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 has been previously prepared for the registry Scholes et al. (2023).

The outline of this report has been derived from the EuroSpine Registry 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.

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.

Term	Definition
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.

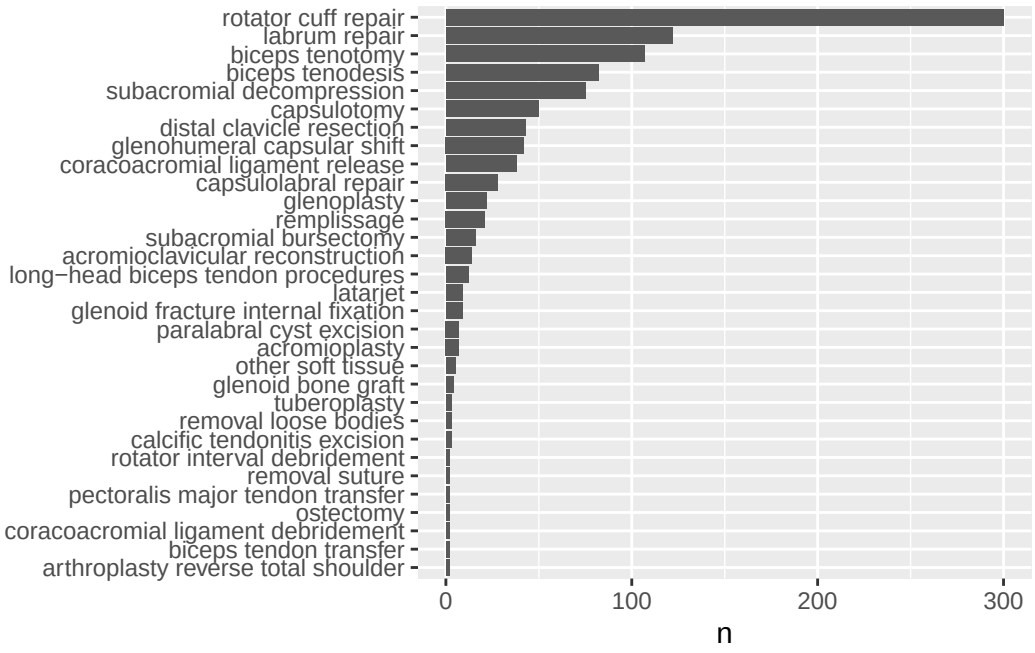

Figure 1: Summary of procedure terms included in registry output

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

```
Discrepancies identified have been added to external table.
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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.

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

Table 2: Summary of diagnoses using ICD-10 coding for primary presentation

Cohort	ICD10	n
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.

Table 3: Summary of PRULO surgical cases by cohort

Characteristic	**Statistic**	**Overall** N = 1,045[1]	**General** N = 428	**Glenohumeral In**
Age at Initial Consultation (Years)	Median (Q1, Q3)	58 (45, 69)	64 (50, 73)	24 (1
Male	% (n)	63 (661)	51 (217)	77 (
Dominant Side	% (n)	59 (440)	57 (173)	57 (
Bilateral Presentation	% (n)	12 (130)	14 (60)	11 (
Symptom Duration (Weeks)	Median (Q1, Q3)	57 (23, 177)	101 (37, 284)	60 (23
Symptom Duration Category[2]				
<=0.5	% (n)	28 (135)	20 (34)	29 (
>0.5	% (n)	72 (346)	80 (138)	71 (
Treatment Record Active[3]	% (n)	94 (987)	96 (412)	98 (
Patient Record Active[4]	% (n)	100 (1,041)	99 (424)	100 (

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[3]Treatment record remains active - no change to follow up

[4]Patient record remains open - no change to consent or mortality status

The overall registry enrolment is summarised in Table 3, describing how the population is summarised into cohorts.

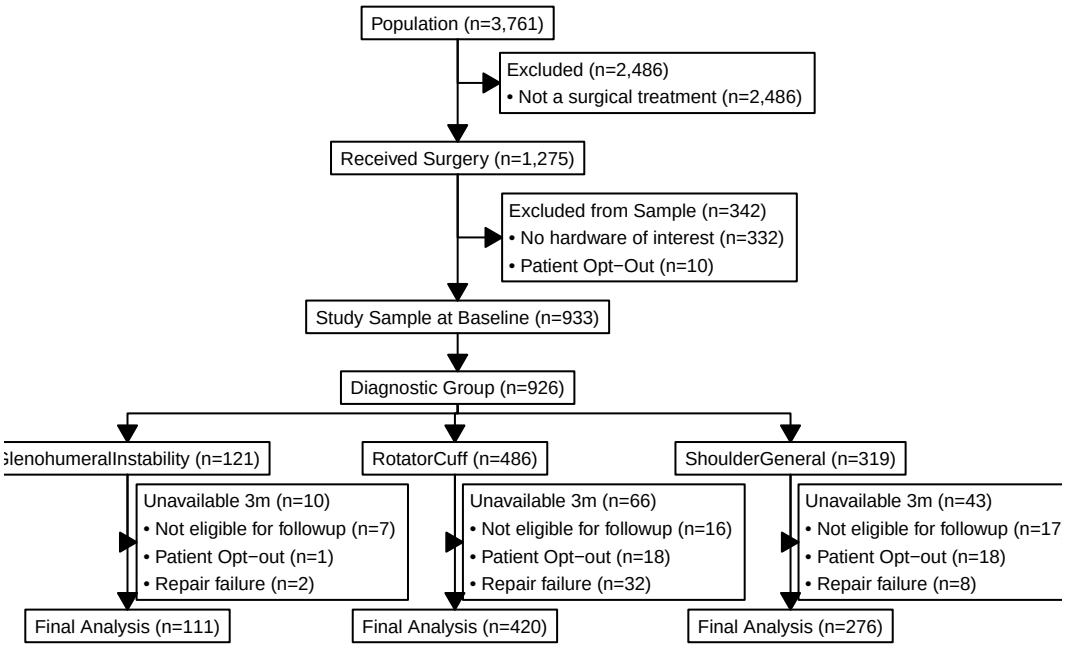

Figure 2: Flowchart of extraction and followup of sample from the Registry

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.

Table 4: Summary of PRULO Report 1 (Rotator Cuff) - Patient Characteristics

Characteristic	**Statistic**	**Overall** N = 178[1]	**None** N = 92	**Tenodesis** N = 20	**Ten**
Age at Initial Consultation (Years)	Median (Q1, Q3)	60 (55, 65)	59 (54, 65)	54 (49, 59)	
Male	% (n)	71 (127)	67 (62)	100 (20)	
Cohort					
General	% (n)	0.6 (1)	1.1 (1)	0 (0)	
Rotator Cuff	% (n)	99 (177)	99 (91)	100 (20)	
Dominant Side	% (n)	62 (73)	63 (36)	62 (8)	
Bilateral Presentation	% (n)	7.3 (13)	3.3 (3)	25 (5)	
Symptom Duration (Weeks)	Median (Q1, Q3)	42 (21, 78)	38 (22, 88)	47 (9, 92)	
Symptom Duration Category[2]					
<=0.5	% (n)	34 (38)	32 (17)	45 (5)	
>0.5	% (n)	66 (74)	68 (36)	55 (6)	
Treatment Record Active[3]	% (n)	84 (149)	87 (80)	80 (16)	
Patient Record Active[4]	% (n)	100 (178)	100 (92)	100 (20)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

Characteristic	Statistic	Overall N = 178[1]	None N = 92	Tenodesis N = 20	Ten

[3]Treatment record remains active - no change to follow up

[4]Patient record remains open - no change to consent or mortality status

6.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

Table 5: Summary of PRULO Report 1 (Rotator Cuff) Cases Pathology and Surgical Deta

Characteristic	Overall N = 178[1]	None N = 92[1]	Tenodesis N = 20
Cuff Status			
Full Tear	91 (161)	89 (81)	85 (17)
Partial Tear	9.0 (16)	11 (10)	15 (3)
Treatment Type			
Primary	95 (169)	91 (84)	100 (20)
Revision Else	1.7 (3)	2.2 (2)	0 (0)
Revision Own	3.4 (6)	6.5 (6)	0 (0)
Product Count			
1	44 (78)	47 (43)	40 (8)
2	42 (75)	41 (38)	40 (8)
3	13 (23)	11 (10)	15 (3)
4	1.1 (2)	1.1 (1)	5.0 (1)
5	0 (0)	0 (0)	0 (0)
Cuff Repair			
Augmented Cuff Repair	12 (21)	12 (11)	25 (5)
Cuff Repair	88 (157)	88 (81)	75 (15)
Repair Augmentation			
Allograft	0.6 (1)	1.1 (1)	0 (0)
Autograft	0.6 (1)	0 (0)	0 (0)

Characteristic	**Overall** N = 178[1]	**None** N = 92[1]	**Tenodesis** N = 20
Autograft; Superior Capsular	0.6 (1)	0 (0)	0 (0)
None	88 (156)	88 (81)	75 (15)
Other[2]	3.4 (6)	2.2 (2)	15 (3)
Superior Capsular	5.6 (10)	7.6 (7)	5.0 (1)
Superior Capsular; advancement	0.6 (1)	1.1 (1)	0 (0)
Superior Capsular; Autograft	0.6 (1)	0 (0)	5.0 (1)
Labrum			
Capsulolabral Repair	0.6 (1)	1.1 (1)	0 (0)
None	99 (177)	99 (91)	100 (20)
Labrum Repair			
None	100 (173)	100 (89)	100 (20)
Capsule | Ligament			
Capsular Reconstruction	4.5 (8)	4.3 (4)	10 (2)
Capsulotomy	5.1 (9)	5.4 (5)	0 (0)
Ligament Release	22 (40)	24 (22)	5.0 (1)
None	68 (121)	66 (61)	85 (17)
Glenoid			
None	100 (178)	100 (92)	100 (20)
Adjunct Procedure			
Distal Clavicle Resection	6.7 (12)	7.6 (7)	5.0 (1)
Infraspinatus Advancement	0.6 (1)	1.1 (1)	0 (0)
None	79 (141)	71 (65)	95 (19)
Removal Suture	0.6 (1)	1.1 (1)	0 (0)
Rotator Interval Debridement	0.6 (1)	0 (0)	0 (0)
Subacromial Bursectomy	3.4 (6)	6.5 (6)	0 (0)
Subacromial Bursectomy; Removal Implants	0.6 (1)	1.1 (1)	0 (0)
Subacromial Bursectomy; Rotator Interval Debridement	0.6 (1)	0 (0)	0 (0)

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

Characteristic	Overall N = 178[1]	None N = 92[1]	Tenodesis N = 20
Subacromial Decompression	6.2 (11)	9.8 (9)	0 (0)
Subacromial Decompression; Distal Clavicle Resection	0.6 (1)	1.1 (1)	0 (0)
Subacromial Decompression; Os Acromiale Excision	0.6 (1)	0 (0)	0 (0)
Subacromial Decompression; Subacromial Bursectomy	0.6 (1)	1.1 (1)	0 (0)

[1]% (n)

[2]Biceps 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.

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.

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

Characteristic	N = 178[1]	95% CI
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
Other[2]	2.2 (4)	0.72 - 6.0
Reoperation[3]	7.3 (13)	4.1 - 12
Subsequent Treatment[4]		
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)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[5]Time between index procedure and reoperation

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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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.

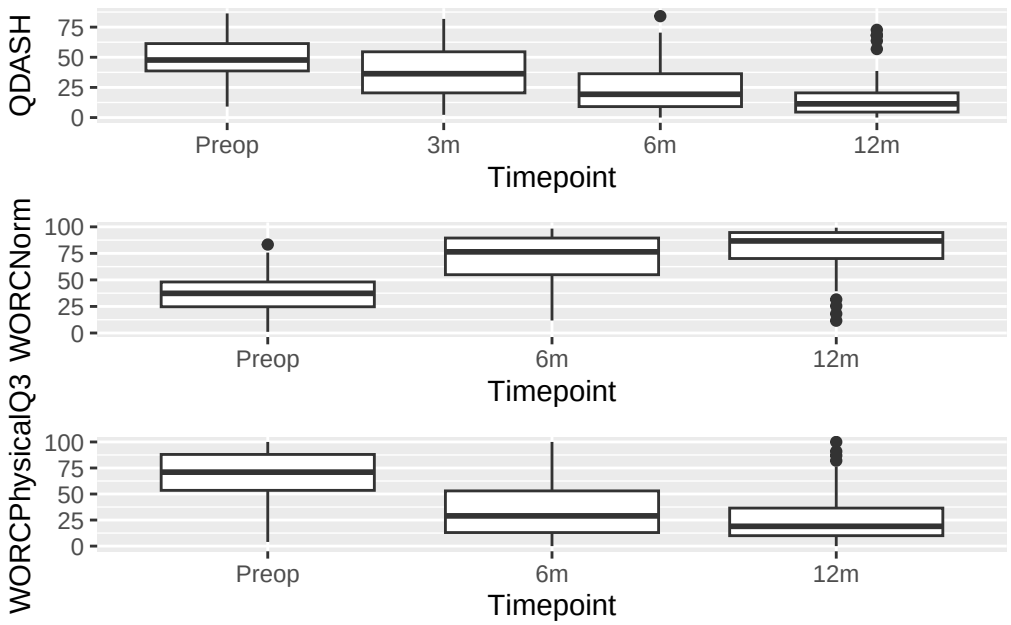

Figure 3: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 9: Summary of PRULO Report 1 (Rotator Cuff) Cases - QuickDASH

Characteristic	**Preop** N = 170[1]	**3m** N = 178[1]	**6m** N = 156[1]	**12m** N = 138[1]
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)

[1]Median (Q1 - Q3)

Table 10: Summary of PRULO Report 1 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index

Characteristic	**Preop** N = 170[1]	**6m** N = 156[1]	**12m** N = 138[1]
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)

Characteristic	Preop N = 170[1]	6m N = 156[1]	12m N = 138[1]

[1]Median (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.

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 Category[1]		
<=0.5	% (n)	38 (5)
>0.5	% (n)	62 (8)
Treatment Record Active[2]	% (n)	82 (18)
Patient Record Active[3]	% (n)	100 (22)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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%)
Other[2]	3 (14%)
Superior Capsular	1 (4.8%)
Superior Capsular; Autograft	1 (4.8%)
Long Head Biceps Procedures	
Tenodesis	22 (100%)

Characteristic	N = 22[1]
Labrum	
Labrum Repair	1 (4.5%)
None	21 (95%)
Labrum Repair	
None	21 (95%)
Other[2]	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%)

[1]n (%)

[2]Biceps 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.

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

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

6.4.4 Adverse Events

Complications and adverse events are summarised below.

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
Reoperation[2]	4.5 (1)	0.24 - 25
Subsequent Treatment[3]		
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)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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6.4.5 Patient-Reported Outcomes

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

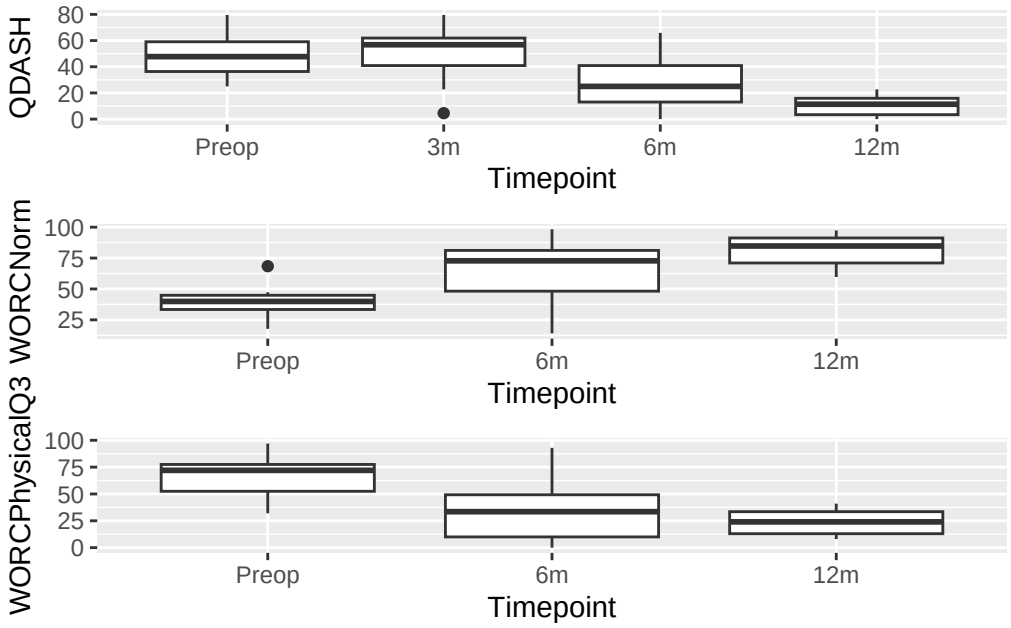

Figure 4: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 16: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - QuickDASH.

Characteristic	**Preop** N = 19[1]	**3m** N = 22[1]	**6m** N = 21[1]	**12m** N = 20[1]
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)

[1]Median (Q1 - Q3)

Table 17: Summary of PRULO Report 1 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index

Characteristic	Preop N = 19[1]	6m N = 21[1]	12m N = 20[1]
WORCNorm	40 (27 - 47)	73 (47 - 83)	85 (68 - 92)
WORCPhysicalQ3	72 (41 - 78)	34 (10 - 50)	24 (11 - 35)

[1]Median (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.

Table 18: Summary of PRULO Report 2 (Rotator Cuff) Case - Patient Characteristics

Characteristic	**Statistic**	**Overall** N = 190[1]	**None** N = 103	**Tenodesis** N = 17	**Te**
Age at Initial Consultation (Years)	Median (Q1, Q3)	60 (55, 65)	59 (53, 65)	53 (51, 58)	
Male	% (n)	70 (133)	65 (67)	100 (17)	
Cohort					
General	% (n)	0.5 (1)	1.0 (1)	0 (0)	
Rotator Cuff	% (n)	99 (189)	99 (102)	100 (17)	
Dominant Side	% (n)	59 (73)	63 (40)	56 (5)	
Bilateral Presentation	% (n)	7.4 (14)	2.9 (3)	29 (5)	
Symptom Duration (Weeks)	Median (Q1, Q3)	37 (21, 77)	43 (22, 90)	15 (9, 135)	
Symptom Duration Category[2]					
<=0.5	% (n)	34 (40)	31 (18)	57 (4)	
>0.5	% (n)	66 (76)	69 (40)	43 (3)	
Treatment Record Active[3]	% (n)	84 (160)	89 (92)	76 (13)	
Patient Record Active[4]	% (n)	100 (190)	100 (103)	100 (17)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[3]Treatment record remains active - no change to follow up

[4]Patient record remains open - no change to consent or mortality status

7.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

Table 19: Summary of PRULO Report 2 (Rotator Cuff) Cases Pathology and Surgical Deta

Characteristic	**Overall** N = 190[1]	**None** N = 103[1]	**Tenodesis** N =
Cuff Status			
Full Tear	91 (172)	86 (88)	94 (16)
Other[2]	0.5 (1)	1.0 (1)	0 (0)
Partial Tear	8.5 (16)	13 (13)	5.9 (1)
Treatment Type			
Primary	96 (182)	93 (96)	100 (17)
Revision Else	1.6 (3)	1.9 (2)	0 (0)
Revision Own	2.6 (5)	4.9 (5)	0 (0)
Product Count			
1	53 (101)	54 (56)	35 (6)
2	41 (77)	41 (42)	65 (11)
3	5.3 (10)	4.9 (5)	0 (0)
4	1.1 (2)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)
Cuff Repair			
Augmented Cuff Repair	13 (25)	15 (15)	35 (6)
Cuff Repair	87 (165)	85 (88)	65 (11)
Repair Augmentation			
Allograft	0.5 (1)	1.0 (1)	0 (0)
Autograft; Superior Capsular	0.5 (1)	0 (0)	0 (0)
None	87 (164)	85 (88)	65 (11)
Other[2]	3.2 (6)	1.9 (2)	18 (3)
Superior Capsular	7.4 (14)	11 (11)	5.9 (1)
Superior Capsular; advancement	0.5 (1)	1.0 (1)	0 (0)
Superior Capsular; Autograft	1.1 (2)	0 (0)	12 (2)
Labrum			

Characteristic	Overall N = 190[1]	None N = 103[1]	Tenodesis N = 1
None	100 (190)	100 (103)	100 (17)
Labrum Repair			
None	100 (186)	100 (101)	100 (17)
Capsule | Ligament			
Capsular Reconstruction	5.8 (11)	5.8 (6)	18 (3)
Capsulotomy	5.8 (11)	6.8 (7)	0 (0)
Ligament Release	22 (42)	24 (25)	0 (0)
None	66 (126)	63 (65)	82 (14)
Glenoid			
None	100 (190)	100 (103)	100 (17)
Adjunct Procedure			
Calcific Tendonitis Excision	0.5 (1)	1.0 (1)	0 (0)
Distal Clavicle Resection	7.4 (14)	8.7 (9)	5.9 (1)
Infraspinatus Advancement	0.5 (1)	1.0 (1)	0 (0)
None	77 (146)	68 (70)	88 (15)
Removal Suture	0.5 (1)	1.0 (1)	0 (0)
Rotator Interval Debridement	0.5 (1)	0 (0)	0 (0)
Subacromial Bursectomy	2.6 (5)	4.9 (5)	0 (0)
Subacromial Bursectomy; Removal Implants	0.5 (1)	1.0 (1)	0 (0)
Subacromial Bursectomy; Rotator Interval Debridement	0.5 (1)	0 (0)	0 (0)
Subacromial Decompression	7.9 (15)	12 (12)	5.9 (1)
Subacromial Decompression; Distal Clavicle Resection	1.1 (2)	1.9 (2)	0 (0)
Subacromial Decompression; Os Acromiale Excision	0.5 (1)	0 (0)	0 (0)
Subacromial Decompression; Subacromial Bursectomy	0.5 (1)	1.0 (1)	0 (0)

[1]% (n)

[2]Biceps tendon integration; Biceps tendon transfer; Tendon advancement

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

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.

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
Other[2]	2.6 (5)	0.97 - 6.4
Reoperation[3]	6.8 (13)	3.8 - 12

Characteristic	N = 190[1]	95% CI
Subsequent Treatment[4]		
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)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[5]Time between index procedure and reoperation

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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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.

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 = 171[1]	3m N = 179[1]	6m N = 157[1]	12m N = 141[1]
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)

[1]Median (Q1 - Q3)

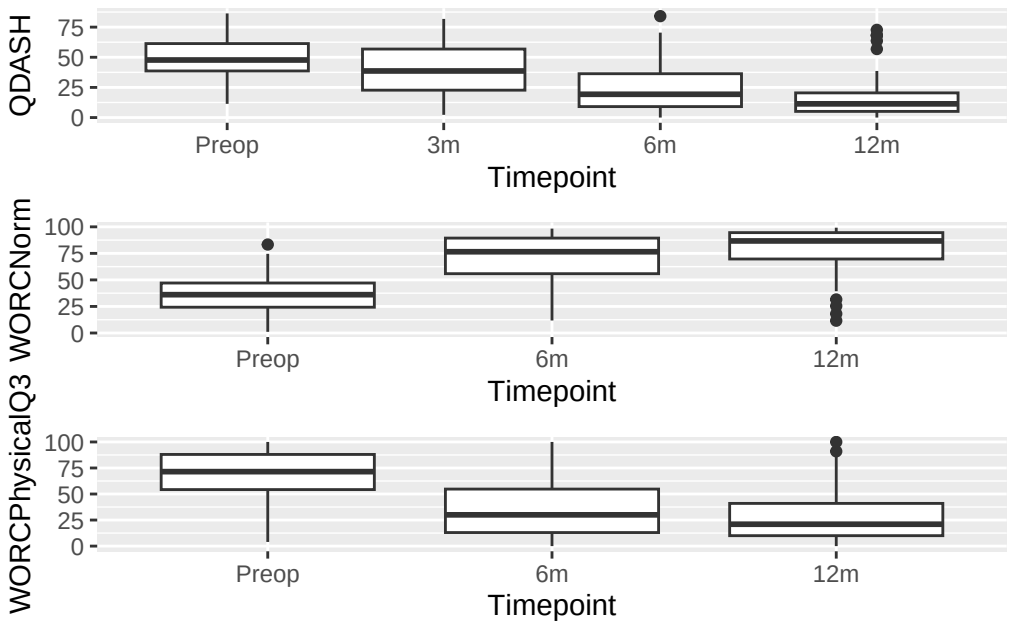

Figure 5: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 24: Summary of PRULO Report 2 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index

Characteristic	**Preop** N = 171[1]	**6m** N = 157[1]	**12m** N = 141[1]
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)

[1]Median (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 Category[1]		
<=0.5	% (n)	57 (4)
>0.5	% (n)	43 (3)
Treatment Record Active[2]	% (n)	76 (13)
Patient Record Active[3]	% (n)	100 (17)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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%)

Characteristic	N = 17[1]
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%)
Other[2]	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%)

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

Characteristic	N = 17[1]
None	15 (88%)
Subacromial Decompression	1 (5.9%)

[1]n (%)

[2]Biceps 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 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

Characteristic	N = 17[1]	95% CI
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
Reoperation[2]	5.9 (1)	0.31 - 31
Subsequent Treatment[3]		
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)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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7.4.5 Patient-Reported Outcomes

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

Table 30: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - QuickDASH

Characteristic	Preop N = 13[1]	3m N = 16[1]	6m N = 15[1]	12m N = 14[1]
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)

[1]Median (Q1 - Q3)

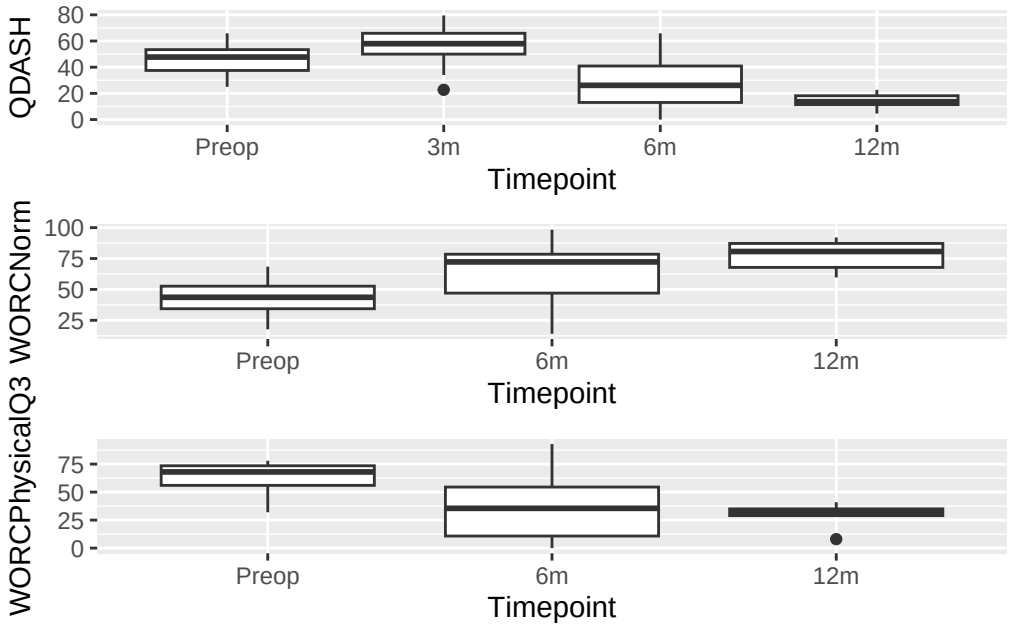

Figure 6: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 31: Summary of PRULO Report 2 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index

Characteristic	**Preop** N = 13[1]	**6m** N = 15[1]	**12m** N = 14[1]
WORCNorm	44 (29 - 58)	72 (45 - 79)	81 (68 - 87)
WORCPhysicalQ3	68 (48 - 75)	36 (11 - 59)	32 (29 - 35)

[1]Median (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 = 62[1]	**None** N = 41	**Tenodesis** N = 19	**Teno**
Age at Initial Consultation (Years)	Median (Q1, Q3)	62 (52, 69)	62 (57, 68)	63 (50, 69)	55
Male	% (n)	76 (47)	71 (29)	95 (18)	
Cohort					
Rotator Cuff	% (n)	100 (62)	100 (41)	100 (19)	
Dominant Side	% (n)	61 (37)	66 (27)	44 (8)	
Bilateral Presentation	% (n)	15 (9)	12 (5)	16 (3)	
Symptom Duration (Weeks)	Median (Q1, Q3)	27 (17, 60)	25 (14, 60)	27 (20, 42)	193
Symptom Duration Category[2]					
<=0.5	% (n)	46 (18)	50 (11)	44 (7)	
>0.5	% (n)	54 (21)	50 (11)	56 (9)	

Characteristic	Statistic	Overall N = 62[1]	None N = 41	Tenodesis N = 19	Teno
Treatment Record Active[3]	% (n)	97 (60)	95 (39)	100 (19)	
Patient Record Active[4]	% (n)	100 (62)	100 (41)	100 (19)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[3]Treatment record remains active - no change to follow up

[4]Patient 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 Patholog

Characteristic	Overall N
Cuff Status	
Degenerative	1.6 (1
Full Tear	94 (58
Partial Tear	4.8 (3
Treatment Type	
Primary	98 (61
Revision Else	1.6 (1
Product Count	
1	52 (32
2	44 (27
3	4.8 (3
4	0 (0)
5	0 (0)
Cuff Repair	
Augmented Cuff Repair	4.8 (3

Characteristic	Overall N
Cuff Repair	95 (59
Repair Augmentation	
Autograft	1.6 (1
None	95 (59
Other[2]	3.2 (2
Labrum	
Capsulolabral Repair	1.6 (1
None	98 (61
Labrum Repair	
None	100 (6
Capsule | Ligament	
Capsulotomy	18 (11
None	82 (51
Glenoid	
None	100 (62
Adjunct Procedure	
Distal Clavicle Resection	1.6 (1
None	42 (26
Subacromial Bursectomy	1.6 (1
Subacromial Bursectomy; Acromioplasty	3.2 (2
Subacromial Decompression	32 (20
Subacromial Decompression; Acromioplasty	1.6 (1
Subacromial Decompression; Clavicle Osteotomy	1.6 (1
Subacromial Decompression; Distal Clavicle Resection	9.7 (6
Subacromial Decompression; Distal Clavicle Resection; Acromioplasty	1.6 (1
Subacromial Decompression; Subacromial Bursectomy	1.6 (1
Subacromial Decompression; Subacromial Bursectomy; Acromioplasty	1.6 (1

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

Characteristic	Overall N
Subacromial Decompression; Subacromial Bursectomy; Distal Clavicle Resection; Acromioplasty	1.6 (1

[1]% (n)

[2]Biceps 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 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

Characteristic	N = 62[1]	95% CI
Stiffness	3.2 (2)	0.56 - 12
Neurological	1.6 (1)	0.08 - 9.8
Thrombosis	0 (0)	0.00 - 7.3
Other[2]	0 (0)	0.00 - 7.3
Reoperation[3]	0 (0)	0.00 - 7.3
Subsequent Treatment[4]		
Not Applicable	100 (62)	93 - 100

[1]% (n)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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There are no reoperations to report.
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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.

Table 37: Summary of PRULO Report 3 (Rotator Cuff) Cases - QuickDASH

Characteristic	Preop N = 60[1]	3m N = 62[1]	6m N = 60[1]	12m N = 59[1]
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)

[1]Median (Q1 - Q3)

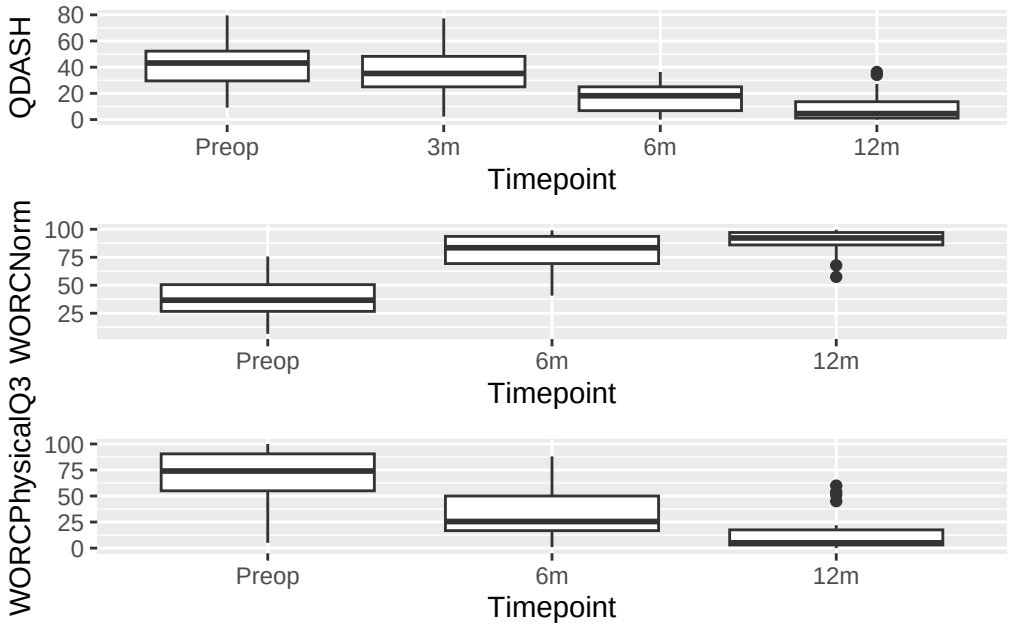

Figure 7: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom)

Table 38: Summary of PRULO Report 3 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index

Characteristic	**Preop** N = 60[1]	**6m** N = 60[1]	**12m** N = 59[1]
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)

[1]Median (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 Category[1]		
<=0.5	% (n)	44 (7)
>0.5	% (n)	56 (9)
Treatment Record Active[2]	% (n)	100 (19)
Patient Record Active[3]	% (n)	100 (19)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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%)

Characteristic	N = 19[1]
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%)
Other[2]	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%)

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

Characteristic	N = 19[1]
Subacromial Decompression	3 (16%)
Subacromial Decompression; Distal Clavicle Resection	2 (11%)
Subacromial Decompression; Subacromial Bursectomy	1 (5.3%)

[1]n (%)

[2]Biceps 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 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

Characteristic	N = 19[1]	95% CI
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
Reoperation[2]	0 (0)	0.00 - 21
Subsequent Treatment[3]		
Not Applicable	100 (19)	79 - 100

[1]% (n)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

```
There are no reoperations to report.
```

8.4.5 Patient-Reported Outcomes

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

Table 44: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - QuickDASH

Characteristic	Preop N = 19[1]	3m N = 19[1]	6m N = 19[1]	12m N = 18[1]
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)

[1]Median (Q1 - Q3)

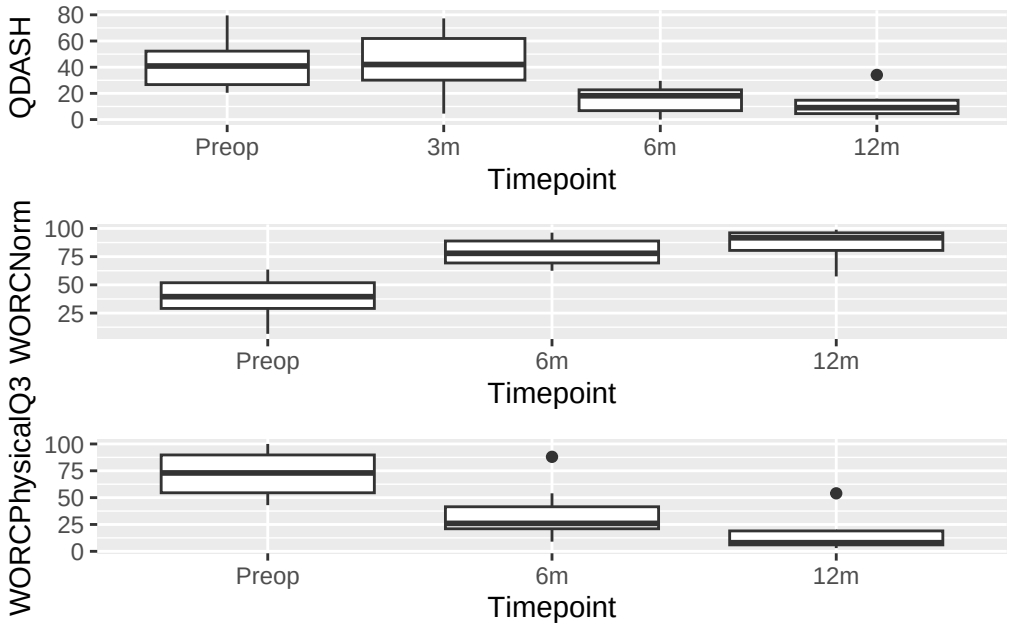

Figure 8: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom)

Table 45: Summary of PRULO Report 3 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index

Characteristic	**Preop** N = 19[1]	**6m** N = 19[1]	**12m** N = 18[1]
WORCNorm	40 (27 - 53)	78 (63 - 96)	92 (73 - 97)
WORCPhysicalQ3	73 (52 - 90)	26 (19 - 54)	8 (6 - 19)

[1]Median (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 = 83[1]	**None** N = 52	**Tenodesis** N = 27	**Teno**
Age at Initial Consultation (Years)	Median (Q1, Q3)	62 (54, 69)	62 (57, 69)	61 (51, 69)	68
Male	% (n)	73 (61)	69 (36)	93 (25)	
Cohort					
General	% (n)	1.2 (1)	1.9 (1)	0 (0)	
Rotator Cuff	% (n)	99 (82)	98 (51)	100 (27)	
Dominant Side	% (n)	61 (49)	67 (35)	48 (12)	
Bilateral Presentation	% (n)	14 (12)	13 (7)	15 (4)	
Symptom Duration (Weeks)	Median (Q1, Q3)	29 (17, 87)	25 (14, 51)	30 (20, 65)	193
Symptom Duration Category[2]					
<=0.5	% (n)	45 (23)	50 (14)	40 (8)	

Characteristic	Statistic	Overall N = 83[1]	None N = 52	Tenodesis N = 27	Teno
>0.5	% (n)	55 (28)	50 (14)	60 (12)	
Treatment Record Active[3]	% (n)	96 (80)	96 (50)	100 (27)	
Patient Record Active[4]	% (n)	100 (83)	100 (52)	100 (27)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[3]Treatment record remains active - no change to follow up

[4]Patient 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 Patholog

Characteristic	Overall N
Cuff Status	
Degenerative	1.2 (1
Full Tear	98 (80
Partial Tear	1.2 (1
Treatment Type	
Primary	99 (82
Revision Else	1.2 (1
Product Count	
1	80 (66
2	18 (15
3	2.4 (2
4	0 (0)
5	0 (0)
Cuff Repair	

Characteristic	Overall N
Augmented Cuff Repair	6.0 (5
Cuff Repair	94 (78
Repair Augmentation	
Autograft	1.2 (1
None	94 (78
Other[2]	3.6 (3
Superior Capsular	1.2 (1
Labrum	
Capsulolabral Repair	1.2 (1
Debridement	1.2 (1
Labrum Repair	1.2 (1
None	96 (80
Labrum Repair	
Bankart	1.2 (1
None	99 (80
Capsule | Ligament	
Capsular Reconstruction	1.2 (1
Capsulotomy	17 (14
None	82 (68
Glenoid	
None	100 (83
Adjunct Procedure	
Distal Clavicle Resection	2.4 (2
None	48 (40
Subacromial Bursectomy; Acromioplasty	2.4 (2
Subacromial Decompression	29 (24
Subacromial Decompression; Acromioplasty	1.2 (1

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

Characteristic	Overall N
Subacromial Decompression; Clavicle Osteotomy	1.2 (1
Subacromial Decompression; Distal Clavicle Resection	11 (9)
Subacromial Decompression; Distal Clavicle Resection; Acromioplasty	1.2 (1
Subacromial Decompression; Subacromial Bursectomy	1.2 (1
Subacromial Decompression; Subacromial Bursectomy; Acromioplasty	1.2 (1
Subacromial Decompression; Subacromial Bursectomy; Distal Clavicle Resection; Acromioplasty	1.2 (1

[1]% (n)

[2]Biceps 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 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

Characteristic	N = 83[1]	95% CI
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
Other[2]	0 (0)	0.00 - 5.5
Reoperation[3]	0 (0)	0.00 - 5.5
Subsequent Treatment[4]		
Nonoperative Management	1.2 (1)	0.06 - 7.5
Not Applicable	99 (82)	93 - 100

[1]% (n)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

```
There are no reoperations to report.
```

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.

Table 51: Summary of PRULO Report 4 (Rotator Cuff) Cases - QuickDASH

Characteristic	Preop N = 80[1]	3m N = 83[1]	6m N = 78[1]	12m N = 77[1]
QDASH	43 (27 - 57)	36 (25 - 50)	18 (7 - 27)	6 (2 - 25)

Characteristic	Preop N = 80[1]	3m N = 83[1]	6m N = 78[1]	12m N = 77[1]
QDASHDelta	NA (NA - NA)	9 (-7 - 18)	27 (11 - 41)	30 (14 - 43)

[1]Median (Q1 - Q3)

Table 52: Summary of PRULO Report 4 (Rotator Cuff) Cases - Western Ontario Rotator Cuff Index

Characteristic	Preop N = 80[1]	6m N = 78[1]	12m N = 77[1]
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)

[1]Median (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 Category[1]		
<=0.5	% (n)	40 (8)
>0.5	% (n)	60 (12)

Characteristic	Statistic	Tenodesis N = 27
Treatment Record Active[2]	% (n)	100 (27)
Patient Record Active[3]	% (n)	100 (27)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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	

Characteristic	N = 27[1]
Autograft	1 (3.7%)
None	25 (93%)
Other[2]	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%)

[1]n (%)

[2]Biceps 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.

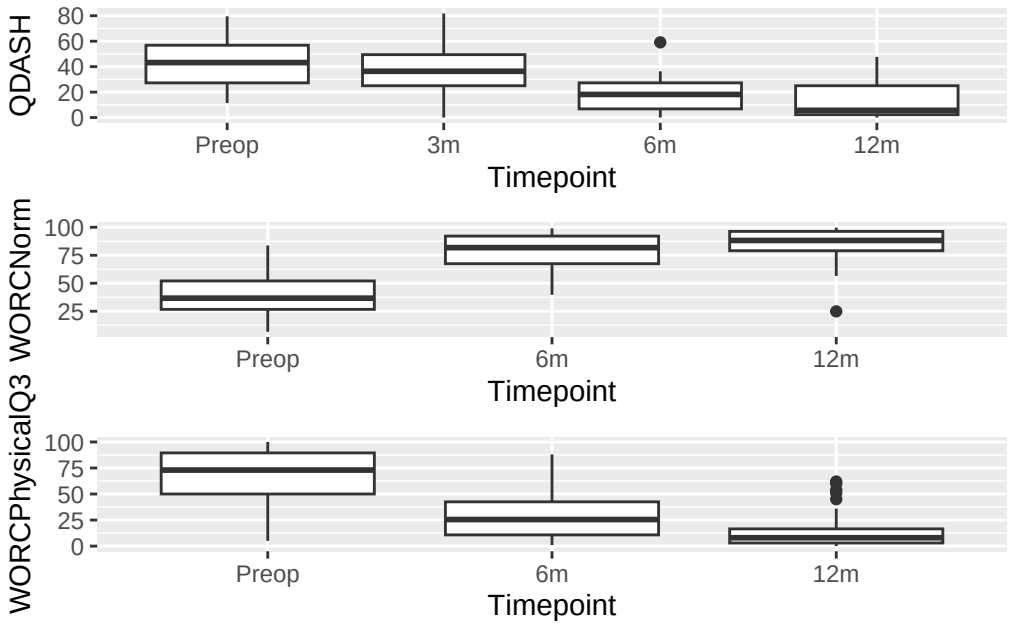

Figure 9: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

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

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 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

Characteristic	N = 27[1]	95% CI

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

```
There are no reoperations to report.
```

9.4.5 Patient-Reported Outcomes

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

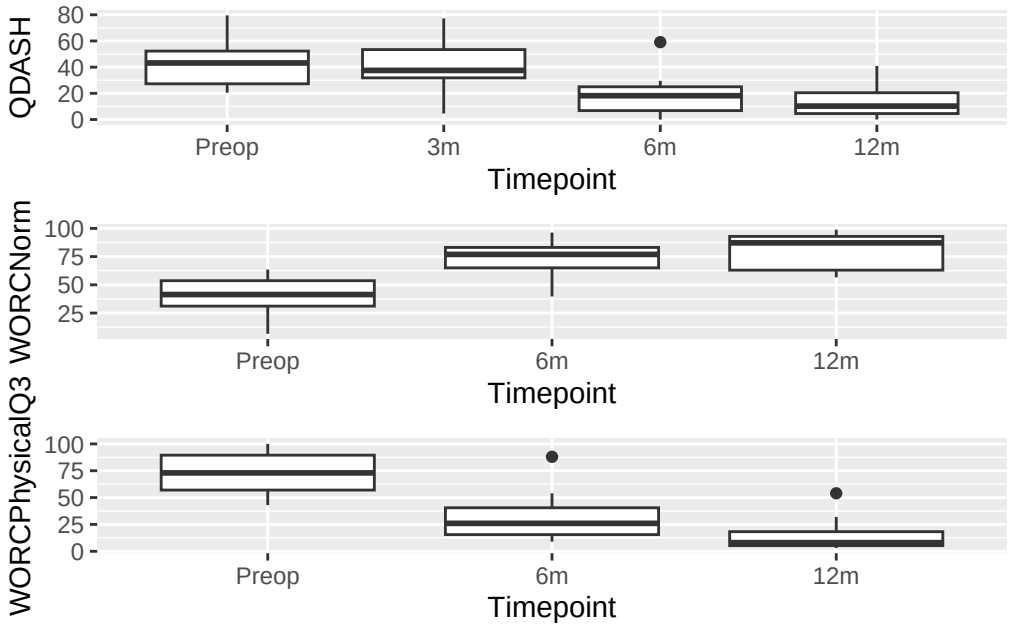

Figure 10: Complete case analysis of QDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 58: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - QuickDASH

Characteristic	Preop N = 26[1]	3m N = 27[1]	6m N = 26[1]	12m N = 25[1]
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)

Characteristic	Preop N = 26[1]	3m N = 27[1]	6m N = 26[1]	12m N = 25[1]

[1]Median (Q1 - Q3)

Table 59: Summary of PRULO Report 4 (Biceps Tenodesis) Cases - Western Ontario Rotator Cuff Index

Characteristic	Preop N = 26[1]	6m N = 26[1]	12m N = 25[1]
WORCNorm	41 (27 - 54)	77 (63 - 84)	87 (63 - 93)
WORCPhysicalQ3	73 (52 - 90)	26 (12 - 44)	8 (5 - 19)

[1]Median (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 = 27[1]	**None** N = 1	**Tenodesis** N = 25	**Ten**
Age at Initial Consultation (Years)	Median (Q1, Q3)	61 (52, 69)	65 (65, 65)	61 (55, 69)	4
Male	% (n)	89 (24)	100 (1)	92 (23)	
Cohort					
Rotator Cuff	% (n)	100 (27)	100 (1)	100 (25)	
Dominant Side	% (n)	52 (13)	0 (0)	52 (12)	
Bilateral Presentation	% (n)	15 (4)	100 (1)	12 (3)	
Symptom Duration (Weeks)	Median (Q1, Q3)	32 (20, 123)	195 (195, 195)	31 (18, 87)	19
Symptom Duration Category[2]					
<=0.5	% (n)	35 (7)	0 (0)	39 (7)	
>0.5	% (n)	65 (13)	100 (1)	61 (11)	
Treatment Record Active[3]	% (n)	100 (27)	100 (1)	100 (25)	
Patient Record Active[4]	% (n)	100 (27)	100 (1)	100 (25)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[3]Treatment record remains active - no change to follow up

[4]Patient 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 = 27[1]	**None** N = 1[1]	**Tenodesis** N = 25[1]
Cuff Status			
Full Tear	89 (24)	100 (1)	88 (22)
Partial Tear	11 (3)	0 (0)	12 (3)
Treatment Type			
Primary	100 (27)	100 (1)	100 (25)
Product Count			
1	100 (27)	100 (1)	100 (25)
2	0 (0)	0 (0)	0 (0)
3	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)
Cuff Repair			
Augmented Cuff Repair	3.7 (1)	0 (0)	4.0 (1)
Cuff Repair	96 (26)	100 (1)	96 (24)
Repair Augmentation			
None	96 (26)	100 (1)	96 (24)
Other[2]	3.7 (1)	0 (0)	4.0 (1)
Labrum			
Capsulolabral Repair	3.7 (1)	0 (0)	4.0 (1)
None	96 (26)	100 (1)	96 (24)
Labrum Repair			
None	100 (26)	100 (1)	100 (24)
Capsule | Ligament			
Capsulotomy	7.4 (2)	0 (0)	8.0 (2)
None	93 (25)	100 (1)	92 (23)
Glenoid			

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

Characteristic	Overall N = 27[1]	None N = 1[1]	Tenodesis N = 25[1]
None	100 (27)	100 (1)	100 (25)
Adjunct Procedure			
None	63 (17)	0 (0)	68 (17)
Subacromial Bursectomy; Acromioplasty	7.4 (2)	0 (0)	4.0 (1)
Subacromial Decompression	15 (4)	0 (0)	16 (4)
Subacromial Decompression; Distal Clavicle Resection	11 (3)	100 (1)	8.0 (2)
Subacromial Decompression; Subacromial Bursectomy	3.7 (1)	0 (0)	4.0 (1)

[1]% (n)

[2]Biceps 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 64: Summary of PRULO Report 5 (Rotator Cuff) Cases - Postoperative Events

Characteristic	N = 27[1]	95% CI
Infection	0 (0)	0.00 - 16

Characteristic	N = 27[1]	95% CI
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[2]	0 (0)	0.00 - 16
Reoperation[3]	0 (0)	0.00 - 16
Subsequent Treatment[4]		
Not Applicable	100 (27)	84 - 100

[1]% (n)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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There are no reoperations to report.
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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.

Table 65: Summary of PRULO Report 5 (Rotator Cuff) Cases - QuickDASH

Characteristic	Preop N = 26[1]	3m N = 27[1]	6m N = 26[1]	12m N = 25[1]
QDASH	39 (27 - 52)	36 (25 - 48)	20 (9 - 27)	8 (2 - 34)

Characteristic	Preop N = 26[1]	3m N = 27[1]	6m N = 26[1]	12m N = 25[1]
QDASHDelta	NA (NA - NA)	11 (0 - 16)	23 (9 - 39)	39 (20 - 50)

[1]Median (Q1 - Q3)

Table 66: Summary of PRULO Report 5 (Rotator Cuff) Cases - WORC Normalised and WORC (Physical) Q3

Characteristic	Preop N = 26[1]	6m N = 26[1]	12m N = 25[1]
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)

[1]Median (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 Category[1]		
<=0.5	% (n)	26 (7)

Characteristic	Statistic	Tenodesis N = 36
>0.5	% (n)	74 (20)
Treatment Record Active[2]	% (n)	97 (35)
Patient Record Active[3]	% (n)	100 (36)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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%)

Characteristic	N = 36[1]
Cuff Repair	24 (67%)
None	11 (31%)
Repair Augmentation	
None	28 (97%)
Other[2]	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%)
Other[2]	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%)

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

Characteristic	N = 36[1]
Subacromial Bursectomy; Acromioplasty	1 (2.8%)
Subacromial Decompression	4 (11%)
Subacromial Decompression; Distal Clavicle Resection	4 (11%)
Subacromial Decompression; Subacromial Bursectomy	1 (2.8%)

[1]n (%)

[2]Biceps 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 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

Characteristic	N = 36[1]	95% CI
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
Reoperation[2]	2.8 (1)	0.15 - 16
Subsequent Treatment[3]		
Nonoperative Management	2.8 (1)	0.15 - 16
Not Applicable	97 (35)	84 - 100

[1]% (n)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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10.4.5 Patient-Reported Outcomes

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

Table 72: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - QuickDASH

Characteristic	Preop N = 35[1]	3m N = 36[1]	6m N = 35[1]	12m N = 33[1]
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)

[1]Median (Q1 - Q3)

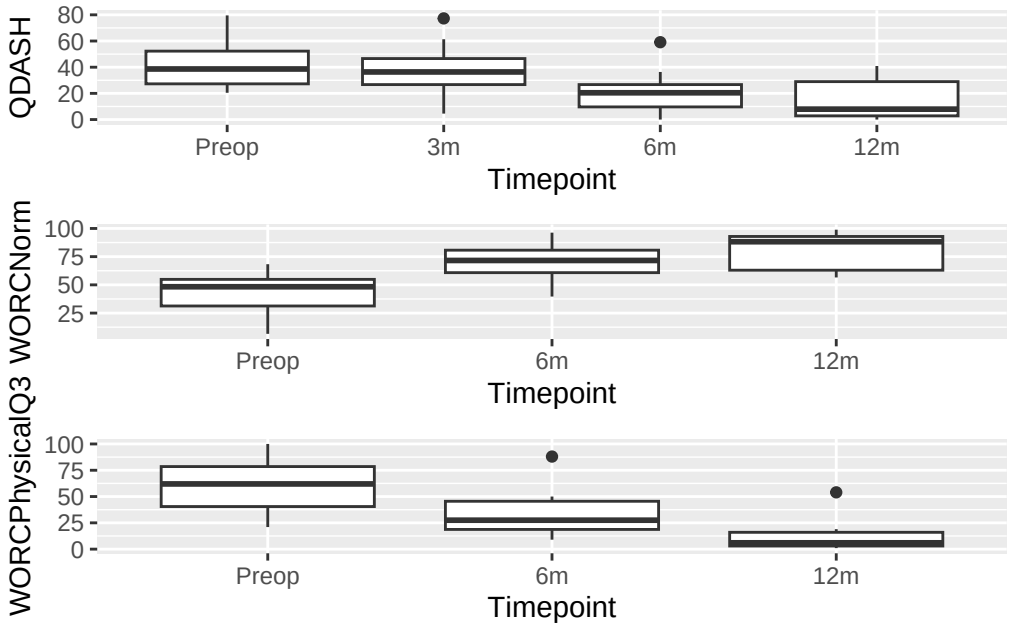

Figure 11: Complete case analysis of QuickDASH(Top), WORC Normalised (Middle) and WORC Physical Question 3 (Bottom).

Table 73: Summary of PRULO Report 5 (Biceps Tenodesis) Cases - WORC Normalised

Characteristic	**Preop** N = 35[1]	**6m** N = 35[1]	**12m** N = 33[1]
WORCNorm	41 (27 - 54)	72 (59 - 84)	84 (57 - 95)
WORCPhysicalQ3	67 (43 - 84)	25 (18 - 44)	16 (5 - 32)

[1]Median (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.

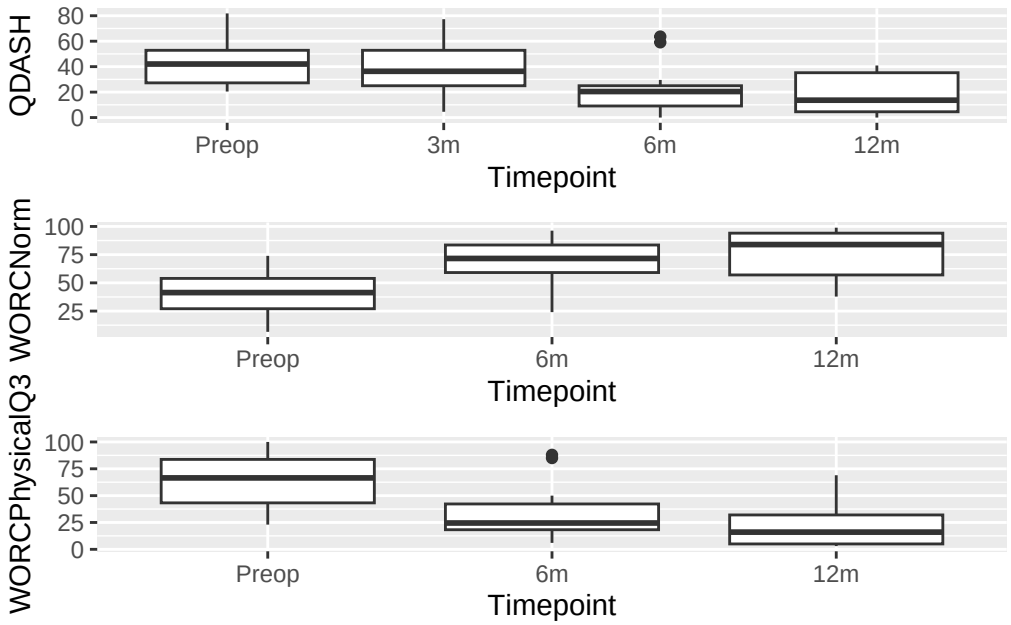

Figure 12: Complete case analysis of QDASH(Top), WORC Normalised (Middle), and WORC Physical Question 3 (Bottom)

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 Category[1]		
<=0.5	% (n)	33 (13)
>0.5	% (n)	68 (27)
Treatment Record Active[2]	% (n)	95 (63)
Patient Record Active[3]	% (n)	100 (66)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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)

Characteristic	N = 66[1]
Labrum Repair	73 (48)
None	20 (13)
LabrumRepair	
Bankart	66 (35)
None	3.8 (2)
Not Repaired	9.4 (5)
Other[2]	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)

Characteristic	N = 66[1]

[1]% (n)

[2]Labral 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)

Characteristic	N = 66[1]
Other	0 (0)
Reoperation[2]	3 (2)
Subsequent Treatment[3]	
New Procedure	2 (1)
Nonoperative Management	2 (1)
Not Applicable	97 (64)
Reoperation Delay (Weeks)[4]	86.4 (3.3)

[1]% (n); Mean (SD)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[4]Time between index procedure and reoperation

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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11.3.5 Patient-Reported Outcomes

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

Table 78: Summary of PRULO Report 6 (All) Cases - QuickDASH

Characteristic	Preop N = 65[1]	3m N = 66[1]	6m N = 64[1]	12m N = 63[1]
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)

[1]Median (Q1 - Q3)

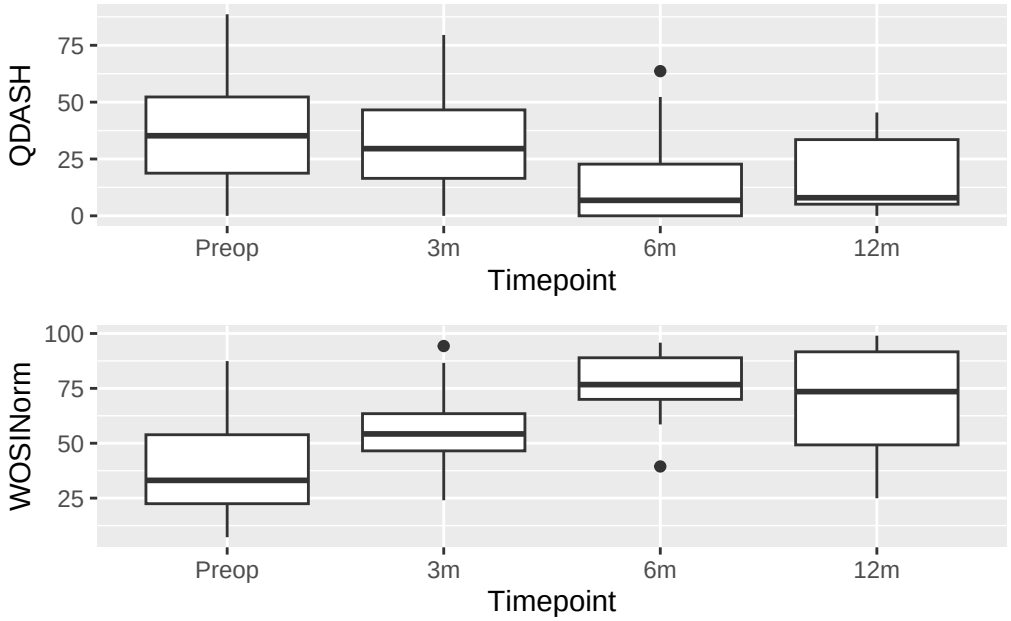

Figure 13: Complete case analysis of QDASH(Top), WOSI Index (Bottom)

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)

Characteristic	Statistic	N = 35
Symptom Duration (Weeks)	Median (Q1, Q3)	39 (18, 139)
Symptom Duration Category[1]		
<=0.5	% (n)	46 (11)
>0.5	% (n)	54 (13)
Treatment Record Active[2]	% (n)	97 (34)
Patient Record Active[3]	% (n)	100 (35)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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)

Characteristic	N = 35[1]
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)

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

Characteristic	N = 35[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 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)

Characteristic	N = 35[1]
Stiffness	3 (1)
Neurological	0 (0)
Thrombosis	0 (0)
Other	0 (0)
Reoperation[2]	3 (1)
Subsequent Treatment[3]	
New Procedure	3 (1)
Not Applicable	97 (34)
Reoperation Delay (Weeks)[4]	88.7 (NA)

[1]% (n); Mean (SD)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[4]Time between index procedure and reoperation

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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11.4.5 Patient-Reported Outcomes

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

Table 84: Summary of PRULO Report 6 (Bankart Repair) Cases - QuickDASH and WOSI Normalised

Characteristic	Preop N = 35[1]	3m N = 35[1]	6m N = 35[1]	12m N = 35[1]
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)

[1]Median (Q1 - Q3)

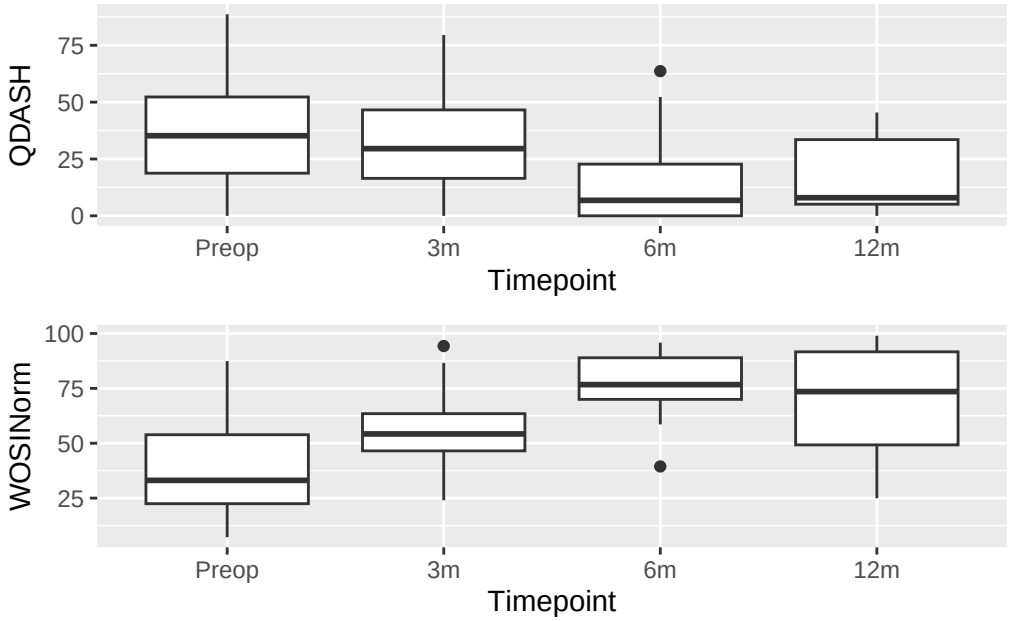

Figure 14: Complete case analysis of QDASH(Top), WOSI Index (Bottom)

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 Category[1]		
<=0.5	% (n)	39 (9)
>0.5	% (n)	61 (14)
Treatment Record Active[2]	% (n)	97 (38)
Patient Record Active[3]	% (n)	100 (39)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient 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)

Characteristic	N = 39[1]
Labrum Repair	
Bankart	80 (28)
None	2.9 (1)
Not Repaired	8.6 (3)
Other[2]	8.6 (3)
Capsule | Ligament	
Capsular Shift	31 (12)
Capsulotomy	2.6 (1)
None	62 (24)
Other[2]	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)

[2]Labral 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)
Reoperation[2]	5 (2)
Subsequent Treatment[3]	
New Procedure	3 (1)
Not Applicable	97 (38)
Reoperation Delay (Weeks)[4]	61.4 (38.7)

[1]% (n); Mean (SD)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

Characteristic	N = 39[1]

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[4]Time between index procedure and reoperation

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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12.3.5 Patient-Reported Outcomes

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

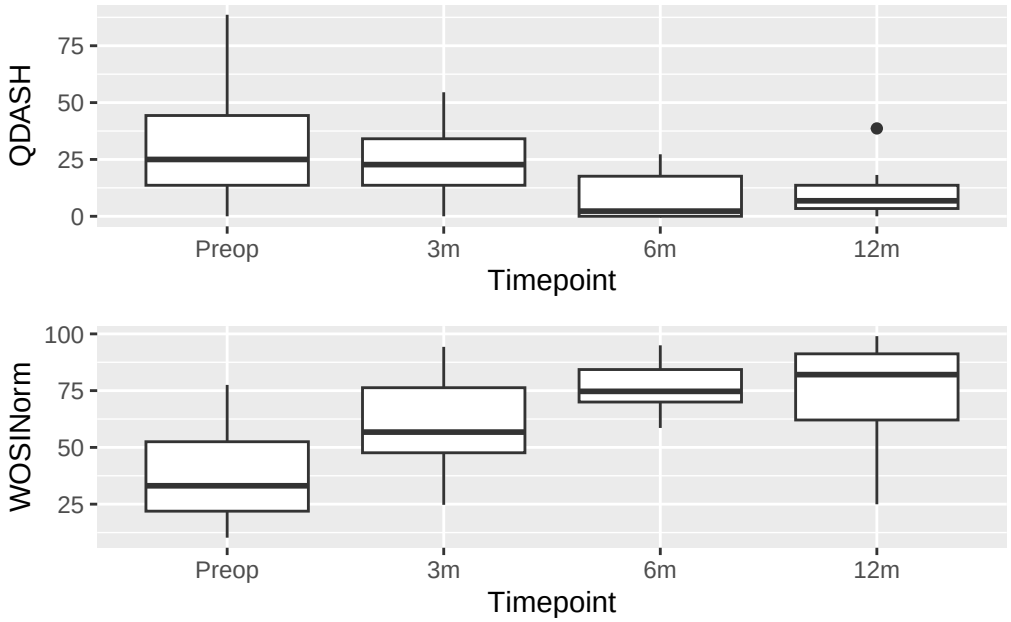

Figure 15: Complete case analysis of QuickDASH and WOSI Normalised

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

Characteristic	Preop N = 39[1]	3m N = 39[1]	6m N = 38[1]	12m N = 37[1]
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)

Characteristic	Preop N = 39[1]	3m N = 39[1]	6m N = 38[1]	12m N = 37[1]
WOSIDelta	NA (NA - NA)	-59 (-79 - -48)	33 (30 - 36)	44 (36 - 58)

[1]Median (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 90: 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 Category[1]		
<=0.5	% (n)	40 (8)
>0.5	% (n)	60 (12)
Treatment Record Active[2]	% (n)	96 (27)
Patient Record Active[3]	% (n)	100 (28)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient record remains open - no change to consent or mortality status

12.4.2 Surgical Details

Surgical findings and management strategies are summarised below.

Table 91: 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)

Characteristic	N = 28[1]
Capsule | Ligament	
Capsular Shift	36 (10)
None	57 (16)
Other[2]	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)

[2]Labral 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 92: 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

Table 93: Summary of PRULO Report 7 (Bankart Repair) Cases - Intraoperative Events

12.4.4 Adverse Events

Complications and adverse events are summarised below.

Table 94: 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)
Reoperation[2]	4 (1)
Subsequent Treatment[3]	
New Procedure	4 (1)
Not Applicable	96 (27)
Reoperation Delay (Weeks)[4]	88.7 (NA)

[1]% (n); Mean (SD)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[4]Time between index procedure and reoperation

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
```

12.4.5 Patient-Reported Outcomes

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

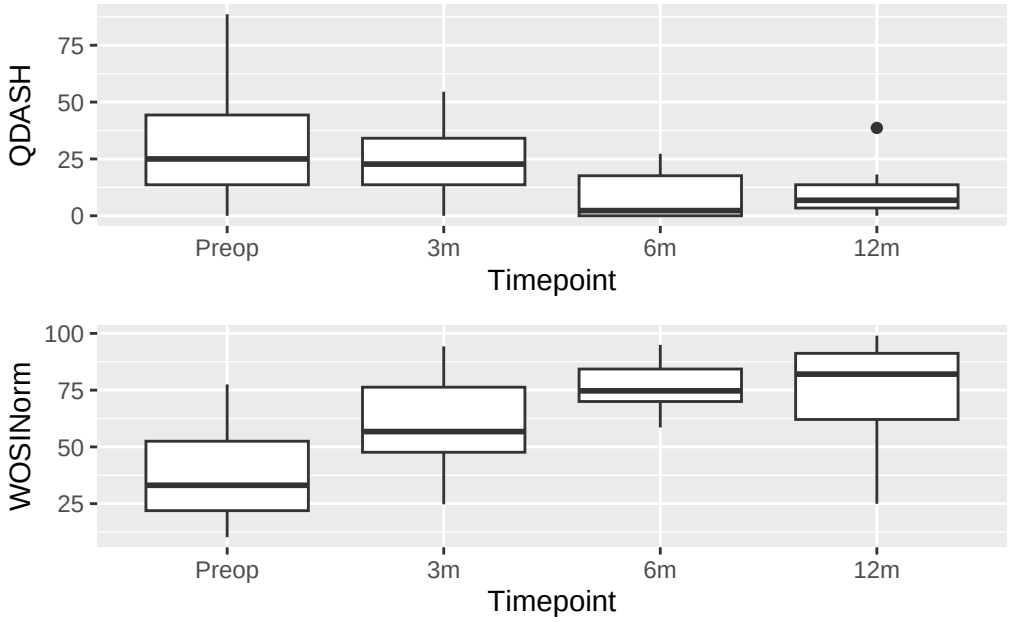

Figure 16: Complete case analysis of QuickDASH and WOSI Normalised

Table 95: Summary of PRULO Report 7 (Bankart Repair) Cases - QuickDASH and WOSI Normalised

Characteristic	**Preop** N = 28[1]	**3m** N = 28[1]	**6m** N = 28[1]	**12m** N = 28[1]
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)

[1]Median (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.

Table 96: Summary of PRULO Report 9 (All) Cases - Intraoperative Events

TreatmentID	Description	Intervention	PostopManagement
2729.1	grphon anchor came out	Modified surgical technique	No

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 97: 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
Other[2]	0 (0)	0.00 - 37
Reoperation[3]	22 (2)	3.9 - 60
Subsequent Treatment[4]		
Not Applicable	100 (9)	63 - 100

[1]% (n)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

Characteristic	N = 9[1]	95% CI

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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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 98: 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)

Characteristic	Statistic	N = 13
Cohort		
Glenohumeral Instability	% (n)	100 (13)
Dominant Side	% (n)	67 (4)
Bilateral Presentation	% (n)	7.7 (1)
Symptom Duration Category[1]		
<=0.5	% (n)	20 (1)
>0.5	% (n)	80 (4)
Treatment Record Active[2]	% (n)	100 (13)
Patient Record Active[3]	% (n)	100 (13)

[1]Dichotomised below or equal to 0.5 years or greater than 0.5 years

[2]Treatment record remains active - no change to follow up

[3]Patient record remains open - no change to consent or mortality status

15.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

Table 99: 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)

Characteristic	N = 13[1]
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)
Other[2]	18 (2)
Posterior	9.1 (1)
Capsule | Ligament	
Capsular Shift	15 (2)
Capsulotomy	7.7 (1)
None	69 (9)
Other[2]	7.7 (1)
Glenoid	
Latarjet	64 (7)

Table 101: Summary of PRULO Report 10 (All) Cases - Intraoperative Events

Characteristic	N = 13[1]
None	36 (4)
Adjunct Procedure	
None	100 (11)

[1]% (n)

[2]Labral 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 100: 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 102: 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

Characteristic	N = 13[1]	95% CI
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
Reoperation[2]	15 (2)	2.7 - 46
Subsequent Treatment[3]		
Not Applicable	100 (13)	72 - 100
Reoperation Delay (Weeks)[4]	31.5 (9.2)	-51 - 114

[1]% (n); Mean (SD)

[2]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[3]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

[4]Time between index procedure and reoperation

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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15.3.5 Patient-Reported Outcomes

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

Table 103: Summary of PRULO Report 10 (All) Cases - QuickDASH and WOSI

Characteristic	Preop N = 11[1]	3m N = 13[1]	6m N = 13[1]	12m N = 12[1]
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)

[1]Median (Q1 - Q3)

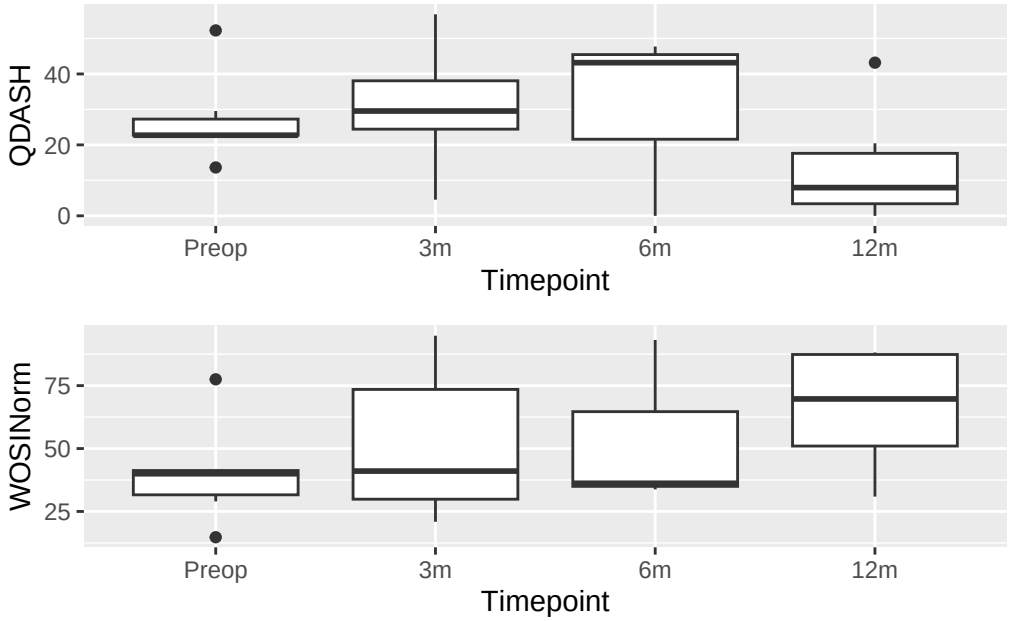

Figure 17: Complete case analysis of QuickDASH (Top) and WOSI Index Normalised (Bottom).

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 104: Summary of PRULO Report 11 (Rotator Cuff) Case - Patient Characteristics

Characteristic	**Statistic**	**Overall** N = 7[1]	**None** N = 4	**Tenodesis** N = 2	**Ten**
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.
Male	% (n)	57 (4)	50 (2)	100 (2)	
Cohort					
Rotator Cuff	% (n)	100 (7)	100 (4)	100 (2)	
Dominant Side	% (n)	100 (3)	100 (2)	NA (0)	
Bilateral Presentation					
No	% (n)	100 (7)	100 (4)	100 (2)	
Symptom Duration (Weeks)	Median (Q1, Q3)	33 (12, 53)	12 (12, 12)	NA (NA, NA)	
Symptom Duration Category[2]					
<=0.5	% (n)	50 (1)	100 (1)	NA (0)	
>0.5	% (n)	50 (1)	0 (0)	NA (0)	
Treatment Record Active[3]	% (n)	100 (7)	100 (4)	100 (2)	
Patient Record Active[4]	% (n)	100 (7)	100 (4)	100 (2)	

[1]Median (Q1, Q3); % (n)

[2]Dichotomised below or equal to 0.5 years or greater than 0.5 years

Characteristic	Statistic	Overall N = 7[1]	None N = 4	Tenodesis N = 2	Ten

[3]Treatment record remains active - no change to follow up

[4]Patient record remains open - no change to consent or mortality status

16.3.2 Surgical Details

Surgical findings and management strategies are summarised below.

Table 105: Summary of PRULO Report 11 (Rotator Cuff) Cases - Pathology and Surgical Details

Characteristic	Overall N = 7[1]	None N = 4[1]	Tenodesis N = 2[1]	Tenotomy N = 1[1]
Cuff Status				
Full Tear	71 (5)	75 (3)	50 (1)	100 (1)
Other[2]	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)

Characteristic	Overall N = 7[1]	None N = 4[1]	Tenodesis N = 2[1]	Tenotomy N = 1[1]
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)

[2]Biceps 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 106: 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

Table 107: Summary of PRULO Report 11 (Rotator Cuff) Cases - Intraoperative Events

16.3.4 Adverse Events

Complications and adverse events are summarised below.

Table 108: 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
Other[2]	0 (0)	0.00 - 44
Reoperation[3]	14 (1)	0.75 - 58
Subsequent Treatment[4]		
Not Applicable	100 (7)	56 - 100

[1]% (n)

[2]Myocardial Infarction

[3]A theatre procedure subsequent to the index surgery that does not involve removal, replacement or modifica

[4]Management undertaken for procedures that have suffered tissue failure or required hardware removal or re

Abbreviation: CI = Confidence Interval

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Failures were written to <a href="{{SheetIDs$AuditReport}}">Attachment 1</a> for further revi
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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.

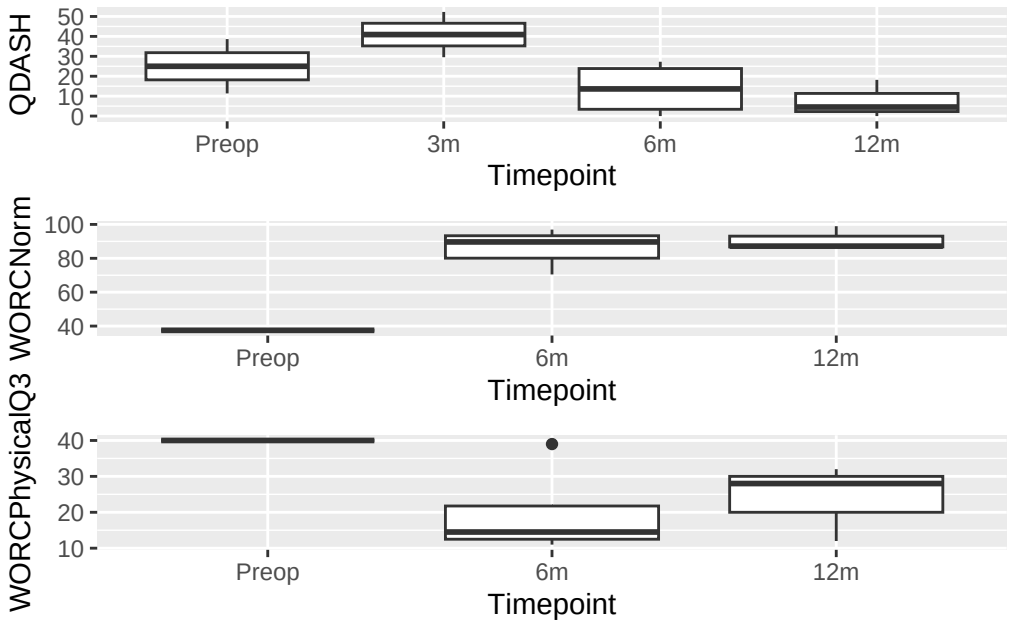

Figure 18: Complete case analysis of QDASH(Top), WORC Index Normalised (Middle), and WORC Physical Question 3 (Bottom)

Table 109: Summary of PRULO Report 11 (Rotator Cuff) Cases - QuickDASH

Characteristic	**Preop** N = 5[1]	**3m** N = 7[1]	**6m** N = 6[1]	**12m** N = 6[1]
QDASH	25 (11 - 39)	41 (30 - 52)	14 (2 - 25)	5 (0 - 18)

[1]Median (Q1 - Q3)

Table 110: Summary of PRULO Report 11 (Rotator Cuff) Cases - WORC Normalised and WORC Physical Question 3.

Characteristic	**Preop** N = 5[1]	**6m** N = 6[1]	**12m** N = 6[1]
WORCNorm	37 (37 - 37)	90 (70 - 97)	87 (86 - 99)

Characteristic	Preop N = 5[1]	6m N = 6[1]	12m N = 6[1]
WORCPhysicalQ3	40 (40 - 40)	15 (12 - 28)	28 (12 - 32)
WORCDelta	NA (NA - NA)	NA (NA - NA)	NA (NA - NA)

[1]Median (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.

Table 111: 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 Adva
Healix Advance Peek with Dynacord	206	100.0	
Healix Advance Knotless Peek	206	92.2	
Healix Advance Knotless BR	63	3.2	
Healix Advance BR with Dynacord	84	1.2	
Milagro Advance BR	44	2.3	
Gryphon ProKnot BR	66	1.5	
Gryphon BR with Orthocord	39	0.0	
Gryphon BR with Dynacord	2	0.0	
Gryphon PEEK with Dynacord	9	0.0	
Latarjet Experience	13	0.0	
Dynacord Freestrand Suture	10	60.0	
Dynatape Freestrand Suture	1	0.0	
Orthocord Freestrand Suture	2	100.0	

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.

19.1 Proportion with multiple products

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

Table 112: 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

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.

Gummesson, Christina, Michael M Ward, and Isam Atroshi. 2006. "The Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire (Quick DASH): Validity and Reliability Based on Responses Within the Full-Length DASH." *BMC Musculoskeletal Disorders* 7 (1). https://doi.org/10.1186/1471-2474-7-44.

Kirkley, Alexandra, Christine Alvarez, and Sharon Griffin. 2003. "The Development and Evaluation of a Disease-Specific Quality-of-Life Questionnaire for Disorders of the Rotator Cuff: The Western Ontario Rotator Cuff Index." *Clinical Journal of Sport Medicine* 13 (2): 84–92. https://doi.org/10.1097/00042752-200303000-00004.

Kirkley, Alexandra, Sharon Griffin, Heidi McLintock, and Linda Ng. 1998. "The Development and Evaluation of a Disease-Specific Quality of Life Measurement Tool for Shoulder Instability." *The American Journal of Sports Medicine* 26 (6): 764–72. https://doi.org/10.1177/03635465980260060501.

Scholes, Corey, Kevin Eng, Meredith Harrison-Brown, Milad Ebrahimi, Graeme Brown, Stephen Gill, and Richard Page. 2023. "Patient Registry of Upper Limb Outcomes (PRULO): A Protocol for an Orthopaedic Clinical Quality Registry to Monitor Treatment Outcomes." *Journal of Surgical Protocols and Research Methodologies* 2023 (4). https://doi.org/10.1093/jsprm/snad014.