent pain after RHHI.

Weakness of the Study: The authors do not identify any limitations in their study.

While statistical significance was achieved, it was limited to that for the LGHO measurement, and not the WOOS outcome score. The study design is unknown. The follow-up duration is short-term at 6-months, so it is unknown if the LHGO remains the same over the course of long-term implantation and its clinical implications in the initial cohort of successful surgeries. While the authors note clinical significance of the results with the WOOS outcome, there was no statistical analysis to back it up due to lack of baseline data. So, it is difficult to gage the true benefit provided. However, it appeared to be comparable to the data from the Danish registry. Also, the study was not designed with a priori acceptance criteria or sample size calculations for determining significant power. Also, hazards related to joint overstuffing due to prosthesis design were noted but there was no discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were limited but appropriate for the stated purpose of this article, i.e., to study if the device results in an anatomical fit. The results measures were well described and appear to be appropriate. This was a well described study with a moderate sample size but a short-term follow-up for the goal of this study. The article was of fair quality for assessment.

Conflict of interest: This study has been financially supported by the Danish Rheumatism Association and The Aase And Ejnar Danielsen Foundation. None of the participants have any economic association with the providers of the economic support. The authors declare that they have no conflict of interest.

Contribution and weight of the evidence: The results of this study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland, in that it notes the issues of overstuffing, which led to the manufacturer modifying the design to minimize/eliminate this issue. The authors state that the device resulted in improved functional outcomes based on similar outcomes noted in a registry database but did not provide any statistical analysis to back this claim. For the purposes of this study, the weight of the evidence is fair quality.

File 434:

Al-Hadithy N et al: Cementless surface replacement arthroplasty of the shoulder for osteoarthritis: results of fifty Mark III Copeland prosthesis from an independent center with four-year mean follow-up

Summary: The aim of this study was to report the clinical and functional results of the **Copeland Mark III** prosthesis as a hemiarthroplasty by a single surgeon, in patients with primary osteoarthritis with a mean follow-up of 4.2 years, from an independent center. The authors retrospectively reviewed 53 consecutive Mark III Copeland CRSA hemiarthroplasties in 46 patients (30 women, 16 men) with glenohumeral osteoarthritis. Patients had a mean age of 69 years (range, 45-94 years). Mean follow-up was 4.2 years (range, 2-8 years). Fifty uncemented hemiarthroplasties were available for review.

Results: On subjective assessment, 35 patients (70%) thought their shoulder was much better, 11 (22%) felt that it was better, 2 (4%) were not sure, and 2 (4%) thought it was worse. Mean (range) age-adjusted Constant and Oxford scores improved from 38.5 (15-61) and 22 (9-31) to 75.1 (38-87) and 42 (18-48), respectively. Anterosuperior escape of the humeral head developed in 1 patient who had an oversized humeral component due to progressive rotator cuff failure at 2 years. Moderate glenoid erosion was present in 12% and correlated with oversizing of the humeral component. There was one revision to a stemmed cemented hemiarthroplasty for periprosthetic fracture. No patients have required revision for aseptic loosening, rotator cuff failure, or glenoid erosion to date.

Conclusion: This study reports the clinical and radiologic outcomes for the Copeland Mark III prosthesis for the treatment of primary osteoarthritis in patients with an intact rotator cuff from an independent center at 4.2 years of follow-up. The authors have shown that hemiarthroplasty with the Mark III prosthesis for glenohumeral osteoarthritis can provide functional results comparable with modular stemmed hemiarthroplasty; however, they did not achieve the same functional improvement as that achieved from the designer's own institution. No patients required revision for aseptic loosening. In contrast to previous studies, they found that periprosthetic fracture, rotator cuff failure, and glenoid erosion were the main complications encountered that may affect future revision surgery, particularly on the glenoid side. Copeland surface replacement hemiarthroplasty for glenohumeral osteoarthritis can provide functional results similar to modular stemmed prostheses, with a relatively low revision rate at 4.2 years of follow-up; however, there is high rate of glenoid erosion that may complicate future revision surgery, and we did not achieve the same functional improvement as that achieved from the designer's institution.

Weakness of the Study: The authors list the following: "We acknowledge the limitations with this study being retrospective without randomization. Measurement bias was minimized by having assessors who were not involved with the original operation and by blinding the operating surgeon to the assessment. The follow-up is heterogeneous; however, we believe the results provide clinicians with important information."

Statistical and clinical significance of the results were discussed briefly in this study. It was not designed with a priori acceptance criteria, sample size calculation or hypothesis testing. Although retrospective in design, the authors seem to have collected baseline data for purposes of comparison. Hazards were noted and there was some discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study albeit with a moderate sample size and mid-term follow-up. The article was of fair quality for assessment.

Conflict of interest: The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes compared to baseline data. The authors note that the device

performance is similar to that of stemmed prosthesis with low revision rates at mid-term follow-up. The weight of the evidence is fair quality.

File 435:

Stilling M et al: Precision of novel radiological methods in relation to resurfacing humeral head implants: assessment by radiostereometric analysis, DXA, and geometrical analysis

Summary: The authors note that from investigations on hip and knee arthroplasty, it is well known that the periprosthetic bone mineral density (BMD) decreases in a period of 2 or more years following arthroplasty. Presumably, there will also be postoperative stress shielding of the bone in conjunction with RHHI; however, it has only been experimentally investigated previously. Therefore, the authors designed a randomized clinical trial (RCT) featuring radiological methods never used with RHHI previously in which two different RHHI designs were compared with a hypothesis of no expected difference. This is a report for a pilot study on 1/3 of the included patients with the goal of (1) describing the new methods used to evaluate the outcome after RHHI, (2) estimating the precision of the radiological methods and (3) presenting preliminary clinical and radiological results at 6 months follow-up. Implants used were **Copeland** and Global Cap RHHI. Twenty-one patients (10 females) at a mean age of 64 (39–82) years and with shoulder osteoarthritis were randomized to a Copeland (n = 11) or Global C.A.P (n = 10) RHHI. Migration of the RHHI was analyzed with radiostereometric analysis (RSA), and bone mineral density (BMD) was measured with dual energy X-ray absorptiometry (DXA). The length of gleno-humeral offset (LGHO) was measured on radiographs. The patients were followed clinically with questionnaires.

Results: At 6 months, 20 patients completed CSS and WOOS. In the group with a Copeland prosthesis, CSS progressed from median 39 to 59 (p = 0.02) and WOOS improved from median 1,020 to 237 (p = 0.01). For the patients with a Global C.A.P. prosthesis, CSS improved from median 42 to 62 (p = 0.02) and WOSS from median 1,305 to 372 (p = 0.01). The length of the gleno-humeral offset was measured for 20 patients at 6 months. The median difference in LGHO preoperative compared to postoperative for the Global C.A.P. was -0.17 (-0.73 to 0.37) cm and the median difference for the Copeland was 0.46 (0.01–0.93) cm (p = 0.002). Precision of the radiological methods was high for the LGHO and acceptable for RSA and for DXA. At 6 months, shoulder function had improved significantly for both RHHI groups. LGHO increased significantly for the Copeland RHHI and was slightly reduced for the Global C.A.P. RHHI. The implant migration and BMD change around the implant from baseline until 6 months follow-up was comparable for both RHHI. None of the RHHI was revised within the 6 months followup period and no major surgical complications were encountered.

Conclusion: Since the patient's own perception of changes in health status is the most important indicator of the success of treatment, the authors suggest that WOOS should be used to assess the outcome in clinical studies of RHHI and for monitoring patients over time. The precision of the radiological methods was high for the LGHO and acceptable for RSA and DXA. In general, both RSA and DXA were found to be precise methods when applied in the proximity to knee and hip implants; however, the arm is not as easily positioned in the same way and the examination protocols need to be improved to make these method applicable to RHHI. Based on these preliminary radiological and clinical results, the performance of the two RHHI is comparable. Yet, the authors consider that the Copeland RHHI causes overstuffing of the shoulder joint and the consequences of this problem need further attention on a larger scale.

Weakness of the Study: The authors note that there are inherit methodical limitations in this study, and that precision of measurements dependent on accuracy of radiography and measuring methods described.

While statistical and clinical significance of the results were discussed in this RCT, the study was not designed with a priori acceptance criteria and there was no sample size calculated although it was an RCT (note: the subsequent follow-up publication in File #424 provides an update to this study where

sample size was taken into consideration, but the set target was not met). However, the study did test a hypothesis comparing the two different devices. This was a pilot study and hence the follow-up with short-term. Hazards discussion was limited to initial observation of migration only, and thus there was no discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study albeit with a very small sample size and short-term follow-up. The article was of fair quality for assessment.

Conflict of interest: This study has been financially supported by the Danish Rheumatism Association, the Aase and Ejnar Danielsen Foundation, the AP Møller Foundation, the Danish Medical Association, Protesekompagniet Denmark and Biomet Denmark. None of the participants have any economic association with the providers of the economic support.

Contribution and weight of the evidence: The results of this pilot RCT study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. While the device resulted in statistically and clinically significant improvements in functional outcomes, the authors noted overstuffing caused by this implant at early stage follow-up. They noted the need to further evaluate this in the longer-term and on a larger scale. The weight of the evidence is fair quality.

File 436:

Deladerrière JY et al: Geometrical analysis results of 42 resurfacing shoulder prostheses: A CT scan study

Summary: The objective of this study was to determine whether shoulder resurfacing arthroplasty (SRA) restored the native proximal humeral anatomy, as assessed using computed tomography (CT) measurements. The hypothesis was that resurfacing prostheses restore the normal anatomy of the proximal humerus. The authors retrospectively reviewed 42 consecutive cases treated with SRA. Mean patient age was 65 years. CT was performed routinely before prosthesis implantation and at re-evaluation. The **Copeland Mark III** implant was used in 32 cases and the Aequalis Resurfacing Head in 10 cases. The post-implantation CT images were used to measure the angle of inclination, medial humeral offset, lateral glenohumeral offset, and version of the implant. Mean follow-up was 18 months (range, 2.6 - 57 months).

Results: The radiographs obtained at re-evaluation showed no periprosthetic lines or evidence of implant migration. The comparison of radiographs obtained preoperatively and at last follow-up showed no osteolysis or macrogeodes in the glenoid cavity. Mean implant inclination on anteroposterior radiographs in neutral rotation was 131.52° (range, 98° - 156°). Mean humeral head inclination before SRA as measured on CT images was 129.79° (range, 110° - 142°). Mean implant inclination at re-evaluation was 129.09° (range, 106.85° - 142.5°). The difference between the preoperative and postoperative angles of inclination was not statistically significant. Mean medial humeral head offset increased significantly, from 4.05 mm (range, 1 - 10 mm) before SRA to 7.52 mm (range, 2.1 - 14.45 mm) at re-evaluation ($P < 0.0001$). The increase was 3.47 mm (range, −2.9 - +13.45 mm). Mean lateral glenohumeral offset was 49.08 mm (range, 30 - 63 mm) before SRA and 49.28 mm (range, 33.2 - 66.25 mm) at re-evaluation. The difference was not statistically significant. Mean implant version relative to the biepicondylar line was 4.23° (range, −35° - +36°). The statistical analysis showed no significant correlation between implant version and the other CT measurements obtained for this study.

Conclusion: Humeral head resurfacing prostheses restore the overall anatomy of the proximal humeral head. The authors note that their CT scan evaluation protocol seems reproducible and enables an evaluation of implant geometry. In their experience, resurfacing arthroplasty restored the native humeral offset. Inadequate retroversion was noted and was probably related to insufficient exposure during surgery.

Weakness of the Study: The authors list the following: "The main limitation of our study is the absence of measurement of humeral head version before SRA. Follow-up in our study was too short."
While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria but there was hypothesis testing. There was no clinical or patient reported outcome measurement made in this study, but that too wasn't the goal set by the authors as this study was conducted to evaluate anatomical fit of the implant only. Therefore, the findings of this study cannot be directly correlated to assumed clinical benefits noted by the authors. Since this was a retrospective study, there was no measurement of sample size. Hazards were noted and there was discussion of benefits compared to hazards but with lack of clinical outcome data.
Quality for Assessment: Outcome measure endpoints were adequate for the goals of this study, well described and appear to be appropriate. This was a well described study albeit with a small sample size and short-term follow-up and no clinical outcome data. The article was of fair quality for assessment.
Conflict of interest: The authors declare that they have no conflicts of interest concerning this article.
Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland, as it relates to the device's ability to provide an anatomical fit at the shoulder joint. The authors note that resurfacing prostheses restore the native anatomy of the humeral head, but accuracy of placement could be improved with increased joint exposure. The weight of the evidence is fair quality.

File 448:

Mullett H et al: Copeland surface replacement of the shoulder. Results of an hydroxyapatite-coated cementless implant in patients over 80 years of age
Summary: This study describes the results of Copeland surface replacement shoulder arthroplasty using the **Copeland Mark III** prosthesis in patients over 80 years of age. End-stage arthritis of the shoulder is a source of significant pain and debilitating functional loss in the elderly. An arthroplasty offers good relief of pain and may allow the patient to maintain independence. The risk benefit ratio of shoulder replacement may be felt to be too high in an elderly age group, but there is no published evidence to support this theory. The authors have assessed whether the procedure was as reliable and safe as previously seen in a younger cohort of patients. Both humeral and glenoid components have an HA coating and a fluted taper-fit peg. The glenoid component has a metal backing. This study prospectively collected data on all the patients and identified 29 who were 80 years of age or more at the time of surgery. Their mean age was 84.3 years (81 to 93). The specific diagnoses were primary osteoarthritis (OA) in 17 shoulders (58.6%), rotator cuff arthropathy in nine (31%), rheumatoid arthritis (RA) in two (6.9%) and avascular necrosis (AVN) in one (3.5%). Of 29 prostheses, 22 (75.9%) were humeral surface arthroplasties and seven (24.1%) were total shoulder replacements (TSRs). This group of patients was followed up for a mean of 4.5 years (2.1 to 9.3). Their mean age was 84.3 years (81 to 93), the mean operating time was 40 minutes (30 to 45) and the mean in-patient stay was five days (2 to 21).
Results: The overall mean Constant score adjusted for age and gender, improved from 15.1% to 77%. The mean age- and gender-adjusted Constant score of those reviewed with diagnosis of OA was 82.1% (52.3% to 100%). The mean forward flexion increased from 48.5° (30° to 67°) to 105.9° (73.5° to 137.5°). The patient satisfaction score was 8.4 of 10 (6.3 to 10). This was based on the visual analogue scale (VAS) between 0 and 10 (0, not satisfied; 10, very satisfied). In patients with rotator cuff arthropathy the mean active flexion increased from 48° (SD 13.3) to 88° (SD 31.1). The mean age- and gender-adjusted Constant score changed from 9.8% (4% to 13%) to 42.6% (25% to 56%). There were no peri-operative deaths or serious morbidities. A revision was required in one shoulder. This patient had a hemiarthroplasty for rotator cuff arthropathy. She had three years of adequate pain relief but then developed increasing pain with poor function. A reverse geometry prosthesis was inserted 44

months after the index procedure. The mean age of the patients who had died was 82.75 years (81 to 92) at the time of surgery. All the deaths were from causes un-related to the operation. There were no peri-operative deaths or significant complications.

Conclusion: A satisfaction score of 84% was achieved after shoulder arthroplasty, which matches well with the high patient satisfaction usually observed in younger patients who have the same procedure. In this elderly group of patients, the mark III cementless surface replacement arthroplasty provided satisfactory results in the intermediate term. The risk of peri-prosthetic fracture and complications of the use of bone cement, can be avoided with the cementless surface replacement arthroplasty, reducing the risk of complications in this vulnerable age group. Copeland surface replacement shoulder arthroplasty may be performed with minimal morbidity and rapid rehabilitation in the elderly.

Weakness of the Study: The authors do not identify any limitations in their study.

This study, although prospective in nature with available baseline data, did not present any statistical analysis, even though significant clinical benefit seems to have been achieved with the improved scores post-operatively. The study was not designed with a priori acceptance criteria or sample size calculation for determining the power of significance, if any. There was no hypothesis testing or subgroup analysis to compare data within groups of different clinical indications or between the elderly and non-elderly. The authors eluded to having data collection performed on all patients that does not seem to have been reported, i.e., for younger cohorts. Hazards were noted and there was discussion of benefits compared to hazards in this group of elderly patients.

Quality for Assessment: Outcome measure endpoints were limited to a single outcome score and ROM measurements, which were narratively described without any statistical analysis to confirm significance of benefits that seems to have been provided. This study had a small sample size and mid-term follow-up. The article was of limited quality for assessment.

Conflict of interest: The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. In addition, benefits have been or will be directed to a research fund, foundation, educational institution, or other nonprofit organization with which one or more of the authors are associated.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes as observed with the improved clinical scores and ROM, but this could not be thoroughly substantiated due to a lack of statistical analysis. The authors note that surface replacement shoulder arthroplasty can be performed with minimal morbidity and rapid rehabilitation in the elderly. The weight of the evidence is of limited quality.

File 457:

Thomas SR et al: Outcome of Copeland surface replacement shoulder arthroplasty

Summary: This study reports medium-term outcome with the **Copeland Mark 3** prosthesis used for humeral head surface replacement hemiarthroplasty. This implant has a hydroxyapatite coating to improve long term fixation of the implant to bone. 56 consecutive Mark 3 Copeland humeral head surface replacement hemiarthroplasties were performed. Six patients had died of other causes by the time of review, and two were lost to follow-up. This left 48 shoulders in 44 patients (4 bilateral). There were 32 female and 16 male shoulders. The mean age was 70 years (range, 34-84 years). The mean follow-up was 34.2 months (range, 24-63 months). The indications for operation were primarily pain and loss of function. Preoperative diagnoses in were osteoarthritis (20), rheumatoid arthritis (26), rotator cuff tear arthropathy (1), and post-traumatic arthrosis (1).

Results: Constant scores for the whole group improved from a mean preoperative score of 16.4 (range, 8-36) to 54.0 (range, 20-83) at last follow-up (P .05). Subgroup analysis according to diagnosis

(rheumatoid arthritis or osteoarthritis) also yielded statistically significant differences. Three cases underwent subsequent arthroscopic subacromial decompression for impingement symptoms. One case required revision for aseptic loosening to a stemmed implant. Contained, nonprogressive osteolysis was seen in 2 cases. One periprosthetic humeral neck fracture was managed successfully nonoperatively. These results are comparable to those obtained with a modern stemmed hemiarthroplasty and are similar to Copeland's own series. With revision of the implant used as the endpoint, the 5-year survival rate was 98.2%. This fell to 91.9% when reoperation for any reason was taken as the endpoint.

Conclusion: This study shows that the good outcomes reported by Levy and Copeland (the designer group) can be replicated in the early to medium term by non-designer groups. Survival analysis shows no variance from acceptable standards for shoulder replacement for the period of study. The low rate of osteolysis with the hydroxyapatite-coated implant is encouraging. Preservation of bone stock for future revision and replication of individual height, version, and offset are compelling reasons for choosing surface replacement.

Weakness of the Study: The authors list the following: "We recognize potential sources of bias in the methodology of this study. Preoperative scoring was done by the same individual who went on to perform the operation. Nonetheless, measurement bias is more likely to occur during the postoperative assessment, which was performed by independent observers. Preoperative scores did not include an assessment of power; however, most patients would have scored 0 at this stage because they could not achieve the required 90° of shoulder abduction. Patients were not randomized to any other form of treatment, such as a stemmed implant or nonoperative therapy."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria or hypothesis testing. The study design is unknown but there is availability of pre-operative baseline data for comparison. There was no sample size calculation. Hazards were noted and there was discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were limited to one score and ROM only but were well described and appear to be appropriate. This was a well described study albeit with a moderate sample size and short- to mid-term follow-up. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. The authors note that preservation of bone stock for future revision and replication of individual height, version, and offset are compelling reasons for choosing surface replacement with this device. Based on implant revision as an endpoint, this study reports a 5-year survival rate of 98%. The weight of the evidence is fair quality.

File 458:

Thomas SR et al: Geometrical analysis of Copeland surface replacement shoulder arthroplasty in relation to normal anatomy

Summary: The aim of this study was first to perform a reliable geometrical analysis of plain films to examine the effect of the Copeland cementless surface replacement arthroplasty (CSRA) on the humeral head geometry and offset. This study examined changes in the center of instant rotation (CIR) and lateralization of the glenohumeral joint in the coronal plane and correlated the findings to clinical outcome, in particular, range of movement. Inclusion criteria were the standard indications for humeral head surface replacement and the use of a **Copeland Mark 3** prosthesis, which has a pegged design with a hydroxyapatite coating for use without cement. There were 39 patients with a minimum 4 years of clinical follow-up that were included in this study. Of these, 32 had hemiarthroplasties, and 7 had total shoulder replacements. The patients' mean age was 70 years

(range, 29 to 88 years). Of the patients, 30 were women and 9 were men. Measurements were taken from coronal radiographs by use of a validated technique.

Results: The mean preoperative humeral head size of 25.4 mm (range, 23 to 31 mm) was decreased to 25 mm by implantation of the prosthesis. Humeral offset increased from a mean of 23 mm (range, 14 to 30 mm) preoperatively to 28 mm (range, 19 to 35 mm) postoperatively, an increase of 5 mm (95% CI, 3.8 to 6.4; P < .01). There was no mean change in these values on the last follow-up films. There was a mean of 6 mm erosion of LGHO (95% CI, 3.6 to 8.6; P < .01) on the preoperative films by use of the data of Iannotti et al for LGHO and humeral head size. It was restored by a mean of 6 mm (95% CI, 4.4 to 8.5; P < .01) on the postoperative films, but this gain was reduced by a mean of 2 mm (95% CI, 3.5 to 0.2; P = .04) on the last film. The CIR moved by a mean of 2 mm superiorly relative to the inferior glenoid postoperatively and a further 1 mm at last follow-up, but neither of these changes was statistically significant (P = .05). Age- and sex-adjusted Constant scores increased by 57 points (95% CI, 43.0 to 64.4; P < .0001), from a mean of 26 points preoperatively to 83 points at last follow-up. There was very little difference in outcome between groups undergoing hemiarthroplasty or total shoulder replacement. Forward flexion and abduction improved from a mean of 66° and 58°, respectively, preoperatively to 124° and 112°, respectively, at last follow-up.

Conclusion: These findings emphasize the importance of adequate and specific restoration of humeral offset in arthritic shoulder replacement and support its functional relationship to the lever arm of the deltoid and supraspinatus. The CSRA restores humeral offset and appears to center the prosthetic surface correctly on the native anatomic neck. Thus, even in shoulders with marked degrees of erosion, the CSRA can position an appropriately sized prosthetic humeral head in a highly favorable position biomechanically. The extent to which this is achieved in an individual case must be optimized by the surgeon against the state of the pathologic soft tissues, with the balance likely to be reflected in the clinical outcome.

Weakness of the Study: The authors list the following: "Whether surface replacement mimics the optimal anatomy for a given individual with arthritis any better than a stemmed implant cannot be proved by this study, which is too small to prove any clinical benefit in terms of movement. This would require a prospective, randomized, controlled trial comparing the two procedures with proper stratification and adequate numbers."

While statistical and clinical significance of the results were discussed in detail in this study, the study was not designed with a priori acceptance criteria even though it was prospective in nature with availability of pre-operative baseline data. Also, there was no sample size calculation and no hypothesis testing. Hazards were noted and there was a discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate for the stated purposes of this study, well described and appear to be appropriate. This was a well described study albeit with a small sample size and short- to mid-term follow-up. The article was of fair quality for assessment.

Conflict of interest: None reported.

Contribution and weight of the evidence: The results of this prospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in an anatomically and geometrically accurate recreation of the shoulder joint, which resulted in improved functional outcomes. The authors note that the device placement needs to be tailored to each individual case depending on the status of the surrounding soft tissue support structures. The weight of the evidence is fair quality.

File 461:

Levy O et al: Cementless surface replacement arthroplasty (Copeland CSRA) for osteoarthritis of the shoulder

Summary: The purpose of this study was to report the results of **Copeland** CSRA in primary osteoarthritis of the shoulder. 79 CSRAs (42 total shoulder replacements and 37 hemiarthroplasties)

were performed for primary osteoarthritis of the shoulder. Total shoulder replacement was done in 12 men and 30 women with a mean age of 71.5 years (range, 50-87 years). Hemiarthroplasty was used in 9 men and 28 women; 5 patients had bilateral hemiarthroplasty. The mean age was 73.4 years (range, 53-88 years). Thirty-nine total shoulder arthroplasties and thirty hemiarthroplasties with a follow- up of more than 2 years were available for review. The mean follow-up was 7.6 years (range, 48 months to 13 years) for total shoulder replacement and 4.4 years (range, 24 months to 6.5 years) for hemiarthroplasty.

Results: The Constant scores improved from an age adjusted Constant score of 33.8% (20.0 points) to 94% (61.9 points) for total shoulder replacement and from an age-adjusted Constant score 40.0% (25.3 points) to 91% (58.1 points) for hemiarthroplasty. Active elevation improved by a mean of 59.9° to a mean of 128° for total shoulder replacement and to a mean of 124° for hemiarthroplasty. Of the patients, 89.9% considered the shoulder to be much better or better as a result of the operation. Radiographically, one humeral implant and three glenoid implants had evidence of loosening. Four revisions were performed in the total shoulder replacement group. No revision surgery was needed in the hemiarthroplasty group.

Conclusion: This study demonstrated good results with the Copeland CSRA for treatment of osteoarthritis that are at least equal to those of conventional stemmed prostheses. This prosthesis is suitable for almost all cases of primary osteoarthritis. The hydroxyapatite-coated implants show no lucent lines, and this is very encouraging. Use of the Copeland CSRA allows anatomic resurfacing with conservation of bone stock and without creating a stress riser in the midshaft of the humerus. It does seem that the humeral component does not need a stem or cement for fixation. The results of this series are at least comparable to those reported for stemmed prostheses with a comparable length of follow-up. The results of total shoulder replacement and hemiarthroplasty in osteoarthritis of the shoulder seem to be comparable. With use of the CSRA prosthesis, several severe complications mainly concerning the humeral shaft and periprosthetic fractures can be avoided. Should the need for revision surgery or arthrodesis arise, these procedures are easily performed, as bone stock has been maintained and no loss of length has been encountered. It does seem that the humeral component does not need a stem or cement for fixation.

Weakness of the Study: The authors do not list or identify any weaknesses in their study.

However, there was no statistical analysis performed on the data presented despite the availability of baseline data and presence of two distinct groups, i.e., total and hemi arthroplasties. While the authors state that improvements observed in the measured data were clinically significant, it was not backed up by statistics. Also, the study design was unknown, and it was not designed with a priori acceptance criteria or hypothesis testing. There was also no sample size calculation, in line with the lack of any statistical data analysis. But hazards were noted and there was discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate but lack statistical backing. This was a well described study albeit with a moderate sample size and mid- to long-term follow-up. The article was of fair quality for assessment.

Conflict of interest: One or more of the authors has declared the following potential conflict of interest or source of funding: M.S. has received educational support from Smith & Nephew. A.M. has received educational support from Arthrex; consulting fees from Amniox Medical, Trice Medical, Linvatec, and Arthrosurface; royalties from Arthrosurface and Zimmer Biomet Holdings; honoraria from Arthrosurface; and hospitality payments from DJO.

Contribution and weight of the evidence: The results of this study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes. The authors note that with use of these types of prostheses, several severe complications mainly concerning the humeral shaft and periprosthetic fractures can be avoided. Should the

need for revision surgery or arthrodesis arise, these procedures are easily performed, as bone stock is maintained, and no loss of length is encountered. The weight of the evidence is fair quality.

File 462:

Levy O et al: Copeland surface replacement arthroplasty of the shoulder in rheumatoid arthritis

Summary: In this paper, the authors present in detail the results of **Copeland** cementless surface replacement arthroplasty in patients with rheumatoid arthritis. Shoulder arthroplasty with a stemmed prosthesis is a recognized treatment for rheumatoid arthritis of the shoulder. The humeral component of the Copeland cementless surface replacement arthroplasty consists of a cup for surface replacement with a short central peg for primary fixation to the bone. The authors hypothesized that surface replacement may offer some advantages over stemmed prostheses. Seventy-five shoulders underwent surface replacement arthroplasty (thirty-three hemiarthroplasties and forty-two total shoulder arthroplasties) for the treatment of rheumatoid arthritis. The results of these procedures were reviewed after an average duration of follow-up of 6.5 years. Patients were assessed with use of the Constant score, a patient satisfaction score, and radiographs.

Results: The average Constant score (and standard deviation) was 53.4 ± 13.6 points (age and sex-adjusted score, 76% ± 13.4%) after the total shoulder arthroplasties and 47.9 ± 17.8 points (age and sex-adjusted score, 71% ± 19.8%) after the hemiarthroplasties. The mean range of active flexion improved from 50° to 101° in the hemiarthroplasty group and from 47°to 104° in the total shoulder replacement group. The mean range of active abduction improved from 35° to 83° in the hemiarthroplasty group and from 37° to 87° in the total shoulder replacement group. The mean range of active external rotation improved from 5° to 44° in the hemiarthroplasty group and from 6° to 47° in the total shoulder replacement group. Seventy-two (96%) of the seventy-five shoulders were considered by the patients to be much better or better at the time of follow-up. Of the sixty-eight humeral implants that were evaluated radiographically, fiftysix (82%) showed no lucencies, eleven (16%) showed localized lucencies of <1 mm in width, and one was definitely loose. Of the thirty-nine glenoid implants that were evaluated radiographically, nineteen (49%) showed no lucencies, nineteen showed localized lucencies of <1 mm, and one was definitely loose. No lucencies were observed adjacent to the hydroxyapatite-coated implants. Thirty-nine (57%) of the sixty-eight shoulders showed some degree of superior subluxation. Three patients required a major reoperation: two required a revision because of loosening of both components, and one patient with pain at the site of a hemiarthroplasty had a revision to a total shoulder arthroplasty to provide relief.

Conclusion: The results of this series are at least comparable with those reported for conventional stemmed humeral head prostheses followed for a comparable duration. Pain relief and an improved range of motion were achieved. The indications for Copeland cementless surface replacement in patients with rheumatoid arthritis are the same as the indications for arthroplasty with a stemmed prosthesis in such patients. The Copeland arthroplasty, however, is not suitable for use in a joint that is so severely damaged that insufficient humeral head bone remains (>40% loss of humeral head bone) and there is no surface to replace or when the humeral head bone is too soft to be able to provide fixation. The decision regarding the suitability of the procedure is made intraoperatively. If, when the surgeon drills the central drill-hole for the peg, the underlying bone beneath the subchondral shell is found to be too soft to provide primary fixation of the Copeland cementless surface replacement, implantation of a stemmed prosthesis should be considered.

Weakness of the Study: The authors do not list or identify any weaknesses in their study.

However, there was no statistical analysis performed on the data presented despite the availability of baseline data and presence of two distinct groups, i.e., total and hemi arthroplasties. While the authors state that improvements observed in the measured data were clinically significant, it was not backed up by statistics. Also, the study design was retrospective but with baseline data available. It was not designed with a priori acceptance criteria. A hypothesis was stated but again there was no

data or statistics to back it up. There was also no sample size calculation, in line with the lack of any statistical data analysis. Hazards were noted and there was discussion of benefits compared to hazards.

Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate but with lack of statistical analysis. This was a well described study albeit with a moderate sample size and mid- to long-term follow-up. The article was of fair quality for assessment.

Conflict of interest: The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. S.A. Copeland received royalties from a commercial entity (Biomet Merck, Ltd.). No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

Contribution and weight of the evidence: The results of this retrospective study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland, and specifically in patients with rheumatoid arthritis. The device resulted in improved functional outcomes, but data presented was not backed by statistical analysis. The authors note that the Copeland arthroplasty, however, is not suitable for use in a joint that is so severely damaged that insufficient humeral head bone remains (>40% loss of humeral head bone) and there is no surface to replace or when the humeral head bone is too soft to be able to provide fixation. The decision regarding the suitability of the procedure is made intraoperatively. The weight of the evidence is fair quality.

File 476:

Levy O et al: Cementless surface replacement arthroplasty of the shoulder. 5- to 10-year results with the Copeland mark-2 prosthesis

Summary: Cementless surface replacement arthroplasty of the shoulder is designed to replace the damaged joint surfaces and restore normal anatomy with minimal resection of bone. For this study, the authors have performed shoulder arthroplasties with 103 **Copeland Mark-2** prostheses that were inserted into 94 patients (9 bilateral). Total shoulder replacement (TSR) was used in 68 shoulders and a hemiarthroplasty in 35. The operations were carried out for the treatment of osteoarthritis, rheumatoid arthritis, avascular necrosis, instability arthropathy, post-traumatic arthropathy and cuff arthropathy. The mean follow-up was for 6.8 years (5 to 10).

Results: The best results were achieved in primary osteoarthritis, with Constant scores of 93.7% for total shoulder replacement and 73.5% for hemiarthroplasty. The poorest results were seen in patients with cuff arthropathy and post-traumatic arthropathy with adjusted Constant scores of 61.3% and 62.7%, respectively. Most patients (93.9%) considered their shoulder to be much better or better than before the operation. Of the 88 humeral implants available for radiological review, 61 (69.3%) showed no evidence of radiolucency, nor did 21 (35.6%) of the 59 glenoid prostheses. Three were definitely loose, and eight shoulders required revision (7.7%), two (1.9%) for primary loosening. Because this is a different design of prosthesis some of the complications differ from those of other models. Those which the authors have observed have been more easily dealt with due to the preservation of bone stock. Removal of the humeral surface component was easily and speedily effected since no cement or stem had to be exposed and removed. Removal of a cemented stemmed prosthesis is associated with loss of bone stock with a risk of perforation and fracture of the humeral shaft. Thus, in the patient who presented with a fractured anatomical neck, the line of bone resection was determined by the injury, and revision to a cemented stemmed prosthesis was easily accomplished. The patient with previous infection and the one with uncontrollable instability were also easily revised to an arthrodesis since bone stock had been preserved with no loss of length. Union of the arthrodesis was achieved rapidly. The incidence of periprosthetic fractures has been quoted as 3% and accounts for approximately 20% of all complications associated with total shoulder arthroplasty both during surgery and later.

Conclusion: The results of this series are comparable with those for stemmed prostheses with a similar follow-up and case mix. The cementless surface replacement arthroplasty diminishes the risk of complications involving the humeral shaft and periprosthetic fractures. Revision or arthrodesis can be undertaken easily since the bone stock has been maintained with no loss of length. Cementless surface replacement arthroplasty of the shoulder differs in many aspects from a non-constrained stemmed shoulder prosthesis, but the results are similar to those published for the latter design including the new generation of modular prostheses.
Weakness of the Study: The authors do not list or identify any weaknesses in their study.
While statistical and clinical significance of the data was achieved, the study design was unknown and without a priori acceptance criteria. While baseline data was available, there was no sample size calculation and no hypothesis testing. Hazards were noted and there was some discussion of benefits compared to hazards.
Quality for Assessment: Outcome measure endpoints were adequate, well described and appear to be appropriate. This was a well described study with a large sample size and mid- to long-term follow-up. The article was of good quality for assessment.
Conflict of interest: One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.
Contribution and weight of the evidence: The results of this study contribute to the body of evidence of this treatment using the comparator device under consideration, i.e., Copeland. The device resulted in improved functional outcomes and patient satisfaction, especially in cases of primary osteoarthritis. They advised caution when using it in patients with cuff arthropathy. The authors note that while this prosthesis differs in many aspects from a non-constrained stemmed shoulder prosthesis, the results are similar to those published for the latter design including the new generation of modular prostheses. The weight of the evidence is good quality.

Evaluation of Product Safety Data – Review of Reported Adverse Event in Literature

The table below summarizes the adverse event/hazards/complications reported/cited in the studies reviewed above for the subject and comparator devices. It is observed that the subject device and comparator device carry the same risks, which have been adequately identified in the device labeling for the subject device.

Adverse events/hazards

File	Author	Device	Unexpected or reported side effects or adverse events or complications	Included in Arthrosurface Instructions for Use?
31	Ibrahim et al	Zimmer Biomet Copeland Mark III	revision surgery; impingement syndrome	Yes
39	Maier et al	Zimmer Biomet Copeland (and other device)	revision surgery; glenoid erosion	Yes
42	Bulhoff et al	Zimmer Biomet Copeland	humeral stem fissure; superficial wound infection	Yes
44	Verstraelen et al	Zimmer Biomet Copeland Mark III	glenoid erosion; subluxation; subsidence; revision surgery; periprosthetic fracture	Yes
47	Werner et al	Zimmer Biomet Copeland Mark III (and other device)	revision surgery; ongoing pain; glenoid erosion; dislocation	Yes

File	Author	Device	Unexpected or reported side effects or adverse events or complications	Included in Arthrosurface Instructions for Use?
60	Soudy et al	Zimmer Biomet Copeland Mark III (and other device)	revision surgery; glenoid erosion; soft tissue tear; superficial wound infection; adhesive capsulitis	Yes
354	Egger et al	Arthrosurface OVO & GRS	soft tissue injury caused by post-operative trauma	Yes
361	Yalcin et al	Arthrosurface OVO & GRS	none reported	N/A
412	Dekker AP et al	Zimmer Biomet Copeland Mark III	revision surgery; pain; stiffness; glenoid erosion; aseptic loosening; deep infection; periprosthetic fracture	Yes
418	Rai P et al	Zimmer Biomet Copeland Mark III	revision surgery; periprosthetic fracture; trauma related bone fracture	Yes
419	Al-Hadithy N et al	Zimmer Biomet Copeland Mark III	glenoid erosion; revision surgery; stiffness; poor function; trauma related bone fracture; dislocation; superficial wound infection; instability; pain	Yes
422	Levy O et al	Zimmer Biomet Copeland Mark II/III	revision surgery; deep infection; instability; stiffness; impingement; trauma related bone fracture; loosening; glenoid erosion; radiolucent lines; migration; soft tissue failure	Yes
424	Mechlenburg I et al	Zimmer Biomet Copeland (and other device)	revision surgery; migration; impingement; bone fracture; pain; soft tissue failure; disease progression; aseptic loosening; immobilization; stiffness; poor ROM; overstuffing	Yes
425	Jerosch J et al	Zimmer Biomet Copeland	temporary radial neuropathy; superficial wound infection; instability	Yes
427	Hwang N et al	Zimmer Biomet Copeland Mark III	glenoid erosion; loosening; periprosthetic fracture; deep infection; pain; revision surgery	Yes
428	Alizadehkhaiyat O et al	Zimmer Biomet Copeland Mark IV/EAS	migration; infection; osteolysis; loosening; revision surgery; pain; poor function; glenoid wear	Yes
432	Mechlenburg I et al	Zimmer Biomet Copeland	revision surgery; pain; overstuffing; soft tissue failure; glenoid attrition; luxation; infection	Yes
434	Al-Hadithy N et al	Zimmer Biomet Copeland Mark III	revision surgery; periprosthetic fracture; migration; soft tissue failure; glenoid erosion; radiolucent lines; overstuffing; trauma related bone fracture; trauma related dislocation	Yes
435	Stilling M et al	Zimmer Biomet Copeland (and other device)	migration	Yes
436	Deladerrière JY et al	Zimmer Biomet Copeland Mark III (and other device)	pain	Yes

File	Author	Device	Unexpected or reported side effects or adverse events or complications	Included in Arthrosurface Instructions for Use?
448	Mullett H et al	Zimmer Biomet Copeland Mark III	revision surgery; soft tissue failure; pain; poor function	Yes
457	Thomas SR et al	Zimmer Biomet Copeland Mark III	revision surgery; impingement; aseptic loosening; osteolysis; periprosthetic fracture; pain; stiffness; trauma related bone fracture	Yes
458	Thomas SR et al	Zimmer Biomet Copeland Mark III	glenoid erosion;	Yes
461	Levy O et al	Zimmer Biomet Copeland Mark I, II, III	revision surgery; loosening; surgical error related bone fracture; superficial wound infection; pain; impingement; implant disassociation; radiolucent lines	Yes
462	Levy O et al	Zimmer Biomet Copeland Mark II, III	revision surgery; loosening; radiolucent lines; subluxation; pain	Yes
476	Levy O et al	Zimmer Biomet Copeland Mark II	revision surgery; loosening; limited ROM; radiolucent lines; subsidence; subluxation; inflammation; pneumothorax; stiffness; soft tissue failure; periprosthetic fracture; superficial wound infection; pain; deep infection; trauma related bone fracture; implant disassociation	Yes

Note: A general warning statement has been included in the IFU's that covers the AE's from this list, which are applicable to any orthopaedic surgery in general.

III: Post-Market Data

Post-Market Clinical Follow-Up

As part of the device approval process for the OVO/GRS Total Shoulder Prosthesis in the EU, the manufacturer conducted a post-market clinical follow-up study in accordance with protocol number AS-CE-TSA-01 dated September 28, 2018 and published the final post-market clinical follow-up study report dated November 14, 2019, which was submitted to the manufacturer's notified body as part of the design dossier (Reference Attachment G3 for PMCF Study Protocol and Report documents).

This post-market clinical study was conducted to evaluate the continued safety and efficacy of the subject device at a minimum follow-up of two years. A total of n = 80 total shoulder procedures with the OVO and GRS devices were studied. Thirty nine procedures were performed on the left shoulder and 41 on the right. The primary indication for surgery was glenohumeral arthritis or avascular necrosis in all patients. On average, patients were assessed at a mean of 44.1 months (range 24-84 months). At the time of last follow-up, all patients had retained their original OVO/GRS implant components, and no component failure modes were observed in this study leading to device removal or revision. Post-operative pain was assessed using a pain scale from zero (no pain) to 10 (worst pain). At last follow-up, the average pain score was 1.1 (range 0-8). Range of motion measurements included forward elevation and external rotation. On average, patients achieved 158.7 degrees of forward elevation (range 11-180 degrees) and 61.5 degrees of external rotation (range 20-90 degrees). As noted in the literature review section for data published on

the comparator device, these end points were found to be similar, or even better in some cases, from both a safety and efficacy perspective. As noted in Section 2.1, these two primary performance outcomes claimed by the manufacturer, were successfully achieved for its OVO and GRS total shoulder arthroplasty system.

The report of this post-market clinical study concluded that "The Arthrosurface Total Shoulder System is safe and effective for continued marketing and has acceptable risks levels as per documented risk management and as compared to other marketed shoulder implants used in the treatment of glenohumeral arthritis." Therefore, these data, along with the data published in the literature for similar devices, continues to support the use of Arthrosurface, Inc.'s shoulder arthroplasty system's implants for safe and effective clinical use.

Evaluation of Product Safety Data – Review of Reported Adverse Event and Recalls in Regulator Databases

The assessment of the safety of the subject device was based on a review of adverse event data collected as part of the clinical literature assessment and data from post-market surveillance activities as detailed in Section 5.4 of the main body of the CER. Details of the anticipated adverse events is presented in Section 5.4.1, details of complaint data is presented in Section 5.4.2, details of implant revision history are presented in Section 5.4.3 and the details of reportable events are presented in Section 5.4.4.

The US FDA maintains Medical Device Reports (MDRs) in the Manufacturer and User Facility Device Experience (MAUDE) database. The database can be searched using a variety of parameters including "manufacturer name", "brand name" and "product code", amongst other parameters. For this evaluation, we used a combination of the available search fields "manufacturer" (Arthrosurface), "brand name" (OVO/GRS) and/or "product code" (HSD/KWS) for the subject device, for the period 01/01/2000 to 08/31/2021, which returned a total of 20 unique records. And for the comparator device, we used the search fields "manufacturer" (Biomet), "brand name" (Copeland/Copeland Mark) and/or "product code" (HSD/KWS) for the same search period, which also returned a total of 20 unique records. These are provided as Attachment G3 within this Appendix. A review of these led to the finding that the noted risks, side-effects, and adverse events reported for the comparator device are the same as those for the subject device.

The US FDA's MAUDE database also identifies reported recalls by search fields such as "product name, "recalling firm" and "product code". For this evaluation, we used a combination of these fields with the following terms: OVO/GRS/Arthrosurface/HSD/KWS for the subject device, and Copeland/Mark/Biomet/HSD/KWS for the comparator device, which resulted in one Class II recall for each device. These recalls are summarized in the tables below:

For Subject Device:

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
02/12/2015	Arthrosurface, Inc.	No Marketing Application	Fully threaded Taper Post Fixation components not cleared for marketing in the US with current indications.

For Comparator Device:

Date	Manufacturer	FDA Determined Cause	Manufacturer Reason for Recall
11/22/2019	Zimmer Biomet, Inc.	Environmental control	Elevated levels of bacterial endotoxin and residual debris remain on the devices due to cleaning issue.

Note: The subject device recall was for a design that was marketed based on an internal letter to file document by the manufacturer that the FDA did not accept during its audit. That design was thus recalled, and the FDA cleared design was re-introduced to the market. Also, the reported recall for the comparator device does not indicate or involve any fundamental issues with the performance of the device and was rather based on device cleaning related issues, which are addressed in the manufacturing process and are not related to device design itself. Also, this recall resulted from isolated issues with specific lots, which does not affect the overall safety profile established for these devices. The overall benefits outweigh the potential risks that may arise when these devices are used as intended.

The UK's MHRA maintains a database of Medical Device Alerts (MDAs) at: https://www.gov.uk/drug-device-alerts

No results were returned for the searches based on specific device names of the subject and comparator devices. Two results were returned for search term "Shoulder" for the alert type "Medical Device Alert" and medical specialty "Orthopaedics". These are listed below:

Comprehensive Reverse Titanium Shoulder Tray (specific lots) - risk of device fracture
Shoulder system: Comprehensive Nano Humeral Components – increased risk of revision when used in reverse configuration

Neither of these alerts is for the subject or comparator devices.

Australia's TGA maintains a database of Medical Device Alerts (MDAs) at: https://www.tga.gov.au/all-alerts

No results were returned for the searches based on specific device names of the subject and comparator devices. Five results were returned for a search on the term "Shoulder". These are listed below:

Affinis Fracture ceramic head (used in shoulder replacements) (24 December 2014)
It has been identified that there is a risk of disconnection of components of the implant from each other due to inadequate fixation during surgery.
Glenosphere Orientation Guide - Instrument used to implant Delta XTEND Reverse Shoulder System (7 June 2013)
It has been identified that, in the affected lot, an arrow etched onto the instrument is located on the wrong side of the device. This etching error could lead to incorrect placement of the glenosphere and consequently a number of potential complications.
PyroTitan humeral resurfacing arthroplasty - used in shoulder replacements (12 August 2013)

It has been identified that there is potential for PyroTitan humeral resurfacing arthroplasty devices to break after being implanted. If this occurs, revision surgery will be necessary.

SMR L2 Metal Back Glenoid Component (used in shoulder replacements) (30 October 2012)

The TGA contacted Lima Orthopaedics Australia, whose subsequent investigations revealed that under certain conditions, for example: rotator cuff failure or patient trauma, the SM L2 Metal Back Glenoid Component's polyethylene liner could become detached from the glenoid component, and that this had increased the revision rate of the SMR. As a result, the SMR L2 Metal Back Glenoid Component has been discontinued

VAIOS Total Shoulder Replacement System (21 October 2015)

Information published by the Australian Orthopaedic Association's National Joint Replacement Registry (link is external) (AOANJRR) indicated that, to December 2013, the VAIOS Total Shoulder Replacement System had a revision rate at two years of 17.6%. The comparable revision rate at two years for all other total conventional shoulder implants was 5.5%.

None of these alerts is for the subject or comparator devices.

Health Canada maintains a database of Medical Device Recalls and Alerts at:
http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php

No results were returned for the searches based on specific device names of the subject and comparator devices. The search of the Health Canada recall and alerts database returned 91 results for the search term “Shoulder”. None of these alerts was for the subject or comparator devices.

Risk-Benefit Analysis

The nature and extent of the expected benefits following implantation of the Arthrosurface shoulder implants are listed in Section 2.1. in the main body of the CER. These benefits are experienced by the patients receiving the subject or comparator devices as is demonstrated by the comprehensive review of the literature detailed in this Appendix.

The data provided in this Appendix support that, following implantation, these devices result in reduced pain, improved range of motion and improved functional outcomes that were evaluated using numerous clinical scoring methods. This was evident for both short-term, i.e., less than 1 year and long-term, i.e., > 10 years, periods. The literature also reflected that there are risks associated with the use of such devices, with the most common reported being the need for revision surgery due to a lack of resolution of pre-operative symptoms. As previously detailed in the benefit/risk analysis in Section 3 of the main body of the CER, shoulder resurfacing arthroplasty implant designs are less disruptive procedures than total or reverse shoulder arthroplasty involving stemmed implants, and yet afford the patients the same level of pain relief with an increased probability of achieving pre-operative levels of functional activity, while also allowing easy revision to traditional or reverse shoulder arthroplasty options where such a need arises subsequently. The benefit of achieving pain-free, pre-operative levels of activity outweighs the risks associated with the use of stemless resurfacing, hemi- or total arthroplasty implants; the predominant risk being the need for a revision surgery frequently due to progression of the disease within the shoulder joint, the latter being facilitated by the bone-sparing technique and design of these devices.

The risk management file has identified the known and potential risks, and addressed applicable risk mitigation strategies that have been implemented to address device safety and operational related issues, which have been documented in the labeling that is presented to the user along with the product. These risks, together with generally accepted risks associated with any surgery, concur with the risks identified in the published literature as is evident from the table above.

In summary, the benefit of using the subject device outweighs the generally accepted risks presented with the use of such devices for a period of up to 10 years. A risk/benefit analysis shows that the subject device is clinically effective when used as intended offering soft-tissue sparing and minimal bone resection, and is associated with a pre-identified risk profile associated with this group of stemless shoulder resurfacing arthroplasty devices and orthopedic surgery in general. The subject device provides a surgery option that can be revised should the need arise due, for example, to disease progression.

The risk management process has identified and assessed hazards that are associated with both subject and comparator devices. All hazards identified in this review are considered in the relevant risk management file documents and are addressed in risk documents or information for use. The residual risk associated with these hazards has been determined to be acceptable by the manufacturer's risk management team.

The risks associated with the subject device are comparable to risks associated with the comparator device, and the frequency of complaints and revisions is low.

Conclusion

Based on this evaluation of clinical data, the subject device, i.e., the OVO/GRS device, considered in this report achieves its intended performance and is safe for use as intended. Specifically, this evaluation has identified that the Arthrosurface Shoulder Arthroplasty Systems, including the OVO/GRS device, comply with the Essential Principles as noted in the TGA's clinical guidance document, as demonstrated by the following elements of this evaluation:

- Acceptability of the risk/benefit profile
    - As an established surgical procedure, there is sufficient clinical study data, and no relevant clinical trials were identified during the literature search period.
    - The clinical data evaluated as part of this report support the continued safety and performance of the Arthrosurface Shoulder Arthroplasty Systems for the stated Indications for Use.
    - The American Academy of Orthopaedic Surgeons: The Treatment of Glenohumeral Joint Osteoarthritis Guideline and Evidence Report, 2009 provides a "moderate" recommendation for total shoulder arthroplasty over hemiarthroplasty when treating patients with glenohumeral joint osteoarthritis. [Note: A Moderate recommendation means that the benefits exceed the potential harm, but the strength of the supporting evidence is not as strong.]
- Adequacy of the information materials
    - Information for Use and the Technique Guide provide adequate information to users.
    - As appropriate, residual risks are communicated to users in documents supplied with the devices.
- Suitability of the device and adequacy of claims/intended purpose
    - The intended purpose and claims for the device are identified in Section 2.3 and Section 2.4 of this report. The clinical data support the use of the Arthrosurface Shoulder Arthroplasty Systems, including the OVO/GRS device, for these purposes.

- Adequacy of clinical data, IFUs and risk management documentation
    - The risks associated with the Arthrosurface Shoulder Arthroplasty Systems, including the OVO/GRS device, appear to be comparable to risks associated with similar devices, and frequency of complaints and revisions is low.
- Consistency between these documents and the current knowledge/ the state of the art
    - There is consistency between the documents and the current knowledge about shoulder arthroplasty. In patient populations for which non-surgical treatment is not effective, shoulder arthroplasty is considered state of the art in appropriate patient populations. The state of the art of the implants used continues to evolve.
- Any residual risks or uncertainties
    - As appropriate, residual risks are communicated to users in documents supplied with the devices.
    - No evidence was found that indicates that an additional Post Market Clinical Follow-up (PMCF) study is required.

In summary:

- **Analysis of the clinical, technical, and biological attributes of the Arthrosurface OVO/GRS device and the selected comparator devices, the Zimmer Biomet Copeland device, demonstrates the substantial equivalence of the two devices and, hence, the direct applicability of the clinical evidence available in the published literature and regulatory authority databases of the comparator device to the Arthrosurface OVO/GRS device.**

- **The published literature demonstrates that the comparator device performs safely and effectively as intended in actual clinical use in 1,374 patients in a time period ranging from 0.5 to 25 years. A review of regulatory authority reporting databases has demonstrated a very low incidence of MDRs, analysis of which has demonstrated no previously unknown or unexpected risks with the device.**

- **Data from the published literature and the manufacturer's PMCF study have shown that the subject device performs safely and effectively in actual clinical use in 128 patients in a time period ranging from 1.2 to 7 years.**

- **Data from the manufacturer's post-market surveillance system have demonstrated very low incidence of adverse events/complaints and revisions associated with the OVO/GRS , i.e., > 9,000 OVO/GRS devices have been implanted since 2011, with less than 0.5% complaint and revision rate reported to date.**

Therefore, the clinical evidence presented and reviewed above and in the supporting Appendices was found acceptable and met the applicable Essential Requirements, Essential Principles, and other necessary requirements. The clinical evidence supports the safety and performance of the Arthrosurface Shoulder Arthroplasty Systems (OVO/GRS) when used as intended in resurfacing, hemi or total shoulder arthroplasty, and the risks associated with the use of the devices are acceptable when weighed against the benefits to the patient.

Attachment G1, G2 and G3 are provided separately.