Stage 2a IDEAL evaluation of a third-generation biocomposite suture anchor in arthroscopic rotator cuff repair: Supplementary analysis report

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# 1. Introduction

This analysis links to the [manuscript](#X6589fc6ab0dc82cf12099d1c2d40ab994e8410c) of the Healix BR product. The dataset is derived from the PRULO registry snapshot and live tables. A protocol has been previously prepared for the registry (Scholes et al. 2023).

## 1.1 Reporting

The study was reported according to the RECORD guidelines (Benchimol et al. 2015) and companion checklist.

The analysis was conducted in RStudio IDE (RStudio 2024.12.0+467 “Kousa Dogwood” Release) using *Rbase*, *quarto* and attached packages to perform the following;

* Data import and preparation
* Sample selection
* Describe and address missingness
* Data manipulation, modelling and visualisation of;
  + Patient characteristics
  + Pathology characteristics (diagnosis)
  + Management and surgical technique
  + Treatment and repair survival
  + Adverse events and complications
  + Patient reported outcomes
* Publish to posit connect for dissemination

## 1.2 Preparation

Packages were loaded initially with *pacman* package. Citations were applied to each library at first use in the text.

if (!require("pacman")) install.packages("pacman")  
pacman::p\_load(  
 "dplyr",  
 "flextable",  
 "litedown",  
 "grateful",  
 "modelsummary",  
 "quantreg",  
 "readr",  
 "knitr",  
 "cardx",  
 "forcats",  
 "gargle",  
 "googledrive",  
 "googlesheets4",  
 "openxlsx2",  
 "tidyverse",  
 "tidymodels",  
 "lubridate",  
 "gt",  
 "consort",  
 "gtsummary",  
 "survival",  
 "ggplot2",  
 "ggdist",  
 "ggfortify",  
 "mice",  
 "marginaleffects",  
 "patchwork",  
 "naniar",  
 "quantreg",  
 "broom",  
 "epoxy",  
 "broom.helpers",  
 "broom.mixed",  
 "lme4",  
 "stringr"  
 )

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| Table 1: Summary of package usage and citations   | Package | Version | Citation | | --- | --- | --- | | base | 4.4.2 | R Core Team (2024) | | broom | 1.0.8 | Robinson, Hayes, and Couch (2025) | | broom.helpers | 1.20.0 | Larmarange and Sjoberg (2025) | | broom.mixed | 0.2.9.6 | Bolker and Robinson (2024) | | cardx | 0.2.3 | Sjoberg, Yogasekaram, and de la Rua (2025) | | consort | 1.2.2 | Dayim (2024) | | dplyr | 1.1.4 | Wickham et al. (2023) | | epoxy | 1.0.0 | Aden-Buie (2023) | | flextable | 0.9.7 | Gohel and Skintzos (2024) | | forcats | 1.0.0 | Wickham (2023a) | | gargle | 1.5.2 | Bryan, Citro, and Wickham (2023) | | ggdist | 3.3.2 | Kay (2024b); Kay (2024a) | | ggfortify | 0.4.17 | Tang, Horikoshi, and Li (2016); Horikoshi and Tang (2018) | | ggplot2 | 3.5.1 | Wickham (2016) | | googledrive | 2.1.1 | D’Agostino McGowan and Bryan (2023) | | googlesheets4 | 1.1.1 | Bryan (2023) | | gt | 0.11.1 | Iannone et al. (2024) | | gtsummary | 2.1.0 | Sjoberg et al. (2021) | | knitr | 1.50 | Xie (2014); Xie (2015); Xie (2025a) | | litedown | 0.6 | Xie (2025b) | | lme4 | 1.1.37 | Bates et al. (2015) | | lubridate | 1.9.4 | Grolemund and Wickham (2011) | | marginaleffects | 0.25.1 | Arel-Bundock, Greifer, and Heiss (2024) | | mice | 3.17.0 | van Buuren and Groothuis-Oudshoorn (2011) | | modelsummary | 2.3.0 | Arel-Bundock (2022) | | naniar | 1.1.0 | Tierney and Cook (2023) | | openxlsx2 | 1.14 | Barbone and Garbuszus (2025) | | pacman | 0.5.1 | Rinker and Kurkiewicz (2018) | | patchwork | 1.3.0 | Pedersen (2024) | | quantreg | 6.1 | Koenker (2025) | | readr | 2.1.5 | Wickham, Hester, and Bryan (2024) | | rmarkdown | 2.29 | Xie, Allaire, and Grolemund (2018); Xie, Dervieux, and Riederer (2020); Allaire et al. (2024) | | stringr | 1.5.1 | Wickham (2023b) | | survival | 3.7.0 | Terry M. Therneau and Patricia M. Grambsch (2000); Therneau (2024) | | tidymodels | 1.3.0 | Kuhn and Wickham (2020) | | tidyverse | 2.0.0 | Wickham et al. (2019) | |

The packages drawn on to produce the following report are summarised in [Table 1](#tbl-pkgcite).

## 1.3 Authorisations

Access to PRULO datasets was pre-authorised using the *gargle* package and *googledrive*.

## 1.4 Functions for Processing

A function was generated to retrieve files using the *googledrive* package, to call on later in the analysis for processing data imports.

get\_specific\_snapshot <- function(folder\_name, base\_folder\_id = base\_folder\_id1) {  
 tryCatch({  
 # Check if the folder exists in the base directory  
 folder <- googledrive::drive\_ls(as\_id(base\_folder\_id), pattern = paste0("^", folder\_name, "$"))  
   
 if(nrow(folder) == 0) {  
 stop(paste("Folder", folder\_name, "not found"))  
 }  
   
 # Find the snapshot file in the specified folder  
 snapshot\_file <- googledrive::drive\_ls(  
 folder$id,   
 pattern = "Registry data snapshot\\.xlsx$"  
 )  
   
 if(nrow(snapshot\_file) == 0) {  
 stop("No snapshot file found in specified folder")  
 }  
   
 # Return both pieces of information as a list  
 return(list(  
 snapshot = snapshot\_file,  
 folder\_name = folder$name  
 ))  
   
 }, error = function(e) {  
 stop(paste("Error finding specified snapshot:", e$message))  
 })  
}

## 1.5 Analysis Aim

To describe the clinical and patient-reported outcomes, in patients presenting for surgical review of shoulder pathology and electing to undergo reconstruction or repair of soft-tissue structures with a biodegradable anchor (Healix Advance BR, Depuy-Mitek, USA), at a private, regional orthopaedic clinic between 2020 - 2024.

## 1.6 Analysis Hypotheses

It was hypothesised that i) a low incidence of adverse events would be observed and ii) that significant improvements in general function (QuickDASH) and pathology-specific (WORC) outcomes would be observed at up to 12months follow up.

# 2. Methods

### 2.0.1 RECORD [4] - Study Design

Subgroup analysis of a clinical registry embedded into private practice. Observational, cohort design.

## 2.1 Data Import and Preparation

Data was retrieved using *googlesheets4* to retrieve live database tables. Source files were specified and stored as global variables to call on in further functions.

# Authenticate for sheets using the same token  
gs4\_auth(token = drive\_token())  
  
  
  
ComplicTable <- googlesheets4::read\_sheet(  
 ss = SheetIDs$DbSS,  
 sheet = "Complications",   
 col\_names = TRUE,   
 col\_types = "tcccDccD"  
 )  
  
ImplantTable <- googlesheets4::range\_read(  
 ss = SheetIDs$ImplantSS,  
 sheet = "Healix",   
 range = "F1:I",  
 col\_names = TRUE,   
 col\_types = "nccc"  
 )  
  
# AcctData <- googlesheets4::range\_read(  
# ss = SheetIDs$AcctSS,  
# sheet = "AcctType2015",   
# range = "A1:G",  
# col\_names = TRUE,   
# col\_types = "ccccDcc"  
# )  
  
#To match to acctData  
PatientTable <- googlesheets4::range\_read(  
 ss = SheetIDs$DbSS,  
 sheet = "Patient",   
 range = "A10:N",  
 col\_names = FALSE,   
 col\_types = "DccccDcccDcicc"  
 )  
  
  
Patient\_Col <- c(  
 "PatientCreationDate",  
 "PatientID",  
 "LastName",   
 "FirstName",   
 "AlternateID",   
 "DateOfBirth",   
 "Sex",   
 "RegistryStatus",   
 "RegistryStatusNotes",   
 "DateRegistryStatus",   
 "NotificationMethod",   
 "NoTreatmentRecords",   
 "Email",   
 "Phone"  
)  
  
colnames(PatientTable) <- Patient\_Col

A static registry snapshot was retrieved using the pre-specified function (see *Functions for Processing)* and formatted using *openxlsx* based on the fixed date of preparation of the snapshot (31-Mar-2024) and using *tidyverse* syntax and associated packages (*dplyr, lubridate*). Date columns were prepared for further analysis using *lubridate*.

# Authenticate for sheets using the same token  
gs4\_auth(token = drive\_token())  
  
# To get a snapshot from a specific folder (e.g., "20230415")  
specific\_snapshot <- get\_specific\_snapshot("20240331")

# You can then use these in your subsequent code:  
temp\_file1 <- tempfile(fileext = ".xlsx")  
drive\_download(  
 file = specific\_snapshot$snapshot$id,  
 path = temp\_file1,  
 overwrite = TRUE  
)  
  
# Correction to reset back to excel origin  
DaysDiff <- as.numeric(as.duration(interval(ymd("1899-12-30"), ymd("1970-01-01"))),"days")  
  
SnapshotGen <- openxlsx2::read\_xlsx(  
 temp\_file1,  
 sheet = "ShoulderGeneral",  
 colNames = TRUE,  
 detectDates = TRUE  
 ) |> dplyr::mutate(  
 Cohort = "General"  
 )  
  
SnapshotRC <- openxlsx2::read\_xlsx(  
 temp\_file1,  
 sheet = "RotatorCuff",  
 colNames = TRUE,  
 detectDates = TRUE  
 ) |> dplyr::mutate(  
 Cohort = "Rotator Cuff"  
 )  
  
SnapshotGH <- openxlsx2::read\_xlsx(  
 temp\_file1,  
 sheet = "GlenohumeralInstability",  
 colNames = TRUE,  
 detectDates = TRUE  
 ) |> dplyr::mutate(  
 Cohort = "Glenohumeral Instability"  
 )  
  
  
STROBEInput <- openxlsx2::read\_xlsx(  
 temp\_file1,  
 sheet = "Strobe\_Input",  
 colNames = TRUE,  
 detectDates = TRUE  
 )

Dataframes were combined into one for further analysis.

SnapshotComb <- SnapshotRC |> dplyr::bind\_rows(  
 dplyr::select(SnapshotGH, -ExternalStudyTag)  
 ) |> bind\_rows(  
 dplyr::select(  
 SnapshotGen,   
 -ExternalStudyTag)  
 ) |> dplyr::mutate(  
 PatientID = stringr::str\_split\_i(TreatmentUID,"\\.",1)  
 ) |> relocate(  
 PatientID, .before = TreatmentUID  
 ) |> mutate(  
 CombID = paste0(PatientID,".",AffectedSide)  
 ) |> relocate(  
 CombID, .after = TreatmentUID  
 ) |> relocate(  
 Cohort, .before = EligibleAtPreop  
 )

## 2.2 Revision 1 - Update Feb 2025

*R316 and R317*

…it is difficult to understand why the available data would be so low with regards to BMI and insurance type. It would seem to this reviewer that this would be fairly straightforward data to obtain from the medical record, if not from the patient themselves.

*BMI is irretrievable from the clinical records - it is stored in another system.*

…it is not clear to me why the data for tear type (full versus partial), involved tendons, etc have less than complete available data.

An additional export of account data was prepared and imported to the workspace using the *readr* package, as well as *tidyverse* syntax and *stringr*, to categorise text fields.

#Read in full text file  
#  
temp\_file2 <- tempfile(fileext = ".txt")  
drive\_download(  
 file = as\_id(AcctNewFile),  
 path = temp\_file2,  
 overwrite = TRUE  
)  
  
AcctDataNew <- readr::read\_tsv(  
 file = temp\_file2,  
 col\_names = TRUE,  
 #trim\_ws = TRUE,  
 col\_types = list(  
 Id = "c",  
 AccountType = "c",  
 Surname = "c",  
 FirstName = "c",  
 DOB = col\_date(format = "%d/%m/%Y"),  
 UsualProvider = "c",  
 HealthFundName = "c",  
 HccPensionNum = "c",  
 DvaNum = "c"  
),  
col\_select = c(  
 AlternateID = Id,  
 LastName = Surname,  
 FirstName,  
 DateOfBirth = DOB,  
 HealthFundName  
 )  
) |> dplyr::mutate(  
 DateOfBirth2 = as.numeric(DateOfBirth),  
 HealthFund2 = str\_to\_lower(HealthFundName),  
 LastName = stringr::str\_to\_title(LastName)  
) |> unite(  
 col = "CombID",  
 sep = ".",  
 c("FirstName","LastName","DateOfBirth2"),  
 remove = FALSE  
) |> mutate(  
 CombID = stringr::str\_squish(CombID),  
 AccountType2 = case\_when(  
 stringr::str\_detect(HealthFund2,"nil|uninsured") == TRUE ~ "Uninsured",  
 stringr::str\_detect(HealthFund2,"fund|pty|limit\*|nib|hcf|bupa|medibank|hbf|ahm|health|hba|a.u|^unity$|cbhs|unity|^yes$") == TRUE ~ "Private",  
 stringr::str\_detect(HealthFund2,"dva|vaff|vet|aff|def") == TRUE ~ "DVA",  
 stringr::str\_detect(HealthFund2,"work\*|wc|w//c\*") == TRUE ~ "WorkCover",  
 stringr::str\_detect(HealthFund2,"^tac$") == TRUE ~ "TAC",  
 stringr::str\_detect(HealthFund2,"sf|self") == TRUE ~ "SelfFund",  
 )  
 ) |> left\_join(  
 PatientTable |> dplyr::select(  
 PatientID,  
 AlternateID  
 ),  
 by = "AlternateID"  
 ) |> dplyr::filter(  
 PatientID %in% SnapshotComb$PatientID  
)

Additional intraoperative data was retrieved manually into a table and imported using *googlesheets.*

# Authenticate for sheets using the same token  
gs4\_auth(token = drive\_token())  
  
  
SurgicalGapFill <- googlesheets4::read\_sheet(  
 ss = SheetIDs$SurgicalGapSS,   
 sheet = "Surgical",   
 col\_names = TRUE,  
 col\_types = "ccccccccccccccccccccc"  
 ) |> dplyr::select(  
 !c(  
 FirstName,  
 LastName  
 )  
 )

Check that column names are aligned

Upon review, one row of data was found to have a data entry error for one field (CuffTearSize) which was manually updated in the table.

SnapshotComb1 <- dplyr::rows\_update(  
 SnapshotComb,  
 SurgicalGapFill,  
 by = "TreatmentUID"  
) |> dplyr::mutate( #Update wayward tear size input  
 CuffTearSizeAP = if\_else(  
 TreatmentUID == "1789.1",  
 "20",  
 CuffTearSizeAP  
 )  
)

### 2.2.1 RECORD [5] - Setting

The PRULO registry is based in a regional private practice for upper limb orthopaedics (Scholes et al. 2023).

The registry has 2681 treatment records with the first patient enrolled 13 October 2020 and the final treatment record created 26 March 2024.The registry snapshot was extracted on 31 March 2024. Patients are followed for up to 2 years after surgery to capture treatment outcomes and patient-reported outcome measures (PROMs).

## 2.3 Record [6] Participants

#### Record [6.1] Sample selection

Identify cases receiving the suture of interest. Cases were identified by SKUs identified from the SKU database maintained as part of implant tracking within the registry. Cases were not restricted by available follow up.

Inclusion criteria;

* Case involves anchor of interest
* Case is the index procedure within the registry (first use of suture)
* Patient has not withdrawn consent for inclusion of data in the registry
* Treatment record is eligible for surgery (it has occurred)

Data manipulation (add columns and filter tables based on column values) was performed with *tidyverse* and converted to display format using *gt*.

##Identify Index List by SKU/Ref  
  
ImplantTable2 <- ImplantTable |> filter(stringr::str\_detect(  
 stringr::str\_to\_lower(Description),  
 "advance.br")  
)  
  
IncludeAny = paste(ImplantTable2$Reference,sep = "|")

ImplantTable2 |> gt(  
 rowname\_col = "row",  
 caption = "Summary of SKUs (Reference) used to identify cases of interest from the PRULO registry"  
 )

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Table 2   | Size (mm) | Description | Category | Reference | | --- | --- | --- | --- | | 4.5 | Healix Advance BR OrthoCord | Anchor + Suture | 10886705021314 | | 4.5 | Healix Advance BR 3 strand Orthocord | Anchor + Suture | 10886705021321 | | 5.5 | Healix Advance BR OrthoCord | Anchor + Suture | 10886705021338 | | 5.5 | Healix Advance BR 3 strand Orthocord | Anchor + Suture | 10886705021345 | | 6.5 | Healix Advance BR OrthoCord | Anchor + Suture | 10886705021369 | | 6.5 | Healix Advance BR 3 strand Orthocord | Anchor + Suture | 10886705021376 | | 4.5 | Healix Advance BR PermaCord | Anchor + Suture | 10886705024803 | | 4.5 | Healix Advance BR 3 strand PermaCord | Anchor + Suture | 10886705024735 | | 5.5 | Healix Advance BR PermaCord | Anchor + Suture | 10886705024810 | | 5.5 | Healix Advance BR 3 strand PermaCord | Anchor + Suture | 10886705024827 | | 6.5 | Healix Advance BR PermaCord | Anchor + Suture | 10886705024834 | | 6.5 | Healix Advance BR 3 strand PermaCord | Anchor + Suture | 10886705024681 | | 4.5 | Healix Advance BR PermaTape (Blue) | Anchor + Tape | 10886705027798 | | 4.5 | Healix Advance BR PermaTape (White/Blue) | Anchor + Tape | 10886705027804 | | 5.5 | Healix Advance BR PermaTape (Blue) | Anchor + Tape | 10886705027811 | | 5.5 | Healix Advance BR PermaTape (White/Blue) | Anchor + Tape | 10886705027828 | | 6.5 | Healix Advance BR PermaTape (Blue) | Anchor + Tape | 10886705029266 | | 6.5 | Healix Advance BR PermaTape (White/Blue) | Anchor + Tape | 10886705029273 | | 4.5 | Healix Advance BR Dynacord (x2) with Needles | Anchor + Suture | 10886705029440 | | 4.5 | Healix Advance BR Dynacord (x2) | Anchor + Suture | 10886705029402 | | 4.5 | Healix Advance BR Dynacord (x3) | Anchor + Suture | 10886705029396 | | 5.5 | Healix Advance BR Dynacord (x2) | Anchor + Suture | 10886705029464 | | 5.5 | Healix Advance BR Dynacord (x3) | Anchor + Suture | 10886705029457 | | 5.5 | Healix Advance BR Dynacord (x2) with Needles | Anchor + Suture | 10886705029471 | | 6.5 | Healix Advance BR Dynacord (x2) | Anchor + Suture | 10886705029525 | | 6.5 | Healix Advance BR Dynacord (x3) | Anchor + Suture | 10886705029518 | | 6.5 | Healix Advance BR Dynacord (x2) with Needles | Anchor + Suture | 10886705029532 | |

A dataframe was prepared to generate a flow chart of record retrieval, screening and patient follow up within the sample of interest.

#| label: Consort-Diagram  
#| code-summary: "CONSORT|STROBE"  
  
# Inclusion  
# - Surgical treatment  
# - With hardware of interest  
# After "induction"  
# - Patient withdraws consent  
# - Treatment fails before analysis date  
# - Not eligible for 12m followup  
#   
CurrentDate <- as.character("20240331")  
  
  
STROBEFlow <- STROBEInput |> dplyr::filter(  
 !is.na(TreatmentUID)  
) |> dplyr::left\_join(  
 SnapshotComb1 |> dplyr::select(  
 TreatmentUID,  
 CombID,  
 DateInitialExamination,  
 EligibleAtPreop,  
 EligibleAtx12months  
 ),  
 by = "TreatmentUID"  
) |> dplyr::mutate(  
 exclusion1 = case\_when(  
 is.na(SurgicalTreatment) ~ "Not a surgical treatment",  
 SurgicalTreatment == "Surgical" ~ NA\_character\_,  
 .default = "Not a surgical treatment"  
 ),  
 exclusion2 = case\_when(  
 is.na(exclusion1) & stringr::str\_detect(RegistryStatus,"Opt-out") ~ "Patient Opt-Out",  
 is.na(exclusion1) & is.na(ImplantCodes) ~ "No hardware of interest",  
 is.na(exclusion1) & Surgeon != "RP" ~ "Other Surgeon",  
 is.na(exclusion1) & stringr::str\_detect(ImplantCodes,paste(IncludeAny,collapse = "|")) ~ NA\_character\_,  
 .default = "No hardware of interest"  
 ),  
 followup = if\_else(  
 is.na(exclusion1) & is.na(exclusion2),  
 TreatmentUID,  
 NA\_character\_  
 ),  
 lost\_followup = case\_when(  
 is.na(exclusion1) & is.na(exclusion2) & TreatmentStatus == "Failed" & (ymd(DateStatusChange) < ymd(CurrentDate)) ~ "Repair failure",  
 is.na(exclusion1) & is.na(exclusion2) & TreatmentStatus == "No further followup" & (ymd(DateStatusChange) < ymd(CurrentDate)) ~ "Patient Opt-out",  
 is.na(exclusion1) & is.na(exclusion2) & TreatmentStatus == "Ongoing" & is.na(EligibleAtx12months) ~ "Not eligible for followup"  
 ),  
 mitt = if\_else(  
 !is.na(followup) & is.na(lost\_followup),  
 TreatmentUID,  
 NA\_character\_  
)  
) |> dplyr::rename(  
 trialno = "TreatmentUID"  
)

The combined snapshot dataframe was filtered using the results of the STROBE flowchart dataframe and the sample of interest retrieved.

SelectComb <- SnapshotComb1 |> dplyr::select(  
 Cohort,  
 EligibleAtPreop:SignificantComorbidities\_Preop,  
 EligibleAtIntraop:OtherShoulderGirdle,  
 starts\_with("QDASH\_TotalScore"),  
 starts\_with("EligibleAt"),   
 starts\_with("WORC"),  
 ComplicationOccurrence) |>   
 filter(  
 TreatmentUID %in% STROBEFlow$followup  
 ) |>   
 relocate(  
 Cohort, .before = EligibleAtPreop  
 ) |> left\_join(  
 SnapshotComb |>  
 group\_by(CombID) |>  
 summarise(CombIDnAll = n()),  
 by = "CombID"  
 ) |>  
 relocate(  
 CombIDnAll, .after = CombID  
 )

The reduced snapshot was filtered further, to remove any non-index surgical procedures from each shoulder from the study mastersheet.

# Add a sequential label of treatment records per patient + joint in order of surgery date  
SelectComb1 <- SelectComb |> group\_by(CombID) |> mutate(  
 CombIDn = row\_number(DateTreatment)  
) |>  
 relocate(  
 CombIDn, .after = CombID  
 ) |> arrange(CombID) |> filter(  
 CombIDn == 1  
 )  
  
# Retrieve all treatment records for each patient + joint regardless of hardware usage  
SelectComb1a <- SnapshotComb1 |> filter(  
 CombID %in% SelectComb1$CombID  
) |> arrange(CombID)  
  
#Add a label with the number of treatments subsequent to the index procedure  
SelectComb1b <- SelectComb1a |> left\_join(  
 SelectComb1 |> dplyr::select(CombID,  
 DateTreatment),  
 by = "CombID"  
) |> filter(  
 DateTreatment.x > DateTreatment.y) |>  
 group\_by(CombID) |>  
 summarise(CombIDnSub = n()  
) |>  
 ungroup()   
  
#Finalise label with number of subsequent treatments  
Mastersheet <- SelectComb1 |> left\_join(  
 SelectComb1b,  
 by = "CombID"  
 ) |> mutate(  
 CombIDnSub2 = case\_when(  
 is.na(CombIDnSub) ~ 0,  
 .default = CombIDnSub  
 ),  
 TreatmentStatus2 = case\_when(  
 stringr::str\_detect(str\_to\_lower(TreatmentStatus),"pend") ~ "Ongoing",  
 .default = TreatmentStatus  
 ),  
 ) |> relocate(  
 CombIDnSub2, .after = CombID  
 ) |> dplyr::select(-CombIDnSub) |> ungroup()

Of the 68 records in the mastersheet, 0 treatment records had withdrawn consent for data inclusion and 1 had declined to participate in PROMs.

### 2.3.1 Record [6.2] Algorithm validation

Record selection code was cross-checked by manual record checking within the registry snapshot for a subset (N = 10) of cases.

### 2.3.2 Record [6.3] Data linkage

No data linkage was utilised for this analysis.

## 2.4 Record [7] Variables

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 3: Summary of variables   | Category | Variable | Comments | Citation | | --- | --- | --- | --- | | Patient Characteristics | Insurance Status | Recode from account data to insurance status |  | | Pathology | Primary diagnosis | Free text coded using ICD-10 international |  | |  | CuffRetraction | Defined as per *modified* Patte grading | (Lädermann et al. 2016) | |  | CuffCondition | Fatty infiltration as assessed by Goutallier scale | (Fuchs et al. 1999) | |  | TearPattern | Shape the tear makes within the margins of the cuff as viewed in the transverse plane | (Lädermann et al. 2016) | |  | OtherShoulderPathology | Free-text coded as present [Yes] or not [No] |  | | Management - Surgery | RepairAugment | Techniques used to augment the repair |  | |  | CuffTension | Surgeon perceived tension to restore anatomical footprint of repair |  | |  | RepairQuality | Surgeon subjective rating of the repair quality |  | | Adverse Events | Modidifed sink grade | Modification of the Sink grading of complication severity | (Felsch et al. 2021) | | Patient-Reported Outcomes | WORC Physical Q3 | How much weakness do you experience in your shoulder? | (Kirkley, Alvarez, and Griffin 2003) | |

Key variables defined as part of this analysis are summarised [Table 3](#tbl-variables).

## 2.5 Record [8] Data sources

Data was sourced directly from the PRULO clinical registry.

## 2.6 Record [9] Bias

For a discussion of biases in the context of the clinical registry utilised for this analysis, refer to (Scholes et al. 2023). Specific to this analysis, the following considerations were noted;

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 4: Biases in analysis of observational cohort of a clinical registry   | Bias | Definition | Source | Mitigation | | --- | --- | --- | --- | | Misclassification | Treatment record labelled into incorrect cohort. PROMs package not aligned to | (Benchimol et al. 2015) | Clinical notes reviewed by experienced reviewer and matched to ICD10 code by definition. | | Confounder | An variable of interest and a target outcome simultaneously influenced by a third variable | (Tennant et al. 2020) | PROMs analysis incorporated adjustment for age and sex | | Missing data | The absence of a data value where a treatment record is eligible to have a data value collected | (Carroll, Morris, and Keogh 2020) | Multiple imputation utilised | | Prevalent user | Follow-up starts after eligible individuals have started the treatment. The follow-up time is left-truncated | (Nguyen et al. 2021) | Eligibility and enrollment is performed prior to treatment offering for any patient or new presentation. Index procedures identified for analysis are followed prior to surgery occurring. | | Selection | Treatments are selected based on post-treatment criteria | (Nguyen et al. 2021) | Unable to be mitigated fully - records are identified by presence of hardware code associated with suture of interest | | Immortal time | Individuals need to meet eligibility criteria that can only be assessed after follow-up has started | (Nguyen et al. 2021) | Patients enrolled at time of diagnosis | | Pseudoreplication | Analyse data while ignoring dependency between observations. Inadequate model specification. | (Davies and Gray 2015; Lazic 2010) | Cluster for patient in survival (all-cause failure and retear). Utilise mixed effects linear model (lme4::lmer) for PROMs analysis with treatment identifier as random effect | |

## 2.7 Record [10] Sample size

Sample size was derived from the available records of the Registry at the time of analysis.

## 2.8 Record [11] Quantitative variables

The anterior-posterior (AP) and mediolateral (ML) dimensions of the cuff tear were reported and multiplied to calculate tear area (mm^2). The tear was also classified according to (Rashid et al. 2017).

* **Small** tears were defined as full-thickness defects in the supraspinatus tendon under 1 cm in the anterior–posterior (AP) dimension.
* **Medium** tears were defined as full-thickness defects in the supraspinatus tendon only, greater than 1 cm and less than 3 cm in the AP dimension.
* **Large** tears involved full-thickness defects of both the supraspinatus and infraspinatus tendons, greater than 3 cm, and less than 5 cm in the AP dimension.
* **Massive** tears involved all 3 tendons (supraspinatus, infraspinatus, and subscapularis) and were greater than 5 cm in the AP dimension.

Partial tears were left labelled as *partial*. Ultimately recoded tear classification based on AP tear length, as the involvement of other tendons for tears of small length was not adequately defined in the original paper.

## Slice inputs for columns and rows  
  
##Sort out variable types; Calculate wait time  
  
Mastersheet1 <- Mastersheet |> rename\_with(  
 ~sub("\_TotalScore\_","\_",.),   
 contains("\_TotalScore\_")  
 ) |> rename\_with(  
 ~sub("EligibleAtx","Eligible\_",.),   
 starts\_with("EligibleAtx")  
 ) |> rename\_with(  
 ~sub("EligibleAt","Eligible\_",.),   
 starts\_with("EligibleAt")  
 ) |> rename\_with(  
 ~sub("WORC\_","WORC",.),   
 starts\_with("WORC\_")  
 ) |> mutate(  
 CuffTearSizeML = as.numeric(CuffTearSizeML),  
 CuffTearSizeAP = as.numeric(CuffTearSizeAP),  
 WaitTime = as.numeric(as.duration(interval(ymd(DateInitialExamination), ymd(DateTreatment))),"weeks"),  
 across(starts\_with("WORC"),as.numeric),  
 across(starts\_with("QDASH"),as.numeric),  
 across(where(is.character) & !contains("ID", ignore.case = TRUE), as.factor),  
 Sex2 = case\_when(  
 Sex == "F" ~ "Female",  
 Sex == "M" ~ "Male"),  
 Surgeon2 = case\_when(  
 Surgeon == "KE" ~ "A",  
 Surgeon == "RP" ~ "B",  
 Surgeon == "GB" ~ "C",  
 .default = NA\_character\_),  
 TearClass = case\_when(  
 CuffStatus == "Partial Tear" ~ "Partial",  
 CuffStatus == "Full Tear" & CuffTearSizeAP <=10 ~ "Small",  
 CuffStatus == "Full Tear" & between(CuffTearSizeAP,11,30) ~ "Medium",  
 CuffStatus == "Full Tear" & between(CuffTearSizeAP,31,50) ~ "Large",  
 CuffStatus == "Full Tear" & CuffTearSizeAP > 50 ~ "Massive",  
 .default = NA\_character\_),  
 TendonsInvolved = case\_when(  
 CuffTendonsInvolved == "No other tendon involved" ~ "Supraspinatus (isolated)",  
 .default = CuffTendonsInvolved  
 ),  
 TearArea = CuffTearSizeAP \* CuffTearSizeML,  
 OtherShoulderPathology = case\_when(  
 stringr::str\_detect(str\_to\_lower(OtherShoulderGirdle),"no",negate = TRUE) & !is.na(OtherShoulderGirdle) ~ "Yes",  
 .default = OtherShoulderGirdle  
 ),  
 RepairAugment2 = case\_when(  
 stringr::str\_detect(str\_to\_lower(AdjunctProcedures), "scr|superior") ~ "Superior Capsular",  
 RepairAugmentation == "Nil" ~ "None",  
 .default = RepairAugmentation  
 ),  
 TreatStatus = case\_when(  
 TreatmentStatus == "Failed" ~ 1,  
 .default = 0  
 ),  
 TreatEndDate = coalesce(DateStatusChange,ymd(CurrentDate))  
 ) |>  
 mutate(  
 TreatDuration = as.numeric(as.duration(interval(ymd(DateTreatment), ymd(TreatEndDate))),"weeks")  
 ) |> relocate(  
 TearClass,   
 .after = CuffCondition) |> relocate(  
 TearArea,   
 .after = CuffCondition  
 )

Data was read in from database table to determine account type.

PatientTable1 <- PatientTable |> filter(  
 !is.na(PatientCreationDate) & !is.na(DateOfBirth)  
) |> mutate(  
 DateOfBirth2 = as.numeric(DateOfBirth),  
 LastName = stringr::str\_to\_title(LastName)  
) |> unite(  
 col = "CombID",  
 sep = ".",  
 c("FirstName","LastName","DateOfBirth2"),  
 remove = FALSE  
)

Mastersheet1b <- Mastersheet1 |> left\_join(  
 PatientTable1 |> dplyr::select(  
 FirstName,  
 LastName,  
 PatientID  
 ),  
 by = "PatientID"  
) |> mutate(  
 DateOfBirth2 = as.numeric(as\_date(DateOfBirth))  
 ) |> unite(  
 col = "CombID",  
 sep = ".",  
 c("FirstName","LastName","DateOfBirth2"),  
 remove = FALSE  
) |> left\_join(  
 AcctDataNew |> dplyr::select(  
 AccountType2,  
 HealthFund2,  
 PatientID  
 ),  
 by = "PatientID"  
 )

Procedure details were extracted from the master table and processed to enable presentations in summary tables.

OpData <- Mastersheet1b |> dplyr::select(  
 TreatmentUID,  
 SurgicalTreatment,  
 PatientPosition,  
 ArthroscopicApproach:OtherShoulderGirdle  
 ) |> dplyr::mutate(  
 AdjunctProcedures = as.character(AdjunctProcedures)  
) |> separate\_longer\_delim(  
 AdjunctProcedures,  
 stringr::regex("[;,]")  
 ) |> dplyr::mutate(  
 AdjunctProcedures2 = str\_squish(AdjunctProcedures)  
 ) |> dplyr::mutate(  
 AdjunctProcedures3 = case\_when(  
 AdjunctProcedures2 == "None performed" ~ "None",  
 str\_detect(str\_to\_lower(AdjunctProcedures2), "resection|osteot") ~ "Clavicle Resection",  
str\_detect(str\_to\_lower(AdjunctProcedures2), "release|debulk") ~ "Ligament|Capsule Release",  
str\_detect(str\_to\_lower(AdjunctProcedures2), "transfer") ~ "Tendon Transfer",  
str\_detect(str\_to\_lower(AdjunctProcedures2), "debride") ~ "Interval|Acromion|Capsule Debridement",  
str\_detect(str\_to\_lower(AdjunctProcedures2), "burs|excis") ~ "Bursectomy",  
str\_detect(str\_to\_lower(AdjunctProcedures2), "scr|superior|calcific|incorporat|supraspin|cable") ~ "None",  
 .default = AdjunctProcedures2  
 )  
 )

OpData2 <- OpData |>  
 group\_by(TreatmentUID) |>  
 summarise(AdjunctProcedures4 = paste(AdjunctProcedures3,collapse = "; ")  
 ) |> mutate(  
 AdjunctProcedures5 = case\_when(  
 stringr::str\_detect(AdjunctProcedures4,"None") & str\_length(AdjunctProcedures4) > 4 ~ str\_replace\_all(AdjunctProcedures4,"(None|None[;\\s]\*|[;\\s]\*None|[;\\s]+)",""),  
 .default = AdjunctProcedures4  
 )  
 ) |> mutate(  
 AdjunctProcedures6 = str\_squish(AdjunctProcedures5)  
 ) |> dplyr::select(-AdjunctProcedures4,-AdjunctProcedures5)

Mastersheet2 <- left\_join(  
 Mastersheet1b,  
 OpData2,  
 by = "TreatmentUID"  
)

The complications table was also processed for further analysis.

# Join sufficient columns to complictable to perform calculations  
  
ComplicTable1 <- ComplicTable |> rename(  
 TreatmentUID = `Treatment ID`) |> left\_join(  
 SnapshotComb1 |> dplyr::select(  
 CombID,  
 TreatmentUID,  
 DateTreatment),   
 by = "TreatmentUID"  
 ) |> mutate(  
 ReopDelay = as.numeric(as.duration(interval(ymd(DateTreatment), ymd(`Reoperation Procedure Date`))),"weeks"),  
 OccurDelay = as.numeric(as.duration(interval(ymd(DateTreatment), ymd(`Date of Occurrence`))),"days"),  
ComplicationNature = str\_replace\_all(str\_to\_lower(`Complication Nature`),"[;.,-]","")  
) |> mutate(  
 Intraop = case\_when(  
 ReopDelay == 0 ~ "Yes",  
 str\_detect(ComplicationNature,"intraop") ~ "Yes",  
 .default = "No"  
 ),  
 Strata = case\_when(  
str\_detect(ComplicationNature,"capsulitis|frozen|stiff|release|enthesop\*") ~ "Capsulitis - Stiffness",  
str\_detect(ComplicationNature,"repair|fail|recurrent|rupture|retear|torn|retorn|remov\*|loose anchor\*") ~"Repair Failure",  
str\_detect(ComplicationNature,"persistent|infarction|palsy|pain|radiculo\*|crps|complex") ~"Pain - Other",  
str\_detect(ComplicationNature,"dvt") ~"Thromboembolic",  
str\_detect(ComplicationNature,"washout|infect|antibiot\*|abx|debrid\*|washout") ~"Infection",  
str\_detect(ComplicationNature,"explant\*|intraop\*|regraft") ~ "Explant",  
str\_detect(ComplicationNature,"fract\*") ~ "Fracture",  
str\_detect(ComplicationNature,"brok\*|snap\*|break") ~ "Hardware",  
str\_detect(ComplicationNature,"annoy\*|irritat\*") ~ "Hardware Irritation",  
str\_detect(ComplicationNature,"skin|wound|rash") ~ "Wound - Skin",  
str\_detect(ComplicationNature,"disloc\*|instabil\*") ~ "Dislocation - Instability",  
),  
 ComplicationOccurrence = case\_when(  
 `Complication Occurrence` == "No" & (!is.na(ComplicationNature) & !(grepl("nil",ComplicationNature, ignore.case = TRUE))) ~ "Yes",  
 .default = `Complication Occurrence`  
 )  
) |> filter(  
 stringr::str\_detect(str\_to\_lower(ComplicationOccurrence),"yes|possible", negate = TRUE) & !is.na(CombID)  
)

ComplicTable2 <- ComplicTable1 |>   
 dplyr::group\_by(CombID, Strata, Intraop) |>  
 dplyr::arrange(`Date of Occurrence`) |>  
 dplyr::slice\_min(`Date of Occurrence`) |>  
 dplyr::ungroup() |>  
 dplyr::filter(  
 TreatmentUID %in% Mastersheet2$TreatmentUID & (Timestamp < ymd(CurrentDate))  
 )|> dplyr::distinct(  
 CombID, Strata, .keep\_all = TRUE  
 )

Complication events were graded in a separate table according to (Felsch et al. 2021) and retrieved into the workspace using *googlesheets4*.

# Authenticate for sheets using the same token  
gs4\_auth(token = drive\_token())  
  
ComplicTable3 <- googlesheets4::range\_read(  
 ss = SheetIDs$SurgicalGapSS,  
 sheet = "Complications",  
 range = "A1:Q",  
 col\_names = TRUE,  
 col\_types = "TcccDccDcDnncccci"  
 )  
  
#Ready for table presentation

Tables were rearranged with *tidyverse* to prepare patient-reported outcomes (PROMs) for analysis in the *long* format. Separate dataframes were created for the QuickDASH and the WORC, as the QuickDASH was collected at 3months and the WORC was not.

MasterPROM <- Mastersheet2 |> dplyr::select(  
 TreatmentUID,  
 starts\_with("QDASH"),  
 starts\_with("WORC"),  
 starts\_with("Eligible")  
) |> pivot\_longer(  
 cols = !TreatmentUID,  
 names\_to = c(".value","TimePoint"),  
 names\_sep = "\_",  
 values\_drop\_na = TRUE  
) |> mutate(  
 TimePoint = factor(TimePoint, levels = c("Preop","3months","6months","12months"), ordered = TRUE, exclude = NA),  
) |> filter(!is.na(TimePoint))  
  
MasterPROMWORC <- MasterPROM |> filter(TimePoint != "3months")

Tables were modified to track anchor usage.

ImplantTable2a <- ImplantTable2 |> mutate(  
 Suture = str\_to\_title(str\_extract(str\_to\_lower(Description), "\\b\\w+cord\\b"))  
)  
  
AnchorUsage <- Mastersheet2 |> dplyr::select(  
 TreatmentUID,  
 ImplantCodes  
) |> separate\_longer\_delim(cols = ImplantCodes,", ") |> left\_join(  
 ImplantTable2a |> dplyr::select(  
 Reference,  
 Suture  
 ),  
 by = join\_by("ImplantCodes" == "Reference")  
)

## 2.9 Record [12] Statistical methods

A number of analytical techniques were employed to i) clean the data inputs as well as ii) evaluate missingness in the dataset and iii) complete the descriptive analysis of;

* Patient characteristics
* Pathology details
* Patient, implant and adverse event time to event
* Patient-reported outcomes

### 2.9.1 Record [12.1] Access to population

The registry system represents all cases presenting to the rooms of a surgical group within Geelong, Australia using the implant of interest from the inception of the clinical registry to the analysis date. All reviewed charts from the operating surgeons practice records (electronic medical record) were entered into database and the present analysis draws data from a regular compilation of the registry records (snapshot) produced quarterly by the registry administration team.

### 2.9.2 Record [12.2] Data cleaning methods

Complication descriptions were pre-processed to remove relational terms (stopwords) and expand abbreviations to improve clarity.

Dates of events (preceding and subsequent surgical records; adverse events including mortality) relative to index surgery date were assessed using coded checks to flag anomalies and were resolved by further manual review to resolve inconsistencies or discrepancies with the chart review input data stored in the registry database.

### 2.9.3 Record [12.3] Data linkage

Not applicable

### 2.9.4 Record [12.4] Missingness

#### Evaluation

Missingness was assessed with visualisation and table functions in the *naniar* package and compiled into figures using *patchwork*.

# Assessing missingness from Mastersheet2  
  
#Patient characteristics  
  
MissFig1 <- Mastersheet2 |>  
 dplyr::select(  
 AgeAtTreatment,   
 Sex2,   
 IndexSide,  
 Surgeon2,  
 BMI,  
 BilateralStatus,  
 WaitTime,  
 AccountType2) |> rename(  
 `Age at Surgery` = "AgeAtTreatment",   
 Sex = "Sex2",   
 `Affected Side` = "IndexSide",  
 Surgeon = "Surgeon2",  
 `Body Mass Index` = "BMI",  
 `Bilateral Status` = "BilateralStatus",  
 `Initial Consult to Surgery` = "WaitTime",  
 `Insurance Status` = "AccountType2"  
 ) |> gg\_miss\_var(show\_pct = TRUE) + labs(title = "Patient Characteristics")  
  
#Pathology characteristics  
  
MissFig2 <- Mastersheet2 |>  
 dplyr::select(  
 TreatmentType,  
 CuffStatus,  
 CuffCondition,  
 CuffTearRetraction,  
 CuffTendonDelaminated,  
 TendonsInvolved,  
 CuffTearSizeAP,   
 CuffTearSizeML,  
 TearArea,   
 TearClass,   
 CuffTearPattern,  
 OtherShoulderPathology  
 ) |> rename(  
 `Primary Presentation` = "TreatmentType",  
 `Full Tear` = "CuffStatus",  
 `Cuff Condition` = "CuffCondition",  
 `Tendon Retraction` = "CuffTearRetraction",  
 `Tendon Delamination` = "CuffTendonDelaminated",  
 `Tendons Involved (+Ssp)` = "TendonsInvolved",  
 `Tear Size AP (mm)` = "CuffTearSizeAP",   
 `Tear Size ML (mm)` = "CuffTearSizeML",  
 `Tear Area (mm^2)` = "TearArea",   
 `Tear Classification` = "TearClass",   
 `Tear Pattern` = "CuffTearPattern",  
 `Other Pathology` = "OtherShoulderPathology"   
 ) |> gg\_miss\_var(show\_pct = TRUE) + labs(title = "Pathology Characteristics")  
  
#Surgical Technique  
  
MissFig3 <- Mastersheet2 |>  
 dplyr::select(  
 ArthroscopicApproach,  
 PatientPosition,  
 CuffTendonsTreated,  
 RepairType,  
 AnchorFixation,  
 RepairAugment2,  
 CuffRepairTension,  
 CuffRepairQuality  
 ) |> rename(  
 Arthroscopy = "ArthroscopicApproach",  
 `Beachchair Position` = "PatientPosition",  
 `Supraspinatus Isolated Repair` = "CuffTendonsTreated",  
 `Double Row Repair` = "RepairType",  
 `Knotted Anchor Fixation` = "AnchorFixation",  
 `Superior Capsular Augment` = "RepairAugment2",  
 `Low Repair Tension` = "CuffRepairTension",  
 `Anatomic Repair` = "CuffRepairQuality"   
 ) |> gg\_miss\_var(show\_pct = TRUE) + labs(title = "Surgical Details")  
  
#PROMs  
MissFig4 <- MasterPROM |>  
 dplyr::select(QDASH,  
 TimePoint) |> gg\_miss\_var(show\_pct = TRUE,  
 facet = TimePoint) + labs(title = "Patient Reported\n Outcomes - 1")  
  
  
MissFig5 <- MasterPROMWORC |>  
 dplyr::select(WORCNorm,  
 TimePoint) |> gg\_miss\_var(show\_pct = TRUE,  
 facet = TimePoint) + labs(title = "Patient Reported\n Outcomes - 2")  
  
MissFig1 + MissFig2 + MissFig3 + MissFig4 + plot\_layout(ncol = 2)  
  
MissFig5

|  |
| --- |
| Figure 1: Missingness rates of patient, pathology, management and patient-reported outcomes |

|  |
| --- |
| Figure 2: Missingness rates of patient, pathology, management and patient-reported outcomes |

PROMsmiss <- MasterPROM |> dplyr::select(-TreatmentUID) |>  
 group\_by(TimePoint) |>  
 miss\_var\_summary() |>  
 pivot\_wider(names\_from = TimePoint,   
 values\_from = c(pct\_miss))

The compliance for the QuickDASH at baseline was 72.1% and for the WORCNorm it was 57.4%.

The compliance for the QuickDASH was 51.7% and for the WORCNorm it was 43.1% at 12months.

#### Management

The data tables were reduced to the required columns (PROMs and adjunct columns) in preparation for multiple imputation using chained equations (White, Royston, and Wood 2010) with the *mice* package. One patient with bilateral records in the sample had one field (EducationLevel\_Preop) mirrored from one side record to the other, where it was missing. Character fields were converted to factors and the dataset was filtered to those cases that were eligible for 12months followup.

QDASHPROMInput <- MasterPROM |> left\_join(  
 dplyr::select(  
 Mastersheet2,  
 TreatmentUID,  
 WaitTime,  
 IndexSide,  
 BilateralStatus,  
 EducationLevel\_Preop,  
 AgeAtTreatment,  
 Sex2,  
 ComplicationOccurrence  
 ),  
 by = "TreatmentUID"  
) |> dplyr::mutate(  
 Complication2 = case\_when(  
 ComplicationOccurrence != "No" ~ "Yes",  
 .default = "No"  
 ),  
 across(where(is.character) & !contains("ID", ignore.case = TRUE), as.factor),  
 TimePoint = fct\_relevel(  
 as.factor(TimePoint),   
 c("Preop", "3months", "6months", "12months")  
 ),  
 Sex2 = fct\_relevel(  
 as.factor(Sex2),   
 c("Female", "Male")  
 ),  
 BilateralStatus = fct\_relevel(  
 as.factor(BilateralStatus),   
 c("No", "Yes")  
 ),  
 EducationLevel\_Preop = fct\_relevel(  
 as.factor(EducationLevel\_Preop),   
 c(  
 "Up to Secondary Year 10",   
 "Secondary - Year 12",  
 "Post-secondary trade certificate or diploma",  
 "Undergraduate degree",  
 "Postgraduate degree")  
 ),  
 TreatmentInt = as.integer(str\_replace(TreatmentUID, "\\.", ""))  
) |> dplyr::select(  
 !c(  
 ComplicationOccurrence,  
 Eligible,  
 WORCPhysical:WORCEmotions,  
 WORCPhysicalQ3,  
 WORCNorm  
 )  
 ) |> dplyr::filter(  
 TreatmentUID %in% STROBEFlow$mitt  
 ) |> mutate(  
   
 ) |> dplyr::rows\_update(  
 tibble(  
 TreatmentUID = "253.2",  
 EducationLevel\_Preop = "Undergraduate degree"  
 ),  
 by = "TreatmentUID"  
 )

A row was inserted for one case that did not return an entry for the 3month timepoint. The dataframe was reordered to create a *visitsequence* for the multiple imputation function.

#   
QDASHPROMInput2 <- dplyr::rows\_append(  
 QDASHPROMInput,  
 tibble(TreatmentUID = "1553.1",  
 TimePoint = "3months",  
 BilateralStatus = "No",  
 AgeAtTreatment = 74,  
 Sex2 = "Female",  
 TreatmentInt = 22,  
 IndexSide = "Dominant",  
 WaitTime = 24.8571429,  
 Complication2 = "No",  
 EducationLevel\_Preop = NA\_character\_  
 )  
) |> dplyr::select(  
 -TreatmentUID  
 ) |> dplyr::relocate( # reorder columns for visitsequence  
 all\_of(  
 c(  
 "TreatmentInt",  
 "TimePoint",  
 "Sex2",  
 "AgeAtTreatment",  
 "BilateralStatus",  
 "WaitTime",  
 "IndexSide",  
 "EducationLevel\_Preop",  
 "Complication2",  
 "QDASH"  
 )  
 )  
   
 )

A predictor matrix was generated to specify the combination of variables to be drawn on for the imputation of each column in the dataset. In addition, a *method* matrix was created to specify varying univariate imputations to account for the multilevel nature of the dataset (van Buuren and Groothuis-Oudshoorn 2011). Patient level variables (education, sex, bilateralstatus) were imputed as level-2 variables and the PROMs columns treated as level-1 variables.

# TreatmentInt - no missing  
# TimePoint - no missing  
# Sex2 - no missing  
# AgeAtTreatment - no missing  
# BilateralStatus - no missing  
# WaitTime - no missing  
# IndexSide - Level 2 missing  
# EducationLevel\_Preop - level 2 missing  
# Complication2 - not missing  
# QDASH - level 2 missing  
  
  
# Make predictor matrix  
#   
QDASHPred <- make.predictorMatrix(  
 QDASHPROMInput2  
)  
  
QDASHPred["TreatmentInt", ] <- 0  
QDASHPred["TimePoint", ] <- 0  
QDASHPred["Sex2", ] <- 0  
QDASHPred["AgeAtTreatment", ] <- 0  
QDASHPred["BilateralStatus", ] <- 0  
QDASHPred["WaitTime", ] <- 0  
QDASHPred["Complication2", ] <- 0  
QDASHPred["IndexSide", ] <- c(-2,0,1,1,1,1,0,1,1,1)  
QDASHPred["EducationLevel\_Preop", ] <- c(-2,0,1,1,1,1,1,0,1,1)  
QDASHPred["QDASH", ] <- c(-2,1,1,1,1,1,1,1,1,0)  
  
# Specify Method  
# Method specification  
QDASHMeth <- make.method(QDASHPROMInput2)  
  
# For time-invariant variables (level-2)  
QDASHMeth["EducationLevel\_Preop"] <- "2lonly.pmm" # Or "2lonly.polyreg" for categorical  
QDASHMeth["IndexSide"] <- "2lonly.bin" # Or "2lonly.polyreg" for categorical  
  
  
# For time-varying variables (level-1)  
QDASHMeth["QDASH"] <- "pmm" # Multilevel imputation allowing for within-person variation  
# Visit sequence  
#   
QDASHseq <- mice::make.visitSequence(QDASHPROMInput2)

QDASHImputed <- mice::mice(  
 data = QDASHPROMInput2,  
 m = 10,  
 predictorMatrix = QDASHPred,  
 visitSequence = QDASHseq,  
 method = QDASHMeth,  
 maxit= 15,  
 printFlag = FALSE  
)  
  
plot(QDASHImputed)

|  |
| --- |
| Figure 3: Stability of imputed variables over iterations for QuickDASH dataset |

WORCPROMInput <- MasterPROM |> left\_join(  
 dplyr::select(  
 Mastersheet2,  
 TreatmentUID,  
 WaitTime,  
 IndexSide,  
 BilateralStatus,  
 EducationLevel\_Preop,  
 AgeAtTreatment,  
 Sex2,  
 ComplicationOccurrence  
 ),  
 by = "TreatmentUID"  
) |> dplyr::mutate(  
 Complication2 = case\_when(  
 ComplicationOccurrence != "No" ~ "Yes",  
 .default = "No"  
 ),  
 across(where(is.character) & !contains("ID", ignore.case = TRUE), as.factor),  
 TimePoint = fct\_relevel(  
 as.factor(TimePoint),   
 c("Preop", "3months", "6months", "12months")  
 ),  
 Sex2 = fct\_relevel(  
 as.factor(Sex2),   
 c("Female", "Male")  
 ),  
 BilateralStatus = fct\_relevel(  
 as.factor(BilateralStatus),   
 c("No", "Yes")  
 ),  
 EducationLevel\_Preop = fct\_relevel(  
 as.factor(EducationLevel\_Preop),   
 c(  
 "Up to Secondary Year 10",   
 "Secondary - Year 12",  
 "Post-secondary trade certificate or diploma",  
 "Undergraduate degree",  
 "Postgraduate degree")  
 ),  
 TreatmentInt = as.integer(str\_replace(TreatmentUID, "\\.", ""))  
) |> dplyr::select(  
 !c(  
 ComplicationOccurrence,  
 Eligible,  
 WORCPhysical:WORCEmotions  
 )  
 ) |> dplyr::filter(  
 TreatmentUID %in% STROBEFlow$mitt,  
 TimePoint != "3months"  
 ) |> mutate(  
   
 ) |> dplyr::rows\_update(  
 tibble(  
 TreatmentUID = "253.2",  
 EducationLevel\_Preop = "Undergraduate degree"  
 ),  
 by = "TreatmentUID"  
 )

# Fix up missing row (General switched to RotatorCuff)  
#   
WORCPROMInput2 <- WORCPROMInput |> dplyr::select(  
 -TreatmentUID  
 ) |> dplyr::relocate( # reorder columns for visitsequence  
 all\_of(  
 c(  
 "TreatmentInt",  
 "TimePoint",  
 "Sex2",  
 "AgeAtTreatment",  
 "BilateralStatus",  
 "WaitTime",  
 "IndexSide",  
 "EducationLevel\_Preop",  
 "Complication2",  
 "QDASH",  
 "WORCPhysicalQ3",  
 "WORCNorm"  
 )  
 )  
   
 )

# TreatmentInt - no missing  
# TimePoint - no missing  
# Sex2 - no missing  
# AgeAtTreatment - no missing  
# BilateralStatus - no missing  
# WaitTime - no missing  
# IndexSide - Level 2 missing  
# EducationLevel\_Preop - level 2 missing  
# Complication2 - not missing  
# QDASH - level 2 missing  
  
  
# Make predictor matrix  
#   
WORCPred <- make.predictorMatrix(  
 WORCPROMInput2  
)  
  
WORCPred["TreatmentInt", ] <- 0  
WORCPred["TimePoint", ] <- 0  
WORCPred["Sex2", ] <- 0  
WORCPred["AgeAtTreatment", ] <- 0  
WORCPred["BilateralStatus", ] <- 0  
WORCPred["WaitTime", ] <- 0  
WORCPred["Complication2", ] <- 0  
WORCPred["IndexSide", ] <- c(-2,0,1,1,1,1,0,1,1,1,1,1)  
WORCPred["EducationLevel\_Preop", ] <- c(-2,0,1,1,1,1,1,0,1,1,1,1)  
WORCPred["QDASH", ] <- c(-2,1,1,1,1,1,1,1,1,0,1,1)  
WORCPred["WORCPhysicalQ3", ] <- c(-2,1,1,1,1,1,1,1,1,1,0,1)  
WORCPred["WORCNorm", ] <- c(-2,1,1,1,1,1,1,1,1,1,1,0)  
  
# Specify Method  
# Method specification  
WORCMeth <- make.method(WORCPROMInput2)  
  
# For time-invariant variables (level-2)  
WORCMeth["EducationLevel\_Preop"] <- "2lonly.pmm" # Or "2lonly.polyreg" for categorical  
WORCMeth["IndexSide"] <- "2lonly.bin" # Or "2lonly.polyreg" for categorical  
  
  
# For time-varying variables (level-1)  
WORCMeth["QDASH"] <- "pmm" # Multilevel imputation allowing for within-person variation  
WORCMeth["WORCPhysicalQ3"] <- "pmm" # Multilevel imputation allowing for within-person variation  
WORCMeth["WORCNorm"] <- "pmm" # Multilevel imputation allowing for within-person variation  
  
# Visit sequence  
#   
WORCseq <- mice::make.visitSequence(WORCPROMInput2)

WORCImputed <- mice::mice(  
 data = WORCPROMInput2,  
 m = 10,  
 predictorMatrix = WORCPred,  
 visitSequence = WORCseq,  
 method = WORCMeth,  
 maxit = 15,  
 printFlag = FALSE  
)  
  
plot(WORCImputed)

|  |
| --- |
| Figure 4: Stability of imputed variables over iterations for WORC dataset |

|  |
| --- |
| Figure 5: Stability of imputed variables over iterations for WORC dataset |

# 3. Analysis Results

## 3.1 Record [13] Participants

The initial export from the registry returned 2681 records of all types.

### 3.1.1 Record [13.1] Treatment selection

A flow chart of individual treatment episodes (treatments) was generated using the *consort* package and prepared for display with the *knitr* package.

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

STROBEPlot <- consort::consort\_plot(  
 data = STROBEFlow,  
 orders = c(  
 trialno = "Population",  
 exclusion1 = "Excluded",  
 trialno = "Received Surgery",  
 exclusion2 = "Excluded from Sample",  
 followup = "Study Sample at Baseline",  
 lost\_followup = "Unavailable 12m data",  
 mitt = "Final Analysis"),  
side\_box = c(  
 "exclusion1",   
 "exclusion2",   
 "lost\_followup"  
 ),  
cex = 0.9  
)  
  
knitr::knit\_print(STROBEPlot)

|  |
| --- |
| Figure 6: Flowchart of extraction and followup of sample from the Registry |

The table below summarises patient diagnoses in the PRULO registry.

TableData <- Mastersheet2 |>  
 mutate(  
 ICD10 = stringr::str\_extract(DiagnosisPrimary,"^[A-Za-z]+[0-9.]+")  
 ) |> count(ICD10, sort = TRUE) |>  
 slice\_head(n = 5) |> gt::gt()  
  
knitr::knit\_print(TableData)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 5: Summary of diagnoses by ICD-10 code   | ICD10 | n | | --- | --- | | M75.1 | 47 | | S46.0 | 12 | | S43.43 | 7 | | M19.0 | 1 | | M75.2 | 1 | |

## 3.2 Record [14] Patient and record characteristics

PatientChar <- Mastersheet2 |>  
 dplyr::select(  
 AgeAtTreatment,   
 Sex2,   
 IndexSide,  
 #Surgeon2,  
 #BMI,  
 BilateralStatus,  
 WaitTime,  
 AccountType2  
 ) |>  
 tbl\_summary(  
 label = list(  
 AgeAtTreatment ~ "Age at Surgery",  
 #Surgeon2 ~ "Surgeon",  
 #BMI ~ "Body Mass Index",  
 BilateralStatus ~ "Bilateral",  
 Sex2 ~ "Female",  
 WaitTime ~ "Exam to surgery delay (weeks)",  
 IndexSide ~ "Non-dominant",  
 AccountType2 ~ "Insurance Type"  
 ),  
 type = list(  
 Sex2 ~ "dichotomous",  
 IndexSide ~ "dichotomous"),  
 value = list(  
 Sex2 ~ "Female",  
 IndexSide ~ "Non-dominant"),  
 statistic = list(  
 AgeAtTreatment ~ "{mean} ({sd})",  
 #BMI ~ "{mean} ({sd})",  
 WaitTime ~ "{mean} ({sd})",  
 all\_categorical() ~ "{p}% ({n})"),  
 missing = "no") |>  
 add\_n() |>  
 add\_ci(statistic = list(all\_categorical() ~ "{conf.low} - {conf.high}",  
 all\_continuous() ~ "{conf.low} - {conf.high}")) |>  
 add\_stat\_label(  
 location = "row"  
 ) |> modify\_table\_styling(  
 columns = label,  
 rows = label == "DVA",  
 footnote = "DVA = Department of Veterans Affairs"  
 ) |> modify\_table\_styling(  
 columns = label,  
 rows = label == "TAC",  
 footnote = "TAC = Transport Accident Commission"  
 )  
  
knitr::knit\_print(PatientChar)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 6: Summary of patient characteristics   | **Characteristic** | **N** | **N = 68** | **95% CI** | | --- | --- | --- | --- | | Age at Surgery, Mean (SD) | 68 | 61 (9) | 58 - 63 | | Female, % (n) | 68 | 31% (21) | 21 - 43 | | Non-dominant, % (n) | 65 | 40% (26) | 28 - 53 | | Bilateral, % (n) | 68 | 16% (11) | 8.7 - 28 | | Exam to surgery delay (weeks), Mean (SD) | 68 | 10 (10) | 7.7 - 13 | | Insurance Type, % (n) | 68 |  |  | | Private |  | 91% (62) | 81 - 96 | | TAC*1* |  | 1.5% (1) | 0.08 - 9.0 | | Uninsured |  | 4.4% (3) | 1.1 - 13 | | WorkCover |  | 2.9% (2) | 0.51 - 11 | | *1*TAC = Transport Accident Commission | | | | | Abbreviation: CI = Confidence Interval | | | | |

Patient characteristics for cases receiving the anchor of interest are summarised in [Table 6](#tbl-characteristics).

### 3.2.1 Record [14.1] Pathology characteristics

PathChar <- Mastersheet2 |>  
 dplyr::select(  
 TreatmentType,  
 CuffStatus,  
 CuffCondition,  
 CuffTearRetraction,  
 CuffTendonDelaminated,  
 TendonsInvolved,  
 CuffTearSizeAP,   
 CuffTearSizeML,  
 TearArea,   
 TearClass,   
 CuffTearPattern,  
 OtherShoulderPathology  
 ) |>  
 tbl\_summary(  
 label = list(  
 TreatmentType ~ "Primary Presentation",  
 CuffStatus ~ "Full Tear",  
 CuffCondition ~ "Fatty Infiltration",  
 CuffTearRetraction ~ "Tendon Retraction",  
 CuffTendonDelaminated ~ "Tendon Delamination",  
 TendonsInvolved ~ "Tendons Involved (+Supraspinatus)",  
 CuffTearSizeAP ~ "Tear Size AP (mm)",   
 CuffTearSizeML ~ "Tear Size ML (mm)",  
 TearArea ~ "Tear Area (mm^2)",   
 TearClass ~ "Tear Classification",   
 CuffTearPattern ~ "Tear Pattern",  
 OtherShoulderPathology ~ "Other Pathology"  
 ),  
 statistic = list(  
 all\_continuous() ~ "{mean} ({sd})",  
 all\_categorical() ~ "{p} ({n})"  
 ),  
 type = list(  
 TreatmentType ~ "dichotomous",  
 CuffStatus ~ "dichotomous",  
 OtherShoulderPathology ~ "dichotomous"  
 ),  
 value = list(  
 TreatmentType ~ "Primary",  
 CuffStatus ~ "Full Tear",  
 OtherShoulderPathology ~ "Yes"  
 ),  
 missing = "no"  
 ) |>  
 add\_n() |>  
 add\_ci(statistic = list(  
 all\_categorical() ~ "{conf.low} - {conf.high}",   
 all\_continuous() ~ "{conf.low} - {conf.high}")  
 ) |> modify\_header(  
 label = "Characteristic",  
 n = "Available\n Sample",  
 stat\_0 = "Summary\n Statistic",  
 ci\_stat\_0 = "95% CI"  
) |> add\_stat\_label(  
 location = "row"  
 ) |> modify\_table\_styling(  
 columns = label,  
 rows = var\_label == "Fatty Infiltration",  
 footnote = "Fuchs et al 1999"  
 ) |> modify\_table\_styling(  
 columns = label,  
 rows = var\_label == "Tendon Retraction",  
 footnote = "Modified Patte Grading (Lädermann et al., 2016)"  
 ) |> modify\_table\_styling(  
 columns = label,  
 rows = var\_label == "Tear Classification",  
 footnote = "(Rashid et al., 2017)"  
 )  
  
knitr::knit\_print(PathChar)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 7: Summary of presenting pathology characteristics   | Characteristic | Available Sample | Summary Statistic | 95% CI | | --- | --- | --- | --- | | Primary Presentation, % (n) | 68 | 100 (68) | 93 - 100 | | Full Tear, % (n) | 68 | 99 (67) | 91 - 100 | | Fatty Infiltration, % (n)*1* | 63 |  |  | | 0*1* |  | 11 (7) | 5.0 - 22 | | 1*1* |  | 51 (32) | 38 - 63 | | 2*1* |  | 33 (21) | 22 - 46 | | 3*1* |  | 4.8 (3) | 1.2 - 14 | | Tendon Retraction, % (n)*2* | 68 |  |  | | I*2* |  | 32 (22) | 22 - 45 | | II*2* |  | 43 (29) | 31 - 55 | | III*2* |  | 21 (14) | 12 - 32 | | IV*2* |  | 4.4 (3) | 1.1 - 13 | | Tendon Delamination, % (n) | 68 | 74 (50) | 61 - 83 | | Tendons Involved (+Supraspinatus), % (n) | 68 |  |  | | Infraspinatus |  | 22 (15) | 13 - 34 | | Infraspinatus; Subscapularis |  | 10 (7) | 4.6 - 21 | | Infraspinatus; Teres Minor; Subscapularis |  | 1.5 (1) | 0.08 - 9.0 | | Subscapularis |  | 16 (11) | 8.7 - 28 | | Subscapularis (isolated) |  | 16 (11) | 8.7 - 28 | | Supraspinatus (isolated) |  | 34 (23) | 23 - 46 | | Tear Size AP (mm), Mean (SD) | 68 | 24 (11) | 21 - 27 | | Tear Size ML (mm), Mean (SD) | 68 | 20 (10) | 18 - 23 | | Tear Area (mm^2), Mean (SD) | 68 | 577 (598) | 432 - 721 | | Tear Classification, % (n)*3* | 68 |  |  | | Large*3* |  | 16 (11) | 8.7 - 28 | | Massive*3* |  | 2.9 (2) | 0.51 - 11 | | Medium*3* |  | 76 (52) | 64 - 86 | | Partial*3* |  | 1.5 (1) | 0.08 - 9.0 | | Small*3* |  | 2.9 (2) | 0.51 - 11 | | Tear Pattern, % (n) | 68 |  |  | | Crescent |  | 49 (33) | 36 - 61 | | L |  | 19 (13) | 11 - 31 | | Reverse L |  | 13 (9) | 6.6 - 24 | | U |  | 16 (11) | 8.7 - 28 | | V |  | 2.9 (2) | 0.51 - 11 | | Other Pathology, % (n) | 51 | 45 (23) | 31 - 60 | | *1*Fuchs et al 1999 | | | | | *2*Modified Patte Grading (Lädermann et al., 2016) | | | | | *3*(Rashid et al., 2017) | | | | | Abbreviation: CI = Confidence Interval | | | | |

Pathology characteristics for cases receiving the anchor of interest are summarised in [Table 7](#tbl-pathology).

### 3.2.2 Record [14.2] Management summary

ManageSum <- Mastersheet2 |>  
 dplyr::select(  
 ArthroscopicApproach,  
 PatientPosition,  
 CuffTendonsTreated,  
 RepairType,  
 AnchorFixation,  
 RepairAugment2,  
 CuffRepairTension,  
 CuffRepairQuality  
 ) |>  
 tbl\_summary(  
 label = list(  
 ArthroscopicApproach ~ "Arthroscopy",  
 PatientPosition ~ "Beachchair Position",  
 CuffTendonsTreated ~ "Supraspinatus (isolated) Repair",  
 RepairType ~ "Double Row Repair",  
 AnchorFixation ~ "Knotted Anchor Fixation",  
 RepairAugment2 ~ "Superior Capsular Augment",  
 CuffRepairTension ~ "Low Repair Tension",  
 CuffRepairQuality ~ "Anatomic Repair"  
 ),  
 statistic = list(  
 all\_continuous() ~ "{mean} ({sd})",  
 all\_categorical() ~ "{p} ({n})"  
 ),  
 type = list(  
 ArthroscopicApproach ~ "dichotomous",  
 PatientPosition ~ "dichotomous",  
 CuffTendonsTreated ~ "dichotomous",  
 RepairType ~ "dichotomous",  
 AnchorFixation ~ "dichotomous",  
 RepairAugment2 ~ "dichotomous",  
 CuffRepairTension ~ "dichotomous",  
 CuffRepairQuality ~ "dichotomous"  
 ),  
 value = list(  
 ArthroscopicApproach ~ "Yes",  
 PatientPosition ~ "Beachchair",  
 CuffTendonsTreated ~ "None",  
 RepairType ~ "Double",  
 AnchorFixation ~ "Knot",  
 RepairAugment2 ~ "Other",  
 CuffRepairTension ~ "Low",  
 CuffRepairQuality ~ "Anatomic"  
 ),  
 missing = "no"  
 ) |>  
 add\_n() |>  
 add\_ci(statistic = list(  
 all\_categorical() ~ "{conf.low} - {conf.high}",   
 all\_continuous() ~ "{conf.low} - {conf.high}")  
 ) |>   
 add\_stat\_label(location = "row") |>  
 modify\_header(  
 label = "\*\*Characteristic\*\*",  
 n = "\*\*Available\n Sample\*\*",  
 stat\_0 = "\*\*Summary\n Statistic\*\*",  
 ci\_stat\_0 = "\*\*95% CI\*\*"  
)  
  
knitr::knit\_print(ManageSum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 8: Summary of management and surgical details   | **Characteristic** | **Available** **Sample** | **Summary** **Statistic** | **95% CI** | | --- | --- | --- | --- | | Arthroscopy, % (n) | 68 | 100 (68) | 93 - 100 | | Beachchair Position, % (n) | 68 | 100 (68) | 93 - 100 | | Supraspinatus (isolated) Repair, % (n) | 68 | 32 (22) | 22 - 45 | | Double Row Repair, % (n) | 68 | 81 (55) | 69 - 89 | | Knotted Anchor Fixation, % (n) | 68 | 97 (66) | 89 - 99 | | Superior Capsular Augment, % (n) | 68 | 2.9 (2) | 0.51 - 11 | | Low Repair Tension, % (n) | 68 | 68 (46) | 55 - 78 | | Anatomic Repair, % (n) | 68 | 78 (53) | 66 - 87 | | Abbreviation: CI = Confidence Interval | | | | |

Details of surgical management are summarised in [Table 8](#tbl-surgery).

### 3.2.3 Record [14.3] Follow up

The sample overall had a mean follow up of 99.7 months.

FollowupTab <- Mastersheet2 |>  
 dplyr::select(  
 TreatDuration,  
 TreatmentStatus  
 ) |>  
 tbl\_summary(  
 by = TreatmentStatus,  
 statistic = list(all\_continuous() ~ "{mean} ({sd})")  
 )   
  
knitr::knit\_print(FollowupTab)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 9: Summary of case follow up (months) at the time of analysis   | **Characteristic** | **No further followup** N = 1*1* | **Ongoing** N = 67*1* | | --- | --- | --- | | TreatDuration | 20 (NA) | 101 (43) | | *1*Mean (SD) | | | |

FollowupSum <- Mastersheet2 |>  
ggplot(aes(y = TreatmentStatus2, x = TreatDuration)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('Follow up duration by treatment status')  
  
knitr::knit\_print(FollowupSum)

|  |
| --- |
| Figure 7: Summary of follow up duration for the included sample. |

## 3.3 Record [15] Outcomes

### 3.3.1 Record [15.3] Adverse events and complications

# Calculate proportion  
  
ComplicInc <- prop.test(length(unique(ComplicTable3$TreatmentUID)),nrow(Mastersheet2), conf.level = 0.95)

Of the 68 cases included in the analysis, there were 6 treatments observed with 6 adverse events of any kind, equating to an incidence of 8.8 (95%CI, 3.6 - 18.9). There were 0 reoperations and 0 events observed intraoperatively.

## Slice inputs for columns and rows  
  
ComplicSum <- ComplicTable3 %>%  
 dplyr::select(  
 #Intraop,  
 Strata,  
 #OccurDelay,  
 #`Reoperation Procedure`,  
 #ReopDelay,  
 GradeFelsch2021  
 ) %>%  
 tbl\_summary(  
 label = list(  
 #Intraop ~ "Intraoperative",  
 Strata ~ "Complication Nature",  
 #OccurDelay ~ "Occurrence Delay (Days)",  
 #`Reoperation Procedure` ~ "Reoperation",  
 #ReopDelay ~ "Reoperation Delay (Weeks)",  
 GradeFelsch2021 ~ "Severity Grade"  
 ),  
 statistic = list(  
 #all\_continuous() ~ "{mean} ({sd})",  
 all\_categorical() ~ "{p} ({n})"  
 ),  
 #type = list(  
 #Intraop ~ "dichotomous"  
 #`Reoperation Procedure` ~ "dichotomous"  
 #),  
 #value = list(  
 #Intraop ~ "Yes"  
 #`Reoperation Procedure` ~ "Yes"  
 #),  
 missing = "no"  
 ) %>%  
 add\_n() %>%  
 add\_stat\_label(location = "row") %>%  
 modify\_header(  
 label = "Characteristic",  
 n = "Available\n Sample",  
 stat\_0 = "Summary\n Statistic"  
 #ci\_stat\_0 = "95% CI"  
)  
  
 # add\_ci(statistic = list(  
 # all\_categorical() ~ "{conf.low} - {conf.high}",  
 # all\_continuous() ~ "{conf.low} - {conf.high}"  
 # )  
 # ) %>%   
  
knitr::knit\_print(ComplicSum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Table 10: Summary of complications in included sample   | Characteristic | Available Sample | Summary Statistic | | --- | --- | --- | | Complication Nature, % (n) | 6 |  | | Capsulitis - Stiffness |  | 50 (3) | | Pain - Other |  | 50 (3) | | Severity Grade, % (n) | 6 |  | | 1 |  | 67 (4) | | 2 |  | 17 (1) | | 4 |  | 17 (1) | |

A summary of the adverse events observed in the same is included in [Table 10](#tbl-complications).

### 3.3.2 Record [15.4] Patient-reported outcome measures

The QuickDASH total score and WORC Normalised Index, as well as Question 3 of the Physical sub-scale of the WORC were visualised using the *ggdist* and *ggplot2* packages. Plots were arranged using the *patchwork* package.

CCADASH <- ggplot(data = MasterPROM, mapping = aes(y = QDASH, x = TimePoint)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 labs(  
 title = "QuickDASH",  
 y = "QuickDASH Total Score"  
 )  
  
CCAWORC1 <- ggplot(data = MasterPROMWORC, mapping = aes(y = WORCNorm, x = TimePoint)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('WORC Normalised')  
  
CCAWORC2 <- ggplot(data = MasterPROMWORC, mapping = aes(y = WORCPhysicalQ3, x = TimePoint)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('WORC Physical Q3')  
  
CCADASH + CCAWORC1 / CCAWORC2

|  |
| --- |
| Figure 8: Patient reported outcomes (QDASH, WORC) trajectories by timepoint |

## 3.4 Record [16] Main results

The imputed datasets for QDASH and WORC were modeled with a linear mixed effects model in *lme4* and summarised with *broom.mixed*. Up to a 38.7 point improvement in QuickDASH total score was observed (Table 11), as well as 47.1 and 54 point improvements in WORC Index Normalised and WORC Physical Question3 respectively (Table 12). Distributions of model-predicted results illustrated variability in recovery trajectories within all PROMs measures (Figure 7).

QDASHfitimp <- with(  
 QDASHImputed,  
 exp = lme4::lmer(  
 QDASH ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2 + (1|TreatmentInt)  
 )  
 )  
  
QDASHfimpsum <- tbl\_regression(  
 QDASHfitimp,   
 tidy\_fun = pool\_and\_tidy\_mice,   
 show\_single\_row = "Sex2",  
 label = list(  
 Sex2 ~ "Male vs Female",  
 AgeAtTreatment ~ "Age at Surgery",  
 `factor(TimePoint, ordered = FALSE)` ~ "TimePoint"),  
 estimate\_fun = function(x) style\_number(x, digits = 2),  
 pvalue\_fun = function(x) style\_pvalue(x, digits = 3))  
  
knitr::knit\_print(QDASHfimpsum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Table 11: Pooled linear mixed effects model for QuickDASH   | **Characteristic** | **Beta** | **95% CI** | **p-value** | | --- | --- | --- | --- | | TimePoint |  |  |  | | Preop | — | — |  | | 3months | -11.20 | -19.19, -3.22 | 0.008 | | 6months | -25.02 | -31.70, -18.34 | <0.001 | | 12months | -30.38 | -37.20, -23.57 | <0.001 | | Age at Surgery | -0.18 | -0.65, 0.28 | 0.419 | | Male vs Female | -6.51 | -15.32, 2.30 | 0.141 | | Abbreviation: CI = Confidence Interval | | | | |

TableQDASHCCA <- tbl\_summary(  
 QDASHPROMInput2 %>% dplyr::select(  
 TimePoint,  
 QDASH  
 ),  
 by = TimePoint,  
 label = list(  
 QDASH ~ "QuickDASH"  
 ),  
 statistic = list(all\_continuous() ~ "{median} ({p25} - {p75})"),  
 #missing = "ifany"  
 )  
  
as\_flex\_table(TableQDASHCCA)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 12: Summary of QuickDASH complete case analysis   | **Characteristic** | **Preop**  N = 581 | **3months**  N = 581 | **6months**  N = 581 | **12months**  N = 581 | | --- | --- | --- | --- | --- | | QuickDASH | 44 (34 - 57) | 32 (20 - 48) | 18 (9 - 30) | 5 (2 - 25) | | Unknown | 12 | 29 | 35 | 28 | | 1Median (Q1 - Q3) | | | | | |

# Fit the lm model(s)  
WORCNormfit <- with(WORCImputed,exp = lmer(WORCNorm ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2 + (1|TreatmentInt)))  
  
WORCNormfitsum <- tbl\_regression(WORCNormfit, tidy\_fun = pool\_and\_tidy\_mice, show\_single\_row = "Sex2",  
 label = list(Sex2 ~ "Male vs Female", AgeAtTreatment ~ "Age at Surgery", `factor(TimePoint, ordered = FALSE)` ~ "TimePoint"),  
 estimate\_fun = function(x) style\_number(x, digits = 2), pvalue\_fun = function(x) style\_pvalue(x, digits = 3))   
  
WORCQ3fit <- with(WORCImputed,exp = lmer(WORCPhysicalQ3 ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2 + (1|TreatmentInt)))  
  
WORCQ3fitsum <- tbl\_regression(WORCQ3fit, tidy\_fun = pool\_and\_tidy\_mice, show\_single\_row = "Sex2",  
 label = list(Sex2 ~ "Male vs Female", AgeAtTreatment ~ "Age at Surgery", `factor(TimePoint, ordered = FALSE)` ~ "TimePoint"),  
 estimate\_fun = function(x) style\_number(x, digits = 2), pvalue\_fun = function(x) style\_pvalue(x, digits = 3))  
  
WORCfitsum <- tbl\_merge(tbls = list(WORCNormfitsum, WORCQ3fitsum),  
 tab\_spanner = c("Normalised Index", "Physical Q3")  
)  
  
knitr::knit\_print(WORCfitsum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Table 13: Pooled linear mixed effects model for WORC normalised total score and WORC Physical sub-scale Question 3   |  | Normalised Index | | | Physical Q3 | | | | --- | --- | --- | --- | --- | --- | --- | | **Characteristic** | **Beta** | **95% CI** | **p-value** | **Beta** | **95% CI** | **p-value** | | TimePoint |  |  |  |  |  |  | | Preop | — | — |  | — | — |  | | 6months | 36.21 | 27.84, 44.58 | <0.001 | -35.98 | -46.33, -25.62 | <0.001 | | 12months | 42.76 | 35.78, 49.74 | <0.001 | -46.98 | -55.55, -38.42 | <0.001 | | Age at Surgery | 0.28 | -0.23, 0.79 | 0.268 | -0.51 | -1.12, 0.09 | 0.095 | | Male vs Female | 11.08 | 1.57, 20.58 | 0.023 | -9.53 | -20.02, 0.95 | 0.074 | | Abbreviation: CI = Confidence Interval | | | | | | | |

QDASHPredict <- marginaleffects::predictions(QDASHfitimp)  
WORCNormPredict <- marginaleffects::predictions(WORCNormfit)  
WORCQ3Predict <- marginaleffects::predictions(WORCQ3fit)

TableQDASHImp <- tbl\_summary(  
 QDASHPredict %>% dplyr::select(  
 TimePoint,  
 QDASH  
 ),  
 by = TimePoint,  
 label = list(  
 QDASH ~ "QuickDASH"  
 ),  
 statistic = list(all\_continuous() ~ "{median} ({p25} - {p75})")  
 )  
  
as\_flex\_table(TableQDASHImp)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 14: Summary of model-predicted QuickDASH by TimePoint   | **Characteristic** | **Preop**  N = 581 | **3months**  N = 581 | **6months**  N = 581 | **12months**  N = 581 | | --- | --- | --- | --- | --- | | QuickDASH | 40 (32 - 57) | 32 (18 - 48) | 15 (5 - 30) | 7 (2 - 30) | | 1Median (Q1 - Q3) | | | | | |

TableWORCsum <- tbl\_summary(  
 WORCNormPredict %>% dplyr::select(  
 TimePoint,  
 WORCNorm  
 ),  
 by = TimePoint,  
 label = list(  
 WORCNorm ~ "WORC Normalised"  
 ),  
 statistic = list(all\_continuous() ~ "{median} ({p25} - {p75})")  
 )  
  
  
TableWORCQ3sum <- tbl\_summary(  
 WORCQ3Predict %>% dplyr::select(  
 TimePoint,  
 WORCPhysicalQ3  
 ),  
 by = TimePoint,  
 label = list(  
 WORCPhysicalQ3 ~ "WORC Physical Q3"  
 ),  
 statistic = list(all\_continuous() ~ "{median} ({p25} - {p75})")  
 )  
  
WORCfitsum <- tbl\_stack(tbls = list(TableWORCsum, TableWORCQ3sum)  
 )  
  
as\_flex\_table(WORCfitsum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 15: Summary of model-predicted WORC Normalised Total Score and WORC Physical sub-scale Question 3 by TimePoint   | **Characteristic** | **Preop**  N = 581 | **6months**  N = 581 | **12months**  N = 581 | | --- | --- | --- | --- | | WORC Normalised | 35 (21 - 57) | 84 (63 - 93) | 86 (78 - 95) | | WORC Physical Q3 | 73 (48 - 87) | 20 (11 - 37) | 9 (3 - 29) | | 1Median (Q1 - Q3) | | | | |

QDASHprPlot <- ggplot(data = QDASHPredict, mapping = aes(y = QDASH, x = TimePoint)) + stat\_slabinterval(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('QuickDASH')  
   
  
   
WORCNormprPlot <- ggplot(data = WORCNormPredict, mapping = aes(y = WORCNorm, x = TimePoint)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('WORC Normalised')  
  
  
  
WORCQ3prPlot <- ggplot(data = WORCQ3Predict, mapping = aes(y = WORCPhysicalQ3, x = TimePoint)) +  
 stat\_slab(aes(thickness = after\_stat(pdf\*n)), scale = 0.7) +  
 stat\_dotsinterval(side = "bottom", scale = 0.7, slab\_linewidth = NA) +  
 scale\_fill\_brewer(palette = "Set2") +  
 ggtitle('WORC Physical Q3')  
  
  
(QDASHprPlot) +  
 (WORCNormprPlot / WORCQ3prPlot) +  
 plot\_layout(ncol = 2)

|  |
| --- |
| Figure 9: Model predicted PROMs (QuickDASH, WORC) trajectories across time points. |

## 3.5 Record [17] Sensitivity analyses

Based on the distribution changes in QDASH and WORC over time, a sensitivity analysis was performed on the model structure using the complete case dataset. A comparison was made between quantile regression using the *quantreg* package and an ordinary least squares linear model from *stats* and a linear mixed effects model with *lme4*. Results were tabulated using the *modelsummary* package as rq models are not supported in *gtsummary*.

QDASHfit <- list(  
 "RQ" = rq(  
 QDASH ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2,  
 tau = 0.5,  
 method = "fn",  
 data = QDASHPROMInput2  
 ),  
 "LM" = lm(  
 QDASH ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2,  
 data = QDASHPROMInput2  
 ),  
 "ME" = lme4::lmer(  
 QDASH ~ factor(TimePoint, ordered = FALSE) + AgeAtTreatment + Sex2 + (1|TreatmentInt),  
 data = QDASHPROMInput2  
 )  
)  
  
SensTablesum <- modelsummary::modelsummary(  
 QDASHfit,  
 statistic = c(  
 "se = {std.error}",  
 "conf.int"),  
 fmt = fmt\_decimal(1),  
 output = "gt",  
 coef\_rename = coef\_rename  
 )  
  
knitr::knit\_print(SensTablesum)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 16: Comparison of linear model types to assess QuickDASH by Timepoints.   |  | RQ | LM | ME | | --- | --- | --- | --- | | (Intercept) | 59.8 | 56.6 | 54.0 | |  | se = 13.5 | se = 11.4 | se = 14.0 | |  | [33.2, 86.5] | [33.9, 79.3] | [26.3, 81.6] | | 3months | -9.9 | -10.8 | -11.6 | |  | se = 4.6 | se = 3.9 | se = 3.3 | |  | [-18.9, -0.8] | [-18.5, -3.0] | [-18.0, -5.1] | | 6months | -25.8 | -24.4 | -25.2 | |  | se = 4.3 | se = 4.2 | se = 3.6 | |  | [-34.3, -17.2] | [-32.8, -16.0] | [-32.2, -18.1] | | 12months | -37.9 | -31.4 | -31.9 | |  | se = 3.7 | se = 3.9 | se = 3.3 | |  | [-45.3, -30.5] | [-39.0, -23.7] | [-38.4, -25.3] | | AgeAtTreatment | -0.2 | -0.1 | -0.0 | |  | se = 0.2 | se = 0.2 | se = 0.2 | |  | [-0.5, 0.2] | [-0.5, 0.2] | [-0.5, 0.4] | | Sex2Male | -8.3 | -7.1 | -8.4 | |  | se = 4.5 | se = 3.6 | se = 4.6 | |  | [-17.2, 0.6] | [-14.3, 0.1] | [-17.5, 0.7] | | SD (Intercept TreatmentInt) |  |  | 10.2 | | SD (Observations) |  |  | 13.1 | | Num.Obs. | 128 | 128 | 128 | | R2 | 0.375 | 0.401 |  | | R2 Adj. |  | 0.377 |  | | R2 Marg. |  |  | 0.397 | | R2 Cond. |  |  | 0.625 | | AIC | 1092.4 | 1088.4 | 1059.1 | | BIC | 1109.6 | 1108.4 | 1081.9 | | ICC |  |  | 0.4 | | Log.Lik. |  | -537.204 |  | | RMSE | 16.43 | 16.09 | 11.23 | |

The comparison between models revealed an underestimate of the difference in 12month score to preoperative baseline of 7.7 points for the QuickDASH (14.7%) in the mixed effects linear model, compared to the quantile regression (50th percentile).

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