Usage and Outcomes of DePuy-Mitek Hardware for Shoulder Surgery

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# 1. Preamble

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# 2. Introduction

The surgeons from Geelong Orthopaedics participating in the Patient Registry of Upper Limb Pathology Outcomes (PRULO) specialise in joint replacement, sports injuries, upper limb and hand surgery, and trauma. The PRULO registry collates and stores patient outcomes collected routinely as part of the standard clinical pathway for upper limb pathology treatment.

The registry comprises three patient cohorts: rotator cuff pathology, glenohumeral instability, and general shoulder pathologies. Outcomes data collected by the registry include objective joint function, patient reported outcomes (pain, satisfaction, quality of life), radiological findings, surgical treatment and rates of revision surgery or complications.

Mitek Products are used across all three cohorts. This report summarises the outcomes of the Mitek product list used within the PRULO registry for the past year.

The dataset is derived from the PRULO registry snapshot and live database tables. A [protocol](https://academic.oup.com/jsprm/article/2023/4/snad014/7317733) has been previously prepared for the registry Scholes et al. (2023).

The outline of this report has been derived from the [EuroSpine Registry](https://drive.google.com/file/d/1ahcwmg50p87BR0AgJQXb740z2g7LUj-J/view?usp=sharing) report supplied as an example by Bruce Robie (Mitek, JnJ MedTech) (Sep 2023) and via summary of meeting minutes provided by Tracey Mealey in email correspondence (26-Jun-2023).

# 3. Glossary

To clarify terms used throughout the report, a glossary is presented below.

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| Table 1: Glossary of terms used in report   | Term | Definition | | --- | --- | | Case Failure | Patient presents in a state such that  i) a repaired construct is deemed to be absent healing, or has reinjured subsequent to the index procedure  ii) the shoulder presents in a state such that removal of hardware or procedure revision (single or multi-stage) is recommended | | Reoperation | A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | Case | A definitive reconstruction procedure performed on a patient, excluding a reoperation, but including revision procedures. | | Revision Else | A repeat definitive procedure performed on a case where the previous definitive procedure has been performed by another surgeon | | Revision Own | A repeat definitive procedure performed on a case where the previous definitive procedure has been performed by the same contributing surgeon | | QuickDASH | Short form of the Disabilities of the Arm, Hand and Shoulder questionnaire. The questions are directed toward pain and disability associated with upper limb activities. A diminishing score over time reflects improved function. | | WORCNorm | Western Ontario Rotator Cuff Index is a questionnaire specific to rotator cuff pathology and is scored as the sum of a series of 10mm visual analogue scales. A normalised score is calculated to convert the sum to a percentage score of normal (100%). | | WORC Physical Question 3 | Question 3 of the Physical subscale of the WORC asks “How much weakness do you experience in your shoulder?” and is a key indicator or rotator cuff integrity, especially after repair. | | WOSINorm | Western Ontario Rotator Cuff Index is a questionnaire specific to glenohumeral instability and associated pathology and is scored as the sum of a series of 10mm visual analogue scales. A normalised score is calculated to convert the sum to a percentage score of normal (100%). | |

# 4. Data Preparation

The steps below outline the process for preparing registry data for analysis.

## 4.1 Load libraries

Load up required packages in advance.

## 4.2 Authorisations

Pre-authorise access to registry datasets.

## 4.3 Functions for Processing

Include a series of functions to call later in the file for processing data imports.

## 4.4 Import Inputs

Data was imported from the PRULO registry. Configuration tables were also loaded, including the product table to describe the products of interest and list identifiers to match to surgical records. The table was modified to include a material column (PEEK or BR) and product identifiers.

Dataframes were combined into one for further analysis.

## 4.5 Combine and filter for 3 month follow up

The dataset was filtered to only include records with a minimum of 3 months follow up at the time of analysis.

## 4.6 Prepare dataset for procedure

Procedure data was combined from all cohorts. New columns were created based on conditional statements, cases were filtered where procedure data was unavailable (non-surgical, missing intraoperative data). Procedure data was further processed to standardise labels, categorised by structure (Rotator Cuff, Labrum, Capsule and Ligament) and adjunct procedures reorganised to account for variation across surgical indication.

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| Figure 1: Summary of procedure terms included in registry output |

## 4.7 Adjust dataset for time to event

To account for variations in follow up, time to event was calculated between date of surgery and change of record status. Treatment record end was defined as any change in state such that the treatment would be considered no longer active, has not achieved its clinical purpose or is no longer relevant. For example, in the case of soft tissue repair, if the target tissue represents with a retear, or the construct presents in a state such that hardware removal or replacement is recommended, then the treatment record status is set to inactive and a new treatment record is created to capture the subsequent treatment. The treatments with inactive statuses were extracted to a shared file for review. The subsequent treatment was manually labelled to create the *Subsequent Treatment* variable.

Additional numeric variables were calculated from inputs collected within the registry (e.g. Symptom Duration).

Read in results of manual review of failure cases and categorise subsequent treatments.

## 4.8 Prepare product groups of interest

Tables were rearranged and the dataset was filtered against an ignore list created from the product configuration table. Regular expressions were used to match products of interest to intraoperative hardware information and to sum the instances of implantation for each product of interest.

Identify the problematic codes that are not linking back to the ProductTable correctly

[1] "Discrepancies identified have been added to external table."

## 4.9 Adjust patient demographics for presentation

Recode Sex for report presentation.

## 4.10 Prepare patient-reported outcomes

The PRULO registry uses the QuickDASH (Gummesson, Ward, and Atroshi 2006) for all cases, Western Ontario Rotator Cuff Index (WORC) (Kirkley, Alvarez, and Griffin 2003) for records placed into the Rotator Cuff cohort and the Western Ontario Shoulder Instability Index (WOSI) (Kirkley et al. 1998) for records placed in the Glenohumeral Instability cohort to monitor patient-reported outcomes before and after surgery at defined time intervals. The metrics utilised for each questionnaire in this report are the total score (QuickDaSH) and the normalised total score (WORC and WOSI). A single question from the WORC was also presented (Question 3 of the Physical subscale) that asks “How much weakness do you experience in your shoulder?” to observe potential patterns relevant specifically to cuff repair. PROMs entries were restricted to cases where the treatment record was “eligible” for the time point. Tables were reshaped and variables refactored, with delta variables generated (difference to baseline at each followup) to enable plotting and table generation.

## 4.11 Prepare adverse events

Adverse events were monitored by near real-time chart review and surgical bookings. Events were added to the registry using an electronic form and linked to the treatment records. The data import was assessed for data entry validity, differences between date of event, date of reoperation and surgery date of the index treatment were calculated to assess date validity. Additional data preparation and cleaning was performed, which included filtering and standardizing key identifiers across multiple datasets. Missing values were identified to ensure data consistency. The adverse events were attached to the treatment data with filters applied to constrain to pertinent records and time periods. Time-based metrics were calculated and classification was performed based on the event descriptions using regular expressions. Finally, it conducted data quality checks, identifying potential discrepancies and duplicate entries. After the data transformation, the revised dataset was exported to an external file for review. The code then generated multiple subset datasets, each focusing on a specific type of complication and isolating the earliest occurrence for each unique treatment. This was used for retrieval for each product report.

Split out into arrays to bounce against for each Product report

Intraoperative complications were reviewed manually for mechanism.

# 5. PRULO Summary

The diagram below summarises recruitment and categorisation of patients into the PRULO registry.

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| Figure 2: Flowchart of extraction and followup of sample from the Registry |

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| Table 2: Summary of diagnoses using ICD-10 coding for primary presentation   | Cohort | ICD10 | n | | --- | --- | --- | | General | M19.0 | 101 | | General | M75.0 | 42 | | General | S42.0 | 25 | | General | M12.0 | 17 | | General | S43.5 | 17 | | Glenohumeral Instability | S43.0 | 29 | | Glenohumeral Instability | S43.42 | 29 | | Glenohumeral Instability | M25.31 | 17 | | Glenohumeral Instability | M24.4 | 16 | | Glenohumeral Instability | M24.21 | 4 | | Rotator Cuff | M75.1 | 261 | | Rotator Cuff | S46.0 | 98 | | Rotator Cuff | S43.43 | 18 | | Rotator Cuff | M75.3 | 16 | | Rotator Cuff | S46.1 | 10 | |

The table below summarises patient diagnoses in the PRULO registry. The primary pathology for a given presentation was derived from clinical notes and labelled with an ICD-10 (international) code. Each code was included in a configuration file to link to a registry cohort.

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| Table 3: Summary of PRULO surgical cases by cohort   | **Characteristic** | **Statistic** | **Overall**  N = 1,0451 | **General**  N = 428 | **Glenohumeral Instability**  N = 179 | **Rotator Cuff**  N = 438 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 58 (45, 69) | 64 (50, 73) | 24 (19, 36) | 60 (53, 66) | | Male | % (n) | 63 (661) | 51 (217) | 77 (138) | 70 (306) | | Dominant Side | % (n) | 59 (440) | 57 (173) | 57 (71) | 62 (196) | | Bilateral Presentation | % (n) | 12 (130) | 14 (60) | 11 (19) | 12 (51) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 57 (23, 177) | 101 (37, 284) | 60 (23, 170) | 43 (21, 90) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 28 (135) | 20 (34) | 29 (23) | 34 (78) | | >0.5 | % (n) | 72 (346) | 80 (138) | 71 (55) | 66 (153) | | Treatment Record Active3 | % (n) | 94 (987) | 96 (412) | 98 (176) | 91 (399) | | Patient Record Active4 | % (n) | 100 (1,041) | 99 (424) | 100 (179) | 100 (438) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

The overall registry enrolment is summarised in [Table 3](#tbl-surgical), describing how the population is summarised into cohorts.

# 6. Product Report 1 - Healix Advance PEEK with Dynacord

## 6.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 6.2 Overview

Usage of the Product within the patient group is summarised below.

There are 206 cases involving the anchor of interest. Surgeries were performed between 2020-Oct-21 and 2025-Jan-07. The procedures included [Cuff Repair] [Cuff Repair; Capsulotomy] [Cuff Repair; Tenotomy; Ligament Release] [Cuff Repair; Ligament Release] [Cuff Repair; Tenotomy] [Cuff Repair; Tenodesis] [Augmented Cuff Repair; Tenodesis; Capsular Reconstruction] [Augmented Cuff Repair; Tenotomy; Capsular Reconstruction] [Augmented Cuff Repair; Capsulotomy] [Augmented Cuff Repair; Capsular Reconstruction] [Cuff Repair; Tenodesis; Ligament Release] [Augmented Cuff Repair] [Augmented Cuff Repair; Tenotomy; Ligament Release] [Augmented Cuff Repair; Tenotomy] [Augmented Cuff Repair; Ligament Release] [Cuff Repair; Tenotomy; Capsulotomy] [Augmented Cuff Repair; Tenodesis] [Cuff Repair; Capsulolabral Repair], and [Tenodesis; Labrum Repair]. There are 178 cases involving the anchor of interest and a rotator cuff repair. Surgeries were performed between 2020-Nov-10 to 2025-Jan-07. There are 22 cases involving the anchor of interest and a biceps tenodesis. Surgeries were performed between 2021-Jun-08 to 2023-Oct-25.

## 6.3 Procedure Report - Rotator Cuff Repair

### 6.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

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| Table 4: Summary of PRULO Report 1 (Rotator Cuff) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 1781 | **None**  N = 92 | **Tenodesis**  N = 20 | **Tenotomy**  N = 66 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 60 (55, 65) | 59 (54, 65) | 54 (49, 59) | 62 (57, 69) | | Male | % (n) | 71 (127) | 67 (62) | 100 (20) | 68 (45) | | Cohort |  |  |  |  |  | | General | % (n) | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Rotator Cuff | % (n) | 99 (177) | 99 (91) | 100 (20) | 100 (66) | | Dominant Side | % (n) | 62 (73) | 63 (36) | 62 (8) | 60 (29) | | Bilateral Presentation | % (n) | 7.3 (13) | 3.3 (3) | 25 (5) | 7.6 (5) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 42 (21, 78) | 38 (22, 88) | 47 (9, 92) | 43 (18, 77) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 34 (38) | 32 (17) | 45 (5) | 33 (16) | | >0.5 | % (n) | 66 (74) | 68 (36) | 55 (6) | 67 (32) | | Treatment Record Active3 | % (n) | 84 (149) | 87 (80) | 80 (16) | 80 (53) | | Patient Record Active4 | % (n) | 100 (178) | 100 (92) | 100 (20) | 100 (66) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 6.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

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| Table 5: Summary of PRULO Report 1 (Rotator Cuff) Cases Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 1781 | **None**  N = 921 | **Tenodesis**  N = 201 | **Tenotomy**  N = 661 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Full Tear | 91 (161) | 89 (81) | 85 (17) | 95 (63) | | Partial Tear | 9.0 (16) | 11 (10) | 15 (3) | 4.5 (3) | | Treatment Type |  |  |  |  | | Primary | 95 (169) | 91 (84) | 100 (20) | 98 (65) | | Revision Else | 1.7 (3) | 2.2 (2) | 0 (0) | 1.5 (1) | | Revision Own | 3.4 (6) | 6.5 (6) | 0 (0) | 0 (0) | | Product Count |  |  |  |  | | 1 | 44 (78) | 47 (43) | 40 (8) | 41 (27) | | 2 | 42 (75) | 41 (38) | 40 (8) | 44 (29) | | 3 | 13 (23) | 11 (10) | 15 (3) | 15 (10) | | 4 | 1.1 (2) | 1.1 (1) | 5.0 (1) | 0 (0) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 12 (21) | 12 (11) | 25 (5) | 7.6 (5) | | Cuff Repair | 88 (157) | 88 (81) | 75 (15) | 92 (61) | | Repair Augmentation |  |  |  |  | | Allograft | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Autograft | 0.6 (1) | 0 (0) | 0 (0) | 1.5 (1) | | Autograft; Superior Capsular | 0.6 (1) | 0 (0) | 0 (0) | 1.5 (1) | | None | 88 (156) | 88 (81) | 75 (15) | 92 (60) | | Other2 | 3.4 (6) | 2.2 (2) | 15 (3) | 1.5 (1) | | Superior Capsular | 5.6 (10) | 7.6 (7) | 5.0 (1) | 3.1 (2) | | Superior Capsular; advancement | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Superior Capsular; Autograft | 0.6 (1) | 0 (0) | 5.0 (1) | 0 (0) | | Labrum |  |  |  |  | | Capsulolabral Repair | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | None | 99 (177) | 99 (91) | 100 (20) | 100 (66) | | Labrum Repair |  |  |  |  | | None | 100 (173) | 100 (89) | 100 (20) | 100 (64) | | Capsule | Ligament |  |  |  |  | | Capsular Reconstruction | 4.5 (8) | 4.3 (4) | 10 (2) | 3.0 (2) | | Capsulotomy | 5.1 (9) | 5.4 (5) | 0 (0) | 6.1 (4) | | Ligament Release | 22 (40) | 24 (22) | 5.0 (1) | 26 (17) | | None | 68 (121) | 66 (61) | 85 (17) | 65 (43) | | Glenoid |  |  |  |  | | None | 100 (178) | 100 (92) | 100 (20) | 100 (66) | | Adjunct Procedure |  |  |  |  | | Distal Clavicle Resection | 6.7 (12) | 7.6 (7) | 5.0 (1) | 6.1 (4) | | Infraspinatus Advancement | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | None | 79 (141) | 71 (65) | 95 (19) | 86 (57) | | Removal Suture | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Rotator Interval Debridement | 0.6 (1) | 0 (0) | 0 (0) | 1.5 (1) | | Subacromial Bursectomy | 3.4 (6) | 6.5 (6) | 0 (0) | 0 (0) | | Subacromial Bursectomy; Removal Implants | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Subacromial Bursectomy; Rotator Interval Debridement | 0.6 (1) | 0 (0) | 0 (0) | 1.5 (1) | | Subacromial Decompression | 6.2 (11) | 9.8 (9) | 0 (0) | 3.0 (2) | | Subacromial Decompression; Distal Clavicle Resection | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Os Acromiale Excision | 0.6 (1) | 0 (0) | 0 (0) | 1.5 (1) | | Subacromial Decompression; Subacromial Bursectomy | 0.6 (1) | 1.1 (1) | 0 (0) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 6.3.3 Treatment Survival

The mean follow up duration is 2.4 years, with a standard deviation of 1.36 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

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| Table 6: Summary of PRULO Report 1 (Rotator Cuff) Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 87% (82% - 92%) | 85% (80% - 91%) | 85% (80% - 91%) | | 1% survival with 95% confidence intervals | | | | | |

### 6.3.4 Adverse Events

Complications and adverse events are summarised below.

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| Table 7: Summary of PRULO Report 1 (Rotator Cuff) Cases - Intraoperative Events |

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| Table 8: Summary of PRULO Report 1 (Rotator Cuff) Cases - Postoperative Events.   | **Characteristic** | **N = 178**1 | **95% CI** | | --- | --- | --- | | Infection | 2.2 (4) | 0.72 - 6.0 | | Ligament|Tendon (Retear) | 21 (38) | 16 - 28 | | Effusion | 0 (0) | 0.00 - 2.6 | | Pain | 1.7 (3) | 0.44 - 5.2 | | Hardware | 1.7 (3) | 0.44 - 5.2 | | Loosening | 0 (0) | 0.00 - 2.6 | | Instability | 0 (0) | 0.00 - 2.6 | | Stiffness | 16 (28) | 11 - 22 | | Neurological | 0.6 (1) | 0.03 - 3.6 | | Thrombosis | 0.6 (1) | 0.03 - 3.6 | | Other2 | 2.2 (4) | 0.72 - 6.0 | | Reoperation3 | 7.3 (13) | 4.1 - 12 | | Subsequent Treatment4 |  |  | | Hardware Removal | 0.6 (1) | 0.03 - 3.6 | | Nonoperative Management | 8.4 (15) | 5.0 - 14 | | Not Applicable | 85 (152) | 79 - 90 | | Removal Of Hardware | 1.1 (2) | 0.19 - 4.4 | | Revision Procedure | 2.2 (4) | 0.72 - 6.0 | | Revision Repair | 2.2 (4) | 0.72 - 6.0 | | Reoperation Delay (Weeks)5 | 44 (33) | 25 - 64 | | 1% (n); Mean (SD) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | 5Time between index procedure and reoperation | | | | Abbreviation: CI = Confidence Interval | | | |

### 6.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

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| Figure 3: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

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| Table 9: Summary of PRULO Report 1 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 1701 | **3m**  N = 1781 | **6m**  N = 1561 | **12m**  N = 1381 | | --- | --- | --- | --- | --- | | QDASH | 48 (39 - 61) | 36 (20 - 55) | 19 (9 - 36) | 11 (5 - 20) | | QDASHDelta | NA (NA - NA) | 11 (-5 - 25) | 26 (13 - 40) | 28 (18 - 41) | | 1Median (Q1 - Q3) | | | | | |

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| Table 10: Summary of PRULO Report 1 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 1701 | **6m**  N = 1561 | **12m**  N = 1381 | | --- | --- | --- | --- | | WORCNorm | 37 (24 - 48) | 76 (54 - 90) | 87 (70 - 95) | | WORCPhysicalQ3 | 71 (53 - 88) | 29 (13 - 53) | 19 (10 - 38) | | WORCDelta | NA (NA - NA) | 33 (19 - 45) | 46 (26 - 55) | | 1Median (Q1 - Q3) | | | | |

## 6.4 Procedure Report - Biceps Tenodesis

### 6.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Table 11: Summary of PRULO Report 1 (Biceps Tenodesis) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Tenodesis**  N = 22 | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 53 (47, 58) | | Male | % (n) | 100 (22) | | Cohort |  |  | | Glenohumeral Instability | % (n) | 4.5 (1) | | Rotator Cuff | % (n) | 95 (21) | | Dominant Side | % (n) | 67 (10) | | Bilateral Presentation | % (n) | 23 (5) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 47 (13, 55) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 38 (5) | | >0.5 | % (n) | 62 (8) | | Treatment Record Active2 | % (n) | 82 (18) | | Patient Record Active3 | % (n) | 100 (22) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 6.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 12: Summary of PRULO Report 1 (Biceps Tenodesis) Cases Pathology and Surgical Details   | **Characteristic** | **N = 22**1 | | --- | --- | | Cuff Status |  | | Full Tear | 17 (81%) | | Partial Tear | 3 (14%) | | Tendinopathy | 1 (4.8%) | | Treatment Type |  | | Primary | 22 (100%) | | Product Count |  | | 1 | 10 (45%) | | 2 | 8 (36%) | | 3 | 3 (14%) | | 4 | 1 (4.5%) | | 5 | 0 (0%) | | Cuff Repair |  | | Augmented Cuff Repair | 5 (23%) | | Cuff Repair | 15 (68%) | | None | 2 (9.1%) | | Repair Augmentation |  | | None | 16 (76%) | | Other2 | 3 (14%) | | Superior Capsular | 1 (4.8%) | | Superior Capsular; Autograft | 1 (4.8%) | | Long Head Biceps Procedures |  | | Tenodesis | 22 (100%) | | Labrum |  | | Labrum Repair | 1 (4.5%) | | None | 21 (95%) | | Labrum Repair |  | | None | 21 (95%) | | Other2 | 1 (4.5%) | | Capsule | Ligament |  | | Capsular Reconstruction | 2 (9.1%) | | Ligament Release | 1 (4.5%) | | None | 19 (86%) | | Glenoid |  | | None | 22 (100%) | | Adjunct Procedure |  | | Distal Clavicle Resection | 2 (9.1%) | | None | 20 (91%) | | 1n (%) | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | |

### 6.4.3 Treatment Survival

The mean follow up duration is 2.6 years, with a standard deviation of 1.04 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

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| Table 13: Summary of PRULO Report 1 (Biceps Tenodesis) procedure survival (   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 91% (80% - 100%) | 91% (80% - 100%) | 91% (80% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 6.4.4 Adverse Events

Complications and adverse events are summarised below.

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| Table 14: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - Intraoperative Events |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 15: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - Postoperative Events   | **Characteristic** | **N = 22**1 | **95% CI** | | --- | --- | --- | | Infection | 4.5 (1) | 0.24 - 25 | | Ligament|Tendon (Retear) | 9.1 (2) | 1.6 - 31 | | Effusion | 0 (0) | 0.00 - 18 | | Pain | 0 (0) | 0.00 - 18 | | Hardware | 4.5 (1) | 0.24 - 25 | | Loosening | 0 (0) | 0.00 - 18 | | Instability | 0 (0) | 0.00 - 18 | | Stiffness | 18 (4) | 6.0 - 41 | | Neurological | 4.5 (1) | 0.24 - 25 | | Thrombosis | 0 (0) | 0.00 - 18 | | Other | 0 (0) | 0.00 - 18 | | Reoperation2 | 4.5 (1) | 0.24 - 25 | | Subsequent Treatment3 |  |  | | Not Applicable | 91 (20) | 69 - 98 | | Removal Of Hardware | 4.5 (1) | 0.24 - 25 | | Revision Procedure | 4.5 (1) | 0.24 - 25 | | 1% (n) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 6.4.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Normalised, and WORC Physical Q3 is summarised below.

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| --- |
| Figure 4: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 16: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - QuickDASH.   | **Characteristic** | **Preop**  N = 191 | **3m**  N = 221 | **6m**  N = 211 | **12m**  N = 201 | | --- | --- | --- | --- | --- | | QDASH | 48 (36 - 59) | 57 (39 - 63) | 25 (13 - 43) | 11 (2 - 18) | | QDASHDelta | NA (NA - NA) | 0 (-11 - 32) | 26 (9 - 32) | 43 (32 - 61) | | 1Median (Q1 - Q3) | | | | | |

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| Table 17: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 191 | **6m**  N = 211 | **12m**  N = 201 | | --- | --- | --- | --- | | WORCNorm | 40 (27 - 47) | 73 (47 - 83) | 85 (68 - 92) | | WORCPhysicalQ3 | 72 (41 - 78) | 34 (10 - 50) | 24 (11 - 35) | | 1Median (Q1 - Q3) | | | | |

# 7. Product Report 2 - Healix Advance Knotless PEEK

## 7.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 7.2 Overview

Usage of the Product within the patient group is summarised below.

There are 219 cases involving the anchor of interest. Surgeries were performed between 2020-Oct-21 and 2025-Jan-07. The procedures included [Cuff Repair] [Cuff Repair; Capsulotomy] [Cuff Repair; Tenotomy; Ligament Release] [Cuff Repair; Ligament Release] [Cuff Repair; Tenotomy] [Cuff Repair; Tenodesis] [Augmented Cuff Repair; Tenodesis; Capsular Reconstruction] [Augmented Cuff Repair; Tenotomy; Capsular Reconstruction] [Augmented Cuff Repair; Capsulotomy] [Augmented Cuff Repair; Capsular Reconstruction] [Augmented Cuff Repair] [Augmented Cuff Repair; Tenotomy; Ligament Release] [Augmented Cuff Repair; Ligament Release] [Cuff Repair; Tenotomy; Capsulotomy] [Augmented Cuff Repair; Tenotomy], and [Augmented Cuff Repair; Tenodesis]. There are 190 cases involving the anchor of interest and a rotator cuff repair. Surgeries were performed between 2020-Nov-10 to 2025-Jan-07. There are 17 cases involving the anchor of interest and a biceps tenodesis. Surgeries were performed between 2021-Jun-10 to 2023-Oct-25.

## 7.3 Procedure Report - Rotator Cuff Repair

### 7.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

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| Table 18: Summary of PRULO Report 2 (Rotator Cuff) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 1901 | **None**  N = 103 | **Tenodesis**  N = 17 | **Tenotomy**  N = 70 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 60 (55, 65) | 59 (53, 65) | 53 (51, 58) | 62 (57, 70) | | Male | % (n) | 70 (133) | 65 (67) | 100 (17) | 70 (49) | | Cohort |  |  |  |  |  | | General | % (n) | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Rotator Cuff | % (n) | 99 (189) | 99 (102) | 100 (17) | 100 (70) | | Dominant Side | % (n) | 59 (73) | 63 (40) | 56 (5) | 55 (28) | | Bilateral Presentation | % (n) | 7.4 (14) | 2.9 (3) | 29 (5) | 8.6 (6) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 37 (21, 77) | 43 (22, 90) | 15 (9, 135) | 35 (17, 75) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 34 (40) | 31 (18) | 57 (4) | 35 (18) | | >0.5 | % (n) | 66 (76) | 69 (40) | 43 (3) | 65 (33) | | Treatment Record Active3 | % (n) | 84 (160) | 89 (92) | 76 (13) | 79 (55) | | Patient Record Active4 | % (n) | 100 (190) | 100 (103) | 100 (17) | 100 (70) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 7.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

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| Table 19: Summary of PRULO Report 2 (Rotator Cuff) Cases Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 1901 | **None**  N = 1031 | **Tenodesis**  N = 171 | **Tenotomy**  N = 701 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Full Tear | 91 (172) | 86 (88) | 94 (16) | 97 (68) | | Other2 | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Partial Tear | 8.5 (16) | 13 (13) | 5.9 (1) | 2.9 (2) | | Treatment Type |  |  |  |  | | Primary | 96 (182) | 93 (96) | 100 (17) | 99 (69) | | Revision Else | 1.6 (3) | 1.9 (2) | 0 (0) | 1.4 (1) | | Revision Own | 2.6 (5) | 4.9 (5) | 0 (0) | 0 (0) | | Product Count |  |  |  |  | | 1 | 53 (101) | 54 (56) | 35 (6) | 56 (39) | | 2 | 41 (77) | 41 (42) | 65 (11) | 34 (24) | | 3 | 5.3 (10) | 4.9 (5) | 0 (0) | 7.1 (5) | | 4 | 1.1 (2) | 0 (0) | 0 (0) | 2.9 (2) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 13 (25) | 15 (15) | 35 (6) | 5.7 (4) | | Cuff Repair | 87 (165) | 85 (88) | 65 (11) | 94 (66) | | Repair Augmentation |  |  |  |  | | Allograft | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Autograft; Superior Capsular | 0.5 (1) | 0 (0) | 0 (0) | 1.4 (1) | | None | 87 (164) | 85 (88) | 65 (11) | 94 (65) | | Other2 | 3.2 (6) | 1.9 (2) | 18 (3) | 1.4 (1) | | Superior Capsular | 7.4 (14) | 11 (11) | 5.9 (1) | 2.9 (2) | | Superior Capsular; advancement | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Superior Capsular; Autograft | 1.1 (2) | 0 (0) | 12 (2) | 0 (0) | | Labrum |  |  |  |  | | None | 100 (190) | 100 (103) | 100 (17) | 100 (70) | | Labrum Repair |  |  |  |  | | None | 100 (186) | 100 (101) | 100 (17) | 100 (68) | | Capsule | Ligament |  |  |  |  | | Capsular Reconstruction | 5.8 (11) | 5.8 (6) | 18 (3) | 2.9 (2) | | Capsulotomy | 5.8 (11) | 6.8 (7) | 0 (0) | 5.7 (4) | | Ligament Release | 22 (42) | 24 (25) | 0 (0) | 24 (17) | | None | 66 (126) | 63 (65) | 82 (14) | 67 (47) | | Glenoid |  |  |  |  | | None | 100 (190) | 100 (103) | 100 (17) | 100 (70) | | Adjunct Procedure |  |  |  |  | | Calcific Tendonitis Excision | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Distal Clavicle Resection | 7.4 (14) | 8.7 (9) | 5.9 (1) | 5.7 (4) | | Infraspinatus Advancement | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | None | 77 (146) | 68 (70) | 88 (15) | 87 (61) | | Removal Suture | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Rotator Interval Debridement | 0.5 (1) | 0 (0) | 0 (0) | 1.4 (1) | | Subacromial Bursectomy | 2.6 (5) | 4.9 (5) | 0 (0) | 0 (0) | | Subacromial Bursectomy; Removal Implants | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | Subacromial Bursectomy; Rotator Interval Debridement | 0.5 (1) | 0 (0) | 0 (0) | 1.4 (1) | | Subacromial Decompression | 7.9 (15) | 12 (12) | 5.9 (1) | 2.9 (2) | | Subacromial Decompression; Distal Clavicle Resection | 1.1 (2) | 1.9 (2) | 0 (0) | 0 (0) | | Subacromial Decompression; Os Acromiale Excision | 0.5 (1) | 0 (0) | 0 (0) | 1.4 (1) | | Subacromial Decompression; Subacromial Bursectomy | 0.5 (1) | 1.0 (1) | 0 (0) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 7.3.3 Treatment Survival

The mean follow up duration is 2.4 years, with a standard deviation of 1.36 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 20: Summary of PRULO Report 2 (Rotator Cuff) Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 86% (81% - 91%) | 86% (81% - 91%) | 86% (81% - 91%) | | 1% survival with 95% confidence intervals | | | | | |

### 7.3.4 Adverse Events

Complications and adverse events are summarised below.

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| --- |
| Table 21: Summary of PRULO Report 2 (Rotator Cuff) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 22: Summary of PRULO Report 2 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 190**1 | **95% CI** | | --- | --- | --- | | Infection | 2.1 (4) | 0.68 - 5.7 | | Ligament|Tendon (Retear) | 22 (42) | 17 - 29 | | Effusion | 0 (0) | 0.00 - 2.5 | | Pain | 2.1 (4) | 0.68 - 5.7 | | Hardware | 1.1 (2) | 0.18 - 4.2 | | Loosening | 0 (0) | 0.00 - 2.5 | | Instability | 0 (0) | 0.00 - 2.5 | | Stiffness | 18 (35) | 13 - 25 | | Neurological | 0.5 (1) | 0.03 - 3.3 | | Thrombosis | 0.5 (1) | 0.03 - 3.3 | | Other2 | 2.6 (5) | 0.97 - 6.4 | | Reoperation3 | 6.8 (13) | 3.8 - 12 | | Subsequent Treatment4 |  |  | | Nonoperative Management | 8.4 (16) | 5.0 - 14 | | Not Applicable | 86 (163) | 80 - 90 | | Removal Of Hardware | 1.6 (3) | 0.41 - 4.9 | | Revision Procedure | 2.1 (4) | 0.68 - 5.7 | | Revision Repair | 2.1 (4) | 0.68 - 5.7 | | Reoperation Delay (Weeks)5 | 44 (33) | 25 - 64 | | 1% (n); Mean (SD) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | 5Time between index procedure and reoperation | | | | Abbreviation: CI = Confidence Interval | | | |

### 7.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

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| --- |
| Figure 5: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

Figure 1: Complete case analysis of QDASH(Top), WORC Index Normalised (Middle), and WORC Physical Question 3 (Bottom).

Table 5:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 23: Summary of PRULO Report 2 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 1711 | **3m**  N = 1791 | **6m**  N = 1571 | **12m**  N = 1411 | | --- | --- | --- | --- | --- | | QDASH | 48 (39 - 61) | 39 (23 - 57) | 19 (9 - 36) | 11 (5 - 20) | | QDASHDelta | NA (NA - NA) | 11 (-5 - 25) | 25 (13 - 41) | 28 (18 - 41) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 24: Summary of PRULO Report 2 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 1711 | **6m**  N = 1571 | **12m**  N = 1411 | | --- | --- | --- | --- | | WORCNorm | 36 (24 - 47) | 77 (56 - 89) | 87 (69 - 95) | | WORCPhysicalQ3 | 72 (54 - 88) | 30 (13 - 55) | 21 (10 - 41) | | WORCDelta | NA (NA - NA) | 34 (20 - 48) | 45 (32 - 55) | | 1Median (Q1 - Q3) | | | | |

## 7.4 Procedure Report - Biceps Tenodesis

### 7.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 25: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - Patient Characteristics   | **Characteristic** | **Statistic** | **Tenodesis**  N = 17 | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 53.0 (51.0, 58.0) | | Male | % (n) | 100 (17) | | Cohort |  |  | | Rotator Cuff | % (n) | 100 (17) | | Dominant Side | % (n) | 56 (5) | | Bilateral Presentation | % (n) | 29 (5) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 57 (4) | | >0.5 | % (n) | 43 (3) | | Treatment Record Active2 | % (n) | 76 (13) | | Patient Record Active3 | % (n) | 100 (17) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 7.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 26: Summary of PRULO Report 2 (Biceps Tenodesis) Cases Pathology and Surgical Details   | **Characteristic** | **N = 17**1 | | --- | --- | | Cuff Status |  | | Full Tear | 16 (94%) | | Partial Tear | 1 (5.9%) | | Treatment Type |  | | Primary | 17 (100%) | | Product Count |  | | 1 | 6 (35%) | | 2 | 11 (65%) | | 3 | 0 (0%) | | 4 | 0 (0%) | | 5 | 0 (0%) | | Cuff Repair |  | | Augmented Cuff Repair | 6 (35%) | | Cuff Repair | 11 (65%) | | Repair Augmentation |  | | None | 11 (65%) | | Other2 | 3 (18%) | | Superior Capsular | 1 (5.9%) | | Superior Capsular; Autograft | 2 (12%) | | Long Head Biceps Procedures |  | | Tenodesis | 17 (100%) | | Labrum |  | | None | 17 (100%) | | Labrum Repair |  | | None | 17 (100%) | | Capsule | Ligament |  | | Capsular Reconstruction | 3 (18%) | | None | 14 (82%) | | Glenoid |  | | None | 17 (100%) | | Adjunct Procedure |  | | Distal Clavicle Resection | 1 (5.9%) | | None | 15 (88%) | | Subacromial Decompression | 1 (5.9%) | | 1n (%) | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | |

### 7.4.3 Treatment Survival

The mean follow up duration is 2.6 years, with a standard deviation of 1.12 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 27: Summary of PRULO Report 2 (Biceps Tenodesis) procedure survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 88% (74% - 100%) | 88% (74% - 100%) | 88% (74% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 7.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 28: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 29: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - Postoperative Events   | **Characteristic** | **N = 17**1 | **95% CI** | | --- | --- | --- | | Infection | 5.9 (1) | 0.31 - 31 | | Ligament|Tendon (Retear) | 12 (2) | 2.1 - 38 | | Effusion | 0 (0) | 0.00 - 23 | | Pain | 0 (0) | 0.00 - 23 | | Hardware | 0 (0) | 0.00 - 23 | | Loosening | 0 (0) | 0.00 - 23 | | Instability | 0 (0) | 0.00 - 23 | | Stiffness | 24 (4) | 7.8 - 50 | | Neurological | 5.9 (1) | 0.31 - 31 | | Thrombosis | 0 (0) | 0.00 - 23 | | Other | 0 (0) | 0.00 - 23 | | Reoperation2 | 5.9 (1) | 0.31 - 31 | | Subsequent Treatment3 |  |  | | Not Applicable | 88 (15) | 62 - 98 | | Removal Of Hardware | 5.9 (1) | 0.31 - 31 | | Revision Procedure | 5.9 (1) | 0.31 - 31 | | 1% (n) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 7.4.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Normalised, and WORC Physical Q3 is summarised below.

|  |
| --- |
| Figure 6: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 30: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 131 | **3m**  N = 161 | **6m**  N = 151 | **12m**  N = 141 | | --- | --- | --- | --- | --- | | QDASH | 48 (36 - 59) | 58 (48 - 68) | 26 (13 - 43) | 14 (11 - 18) | | QDASHDelta | NA (NA - NA) | -6 (-11 - 2) | 24 (9 - 27) | 36 (25 - 48) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 31: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 131 | **6m**  N = 151 | **12m**  N = 141 | | --- | --- | --- | --- | | WORCNorm | 44 (29 - 58) | 72 (45 - 79) | 81 (68 - 87) | | WORCPhysicalQ3 | 68 (48 - 75) | 36 (11 - 59) | 32 (29 - 35) | | 1Median (Q1 - Q3) | | | | |

# 8. Product Report 3 - Healix Advance Knotless BR

## 8.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 8.2 Overview

Usage of the Product within the patient group is summarised below.

There are 63 cases involving the anchor of interest. Surgeries were performed between 2021-Mar-02 and 2024-Nov-14. The procedures included [Cuff Repair] [Cuff Repair; Tenodesis] [Cuff Repair; Tenotomy] [Cuff Repair; Capsulotomy] [Augmented Cuff Repair] [Cuff Repair; Tenodesis; Capsulotomy] [Augmented Cuff Repair; Tenodesis], and [Cuff Repair; Capsulolabral Repair]. There are 62 cases involving the anchor of interest and a rotator cuff repair. Surgeries were performed between 2021-Mar-02 to 2024-Nov-14. There are 19 cases involving the anchor of interest and a biceps tenodesis. Surgeries were performed between 2021-Jun-03 to 2024-Oct-22.

## 8.3 Procedure Report - Rotator Cuff Repair

### 8.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 32: Summary of PRULO Report 3 (Rotator Cuff) Cases - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 621 | **None**  N = 41 | **Tenodesis**  N = 19 | **Tenotomy**  N = 2 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 62 (52, 69) | 62 (57, 68) | 63 (50, 69) | 55 (44, 66) | | Male | % (n) | 76 (47) | 71 (29) | 95 (18) | 0 (0) | | Cohort |  |  |  |  |  | | Rotator Cuff | % (n) | 100 (62) | 100 (41) | 100 (19) | 100 (2) | | Dominant Side | % (n) | 61 (37) | 66 (27) | 44 (8) | 100 (2) | | Bilateral Presentation | % (n) | 15 (9) | 12 (5) | 16 (3) | 50 (1) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 27 (17, 60) | 25 (14, 60) | 27 (20, 42) | 193 (193, 193) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 46 (18) | 50 (11) | 44 (7) | 0 (0) | | >0.5 | % (n) | 54 (21) | 50 (11) | 56 (9) | 100 (1) | | Treatment Record Active3 | % (n) | 97 (60) | 95 (39) | 100 (19) | 100 (2) | | Patient Record Active4 | % (n) | 100 (62) | 100 (41) | 100 (19) | 100 (2) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 8.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 33: Summary of PRULO Report 3 (Rotator Cuff) Cases Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 621 | **None**  N = 411 | **Tenodesis**  N = 191 | **Tenotomy**  N = 21 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Degenerative | 1.6 (1) | 0 (0) | 5.3 (1) | 0 (0) | | Full Tear | 94 (58) | 93 (38) | 95 (18) | 100 (2) | | Partial Tear | 4.8 (3) | 7.3 (3) | 0 (0) | 0 (0) | | Treatment Type |  |  |  |  | | Primary | 98 (61) | 98 (40) | 100 (19) | 100 (2) | | Revision Else | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Product Count |  |  |  |  | | 1 | 52 (32) | 61 (25) | 37 (7) | 0 (0) | | 2 | 44 (27) | 34 (14) | 58 (11) | 100 (2) | | 3 | 4.8 (3) | 4.9 (2) | 5.3 (1) | 0 (0) | | 4 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 4.8 (3) | 2.4 (1) | 11 (2) | 0 (0) | | Cuff Repair | 95 (59) | 98 (40) | 89 (17) | 100 (2) | | Repair Augmentation |  |  |  |  | | Autograft | 1.6 (1) | 0 (0) | 5.3 (1) | 0 (0) | | None | 95 (59) | 98 (40) | 89 (17) | 100 (2) | | Other2 | 3.2 (2) | 2.4 (1) | 5.3 (1) | 0 (0) | | Labrum |  |  |  |  | | Capsulolabral Repair | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | None | 98 (61) | 98 (40) | 100 (19) | 100 (2) | | Labrum Repair |  |  |  |  | | None | 100 (61) | 100 (40) | 100 (19) | 100 (2) | | Capsule | Ligament |  |  |  |  | | Capsulotomy | 18 (11) | 24 (10) | 5.3 (1) | 0 (0) | | None | 82 (51) | 76 (31) | 95 (18) | 100 (2) | | Glenoid |  |  |  |  | | None | 100 (62) | 100 (41) | 100 (19) | 100 (2) | | Adjunct Procedure |  |  |  |  | | Distal Clavicle Resection | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | None | 42 (26) | 34 (14) | 63 (12) | 0 (0) | | Subacromial Bursectomy | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Subacromial Bursectomy; Acromioplasty | 3.2 (2) | 0 (0) | 5.3 (1) | 50 (1) | | Subacromial Decompression | 32 (20) | 39 (16) | 16 (3) | 50 (1) | | Subacromial Decompression; Acromioplasty | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Clavicle Osteotomy | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Distal Clavicle Resection | 9.7 (6) | 9.8 (4) | 11 (2) | 0 (0) | | Subacromial Decompression; Distal Clavicle Resection; Acromioplasty | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy | 1.6 (1) | 0 (0) | 5.3 (1) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy; Acromioplasty | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy; Distal Clavicle Resection; Acromioplasty | 1.6 (1) | 2.4 (1) | 0 (0) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 8.3.3 Treatment Survival

The mean follow up duration is 2.7 years, with a standard deviation of 1.07 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 34: Summary of PRULO Report 3 (Rotator Cuff) Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 8.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 35: Summary of PRULO Report 3 (Rotator Cuff) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 36: Summary of PRULO Report 3 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 62**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 7.3 | | Ligament|Tendon (Retear) | 1.6 (1) | 0.08 - 9.8 | | Effusion | 0 (0) | 0.00 - 7.3 | | Pain | 4.8 (3) | 1.3 - 14 | | Hardware | 0 (0) | 0.00 - 7.3 | | Loosening | 0 (0) | 0.00 - 7.3 | | Instability | 0 (0) | 0.00 - 7.3 | | Stiffness | 3.2 (2) | 0.56 - 12 | | Neurological | 1.6 (1) | 0.08 - 9.8 | | Thrombosis | 0 (0) | 0.00 - 7.3 | | Other2 | 0 (0) | 0.00 - 7.3 | | Reoperation3 | 0 (0) | 0.00 - 7.3 | | Subsequent Treatment4 |  |  | | Not Applicable | 100 (62) | 93 - 100 | | 1% (n) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 8.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

|  |
| --- |
| Figure 7: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 37: Summary of PRULO Report 3 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 601 | **3m**  N = 621 | **6m**  N = 601 | **12m**  N = 591 | | --- | --- | --- | --- | --- | | QDASH | 43 (27 - 52) | 35 (25 - 49) | 18 (7 - 27) | 5 (0 - 14) | | QDASHDelta | NA (NA - NA) | 9 (-11 - 16) | 27 (15 - 41) | 39 (23 - 43) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 38: Summary of PRULO Report 3 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 601 | **6m**  N = 601 | **12m**  N = 591 | | --- | --- | --- | --- | | WORCNorm | 37 (27 - 51) | 83 (68 - 94) | 92 (86 - 97) | | WORCPhysicalQ3 | 74 (52 - 91) | 26 (16 - 54) | 5 (3 - 18) | | WORCDelta | NA (NA - NA) | 47 (35 - 58) | 54 (38 - 61) | | 1Median (Q1 - Q3) | | | | |

## 8.4 Procedure Report - Biceps Tenodesis

### 8.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 39: Summary of PRULO Report 3 (Biceps Tenodesis) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Tenodesis**  N = 19 | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 63 (50, 69) | | Male | % (n) | 95 (18) | | Cohort |  |  | | Rotator Cuff | % (n) | 100 (19) | | Dominant Side | % (n) | 44 (8) | | Bilateral Presentation | % (n) | 16 (3) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 44 (7) | | >0.5 | % (n) | 56 (9) | | Treatment Record Active2 | % (n) | 100 (19) | | Patient Record Active3 | % (n) | 100 (19) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 8.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 40: Summary of PRULO Report 3 (Biceps Tenodesis) Cases Pathology and Surgical Details   | **Characteristic** | **N = 19**1 | | --- | --- | | Cuff Status |  | | Degenerative | 1 (5.3%) | | Full Tear | 18 (95%) | | Treatment Type |  | | Primary | 19 (100%) | | Product Count |  | | 1 | 7 (37%) | | 2 | 11 (58%) | | 3 | 1 (5.3%) | | 4 | 0 (0%) | | 5 | 0 (0%) | | Cuff Repair |  | | Augmented Cuff Repair | 2 (11%) | | Cuff Repair | 17 (89%) | | Repair Augmentation |  | | Autograft | 1 (5.3%) | | None | 17 (89%) | | Other2 | 1 (5.3%) | | Long Head Biceps Procedures |  | | Tenodesis | 19 (100%) | | Labrum |  | | None | 19 (100%) | | Labrum Repair |  | | None | 19 (100%) | | Capsule | Ligament |  | | Capsulotomy | 1 (5.3%) | | None | 18 (95%) | | Glenoid |  | | None | 19 (100%) | | Adjunct Procedure |  | | None | 12 (63%) | | Subacromial Bursectomy; Acromioplasty | 1 (5.3%) | | Subacromial Decompression | 3 (16%) | | Subacromial Decompression; Distal Clavicle Resection | 2 (11%) | | Subacromial Decompression; Subacromial Bursectomy | 1 (5.3%) | | 1n (%) | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | |

### 8.4.3 Treatment Survival

The mean follow up duration is 2.4 years, with a standard deviation of 1.09 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 41: Summary of PRULO Report 3 (Biceps Tenodesis) procedure survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 8.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 42: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 43: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - Postoperative Events   | **Characteristic** | **N = 19**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 21 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 21 | | Effusion | 0 (0) | 0.00 - 21 | | Pain | 5.3 (1) | 0.28 - 28 | | Hardware | 0 (0) | 0.00 - 21 | | Loosening | 0 (0) | 0.00 - 21 | | Instability | 0 (0) | 0.00 - 21 | | Stiffness | 0 (0) | 0.00 - 21 | | Neurological | 0 (0) | 0.00 - 21 | | Thrombosis | 0 (0) | 0.00 - 21 | | Other | 0 (0) | 0.00 - 21 | | Reoperation2 | 0 (0) | 0.00 - 21 | | Subsequent Treatment3 |  |  | | Not Applicable | 100 (19) | 79 - 100 | | 1% (n) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 8.4.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Normalised, and WORC Physical Q3 is summarised below.

|  |
| --- |
| Figure 8: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 44: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 191 | **3m**  N = 191 | **6m**  N = 191 | **12m**  N = 181 | | --- | --- | --- | --- | --- | | QDASH | 41 (26 - 52) | 42 (28 - 63) | 18 (7 - 23) | 9 (5 - 16) | | QDASHDelta | NA (NA - NA) | 6 (-11 - 13) | 25 (14 - 41) | 39 (30 - 43) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 45: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 191 | **6m**  N = 191 | **12m**  N = 181 | | --- | --- | --- | --- | | WORCNorm | 40 (27 - 53) | 78 (63 - 96) | 92 (73 - 97) | | WORCPhysicalQ3 | 73 (52 - 90) | 26 (19 - 54) | 8 (6 - 19) | | 1Median (Q1 - Q3) | | | | |

# 9. Product Report 4 - Healix Advance BR with Dynacord

## 9.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 9.2 Overview

Usage of the Product within the patient group is summarised below.

There are 84 cases involving the anchor of interest. Surgeries were performed between 2021-Mar-02 and 2025-Jan-07. The procedures included [Cuff Repair; Tenodesis] [Cuff Repair] [Cuff Repair; Tenotomy] [Cuff Repair; Labrum Repair] [Cuff Repair; Capsulotomy] [Cuff Repair; Debridement; Capsulotomy] [Augmented Cuff Repair] [Cuff Repair; Tenodesis; Capsulotomy] [Augmented Cuff Repair; Tenodesis] [Augmented Cuff Repair; Capsular Reconstruction], and [Cuff Repair; Capsulolabral Repair]. There are 83 cases involving the anchor of interest and a rotator cuff repair. Surgeries were performed between 2021-Mar-02 to 2025-Jan-07. There are 27 cases involving the anchor of interest and a biceps tenodesis. Surgeries were performed between 2021-Mar-02 to 2025-Jan-07.

## 9.3 Procedure Report - Rotator Cuff Repair

### 9.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 46: Summary of PRULO Report 4 (Rotator Cuff) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 831 | **None**  N = 52 | **Tenodesis**  N = 27 | **Tenotomy**  N = 4 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 62 (54, 69) | 62 (57, 69) | 61 (51, 69) | 68 (55, 71) | | Male | % (n) | 73 (61) | 69 (36) | 93 (25) | 0 (0) | | Cohort |  |  |  |  |  | | General | % (n) | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Rotator Cuff | % (n) | 99 (82) | 98 (51) | 100 (27) | 100 (4) | | Dominant Side | % (n) | 61 (49) | 67 (35) | 48 (12) | 67 (2) | | Bilateral Presentation | % (n) | 14 (12) | 13 (7) | 15 (4) | 25 (1) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 29 (17, 87) | 25 (14, 51) | 30 (20, 65) | 193 (22, 216) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 45 (23) | 50 (14) | 40 (8) | 33 (1) | | >0.5 | % (n) | 55 (28) | 50 (14) | 60 (12) | 67 (2) | | Treatment Record Active3 | % (n) | 96 (80) | 96 (50) | 100 (27) | 75 (3) | | Patient Record Active4 | % (n) | 100 (83) | 100 (52) | 100 (27) | 100 (4) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 9.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 47: Summary of PRULO Report 4 (Rotator Cuff) Cases Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 831 | **None**  N = 521 | **Tenodesis**  N = 271 | **Tenotomy**  N = 41 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Degenerative | 1.2 (1) | 0 (0) | 3.7 (1) | 0 (0) | | Full Tear | 98 (80) | 98 (50) | 96 (26) | 100 (4) | | Partial Tear | 1.2 (1) | 2.0 (1) | 0 (0) | 0 (0) | | Treatment Type |  |  |  |  | | Primary | 99 (82) | 98 (51) | 100 (27) | 100 (4) | | Revision Else | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Product Count |  |  |  |  | | 1 | 80 (66) | 88 (46) | 67 (18) | 50 (2) | | 2 | 18 (15) | 12 (6) | 26 (7) | 50 (2) | | 3 | 2.4 (2) | 0 (0) | 7.4 (2) | 0 (0) | | 4 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 6.0 (5) | 5.8 (3) | 7.4 (2) | 0 (0) | | Cuff Repair | 94 (78) | 94 (49) | 93 (25) | 100 (4) | | Repair Augmentation |  |  |  |  | | Autograft | 1.2 (1) | 0 (0) | 3.7 (1) | 0 (0) | | None | 94 (78) | 94 (49) | 93 (25) | 100 (4) | | Other2 | 3.6 (3) | 3.8 (2) | 3.7 (1) | 0 (0) | | Superior Capsular | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Labrum |  |  |  |  | | Capsulolabral Repair | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Debridement | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Labrum Repair | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | None | 96 (80) | 94 (49) | 100 (27) | 100 (4) | | Labrum Repair |  |  |  |  | | Bankart | 1.2 (1) | 2.0 (1) | 0 (0) | 0 (0) | | None | 99 (80) | 98 (49) | 100 (27) | 100 (4) | | Capsule | Ligament |  |  |  |  | | Capsular Reconstruction | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Capsulotomy | 17 (14) | 23 (12) | 7.4 (2) | 0 (0) | | None | 82 (68) | 75 (39) | 93 (25) | 100 (4) | | Glenoid |  |  |  |  | | None | 100 (83) | 100 (52) | 100 (27) | 100 (4) | | Adjunct Procedure |  |  |  |  | | Distal Clavicle Resection | 2.4 (2) | 3.8 (2) | 0 (0) | 0 (0) | | None | 48 (40) | 38 (20) | 70 (19) | 25 (1) | | Subacromial Bursectomy; Acromioplasty | 2.4 (2) | 0 (0) | 3.7 (1) | 25 (1) | | Subacromial Decompression | 29 (24) | 35 (18) | 15 (4) | 50 (2) | | Subacromial Decompression; Acromioplasty | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Clavicle Osteotomy | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Distal Clavicle Resection | 11 (9) | 13 (7) | 7.4 (2) | 0 (0) | | Subacromial Decompression; Distal Clavicle Resection; Acromioplasty | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy | 1.2 (1) | 0 (0) | 3.7 (1) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy; Acromioplasty | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy; Distal Clavicle Resection; Acromioplasty | 1.2 (1) | 1.9 (1) | 0 (0) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 9.3.3 Treatment Survival

The mean follow up duration is 2.5 years, with a standard deviation of 1.13 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 48: Summary of PRULO Report 4 (Rotator Cuff) Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 99% (96% - 100%) | 99% (96% - 100%) | 99% (96% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 9.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 49: Summary of PRULO Report 4 (Rotator Cuff) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 50: Summary of PRULO Report 4 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 83**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 5.5 | | Ligament|Tendon (Retear) | 2.4 (2) | 0.42 - 9.2 | | Effusion | 0 (0) | 0.00 - 5.5 | | Pain | 3.6 (3) | 0.94 - 11 | | Hardware | 0 (0) | 0.00 - 5.5 | | Loosening | 0 (0) | 0.00 - 5.5 | | Instability | 0 (0) | 0.00 - 5.5 | | Stiffness | 3.6 (3) | 0.94 - 11 | | Neurological | 1.2 (1) | 0.06 - 7.5 | | Thrombosis | 0 (0) | 0.00 - 5.5 | | Other2 | 0 (0) | 0.00 - 5.5 | | Reoperation3 | 0 (0) | 0.00 - 5.5 | | Subsequent Treatment4 |  |  | | Nonoperative Management | 1.2 (1) | 0.06 - 7.5 | | Not Applicable | 99 (82) | 93 - 100 | | 1% (n) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 9.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

|  |
| --- |
| Figure 9: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 51: Summary of PRULO Report 4 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 801 | **3m**  N = 831 | **6m**  N = 781 | **12m**  N = 771 | | --- | --- | --- | --- | --- | | QDASH | 43 (27 - 57) | 36 (25 - 50) | 18 (7 - 27) | 6 (2 - 25) | | QDASHDelta | NA (NA - NA) | 9 (-7 - 18) | 27 (11 - 41) | 30 (14 - 43) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 52: Summary of PRULO Report 4 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 801 | **6m**  N = 781 | **12m**  N = 771 | | --- | --- | --- | --- | | WORCNorm | 37 (27 - 53) | 82 (67 - 93) | 88 (79 - 97) | | WORCPhysicalQ3 | 73 (50 - 90) | 26 (11 - 43) | 8 (3 - 17) | | WORCDelta | NA (NA - NA) | 45 (29 - 58) | 39 (30 - 59) | | 1Median (Q1 - Q3) | | | | |

## 9.4 Procedure Report - Biceps Tenodesis

### 9.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 53: Summary of PRULO Report 4 (Biceps Tenodesis) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Tenodesis**  N = 27 | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 61 (51, 69) | | Male | % (n) | 93 (25) | | Cohort |  |  | | Rotator Cuff | % (n) | 100 (27) | | Dominant Side | % (n) | 48 (12) | | Bilateral Presentation | % (n) | 15 (4) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 40 (8) | | >0.5 | % (n) | 60 (12) | | Treatment Record Active2 | % (n) | 100 (27) | | Patient Record Active3 | % (n) | 100 (27) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 9.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 54: Summary of PRULO Report 1 (Biceps Tenodesis) Cases Pathology and Surgical Details   | **Characteristic** | **N = 27**1 | | --- | --- | | Cuff Status |  | | Degenerative | 1 (3.7%) | | Full Tear | 26 (96%) | | Treatment Type |  | | Primary | 27 (100%) | | Product Count |  | | 1 | 18 (67%) | | 2 | 7 (26%) | | 3 | 2 (7.4%) | | 4 | 0 (0%) | | 5 | 0 (0%) | | Cuff Repair |  | | Augmented Cuff Repair | 2 (7.4%) | | Cuff Repair | 25 (93%) | | Repair Augmentation |  | | Autograft | 1 (3.7%) | | None | 25 (93%) | | Other2 | 1 (3.7%) | | Long Head Biceps Procedures |  | | Tenodesis | 27 (100%) | | Labrum |  | | None | 27 (100%) | | Labrum Repair |  | | None | 27 (100%) | | Capsule | Ligament |  | | Capsulotomy | 2 (7.4%) | | None | 25 (93%) | | Glenoid |  | | None | 27 (100%) | | Adjunct Procedure |  | | None | 19 (70%) | | Subacromial Bursectomy; Acromioplasty | 1 (3.7%) | | Subacromial Decompression | 4 (15%) | | Subacromial Decompression; Distal Clavicle Resection | 2 (7.4%) | | Subacromial Decompression; Subacromial Bursectomy | 1 (3.7%) | | 1n (%) | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | |

### 9.4.3 Treatment Survival

The mean follow up duration is 2.3 years, with a standard deviation of 1.12 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 55: Summary of PRULO Report 4 (Biceps Tenodesis) procedure survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 9.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 56: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 57: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - Postoperative Events   | **Characteristic** | **N = 27**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 16 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 16 | | Effusion | 0 (0) | 0.00 - 16 | | Pain | 3.7 (1) | 0.19 - 21 | | Hardware | 0 (0) | 0.00 - 16 | | Loosening | 0 (0) | 0.00 - 16 | | Instability | 0 (0) | 0.00 - 16 | | Stiffness | 0 (0) | 0.00 - 16 | | Neurological | 0 (0) | 0.00 - 16 | | Thrombosis | 0 (0) | 0.00 - 16 | | Other | 0 (0) | 0.00 - 16 | | Reoperation2 | 0 (0) | 0.00 - 16 | | Subsequent Treatment3 |  |  | | Not Applicable | 100 (27) | 84 - 100 | | 1% (n) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 9.4.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Normalised, and WORC Physical Q3 is summarised below.

|  |
| --- |
| Figure 10: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 58: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 261 | **3m**  N = 271 | **6m**  N = 261 | **12m**  N = 251 | | --- | --- | --- | --- | --- | | QDASH | 43 (27 - 52) | 38 (32 - 55) | 18 (7 - 25) | 10 (5 - 25) | | QDASHDelta | NA (NA - NA) | 9 (-5 - 16) | 27 (20 - 39) | 39 (20 - 50) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 59: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index   | **Characteristic** | **Preop**  N = 261 | **6m**  N = 261 | **12m**  N = 251 | | --- | --- | --- | --- | | WORCNorm | 41 (27 - 54) | 77 (63 - 84) | 87 (63 - 93) | | WORCPhysicalQ3 | 73 (52 - 90) | 26 (12 - 44) | 8 (5 - 19) | | 1Median (Q1 - Q3) | | | | |

# 10. Product Report 5 - Milagro Advance BR

## 10.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 10.2 Overview

Usage of the Product within the patient group is summarised below.

There are 44 cases involving the anchor of interest. Surgeries were performed between 2021-Mar-02 and 2025-Jan-07. The procedures included [Cuff Repair; Tenodesis] [Cuff Repair] [Augmented Cuff Repair; Tenodesis] [Tenodesis; Labrum Repair] [Cuff Repair; Tenodesis; Capsulotomy] [Tenodesis; Capsulolabral Repair] [Cuff Repair; Tenodesis; Capsulolabral Repair] [Cuff Repair; Tenotomy], and [Unknown; Labrum Repair]. There are 27 cases involving the anchor of interest and a rotator cuff repair. Surgeries were performed between 2021-Mar-02 to 2025-Jan-07. There are 36 cases involving the anchor of interest and a biceps tenodesis. Surgeries were performed between 2021-Mar-02 to 2025-Jan-07.

## 10.3 Procedure Report - Rotator Cuff Repair

### 10.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 60: Summary of PRULO Report 5 (Rotator Cuff) Cases - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 271 | **None**  N = 1 | **Tenodesis**  N = 25 | **Tenotomy**  N = 1 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 61 (52, 69) | 65 (65, 65) | 61 (55, 69) | 44 (44, 44) | | Male | % (n) | 89 (24) | 100 (1) | 92 (23) | 0 (0) | | Cohort |  |  |  |  |  | | Rotator Cuff | % (n) | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | Dominant Side | % (n) | 52 (13) | 0 (0) | 52 (12) | 100 (1) | | Bilateral Presentation | % (n) | 15 (4) | 100 (1) | 12 (3) | 0 (0) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 32 (20, 123) | 195 (195, 195) | 31 (18, 87) | 193 (193, 193) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 35 (7) | 0 (0) | 39 (7) | 0 (0) | | >0.5 | % (n) | 65 (13) | 100 (1) | 61 (11) | 100 (1) | | Treatment Record Active3 | % (n) | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | Patient Record Active4 | % (n) | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 10.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 61: Summary of PRULO Report 5 (Rotator Cuff) Cases - Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 271 | **None**  N = 11 | **Tenodesis**  N = 251 | **Tenotomy**  N = 11 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Full Tear | 89 (24) | 100 (1) | 88 (22) | 100 (1) | | Partial Tear | 11 (3) | 0 (0) | 12 (3) | 0 (0) | | Treatment Type |  |  |  |  | | Primary | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | Product Count |  |  |  |  | | 1 | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | 2 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 3 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 4 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 3.7 (1) | 0 (0) | 4.0 (1) | 0 (0) | | Cuff Repair | 96 (26) | 100 (1) | 96 (24) | 100 (1) | | Repair Augmentation |  |  |  |  | | None | 96 (26) | 100 (1) | 96 (24) | 100 (1) | | Other2 | 3.7 (1) | 0 (0) | 4.0 (1) | 0 (0) | | Labrum |  |  |  |  | | Capsulolabral Repair | 3.7 (1) | 0 (0) | 4.0 (1) | 0 (0) | | None | 96 (26) | 100 (1) | 96 (24) | 100 (1) | | Labrum Repair |  |  |  |  | | None | 100 (26) | 100 (1) | 100 (24) | 100 (1) | | Capsule | Ligament |  |  |  |  | | Capsulotomy | 7.4 (2) | 0 (0) | 8.0 (2) | 0 (0) | | None | 93 (25) | 100 (1) | 92 (23) | 100 (1) | | Glenoid |  |  |  |  | | None | 100 (27) | 100 (1) | 100 (25) | 100 (1) | | Adjunct Procedure |  |  |  |  | | None | 63 (17) | 0 (0) | 68 (17) | 0 (0) | | Subacromial Bursectomy; Acromioplasty | 7.4 (2) | 0 (0) | 4.0 (1) | 100 (1) | | Subacromial Decompression | 15 (4) | 0 (0) | 16 (4) | 0 (0) | | Subacromial Decompression; Distal Clavicle Resection | 11 (3) | 100 (1) | 8.0 (2) | 0 (0) | | Subacromial Decompression; Subacromial Bursectomy | 3.7 (1) | 0 (0) | 4.0 (1) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 10.3.3 Treatment Survival

The mean follow up duration is 2.3 years, with a standard deviation of 1.16 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 62: Summary of PRULO Report 5 (Rotator Cuff) Cases - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 10.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 63: Summary of PRULO Report 5 (Rotator Cuff) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 64: Summary of PRULO Report 5 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 27**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 16 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 16 | | Effusion | 0 (0) | 0.00 - 16 | | Pain | 3.7 (1) | 0.19 - 21 | | Hardware | 0 (0) | 0.00 - 16 | | Loosening | 0 (0) | 0.00 - 16 | | Instability | 0 (0) | 0.00 - 16 | | Stiffness | 0 (0) | 0.00 - 16 | | Neurological | 0 (0) | 0.00 - 16 | | Thrombosis | 0 (0) | 0.00 - 16 | | Other2 | 0 (0) | 0.00 - 16 | | Reoperation3 | 0 (0) | 0.00 - 16 | | Subsequent Treatment4 |  |  | | Not Applicable | 100 (27) | 84 - 100 | | 1% (n) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 10.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

|  |
| --- |
| Figure 11: Complete case analysis of QuickDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom). |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 65: Summary of PRULO Report 5 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 261 | **3m**  N = 271 | **6m**  N = 261 | **12m**  N = 251 | | --- | --- | --- | --- | --- | | QDASH | 39 (27 - 52) | 36 (25 - 48) | 20 (9 - 27) | 8 (2 - 34) | | QDASHDelta | NA (NA - NA) | 11 (0 - 16) | 23 (9 - 39) | 39 (20 - 50) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 66: Summary of PRULO Report 5 (Rotator Cuff) Cases - WORC Normalised and WORC (Physical) Q3   | **Characteristic** | **Preop**  N = 261 | **6m**  N = 261 | **12m**  N = 251 | | --- | --- | --- | --- | | WORCNorm | 48 (29 - 55) | 72 (59 - 84) | 88 (63 - 93) | | WORCPhysicalQ3 | 62 (38 - 84) | 28 (19 - 47) | 6 (3 - 16) | | WORCDelta | NA (NA - NA) | 35 (10 - 36) | 38 (29 - 63) | | 1Median (Q1 - Q3) | | | | |

## 10.4 Procedure Report - Biceps Tenodesis

### 10.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 67: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - Patient Characteristics   | **Characteristic** | **Statistic** | **Tenodesis**  N = 36 | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 60 (52, 69) | | Male | % (n) | 83 (30) | | Cohort |  |  | | Glenohumeral Instability | % (n) | 11 (4) | | Rotator Cuff | % (n) | 89 (32) | | Dominant Side | % (n) | 56 (19) | | Bilateral Presentation | % (n) | 14 (5) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 26 (7) | | >0.5 | % (n) | 74 (20) | | Treatment Record Active2 | % (n) | 97 (35) | | Patient Record Active3 | % (n) | 100 (36) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 10.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 68: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - Pathology and Surgical Details   | **Characteristic** | **N = 36**1 | | --- | --- | | Cuff Status |  | | Full Tear | 23 (72%) | | Partial Tear | 6 (19%) | | Tendinopathy | 3 (9.4%) | | Treatment Type |  | | Primary | 36 (100%) | | Product Count |  | | 1 | 36 (100%) | | 2 | 0 (0%) | | 3 | 0 (0%) | | 4 | 0 (0%) | | 5 | 0 (0%) | | Cuff Repair |  | | Augmented Cuff Repair | 1 (2.8%) | | Cuff Repair | 24 (67%) | | None | 11 (31%) | | Repair Augmentation |  | | None | 28 (97%) | | Other2 | 1 (3.4%) | | Long Head Biceps Procedures |  | | Tenodesis | 36 (100%) | | Labrum |  | | Capsulolabral Repair | 2 (5.6%) | | Labrum Repair | 5 (14%) | | None | 29 (81%) | | Labrum Repair |  | | Bankart | 1 (2.9%) | | None | 29 (85%) | | Other2 | 3 (8.8%) | | SLAP | 1 (2.9%) | | Capsule | Ligament |  | | Capsulotomy | 2 (5.6%) | | None | 34 (94%) | | Glenoid |  | | Glenoplasty | 1 (2.8%) | | None | 35 (97%) | | Adjunct Procedure |  | | Acromioplasty | 1 (2.8%) | | Distal Clavicle Resection | 1 (2.8%) | | None | 23 (64%) | | Paralabral Cyst Excision | 1 (2.8%) | | Subacromial Bursectomy; Acromioplasty | 1 (2.8%) | | Subacromial Decompression | 4 (11%) | | Subacromial Decompression; Distal Clavicle Resection | 4 (11%) | | Subacromial Decompression; Subacromial Bursectomy | 1 (2.8%) | | 1n (%) | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | |

### 10.4.3 Treatment Survival

The mean follow up duration is 2.1 years, with a standard deviation of 1.11 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 69: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 95% (87% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 10.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 70: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 71: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - Postoperative Events   | **Characteristic** | **N = 36**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 12 | | Ligament|Tendon (Retear) | 2.8 (1) | 0.15 - 16 | | Effusion | 0 (0) | 0.00 - 12 | | Pain | 2.8 (1) | 0.15 - 16 | | Hardware | 0 (0) | 0.00 - 12 | | Loosening | 2.8 (1) | 0.15 - 16 | | Instability | 0 (0) | 0.00 - 12 | | Stiffness | 0 (0) | 0.00 - 12 | | Neurological | 0 (0) | 0.00 - 12 | | Thrombosis | 0 (0) | 0.00 - 12 | | Other | 0 (0) | 0.00 - 12 | | Reoperation2 | 2.8 (1) | 0.15 - 16 | | Subsequent Treatment3 |  |  | | Nonoperative Management | 2.8 (1) | 0.15 - 16 | | Not Applicable | 97 (35) | 84 - 100 | | 1% (n) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 10.4.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Normalised, and WORC Physical Q3 is summarised below.

|  |
| --- |
| Figure 12: Complete case analysis of QDASH(Top), WORC Normalised (Middle), and WORC Physical Question 3 (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 72: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 351 | **3m**  N = 361 | **6m**  N = 351 | **12m**  N = 331 | | --- | --- | --- | --- | --- | | QDASH | 42 (27 - 53) | 36 (25 - 53) | 20 (9 - 25) | 14 (5 - 36) | | QDASHDelta | NA (NA - NA) | 11 (-5 - 20) | 25 (9 - 39) | 20 (14 - 50) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 73: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - WORC Normalised   | **Characteristic** | **Preop**  N = 351 | **6m**  N = 351 | **12m**  N = 331 | | --- | --- | --- | --- | | WORCNorm | 41 (27 - 54) | 72 (59 - 84) | 84 (57 - 95) | | WORCPhysicalQ3 | 67 (43 - 84) | 25 (18 - 44) | 16 (5 - 32) | | 1Median (Q1 - Q3) | | | | |

# 11. Product Report 6 - Gryphon ProKnot BR

## 11.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 11.2 Overview

Usage of the Product within the patient group is summarised below.

There are 66 cases involving the anchor of interest. Surgeries were performed between 2020-Dec-02 and 2024-Nov-14. The procedures included [Cuff Repair; Labrum Repair] [Tenodesis; Labrum Repair] [Tenodesis; Capsulolabral Repair] [Cuff Repair; Tenodesis; Capsulolabral Repair] [Cuff Repair; Tenodesis] [Cuff Repair; Capsulolabral Repair] [Labrum Repair] [Capsulotomy] [Labrum Repair; Capsular Shift] [Remplissage; Labrum Repair; Capsular Shift] [Tenodesis; Labrum Repair; Capsular Shift] [Remplissage; Labrum Repair] [Capsulolabral Repair; Capsular Shift] [Remplissage; Capsulolabral Repair; Repair], and [Unknown; Labrum Repair].

There are 35 cases involving the anchor of interest and a Bankart repair. Surgeries were performed between 2021-Jul-01 to 2024-Mar-19.

There are 3 cases involving the anchor of interest and a SLAP repair. Surgeries were performed between 2022-Sep-20 to 2023-Nov-16. There is insufficient sample size to provide a report.

## 11.3 Procedure Report - All

### 11.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 74: Summary of PRULO Report 6 (All) - Patient Characteristics   | **Characteristic** | **Statistic** | **N = 66** | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 29 (21, 38) | | Male | % (n) | 79 (52) | | Cohort |  |  | | General | % (n) | 14 (9) | | Glenohumeral Instability | % (n) | 76 (50) | | Rotator Cuff | % (n) | 11 (7) | | Dominant Side | % (n) | 51 (30) | | Bilateral Presentation | % (n) | 18 (12) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 55 (22, 178) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 33 (13) | | >0.5 | % (n) | 68 (27) | | Treatment Record Active2 | % (n) | 95 (63) | | Patient Record Active3 | % (n) | 100 (66) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 11.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 75: Summary of PRULO Report 6 (All) Cases Pathology and Surgical Details   | **Characteristic** | **N = 66**1 | | --- | --- | | Cuff Status |  | | Full Tear | 3.6 (2) | | Intact | 88 (49) | | Partial Tear | 5.4 (3) | | Tendinopathy | 3.6 (2) | | Treatment Type |  | | Primary | 98 (65) | | Revision Own | 1.5 (1) | | Product Count |  | | 1 | 20 (13) | | 2 | 20 (13) | | 3 | 39 (26) | | 4 | 18 (12) | | 5 | 3.0 (2) | | CuffRepair |  | | Cuff Repair | 7.6 (5) | | None | 88 (58) | | Remplissage | 4.5 (3) | | RepairAugmentation |  | | None | 100 (49) | | LongHeadBiceps |  | | None | 82 (54) | | Tenodesis | 17 (11) | | Unknown | 1.5 (1) | | Labrum |  | | Capsulolabral Repair | 7.6 (5) | | Labrum Repair | 73 (48) | | None | 20 (13) | | LabrumRepair |  | | Bankart | 66 (35) | | None | 3.8 (2) | | Not Repaired | 9.4 (5) | | Other2 | 11 (6) | | Posterior | 3.8 (2) | | SLAP | 5.7 (3) | | CapsuleLigament |  | | Capsular Shift | 18 (12) | | Capsulotomy | 1.5 (1) | | None | 79 (52) | | Repair | 1.5 (1) | | Glenoid |  | | Fracture fixation | 5.2 (3) | | Glenoplasty | 34 (20) | | None | 60 (35) | | AdjunctProcedure |  | | Chondral Debridement | 1.7 (1) | | Distal Clavicle Resection | 1.7 (1) | | None | 79 (46) | | Ostectomy | 1.7 (1) | | Paralabral Cyst Excision | 6.9 (4) | | Removal Loose Bodies | 5.2 (3) | | Subacromial Bursectomy | 1.7 (1) | | Subacromial Bursectomy; Acromioplasty | 1.7 (1) | | 1% (n) | | | 2Labral tear uncategorised | | |

### 11.3.3 Treatment Survival

The mean follow up duration is 2.4 years, with a standard deviation of 1.06 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 76: Summary of PRULO Report 6 (All) Cases - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 96% (91% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 11.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 77: Summary of PRULO Report 6 (All) Cases - Postoperative Events   | **Characteristic** | **N = 66**1 | | --- | --- | | Infection | 0 (0) | | Ligament|Tendon (Retear) | 6 (4) | | Effusion | 0 (0) | | Pain | 0 (0) | | Hardware | 0 (0) | | Loosening | 3 (2) | | Instability | 3 (2) | | Stiffness | 5 (3) | | Neurological | 2 (1) | | Thrombosis | 0 (0) | | Other | 0 (0) | | Reoperation2 | 3 (2) | | Subsequent Treatment3 |  | | New Procedure | 2 (1) | | Nonoperative Management | 2 (1) | | Not Applicable | 97 (64) | | Reoperation Delay (Weeks)4 | 86.4 (3.3) | | 1% (n); Mean (SD) | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | 4Time between index procedure and reoperation | | |

### 11.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH and WOSI Index Normalised is summarised below.

|  |
| --- |
| Figure 13: Complete case analysis of QDASH(Top), WOSI Index (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 78: Summary of PRULO Report 6 (All) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 651 | **3m**  N = 661 | **6m**  N = 641 | **12m**  N = 631 | | --- | --- | --- | --- | --- | | QDASH | 35 (18 - 52) | 30 (16 - 48) | 7 (0 - 23) | 8 (5 - 34) | | QDASHDelta | NA (NA - NA) | -5 (-14 - 7) | 14 (5 - 30) | 16 (9 - 23) | | WOSINorm | 33 (22 - 55) | 54 (47 - 63) | 77 (67 - 90) | 74 (49 - 92) | | WOSIDelta | NA (NA - NA) | -57 (-76 - -47) | 32 (22 - 41) | 44 (33 - 52) | | 1Median (Q1 - Q3) | | | | | |

## 11.4 Procedure Report - Bankart Repair

### 11.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 79: Summary of PRULO Report 6 (Bankart Repair) - Patient Characteristics   | **Characteristic** | **Statistic** | **N = 35** | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 22 (18, 31) | | Male | % (n) | 86 (30) | | Cohort |  |  | | Glenohumeral Instability | % (n) | 94 (33) | | Rotator Cuff | % (n) | 5.7 (2) | | Dominant Side | % (n) | 61 (20) | | Bilateral Presentation | % (n) | 20 (7) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 39 (18, 139) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 46 (11) | | >0.5 | % (n) | 54 (13) | | Treatment Record Active2 | % (n) | 97 (34) | | Patient Record Active3 | % (n) | 100 (35) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 11.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 80: Summary of PRULO Report 6 (Bankart Repair) Cases Pathology and Surgical Details   | **Characteristic** | **N = 35**1 | | --- | --- | | Cuff Status |  | | Full Tear | 2.9 (1) | | Intact | 94 (33) | | Tendinopathy | 2.9 (1) | | Treatment Type |  | | Primary | 100 (35) | | Product Count |  | | 1 | 5.7 (2) | | 2 | 23 (8) | | 3 | 49 (17) | | 4 | 20 (7) | | 5 | 2.9 (1) | | Cuff Repair |  | | Cuff Repair | 5.7 (2) | | None | 86 (30) | | Remplissage | 8.6 (3) | | Repair Augmentation |  | | None | 100 (31) | | LongHeadBiceps |  | | None | 97 (34) | | Tenodesis | 2.9 (1) | | Labrum |  | | Capsulolabral Repair | 5.7 (2) | | Labrum Repair | 94 (33) | | Labrum Repair |  | | Bankart | 100 (35) | | Capsule | Ligament |  | | Capsular Shift | 29 (10) | | None | 69 (24) | | Repair | 2.9 (1) | | Glenoid |  | | Fracture fixation | 5.7 (2) | | Glenoplasty | 46 (16) | | None | 49 (17) | | Adjunct Procedure |  | | Chondral Debridement | 2.9 (1) | | None | 83 (29) | | Ostectomy | 2.9 (1) | | Paralabral Cyst Excision | 2.9 (1) | | Removal Loose Bodies | 8.6 (3) | | 1% (n) | | |

### 11.4.3 Treatment Survival

The mean follow up duration is 2.3 years, with a standard deviation of 0.77 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 81: Summary of PRULO Report 6 (Bankart Repair) Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 97% (91% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 11.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 82: Summary of PRULO Report 6 (Bankart Repair) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 83: Summary of PRULO Report 6 (Bankart Repair) Cases - Postoperative Events   | **Characteristic** | **N = 35**1 | | --- | --- | | Infection | 0 (0) | | Ligament|Tendon (Retear) | 6 (2) | | Effusion | 0 (0) | | Pain | 0 (0) | | Hardware | 0 (0) | | Loosening | 0 (0) | | Instability | 6 (2) | | Stiffness | 3 (1) | | Neurological | 0 (0) | | Thrombosis | 0 (0) | | Other | 0 (0) | | Reoperation2 | 3 (1) | | Subsequent Treatment3 |  | | New Procedure | 3 (1) | | Not Applicable | 97 (34) | | Reoperation Delay (Weeks)4 | 88.7 (NA) | | 1% (n); Mean (SD) | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | 4Time between index procedure and reoperation | | |

### 11.4.5 Patient-Reported Outcomes

Complete case analysis of QuickDASH and WOSI Index Normalised are summarised below.

|  |
| --- |
| Figure 14: Complete case analysis of QDASH(Top), WOSI Index (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 84: Summary of PRULO Report 6 (Bankart Repair) Cases - QuickDASH and WOSI Normalised   | **Characteristic** | **Preop**  N = 351 | **3m**  N = 351 | **6m**  N = 351 | **12m**  N = 351 | | --- | --- | --- | --- | --- | | QDASH | 27 (16 - 55) | 24 (15 - 39) | 16 (2 - 23) | 7 (0 - 32) | | WOSINorm | 32 (22 - 56) | 57 (48 - 76) | 76 (60 - 82) | 78 (59 - 91) | | 1Median (Q1 - Q3) | | | | | |

# 12. Product Report 7 - Gryphon BR with Orthocord

## 12.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 12.2 Overview

Usage of the Product within the patient group is summarised below.

There are 39 cases involving the anchor of interest. Surgeries were performed between 2021-Apr-20 and 2024-Nov-14. The procedures included [Labrum Repair] [Capsulolabral Repair; Other] [Capsulotomy] [Cuff Repair; Labrum Repair] [Labrum Repair; Capsular Shift] [Remplissage; Labrum Repair; Capsular Shift] [Tenodesis; Labrum Repair; Capsular Shift] [Remplissage; Labrum Repair] [Capsulolabral Repair; Capsular Shift], and [Remplissage; Capsulolabral Repair; Repair].

There are 28 cases involving the anchor of interest and a Bankart repair. Surgeries were performed between 2021-Jul-01 to 2024-Mar-19.

There is 0 case(s) involving the anchor of interest and a SLAP repair. There is insufficient sample size to provide a report.

## 12.3 Procedure Report - All

### 12.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 85: Summary of PRULO Report 7 (All) - Patient Characteristics   | **Characteristic** | **Statistic** | **N = 39** | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 22 (18, 28) | | Male | % (n) | 79 (31) | | Cohort |  |  | | General | % (n) | 7.7 (3) | | Glenohumeral Instability | % (n) | 90 (35) | | Rotator Cuff | % (n) | 2.6 (1) | | Dominant Side | % (n) | 56 (20) | | Bilateral Presentation | % (n) | 26 (10) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 45 (20, 150) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 39 (9) | | >0.5 | % (n) | 61 (14) | | Treatment Record Active2 | % (n) | 97 (38) | | Patient Record Active3 | % (n) | 100 (39) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 12.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 86: Summary of PRULO Report 7 (All) Cases Pathology and Surgical Details   | **Characteristic** | **N = 39**1 | | --- | --- | | Cuff Status |  | | Intact | 100 (35) | | Treatment Type |  | | Primary | 100 (39) | | Product Count |  | | 1 | 87 (34) | | 2 | 13 (5) | | 3 | 0 (0) | | 4 | 0 (0) | | 5 | 0 (0) | | Cuff Repair |  | | Cuff Repair | 2.6 (1) | | None | 90 (35) | | Remplissage | 7.7 (3) | | Repair Augmentation |  | | None | 100 (30) | | LongHeadBiceps |  | | None | 95 (37) | | Tenodesis | 5.1 (2) | | Labrum |  | | Capsulolabral Repair | 7.7 (3) | | Labrum Repair | 74 (29) | | None | 18 (7) | | Labrum Repair |  | | Bankart | 80 (28) | | None | 2.9 (1) | | Not Repaired | 8.6 (3) | | Other2 | 8.6 (3) | | Capsule | Ligament |  | | Capsular Shift | 31 (12) | | Capsulotomy | 2.6 (1) | | None | 62 (24) | | Other2 | 2.6 (1) | | Repair | 2.6 (1) | | Glenoid |  | | Fracture fixation | 8.6 (3) | | Glenoplasty | 43 (15) | | Latarjet | 5.7 (2) | | None | 43 (15) | | Adjunct Procedure |  | | Chondral Debridement | 2.9 (1) | | None | 89 (31) | | Ostectomy | 2.9 (1) | | Removal Loose Bodies | 5.7 (2) | | 1% (n) | | | 2Labral tear uncategorised | | |

### 12.3.3 Treatment Survival

The mean follow up duration is 2.3 years, with a standard deviation of 0.99 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 87: Summary of PRULO Report 7 (Rotator Cuff) - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 97% (91% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 12.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 88: Summary of PRULO Report 7 (All) Cases - Postoperative Events   | **Characteristic** | **N = 39**1 | | --- | --- | | Infection | 0 (0) | | Ligament|Tendon (Retear) | 8 (3) | | Effusion | 0 (0) | | Pain | 3 (1) | | Hardware | 0 (0) | | Loosening | 3 (1) | | Instability | 5 (2) | | Stiffness | 3 (1) | | Neurological | 0 (0) | | Thrombosis | 0 (0) | | Other | 0 (0) | | Reoperation2 | 5 (2) | | Subsequent Treatment3 |  | | New Procedure | 3 (1) | | Not Applicable | 97 (38) | | Reoperation Delay (Weeks)4 | 61.4 (38.7) | | 1% (n); Mean (SD) | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | 4Time between index procedure and reoperation | | |

### 12.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH and WOSI Index Normalised is summarised below.

|  |
| --- |
| Figure 15: Complete case analysis of QuickDASH and WOSI Normalised |

::: {#tbl-TableRep75 .cell tbl-cap=’ Summary of PRULO Report 7 (All) Cases - QuickDASH’} ::: {.cell-output-display}

| **Characteristic** | **Preop**  N = 391 | **3m**  N = 391 | **6m**  N = 381 | **12m**  N = 371 |
| --- | --- | --- | --- | --- |
| QDASH | 25 (14 - 48) | 23 (14 - 34) | 2 (0 - 19) | 7 (0 - 18) |
| QDASHDelta | NA (NA - NA) | -7 (-14 - 25) | 12 (9 - 23) | 14 (2 - 23) |
| WOSINorm | 33 (22 - 53) | 57 (47 - 77) | 75 (67 - 87) | 82 (59 - 91) |
| WOSIDelta | NA (NA - NA) | -59 (-79 - -48) | 33 (30 - 36) | 44 (36 - 58) |
| 1Median (Q1 - Q3) | | | | |

::: :::

## 12.4 Procedure Report - Bankart Repair

### 12.4.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 89: Summary of PRULO Report 7 (Bankart Repair) - Patient Characteristics   | **Characteristic** | **Statistic** | **N = 28** | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 22 (18, 24) | | Male | % (n) | 82 (23) | | Cohort |  |  | | Glenohumeral Instability | % (n) | 100 (28) | | Dominant Side | % (n) | 59 (16) | | Bilateral Presentation | % (n) | 25 (7) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 43 (21, 108) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 40 (8) | | >0.5 | % (n) | 60 (12) | | Treatment Record Active2 | % (n) | 96 (27) | | Patient Record Active3 | % (n) | 100 (28) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 12.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 90: Summary of PRULO Report 7 (Bankart Repair) Cases - Pathology and Surgical Details   | **Characteristic** | **N = 28**1 | | --- | --- | | Cuff Status |  | | Intact | 100 (28) | | Treatment Type |  | | Primary | 100 (28) | | Product Count |  | | 1 | 89 (25) | | 2 | 11 (3) | | 3 | 0 (0) | | 4 | 0 (0) | | 5 | 0 (0) | | Cuff Repair |  | | Cuff Repair | 3.6 (1) | | None | 86 (24) | | Remplissage | 11 (3) | | Repair Augmentation |  | | None | 100 (25) | | LongHeadBiceps |  | | None | 100 (28) | | Labrum |  | | Capsulolabral Repair | 11 (3) | | Labrum Repair | 89 (25) | | Labrum Repair |  | | Bankart | 100 (28) | | Capsule | Ligament |  | | Capsular Shift | 36 (10) | | None | 57 (16) | | Other2 | 3.6 (1) | | Repair | 3.6 (1) | | Glenoid |  | | Fracture fixation | 7.1 (2) | | Glenoplasty | 46 (13) | | Latarjet | 3.6 (1) | | None | 43 (12) | | Adjunct Procedure |  | | Chondral Debridement | 3.6 (1) | | None | 86 (24) | | Ostectomy | 3.6 (1) | | Removal Loose Bodies | 7.1 (2) | | 1% (n) | | | 2Labral tear uncategorised | | |

### 12.4.3 Treatment Survival

The mean follow up duration is 2.2 years, with a standard deviation of 0.82 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 91: Summary of PRULO Report 7 (Bankart Repair) Cases - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 96% (88% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 12.4.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 92: Summary of PRULO Report 7 (Bankart Repair) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 93: Summary of PRULO Report 7 (Bankart Repair) Cases - Postoperative Events   | **Characteristic** | **N = 28**1 | | --- | --- | | Infection | 0 (0) | | Ligament|Tendon (Retear) | 7 (2) | | Effusion | 0 (0) | | Pain | 0 (0) | | Hardware | 0 (0) | | Loosening | 0 (0) | | Instability | 7 (2) | | Stiffness | 4 (1) | | Neurological | 0 (0) | | Thrombosis | 0 (0) | | Other | 0 (0) | | Reoperation2 | 4 (1) | | Subsequent Treatment3 |  | | New Procedure | 4 (1) | | Not Applicable | 96 (27) | | Reoperation Delay (Weeks)4 | 88.7 (NA) | | 1% (n); Mean (SD) | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | 4Time between index procedure and reoperation | | |

### 12.4.5 Patient-Reported Outcomes

Complete case analysis of QuickDASH and WOSI Index Normalised is summarised below.

|  |
| --- |
| Figure 16: Complete case analysis of QuickDASH and WOSI Normalised |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 94: Summary of PRULO Report 7 (Bankart Repair) Cases - QuickDASH and WOSI Normalised   | **Characteristic** | **Preop**  N = 281 | **3m**  N = 281 | **6m**  N = 281 | **12m**  N = 281 | | --- | --- | --- | --- | --- | | QDASH | 25 (18 - 55) | 24 (14 - 34) | 16 (2 - 23) | 7 (0 - 18) | | WOSINorm | 32 (22 - 51) | 54 (48 - 76) | 74 (60 - 82) | 78 (59 - 91) | | 1Median (Q1 - Q3) | | | | | |

# 13. Product Report 8 - Gryphon BR with Dynacord

## 13.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 13.2 Overview

Usage of the Product within the patient group is summarised below.

There are 2 cases involving the anchor of interest. Surgeries were performed between 2022-Jul-12 and 2022-Aug-16. The procedures included [Labrum Repair].

There is 1 case involving the anchor of interest. There is insufficient sample size to provide a report.

# 14. Product Report 9 - Gryphon PEEK with Dynacord

## 14.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 14.2 Overview

Usage of the Product within the patient group is summarised below.

There are 9 cases involving the anchor of interest. Surgeries were performed between 2022-May-19 and 2024-Sep-25. The procedures included [Labrum Repair] [Remplissage; Labrum Repair], and [Remplissage; Labrum Repair; Capsular Shift].

There are 6 cases involving the anchor of interest and a Bankart repair. Surgeries were performed between 2022-May-19 to 2024-Jun-12.

## 14.3 Adverse Events

Complications and adverse events are summarised below.

Intraoperative events occurred in 1 of 9 cases (11.1%, 95% CI: 2%-43.5%).

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 95: Summary of PRULO Report 9 (All) Cases - Intraoperative Events   | TreatmentID | Description | Intervention | PostopManagement | | --- | --- | --- | --- | | 2729.1 | grphon anchor came out | Modified surgical technique | No | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 96: Summary of PRULO Report 4 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 9**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 37 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 37 | | Effusion | 0 (0) | 0.00 - 37 | | Pain | 0 (0) | 0.00 - 37 | | Hardware | 0 (0) | 0.00 - 37 | | Loosening | 33 (3) | 9.0 - 69 | | Instability | 0 (0) | 0.00 - 37 | | Stiffness | 22 (2) | 3.9 - 60 | | Neurological | 0 (0) | 0.00 - 37 | | Thrombosis | 0 (0) | 0.00 - 37 | | Other2 | 0 (0) | 0.00 - 37 | | Reoperation3 | 22 (2) | 3.9 - 60 | | Subsequent Treatment4 |  |  | | Not Applicable | 100 (9) | 63 - 100 | | 1% (n) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

# 15. Product Report 10 - Latarjet Screw

## 15.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 15.2 Overview

Usage of the Product within the patient group is summarised below.

There are 13 cases involving the anchor of interest. Surgeries were performed between 2021-Feb-10 and 2024-Jul-17. The procedures included [Capsulolabral Repair; Other] [Labrum Repair] [Tenodesis; Labrum Repair; Capsular Shift] [Capsulotomy], and [Labrum Repair; Capsular Shift].

## 15.3 Procedure Report - All

### 15.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 97: Summary of PRULO Report 10 (All) - Patient Characteristics   | **Characteristic** | **Statistic** | **N = 13** | | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 24.0 (21.0, 30.0) | | Male | % (n) | 100 (13) | | Cohort |  |  | | Glenohumeral Instability | % (n) | 100 (13) | | Dominant Side | % (n) | 67 (4) | | Bilateral Presentation | % (n) | 7.7 (1) | | Symptom Duration Category1 |  |  | | <=0.5 | % (n) | 20 (1) | | >0.5 | % (n) | 80 (4) | | Treatment Record Active2 | % (n) | 100 (13) | | Patient Record Active3 | % (n) | 100 (13) | | 1Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | 2Treatment record remains active - no change to follow up | | | | 3Patient record remains open - no change to consent or mortality status | | | |

### 15.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 98: Summary of PRULO Report 10 (All) Cases - Pathology and Surgical Details   | **Characteristic** | **N = 13**1 | | --- | --- | | Cuff Status |  | | Intact | 100 (11) | | Treatment Type |  | | Primary | 85 (11) | | Revision Else | 7.7 (1) | | Revision Own | 7.7 (1) | | Product Count |  | | 3 | 85 (11) | | 1 | 0 (0) | | 2 | 0 (0) | | 4 | 15 (2) | | 5 | 0 (0) | | Cuff Repair |  | | None | 100 (13) | | Repair Augmentation |  | | None | 100 (13) | | LongHeadBiceps |  | | None | 92 (12) | | Tenodesis | 7.7 (1) | | Labrum |  | | Capsulolabral Repair | 7.7 (1) | | Labrum Repair | 38 (5) | | None | 54 (7) | | Labrum Repair |  | | Bankart | 27 (3) | | None | 9.1 (1) | | Not Repaired | 36 (4) | | Other2 | 18 (2) | | Posterior | 9.1 (1) | | Capsule | Ligament |  | | Capsular Shift | 15 (2) | | Capsulotomy | 7.7 (1) | | None | 69 (9) | | Other2 | 7.7 (1) | | Glenoid |  | | Latarjet | 64 (7) | | None | 36 (4) | | Adjunct Procedure |  | | None | 100 (11) | | 1% (n) | | | 2Labral tear uncategorised | | |

### 15.3.3 Treatment Survival

The mean follow up duration is 3.1 years, with a standard deviation of 0.91 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 99: Summary of PRULO Report 10 (All) - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 15.3.4 Adverse Events

Complications and adverse events are summarised below.

|  |
| --- |
| Table 100: Summary of PRULO Report 10 (All) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 101: Summary of PRULO Report 10 (All) Cases - Postoperative Events   | **Characteristic** | **N = 13**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 28 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 28 | | Effusion | 0 (0) | 0.00 - 28 | | Pain | 0 (0) | 0.00 - 28 | | Hardware | 15 (2) | 2.7 - 46 | | Loosening | 0 (0) | 0.00 - 28 | | Instability | 0 (0) | 0.00 - 28 | | Stiffness | 0 (0) | 0.00 - 28 | | Neurological | 0 (0) | 0.00 - 28 | | Thrombosis | 0 (0) | 0.00 - 28 | | Other | 0 (0) | 0.00 - 28 | | Reoperation2 | 15 (2) | 2.7 - 46 | | Subsequent Treatment3 |  |  | | Not Applicable | 100 (13) | 72 - 100 | | Reoperation Delay (Weeks)4 | 31.5 (9.2) | -51 - 114 | | 1% (n); Mean (SD) | | | | 2A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 3Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | 4Time between index procedure and reoperation | | | | Abbreviation: CI = Confidence Interval | | | |

### 15.3.5 Patient-Reported Outcomes

Complete case analysis of QuickDASH and WOSI Index Normalised is summarised below.

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| --- |
| Figure 17: Complete case analysis of QuickDASH (Top) and WOSI Index Normalised (Bottom). |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 102: Summary of PRULO Report 10 (All) Cases - QuickDASH and WOSI   | **Characteristic** | **Preop**  N = 111 | **3m**  N = 131 | **6m**  N = 131 | **12m**  N = 121 | | --- | --- | --- | --- | --- | | QDASH | 23 (23 - 30) | 30 (24 - 44) | 43 (0 - 48) | 8 (2 - 20) | | QDASHDelta | NA (NA - NA) | -3 (-5 - 0) | 19 (9 - 30) | 15 (6 - 25) | | WOSINorm | 40 (29 - 42) | 41 (28 - 76) | 36 (34 - 93) | 70 (51 - 87) | | WOSIDelta | NA (NA - NA) | -59 (-82 - -34) | 43 (21 - 64) | 48 (16 - 58) | | 1Median (Q1 - Q3) | | | | | |

# 16. Product Report 11 - Dynacord Freestrand Suture

## 16.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 16.2 Overview

Usage of the Product within the patient group is summarised below.

There are 10 cases involving the anchor of interest. Surgeries were performed between 2020-Dec-22 and 2025-Jan-07. The procedures included [Cuff Repair] [Cuff Repair; Tenodesis] [Augmented Cuff Repair; Capsular Reconstruction] [Cuff Repair; Tenotomy; Capsulotomy], and [Labrum Repair].

There are 7 cases involving the suture of interest and a Cuff repair. Surgeries were performed between 2021-Apr-15 to 2025-Jan-07. The procedures included Rotator Cuff Repair; Calcific tendinopathy, Rotator Cuff Repair, Rotator Cuff Repair; Biceps Tenodesis; Biceps Tenotomy; Subacromial Decompression, Rotator Cuff Repair; bicep transfer to reinforce supra repair, Rotator Cuff Repair; Biceps Tenotomy; Capsulotomy, Rotator Cuff Repair; Biceps Tenodesis.

There are 2 cases involving the suture of interest and a Biceps Tenodesis. Surgeries were performed between 2021-Jul-08 to 2022-Sep-22. There is insufficient sample size to provide a report.

## 16.3 Procedure Report - Rotator Cuff Repair

### 16.3.1 Patient Characteristics

Patient demographic, pathology, and treatment characteristics for this cohort receiving the Product are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 103: Summary of PRULO Report 11 (Rotator Cuff) Case - Patient Characteristics   | **Characteristic** | **Statistic** | **Overall**  N = 71 | **None**  N = 4 | **Tenodesis**  N = 2 | **Tenotomy**  N = 1 | | --- | --- | --- | --- | --- | --- | | Age at Initial Consultation (Years) | Median (Q1, Q3) | 54.0 (49.0, 56.0) | 54.5 (51.5, 59.5) | 46.5 (42.0, 51.0) | 56.0 (56.0, 56.0) | | Male | % (n) | 57 (4) | 50 (2) | 100 (2) | 0 (0) | | Cohort |  |  |  |  |  | | Rotator Cuff | % (n) | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Dominant Side | % (n) | 100 (3) | 100 (2) | NA (0) | 100 (1) | | Bilateral Presentation |  |  |  |  |  | | No | % (n) | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Symptom Duration (Weeks) | Median (Q1, Q3) | 33 (12, 53) | 12 (12, 12) | NA (NA, NA) | 53 (53, 53) | | Symptom Duration Category2 |  |  |  |  |  | | <=0.5 | % (n) | 50 (1) | 100 (1) | NA (0) | 0 (0) | | >0.5 | % (n) | 50 (1) | 0 (0) | NA (0) | 100 (1) | | Treatment Record Active3 | % (n) | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Patient Record Active4 | % (n) | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | 1Median (Q1, Q3); % (n) | | | | | | | 2Dichotomised below or equal to 0.5 years or greater than 0.5 years | | | | | | | 3Treatment record remains active - no change to follow up | | | | | | | 4Patient record remains open - no change to consent or mortality status | | | | | | |

### 16.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 104: Summary of PRULO Report 11 (Rotator Cuff) Cases - Pathology and Surgical Details   | **Characteristic** | **Overall**  N = 71 | **None**  N = 41 | **Tenodesis**  N = 21 | **Tenotomy**  N = 11 | | --- | --- | --- | --- | --- | | Cuff Status |  |  |  |  | | Full Tear | 71 (5) | 75 (3) | 50 (1) | 100 (1) | | Other2 | 14 (1) | 25 (1) | 0 (0) | 0 (0) | | Partial Tear | 14 (1) | 0 (0) | 50 (1) | 0 (0) | | Treatment Type |  |  |  |  | | Primary | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Product Count |  |  |  |  | | 1 | 71 (5) | 75 (3) | 50 (1) | 100 (1) | | 2 | 29 (2) | 25 (1) | 50 (1) | 0 (0) | | 3 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 4 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | 5 | 0 (0) | 0 (0) | 0 (0) | 0 (0) | | Cuff Repair |  |  |  |  | | Augmented Cuff Repair | 14 (1) | 25 (1) | 0 (0) | 0 (0) | | Cuff Repair | 86 (6) | 75 (3) | 100 (2) | 100 (1) | | Repair Augmentation |  |  |  |  | | None | 86 (6) | 75 (3) | 100 (2) | 100 (1) | | Superior Capsular | 14 (1) | 25 (1) | 0 (0) | 0 (0) | | Labrum |  |  |  |  | | None | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Labrum Repair |  |  |  |  | | None | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Capsule | Ligament |  |  |  |  | | Capsular Reconstruction | 14 (1) | 25 (1) | 0 (0) | 0 (0) | | Capsulotomy | 14 (1) | 0 (0) | 0 (0) | 100 (1) | | None | 71 (5) | 75 (3) | 100 (2) | 0 (0) | | Glenoid |  |  |  |  | | None | 100 (7) | 100 (4) | 100 (2) | 100 (1) | | Adjunct Procedure |  |  |  |  | | Calcific Tendonitis Excision | 14 (1) | 25 (1) | 0 (0) | 0 (0) | | None | 71 (5) | 75 (3) | 50 (1) | 100 (1) | | Subacromial Decompression | 14 (1) | 0 (0) | 50 (1) | 0 (0) | | 1% (n) | | | | | | 2Biceps tendon integration; Biceps tendon transfer; Tendon advancement | | | | | |

### 16.3.3 Treatment Survival

The mean follow up duration is 2.7 years, with a standard deviation of 1.23 years.

Failure or revision events as identified in the registry for this cohort are summarised below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 105: Summary of PRULO Report 11 (Rotator Cuff) Cases - Procedure Survival   | **Characteristic** | **1 Weeks**1 | **26 Weeks**1 | **52 Weeks**1 | **104 Weeks**1 | | --- | --- | --- | --- | --- | | Procedure Survival | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | 100% (100% - 100%) | | 1% survival with 95% confidence intervals | | | | | |

### 16.3.4 Adverse Events

Complications and adverse events are summarised below.

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| --- |
| Table 106: Summary of PRULO Report 11 (Rotator Cuff) Cases - Intraoperative Events |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 107: Summary of PRULO Report 11 (Rotator Cuff) Cases - Postoperative Events   | **Characteristic** | **N = 7**1 | **95% CI** | | --- | --- | --- | | Infection | 0 (0) | 0.00 - 44 | | Ligament|Tendon (Retear) | 0 (0) | 0.00 - 44 | | Effusion | 0 (0) | 0.00 - 44 | | Pain | 0 (0) | 0.00 - 44 | | Hardware | 0 (0) | 0.00 - 44 | | Loosening | 0 (0) | 0.00 - 44 | | Instability | 0 (0) | 0.00 - 44 | | Stiffness | 14 (1) | 0.75 - 58 | | Neurological | 0 (0) | 0.00 - 44 | | Thrombosis | 0 (0) | 0.00 - 44 | | Other2 | 0 (0) | 0.00 - 44 | | Reoperation3 | 14 (1) | 0.75 - 58 | | Subsequent Treatment4 |  |  | | Not Applicable | 100 (7) | 56 - 100 | | 1% (n) | | | | 2Myocardial Infarction | | | | 3A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modification of the construct. | | | | 4Management undertaken for procedures that have suffered tissue failure or required hardware removal or replacement | | | | Abbreviation: CI = Confidence Interval | | | |

### 16.3.5 Patient-Reported Outcomes

Complete case analysis of QDASH, WORC Index Normalised, and WORC Physical Question 3 (How much weakness do you experience in your shoulder?) is summarised below.

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| Figure 18: Complete case analysis of QDASH(Top), WORC Index Normalised (Middle), and WORC Physical Question 3 (Bottom) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 108: Summary of PRULO Report 11 (Rotator Cuff) Cases - QuickDASH   | **Characteristic** | **Preop**  N = 51 | **3m**  N = 71 | **6m**  N = 61 | **12m**  N = 61 | | --- | --- | --- | --- | --- | | QDASH | 25 (11 - 39) | 41 (30 - 52) | 14 (2 - 25) | 5 (0 - 18) | | 1Median (Q1 - Q3) | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 109: Summary of PRULO Report 11 (Rotator Cuff) Cases - WORC Normalised and WORC Physical Question 3.   | **Characteristic** | **Preop**  N = 51 | **6m**  N = 61 | **12m**  N = 61 | | --- | --- | --- | --- | | WORCNorm | 37 (37 - 37) | 90 (70 - 97) | 87 (86 - 99) | | WORCPhysicalQ3 | 40 (40 - 40) | 15 (12 - 28) | 28 (12 - 32) | | WORCDelta | NA (NA - NA) | NA (NA - NA) | NA (NA - NA) | | 1Median (Q1 - Q3) | | | | |

# 17. Product Report 12 - Dynatape Freestrand Suture

## 17.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 17.2 Overview

Usage of the Product within the patient group is summarised below.

There is 1 case involving the product of interest. There is insufficient sample size to provide a report.

There are 0 cases involving the suture of interest and a Cuff Repair. There is insufficient sample size to provide a report.

# 18. Product Report 13 - Orthocord Freestrand Suture

## 18.1 Sample Selection

The sample of patients with the relevant product group were identified and data were retrieved for analysis by matching registry records to the relevant stock keeping units (SKUs) for the product group of interest. Usage statistics for the product group were added, and adverse events data were attached. Patient-reported data were retrieved and the dataset was manipulated to include relevant details for procedures of interest.

## 18.2 Overview

Usage of the Product within the patient group is summarised below.

There are 2 cases involving the suture of interest. Surgeries were performed between 2021-Jun-10 to 2021-Jul-08. There is insufficient sample size to provide a report.

# 19. Product usage patterns

Product usage patterns were determined by merging multiple product datasets into a single table. This combined data was then modified to include additional information and restructured to have separate columns for different product groups. Following this, a list of product category names was established and proportions for various combinations were calculated. The results were reformatted for presentation, with count data incorporated and proportions displayed as percentages.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 110: Summary of product overlap for each report sample (row), the proportion of cases within that sample that also include products included in the remaining reports (columns)   |  | CaseCount | Healix Advance Peek with Dynacord | Healix Advance Knotless Peek | Healix Advance Knotless BR | Healix Advance BR with Dynacord | Milagro Advance BR | Gryphon ProKnot BR | Gryphon BR with Orthocord | Gryphon BR with Dynacord | Gryphon PEEK with Dynacord | Latarjet Experience | Dynacord Freestrand Suture | Dynatape Freestrand Suture | Orthocord Freestrand Suture | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Healix Advance Peek with Dynacord | 206 | 100.0 | 92.2 | 1.0 | 0.5 | 0.5 | 0.5 | 0.0 | 0.0 | 0.0 | 0.0 | 2.9 | 0.0 | 1.0 | | Healix Advance Knotless Peek | 206 | 92.2 | 100.0 | 1.0 | 2.4 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 3.9 | 0.0 | 1.0 | | Healix Advance Knotless BR | 63 | 3.2 | 3.2 | 100.0 | 95.2 | 25.4 | 3.2 | 1.6 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | | Healix Advance BR with Dynacord | 84 | 1.2 | 6.0 | 71.4 | 100.0 | 28.6 | 2.4 | 1.2 | 0.0 | 0.0 | 0.0 | 1.2 | 0.0 | 0.0 | | Milagro Advance BR | 44 | 2.3 | 0.0 | 36.4 | 54.5 | 100.0 | 25.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | | Gryphon ProKnot BR | 66 | 1.5 | 0.0 | 3.0 | 3.0 | 16.7 | 100.0 | 53.0 | 1.5 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | | Gryphon BR with Orthocord | 39 | 0.0 | 0.0 | 2.6 | 2.6 | 0.0 | 89.7 | 100.0 | 0.0 | 0.0 | 5.1 | 0.0 | 0.0 | 0.0 | | Gryphon BR with Dynacord | 2 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 50.0 | 0.0 | 100.0 | 0.0 | 50.0 | 0.0 | 0.0 | 0.0 | | Gryphon PEEK with Dynacord | 9 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 100.0 | 11.1 | 0.0 | 0.0 | 0.0 | | Latarjet Experience | 13 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 15.4 | 7.7 | 7.7 | 100.0 | 0.0 | 0.0 | 0.0 | | Dynacord Freestrand Suture | 10 | 60.0 | 80.0 | 0.0 | 10.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 100.0 | 0.0 | 10.0 | | Dynatape Freestrand Suture | 1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 100.0 | 0.0 | | Orthocord Freestrand Suture | 2 | 100.0 | 100.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 50.0 | 0.0 | 100.0 | |

## 19.1 Proportion with multiple products

The proportion of cases that contained hardware from different product codes was summarised.

A cross-tabulation of usage for all products was generated and written to an external file for further review.

A summary table was generated to illustrate the proportion of cases where multiple product codes were utilised.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 111: Summary of cross-product usage in the PRULO dataset   |  | Report | Total | Multiple | Proportion*1* | | --- | --- | --- | --- | --- | | 1 | Report1 | 206 | 192 | 93.2 | | 2 | Report2 | 206 | 197 | 95.6 | | 3 | Report3 | 63 | 62 | 98.4 | | 4 | Report4 | 84 | 73 | 86.9 | | 5 | Report5 | 44 | 34 | 77.3 | | 6 | Report6 | 66 | 49 | 74.2 | | 7 | Report7 | 39 | 38 | 97.4 | | 8 | Report8 | 2 | 2 | 100.0 | | 9 | Report9 | 9 | 1 | 11.1 | | 10 | Report10 | 13 | 4 | 30.8 | | 11 | Report11 | 10 | 8 | 80.0 | | 12 | Report12 | 1 | 0 | 0.0 | | 13 | Report13 | 2 | 2 | 100.0 | | *1*Proportion as a % of the Total | | | | | |

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