

British Orthopaedic Foot and Ankle Society

Registry Report 2023

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Introduction

The data presented in this report covers procedures entered into the British Orthopaedic Foot & Ankle Society (BOFAS) Registry from its inception in 2014 until the end of December 2022. The 1st Metatarsophalangeal Joint Arthrodesis Pathway (1st MTPJAP) and the Ankle Arthrodesis Pathway (AAP) have been open since the registry started, the Foot and Ankle General Pathway (FAGP) was opened towards the end of 2016. 2020 saw the introduction of both the Achilles Rupture Trauma Pathway and Achilles Tendinopathy Pathway and also the Ankle Primary & Revision Arthroplasty pathways. In 2021 the Ankle Fracture and Foot and Ankle Trauma pathways were launched, and this year saw the launch of a dedicated 1st MTPJ Arthroplasty pathway.

Over this period we have seen a steady increase in data entry but, it is clear that as it currently stands, the Registry only captures a small proportion of national activity, both in the Private & NHS sectors. We are making headway in including data from some, already established, Amplitude based Hospital systems and are also exploring how we may import data from other established Hospital Patient Related Outcome Measure (PROM) collection systems.

The majority of the information in this report is summary data, however we have begun to statistically analyse certain outcomes where we have sufficient pathway

numbers. The information contained within this report will be useful for BOFAS members in their appraisals and, as we continue to collect data, it will aid quality improvement and may help direct practice and future research priorities nationally.

The BOFAS Registry is one of the eight Emerging Registries forming part of the Trauma & Orthopaedic Registries Unifying Structure (TORUS). TORUS is a collaborative project of the British Orthopaedic Association (BOA) in conjunction with the specialist societies. The BOFAS Registry is a national audit and is available to all foot and ankle surgeons who are members of the society. Surgical disciplines lend themselves to evidence capture, and a registry is an ideal method of demonstrating the nature and success of one's practice. The BOFAS Registry incorporates a downloadable personal Revalidation Report, which in conjunction with the annual report, can be used to assess your own practice against the average nationally.



BOFAS Registry

Aims

The broad aims of the BOFAS Registry are in line with those of the BOA Quality Outcomes project:

- Help surgeons to track the outcomes of their patients.
- Allow Surgeons/Trusts to compare themselves to others or the average and to identify areas for improvement.
- Provide surgeons with information for revalidation.
- Provide evidence on trends in outcomes, performance of different implants/procedures/etc.
- Enable individuals and Trusts who may be potential outliers to be alerted to this in order to take action.

Section 1: Outcomes Committee

Background

The BOFAS Registry is the responsibility of the BOFAS Outcomes Committee. The role of the committee is to support the Society and Council in developing suitable processes to collect patient outcome measures.

Duties of the Outcomes Committee include:

- Working with the platform provider to enable collection of information into central BOFAS registry.
- Ensuring that the consent from remains compliant with legal requirements.
- Oversight of information governance.
- Publication of data.
- Registry funding.
- Long term strategy.

Further details regarding the BOFAS Registry can be found on the BOFAS website.

Membership of Outcomes Committee

- | | | | |
|---------------------|----------------|------------------------------|----------------|
| • Chair: | Lyndon Mason | • Co-opted: | Karan Malhotra |
| • Secretary: | Ed Wood | • Co-opted: | Toby Jennison |
| • Member: | Tim Clough | • Co-opted: | Tom Lewis |
| • Member: | Nilesh Makwana | • Caldicott Guardian: | Mark Davies |
| • Member: | James McKenzie | • President: | Paul Halliwell |
| • Member: | Robbie Ray | • Treasurer: | Hiro Tanaka |
| • Co-opted: | Andy Goldberg | • SciComm Liaison: | Rajesh Kakwani |

Uptake

The degree of uptake of the registry by the BOFAS membership is increasing with time, however it remains a minority of members actively entering data.

Over the last few years we have seen an almost

exponential increase in the total number of pathways and, by the end of 2022, have over 14,000 patients within the registry (Fig 1.1). This is still however, only a small proportion of the national figures.

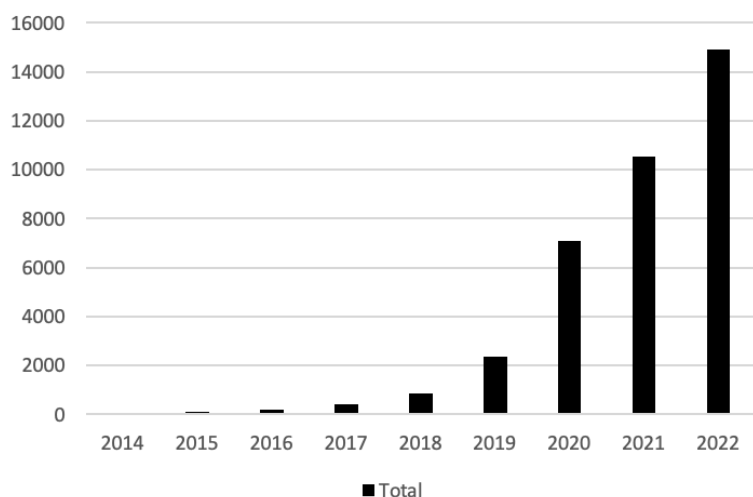


Figure 1.1 - Registry totals by year

The impact of the Covid pandemic on clinical activity was reflected in the low number of new pathways generated in the previous 2 years, with an average of 48 and 99 new pathways per month in 2020 and 2021 respectively.

Excluding bulk data imports, in 2022, there has been a significant increase in activity, with an average of 152 new pathways per month (Fig 1.2).

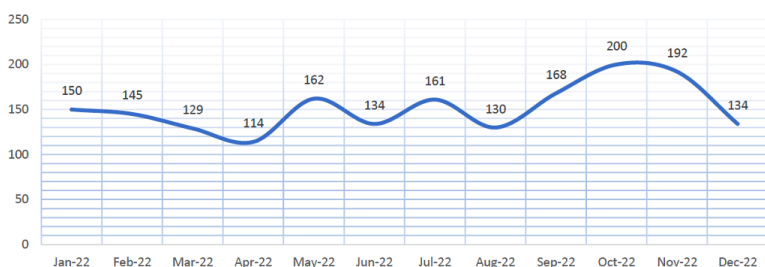


Figure 1.2 - Number of new registry pathways per month in 2022

A number of factors may prevent surgeons from registering and entering cases: time pressure, unfamiliarity, concern regarding data use.

We believe the registry will be a valuable tool for our members, both for revalidation and appraisal, and may become something that the Responsible Officers look to.

As the registry is not currently mandated, support from Trusts regarding data collection and input is widely variable.

Videos on how to use the registry are now available on the BOFAS website.

Compliance

Compliance with consent is 67.8% across all pathways. Where consent has been gained, surgeons can look back at individual outcomes. Where consent is absent, the record is anonymised. In this scenario, the PROMS enter the registry summary data, but it is not possible to identify the individual or add follow up data. It is still necessary to take paper consent and file this in the notes even though patients confirm consent online when they first log in, since their details have been entered to enable them to be contacted, and that is only legal if consent has already been taken.

Approximately 15% of patients have no email address associated with their pathway. This removes the ability of the registry to automate data collection. In this scenario different strategies for post-op PROMS collection need to be put in place. Making use of telephone review streams can be a good solution.

To improve compliance for PROMS, BOFAS commissioned OpenMarket to provide a SMS text messaging service. This was administered by Amplitude and commenced in March/April 2021. The overall compliance for both e-mail and SMS has been in the order of 60%. The SMS service increased the compliance by 12% on average, over one year (fig 1.3). OpenMarket ceased to be a company at the end of December 2022 and as a result Amplitude has taken over the role of SMS provider for BOFAS.

We have also seen a significant proportion of patients registered but with no initial PROMS entered. It is not clear if this reflects patients registered in clinic, who are yet to come to their procedure, or if it has simply not been recorded.

TASK-SETS DUE FOR COMPLETION PER MONTH

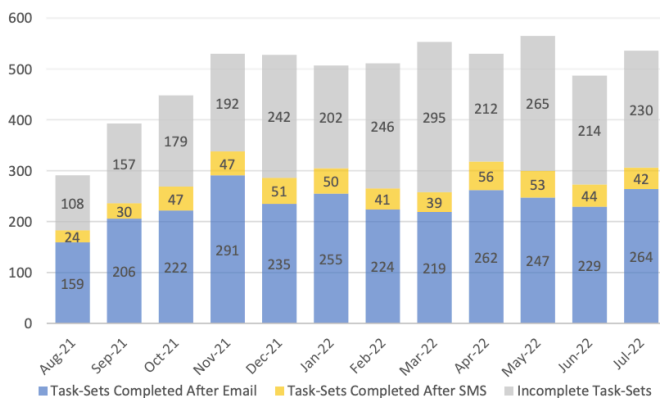


Figure 1.3 - Number of completed tasks per month on the registry pathways

Active Pathway Owners

Although there are over 100 registered pathway owners on the BOFAS registry, only 39 have actively contributed to the registry this year. The list of the active contributors for the last year is shown below.

The highest number of pathways registered this year was by Robbie Ray, second was Nilesh Makwana and third was Devendra Mahadevan, each of whom were presented with awards by BOFAS.

| | |
|---------------------|---------------------------|
| Abbasian, Ali | Lyle, Shirley |
| Acharya, Ashok | Machin, David |
| Barnes, Simon | Mahadevan, Devendra |
| Barrett, Mike | Makwana, Nilesh |
| Bing, Andrew | Marquis, Christopher |
| Chlebinkas, Donatas | Mason, Lyndon |
| Clint, Simon | May, Jonathan |
| Cooper, Lucy | McKenzie, Jamie |
| Dawe, Edward | Mobbassar Siddiqui, Bobby |
| Devany, Adam | Molloy, Andy |
| Goff, Thomas | Ray, Robbie |
| Grice, John | Robinson, Peter |
| Heaver, Catriona | Rose, Barry |
| Heyes, Gavin | Singh, Anjani |
| Hickey, Ben | Sirikonda, Siva |
| Humphrey, Joel | Smith, George |
| Islam, Amirul | Williams, Timothy |
| Koc, Togay | Wood, Edward |
| Latif, Ahmed | Zaidi, Razi |
| Loveday, David | |

A live, continuously updated, list of surgeons who actively contribute to the registry, can be found on the BOFAS website: <https://www.bofas.org.uk/clinician/bofas-registry/contributors>



Section 2: Overview of PROM Scores

The BOFAS Registry allows foot and ankle surgeons to use the outcome scores to assess patients both pre- and post-operatively. The standard outcomes scores for each pathway are detailed in table 2.1. Other scores are available, depending on Surgeon choice, and may be configured in the Surgeon's registry settings. For example, one may choose to record MOXFQ & EQ-5D for all patient groups. Scores are recorded pre-operatively then routinely via email, SMS text, or in person, at regular intervals post-operatively, depending on the pathway.

EQ-5D-5L and EQ-5D Health VAS

EQ-5D is a standardised measure of health status developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic appraisal.

The five level EQ-5D consist of two pages: the EQ-5D descriptive system and the EQ VAS. The EQ-5D comprises five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no, slight, moderate, severe and extreme problems. The digit generated for each dimension is combined into a 5 digit number that describes the patient's health state. For example, a health state 21143 represents a patient who indicates slight problems with mobility, no problems with self-care, and usual activities dimension, severe pain or discomfort and moderate

problems on the anxiety/depression dimension. The health states can then be converted into a single index value.

The EQ VAS records the patient's self-rated health on a vertical 20cm VAS line, where the end points are labelled 'The best health you can imagine' (100 points) and 'The worst health you can imagine' (0 points). The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement. The EQ-5D-5L has been validated in a diverse patient population in 6 countries. The EQ-5D data can be compared against data for the average person of the same age and/or gender in the general population, helping identify the burden of disease in a particular patient population.

Manchester-Oxford Foot Questionnaire

The MOXFQ is a 16-item PROM instrument, which is self-administered. It assesses how foot and ankle problems impair health-related quality of life and is completed pre- and post-operatively. It was originally intended for use for hallux valgus surgery and more recently proven for use with a variety of foot and ankle problems

The questionnaire consists of three domains/scales:

- Walking/standing – 7 items. (MOXFQ-W)
- Pain – 5 items. (MOXFQ-P)
- Social interaction – 4 items (MOXFQ-S)

The responses consist of a 5 point Likert scale (0-4), which ranges from no limitation (0) to maximum limitation (4). Scores for each domain are calculated by summing the responses in each domain. The raw scale scores are then converted to a metric from 0-100, where 100 denotes the most severe. The raw scores can also be used to generate a summary Index score (MOXFQ- Index).

The questionnaire has been validated.

The Achilles Tendon Total Rupture Score

The ATRS is a validated, patient reported score for measuring outcome after total Achilles tendon rupture. There are 10 parameters, each of which is scored on a scale from 0 – 10, where 0 represents major limitations/symptoms and 10 represents no limitations or symptoms.

Outcomes are recorded in the following domains:

- Are you limited because of decreased strength in the calf/ Achilles tendon/foot?
- Are you limited because of fatigue in the calf/ Achilles tendon/foot?
- Are you limited due to stiffness in the calf/Achilles tendon/foot?
- Are you limited because of pain in the calf/Achilles tendon/foot?
- Are you limited during activities of daily living?
- Are you limited when walking on uneven surfaces?
- Are you limited when walking quickly upstairs or uphill?
- Are you limited during activities that include running?
- Are you limited during activities that include jumping?
- Are you limited in performing hard physical labor?

The original article demonstrates good construct and convergent validity with both the FAOS and VISA-A scores. Intraclass correlation coefficient was 0.98 and the internal consistency was shown to be 0.96 (Cronbach's alpha) showing good test-retest reliability (Nilsson-Helander K et al, 2007). A modified, 'cross cultural' version of the score was validated in the English population by Carmont et al, where it was shown to have excellent reliability (Carmont M et al 2012). The minimal detectable change was 6.75 points.

The BOFAS Registry uses the original Swedish/English language version. There were no significant differences in results comparing the 'cross cultural' & Swedish versions (Carmont M et al 2012).

The Minimally Important Change (MIC) was determined for the Dutch version of the score (Dams OC et al 2020). Using an anchor-based approach they showed MICs of 13.5 (cf EQ-5D-5L mobility), 25.5 (cf EQ-5D-5L usual activities) and 28.5 (cf GROC).

The Achilles Tendon Rupture Repair Score

Not to be confused with the ATRS above, the Achilles Tendon Rupture Repair Score (AS) was originally described by Leppilahti et al in 1998 for measurement of the outcome of surgically treated Achilles ruptures. The version provided by the registry uses the modification described by Hutchison et al who, in lieu of an isokinetic dynamometer, used a single heel raise test to assess muscle strength (Hutchison AM et al 2015).

Outcomes are recorded in the following domains:

- Pain
- Stiffness
- Calf muscle weakness (subjective)
- Footwear restrictions

- Active range of motion difference between ankles
- Subjective result
- Isokinetic muscle strength (modification)

The maximum score is 100 indicating no impairment, with 0 representing a poor result.

To the best of the authors' knowledge, the score and its modifications have not been validated and MIC not determined.

As this outcome measure requires face to face review it is acknowledged that it is optional, should those facilities exist.

Olerud Molander Ankle Score

The OMAS is a nine item, disease specific, outcome score designed to evaluate symptoms after an ankle fracture. The scale is a functional rating with a maximum score of 100, indicating an unimpaired ankle.

Subjective outcomes are recorded in the following parameters:

- Pain
- Stiffness
- Swelling
- Stair climbing
- Running
- Jumping
- Squatting
- Use of supports
- Work/ADL

The original article describes significant correlation with patients' reported outcomes on a linear analogue scale, range of motion, presence of osteoarthritis and presence of dislocations (Olerud & Molander, 1984).

There is evidence for test-retest reliability and construct validity for the English, Swedish & Turkish versions (Garratt 2018, Nilsson 2013, Turhan 2017).

The Smallest Detectable Change (SDC) is 20.6: this indicates the level of change that can be considered a real difference (Garratt 2018). The SDC does not however represent a clinically significant change, however the MIC for OMAS has yet to be defined.

Victorian Institute of Sports Assessment

The VISA-A outcome score is specific to Achilles tendinopathy, originally described by Robinson et al, 2001. The score consists of 8 questions measuring domains of pain, function in daily living and sporting activity. The maximum score is 100, with high scores indicating a good outcome. The original article reported

good reliability and stability in a sporting population, however evidence of reliability has not been established in the non-sporting population. One may therefore wish to consider additional PROMS in this group. The MIC has been estimated for patients with Insertional Achilles Tendinopathy (see below).

Minimally Important Change

Whilst changes in outcome scores may be statistically significant, this may or may not, represent a clinically significant difference in patients' symptoms. The Minimally Important Change (MIC) represents a change in the outcome score that is clinically relevant. The MIC for the EQ-5D index score has been shown to be 0.074 (Walters 2005). For the MOXFQ components Walking/

Standing, Pain, Social Interaction the MICs are 16, 12 and 24 respectively (Dawson 2012). As yet, the MIC for OMAS has not been determined. The MICs for the ATRS range from 13.5 to 28.5 and are documented above (Dams OC et al 2020). For the VISA-A an MIC of 6.5 points has been suggested for Insertional Achilles Tendinopathy (McCormack et al 2015).

Data Analysis

As the number of cases are small, only summary data is presented in this report. As the numbers grow, we aim to provide more robust, statistical analysis. For the 1st MTPJ fusion and Ankle Fusion pathways the criteria are clearly defined, and analysis of the variables can be achieved. The general Foot and Ankle pathway is more difficult to analyse because of the sheer variety of procedures

undertaken. However, in this report, we have undertaken a limited analysis based on four common diagnoses found within the pathway. We are working with Amplitude to try to achieve consistency, particularly with definition of procedures, to help us achieve this in the future. All box-plot graphs illustrate median and range.

Statistical Analysis

Where statistical tests were performed the following rules were followed: Continuous variables were tested for normality distribution and presented as means and 95% confidence intervals. Categorical and qualitative variables are expressed as numbers and percentages. The Student t-test and ANOVA was used for continuous variables if the criteria for normality and equality of variances were fulfilled. Alternatively, the Mann-Whitney U test was performed if independent variables or the Wilcoxon

signed-rank test if dependent variables. Categorical variables were analysed using the Chi-square test for sample sets greater than 5, otherwise the Fisher's exact test was used. Missing data were included in flowcharts and descriptive analyses, allowing denominators to remain consistent in calculations. All data were assessed using SPSS Version 26.0 (SPSS Inc., IBM, Chicago, IL). Where expressed, a 95% confidence interval has been used.

Table 2.1 - Standard PROMS for each Pathway

| Pathway | MOXFQ | EQ-5D | VAS Pain | OMAS | ATRS | AS | VISA-A |
|----------------------------|-------|-------|----------|------|------|----|--------|
| 1 st MTP Fusion | ✓ | ✓ | ✓ | | | | |
| Ankle Arthrodesis | ✓ | ✓ | ✓ | | | | |
| Foot & Ankle Generic | ✓ | ✓ | ✓ | | | | |
| TAR Primary | ✓ | ✓ | | | | | |
| TAR Revision | ✓ | ✓ | | | | | |
| Achilles Rupture | | | | | ✓ | ✓ | |
| Achilles Tendinopathy | | ✓ | | | | | ✓ |
| Trauma Ankle Fracture | | ✓ | ✓ | ✓ | | | |
| Trauma Foot & Ankle | ✓ | ✓ | ✓ | | | | |

Section 3: 1st Metatarsophalangeal Joint Arthrodesis Pathway

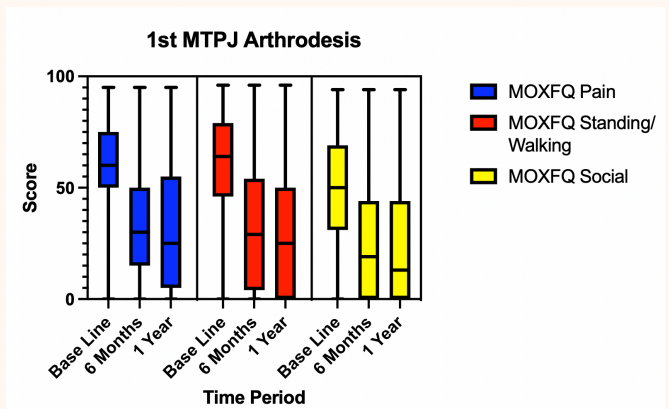
Within the registry, 1092 1st MTPJ Arthrodesis pathways have been instituted since it originally opened. Previously, the completion rate for pre-operative PROMS was reasonable, at approximately 80% across the 3 outcome measures. With the import of external data sets, accounting for approximately 400 pathways, this rate has fallen. Across the whole dataset, complete pre-operative PROMS (MOXFQ, EQ-5D & VAS Pain) were found for 46%, 64% and 54% of pathways respectively. At 6 months there were fewer with 26%, 33% and 28% and at 12 months this fell further to 22%, 23% and 20% of all pathways with completed PROMS respectively.

The mean age was 65 (SD 17.31). Recorded gender was 34% male and 65% female. BMI was recorded in 584 pathways, with the majority of patients being either overweight or obese (BMI ≥ 25). The operation was undertaken on the right foot in 52% of individuals and left side in 43% of individuals, in the remainder the side was not recorded. Of the 462 pathways where smoking status was recorded: 7% of individuals were smokers, 21% were ex-smokers and 72% were non-smokers. The numbers for smoking were too small to make any comparison in outcomes. In the 602 pathways where recorded, 94% of patients were classed as primary procedures, with 3% as revision procedures, 0.3% as second revision, 1% conversion from arthroplasty and 2% as 'other' indication. Additional procedures were recorded in 199 cases: 86 of these were lesser toe corrections, 46 were recorded as either Weil's, Forefoot Arthroplasties or Forefoot reconstructions, and a further 56 were recorded as having 'other' procedures.

The PROMS results are summarised in table 3.1. The average increase in the EQ-5D Index was from 0.58 preoperative to 0.72 and 0.77 at 6 and 12 months post-operative respectively, a statistically significant change. In comparison to population norms (Kind 1999) this is favourable, as the mean EQ-5D index is 0.713 (Std Dev 0.229, Median 0.786) for England. At both 6 and 12 months the improvement was greater than the MIC, indicating a clinically relevant change. Regarding the EQ-5D Health VAS, at 12 months, no significant change was seen. The number of patients with scores recorded at 2 years is too small for meaningful analysis.

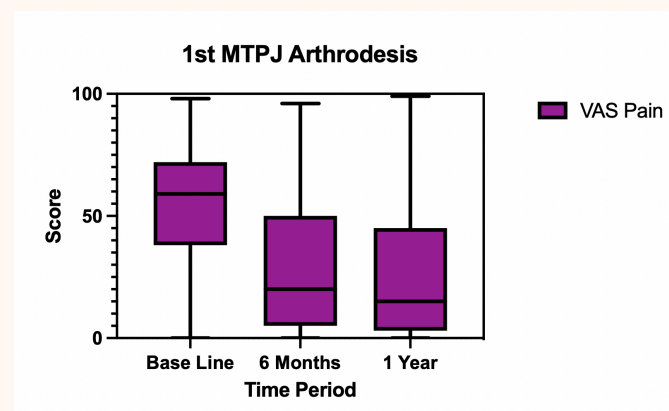
The MOXFQ components all revealed a clinically relevant and statistically significant improvement in symptoms at 6 months post-operative, with changes greater than the MIC in all domains. The Pain scores improved from a pre-operative baseline of 60.91 to 30.48 at 12 months post-operative, the Walking/Standing scores improved from 60.83 to 28.67 and the Social Interaction scores from 50.02 to 23.01 (Fig 3.1). The number of patients with recorded scores at 2 years is too small for meaningful analysis.

Figure 3.1 - MOXFQ 1st MTPJ Pathway



The VAS pain score again showed a significant improvement from 53.35 pre-operatively, to 28.26 and 23.52 at 6 and 12 months post-operative respectively (Fig 3.2).

Figure 3.2 - VAS Pain 1st MTPJ Pathway



Details of complications and revision surgery were inconsistently documented, and it is not possible to draw meaningful conclusions from the dataset as it currently stands.

Table 3.1 - PROMS Scores for 1st MTPJ Pathway Pathway

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|-------------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 581 | 282 | 201 | |
| MOXFQ Pain | Mean | 60.91 | 34.13 | 30.48 | |
| | Lower | 58.93 | 30.79 | 26.34 | <.001 |
| | Upper | 62.89 | 37.48 | 34.61 | |
| MOXFQ Walking/Standing | Mean | 60.83 | 35.10 | 28.67 | |
| | Lower | 58.41 | 31.07 | 24.24 | <.001 |
| | Upper | 63.25 | 39.13 | 33.09 | |
| MOXFQ Social | Mean | 50.02 | 26.63 | 23.01 | |
| | Lower | 47.62 | 23.14 | 18.85 | <.001 |
| | Upper | 52.43 | 30.11 | 27.16 | |
| EQ5D Index | Mean | 0.58 | 0.72 | 0.77 | |
| | Lower | 0.56 | 0.69 | 0.75 | <.001 |
| | Upper | 0.61 | 0.74 | 0.8 | |
| VAS Pain | Mean | 53.35 | 28.26 | 23.52 | |
| | Lower | 50.98 | 24.86 | 19.64 | <.001 |
| | Upper | 55.72 | 31.65 | 27.41 | |

Section 4: Ankle Arthrodesis Pathway

41 hospitals and 58 surgeons currently contribute to this pathway. Within the registry, 461 AA pathways have been instituted since it went live in 2016. This is a 35% increase since last year and 91% more than the previous year. Completed procedure forms were available for 272 cases, that is 59% of the total pathways. The MOXFQ score was completed at baseline in 272 patients, 126 have completed 6 month and 82 patients have completed 12 months.

The mean age was 64 (SD 17.96). Recorded gender was 65% male and 35% female. BMI was recorded in 205 pathways with a mean of 30.93, the majority being overweight or obese. Smoking was recorded in 7% of individuals, ex-smoker in 18% of individuals and non-smoker in 75% of individuals. A comparison was made comparing smoking status and outcomes: no significant difference could be found with EQ5D-Index, MOXFQ (Pain, Walking/Standing and Social) and VAS scores.

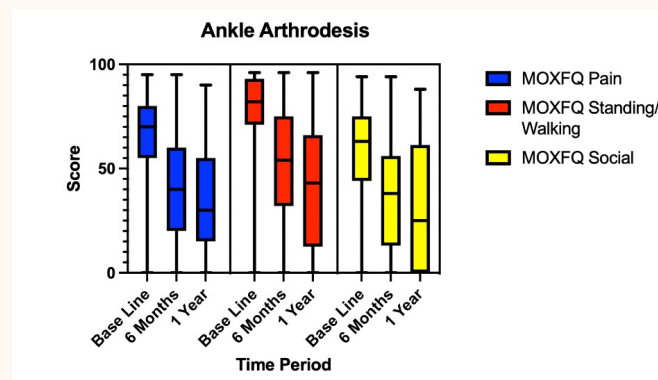
The most common indications for fusion were primary arthritis and post-traumatic arthritis. Other indications included inflammatory arthritis and avascular necrosis of talus.

Primary fusion accounted for 97.5% of cases and revision in 2.5% cases. Arthroscopic fusions accounted for 52.1% of the recorded pathways and 45.4% were open. Mini-open arthroscopic assisted was used in 2.6% cases.

Ankle fusion fixation was undertaken using cannulated screws in 78% of patients. The other forms of fixation include plates (19%), external fixator (1%), IM nail (1.5%) and staples. In those individuals undergoing fusion using screws, 2 screws were used in 78.8% and 3 screws in 12.4%. Most screws were inserted in parallel (73.3%) with some inserted crossed (19.3%). The most common combination of screw insertion were 2 screws in parallel (70%). All arthroscopic fusions were fixed using screws. Open fusions used a combination of screws (51%), plates (43%) and the remaining with an external fixator, IM nail and staples.

The MOXFQ Pain, Walking and Social interaction indices all improved significantly from baseline to 12 months ($P < 0.001$ (Fig 4.1)). This was greater than the MIC when comparing baseline with the outcome at 12 months.

Figure 4.1 - MOXFQ Ankle Arthrodesis Pathway



Further analysis of the data looked at arthroscopic and non-arthroscopic approach for ankle fusion with outcome scores. A significant difference was found for EQ5D-Index ($P=0.014$) and MOXFQ Social ($P=0.027$) favouring arthroscopic approach. It was not found to be significant for MOXFQ Pain, MOXFQ Social and VAS.

The average increase in the EQ-5D index was significant from a baseline 0.42 preoperative to 0.64 at 6 months and 0.68 ($p < .001$) at 1 year post operative. This was greater than the MIC at 6 and 12 months. In comparison to population norms, this is favourable as the mean EQ-5D index is 0.713 (Std Dev 0.229, Median 0.786) for England.

The EQ5D-L VAS improved from a baseline 64.05 to 70.5 at 12 months, however this was not significant ($P < 0.103$). The VAS Pain score significantly improved from a baseline 64.82 to 34.92 at six months and 27.2 at 12 months ($P < 0.001$ (Fig 4.2)). This was also clinically relevant with the change being greater than the MIC.

It was possible to compare VAS scores for primary ankle arthroplasty and arthrodesis graphically (Fig 4.3) and open with arthroscopic arthrodesis (Fig 4.4). The data show both ankle arthrodesis and arthroplasty and arthroscopic and open fusions lead to significantly improved patient outcomes at 12 months.

Table 4.1 - PROMS Scores for Ankle Arthrodesis Pathway

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|-------------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 272 | 126 | 82 | |
| MOXFQ Pain | Mean | 68.48 | 40.66 | 33.23 | <.001 |
| | Lower | 65.88 | 35 | 26.66 | |
| | Upper | 71.09 | 46.32 | 39.8 | |
| MOXFQ Walking/Standing | Mean | 81.81 | 54.11 | 44.6 | <.001 |
| | Lower | 79.31 | 47.11 | 36.46 | |
| | Upper | 84.31 | 61.11 | 52.74 | |
| MOXFQ Social | Mean | 62.23 | 37.95 | 34.85 | <.001 |
| | Lower | 58.83 | 31.82 | 26.9 | |
| | Upper | 65.64 | 44.07 | 42.79 | |
| EQ5D Index | Mean | 0.42 | 0.64 | 0.68 | <.001 |
| | Lower | 0.39 | 0.58 | 0.62 | |
| | Upper | 0.45 | 0.69 | 0.75 | |
| EQ5D VAS | Mean | 64.05 | 68.57 | 70.5 | 0.103 |
| | Lower | 58.51 | 63.72 | 65.61 | |
| | Upper | 69.59 | 73.42 | 75.39 | |
| VAS Pain | Mean | 64.82 | 34.92 | 27.2 | <.001 |
| | Lower | 61.77 | 29.22 | 21.24 | |
| | Upper | 67.88 | 40.63 | 33.16 | |

Figure 4.2 - VAS Pain Ankle Arthrodesis Pathway

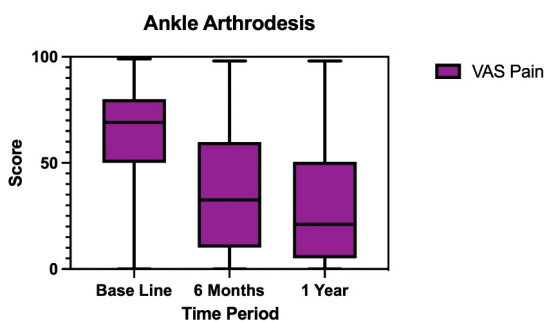


Figure 4.3 - VAS Pain Ankle Arthrodesis vs Arthroplasty

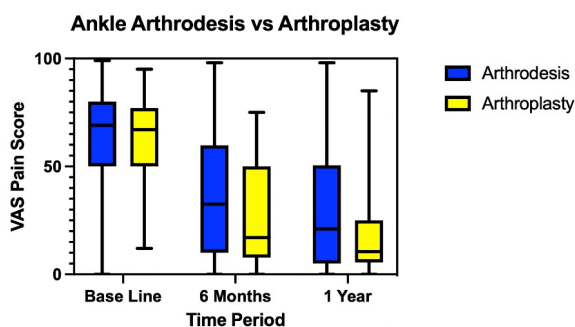
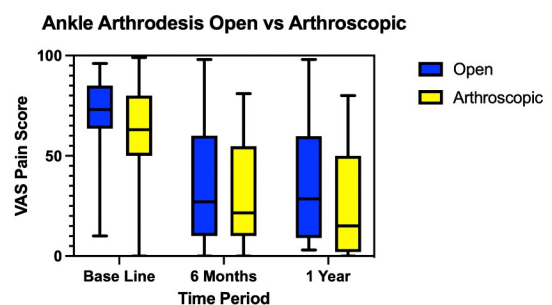


Figure 4.4 - VAS Pain Ankle Arthrodesis Open vs Arthroscopic



Section 5: Primary Ankle Arthroplasty Pathway

Within the registry, 174 primary arthroplasty pathways have been instituted since the pathway went live in 2020. Completed procedure forms were available for 110 cases at baseline, that is 63% of the total pathways. There were 41 (23%) completed forms at 6 months and 25 (14%) at 12 months.

The mean age was 70 (SD 14.18). Recorded gender was 55% male and 45% female. BMI was recorded in 118 pathways with a mean of 28.36, with the majority of arthroplasty patients categorized either as overweight or obese with 74.58% having a BMI ≥ 25 . The operated side was the left in 44% and the right in 54% of cases, with unrecorded in 2%. The ASA grade was recorded in 74 cases with most being ASA 2 (68%) or ASA 3 (23%). The majority were non-smokers (78%) with 17% ex-smokers and 5% smokers.

The diagnosis was primary osteoarthritis in 74% of cases, secondary osteoarthritis in 20% and inflammatory arthritis in 7%.

All recorded approaches were the anterior approach using an uncemented implant.

Numbers for complications were too small for any meaningful analysis.

The PROMS Scores are summarised in Table 5.1. The average increase in the EQ-5D Index was from 0.42 preoperatively to 0.73 and 0.73 at 6 and 12 months respectively. This was significant ($p=0.003$) between baseline and 12 months. This was also greater than the MIC, indicating a clinically relevant change.

The MOXFQ components all showed a clinically relevant and significant improvement in scores, in all domains, which was greater than the MIC at both 6 and 12 months (table 5.1 and Fig 5.1).

The VAS pain score improved from 65.32 to 31.2 at 6 months and 24.29 at 12 months. This was a significant change from baseline to 12 months ($P=0.005$) and greater than the MIC at 6 and 12 months (Fig 5.2).

Figure 5.1 - MOXFQ Ankle Arthroplasty Pathway

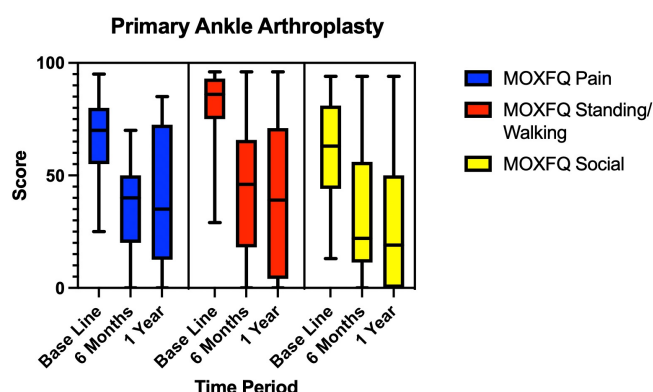


Figure 5.2 - VAS Pain Ankle Arthroplasty Pathway

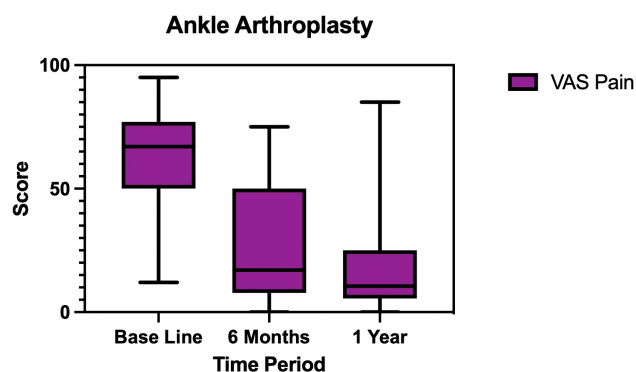


Table 5.1 - PROMS Scores for Primary Ankle Arthroplasty

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|-----------------------------------|-------|------------------|-----------------|------------------|--|
| Number | | 110 | 41 | 25 | |
| MOXFQ Pain | Mean | 60.95 | 24.33 | 19 | <.001 |
| | Lower | 56.27 | 16.07 | 6.12 | |
| | Upper | 65.63 | 32.6 | 31.88 | |
| MOXFQ Walking/Standing | Mean | 67.86 | 36.17 | 29.12 | <.001 |
| | Lower | 64.04 | 29.45 | 16.13 | |
| | Upper | 71.67 | 42.88 | 42.11 | |
| MOXFQ Social | Mean | 85.17 | 45.33 | 34.65 | 0.003 |
| | Lower | 82.12 | 34.72 | 17.52 | |
| | Upper | 88.22 | 55.95 | 51.77 | |
| EQ5D Index | Mean | 0.42 | 0.73 | 0.73 | 0.003 |
| | Lower | 0.36 | 0.65 | 0.63 | |
| | Upper | 0.47 | 0.81 | 0.83 | |
| VAS Pain | Mean | 65.32 | 31.2 | 24.29 | 0.005 |
| | Lower | 60.11 | 20.91 | 9.00 | |
| | Upper | 70.54 | 41.49 | 39.59 | |

Section 6: Achilles Tendon Rupture Pathway

The Achilles Tendon Rupture pathway was opened in 2020. This pathway allows both operative and non-operative management to be recorded, along with radiological findings. The standard PROMS for this pathway are the Achilles Tendon Total Rupture Score (ATRS) and Achilles Tendon Rupture Repair Score (AS).

A total of 150 pathways have been generated. Of these 116 are acute body ruptures, 19 acute myotendinous junction ruptures, 12 chronic ruptures and 3 re-ruptures. Of the 116 acute body ruptures 85 underwent conservative treatment, 20 MIS repair and 11 open repair.

Of the 19 acute MT junction injuries all underwent conservative treatment. Of the 3 re-ruptures, 2 underwent open repair and 1 conservative treatment. Of the 12 chronic ruptures, 9 underwent open repair and 3 conservative treatment.

The PROMS Scores are summarised in table 6.1. The completion rate for PROMS showed 55 completing 3 month PROMS, 57 at 6 months and 59 of the 150 at 12 months. Analysing the AS and ATRS scores there were no

significant differences between scores at 12 months between open repairs, conservative or MIS surgery. This was true for acute body ruptures and for all Achilles rupture patients in total.

The AS for open repairs was 25 (12.58-37.42) at 3 months and improved to 45 (27.81-62.19) at 12 months. For MIS the 3 month score was 48.75 (22.46-75.04) and 12 month score 58 (35.36-80.64). For conservative treatment the 3 month score was 54.62 (50.42-58.81), and 12 month score 56.3 (49.65-62.96). There were no significant differences in AS score ($P=0.291$ (Figure 6.1)).

The ATRS for open repairs was 27.33 (11.17-43.5) at 3 months and improved to 70.5 (64.34-76.66) at 12 months. For MIS the 3 month score was 55.75 (9.66-101.84) and 12 month score 72.2 (54.5-89.9). For conservative treatment the 3 month score was 48.69 (42.5-54.89), and 12 month score was 79.61 (72.47-86.75). There were no significant differences in ATRS score between groups ($P=0.291$ (Fig 6.2)). Comparison between 3 months and 12 months, ATRS were significant for conservative and MIS patient groups.

Figure 6.1 - AS Score for Achilles Tendon Rupture

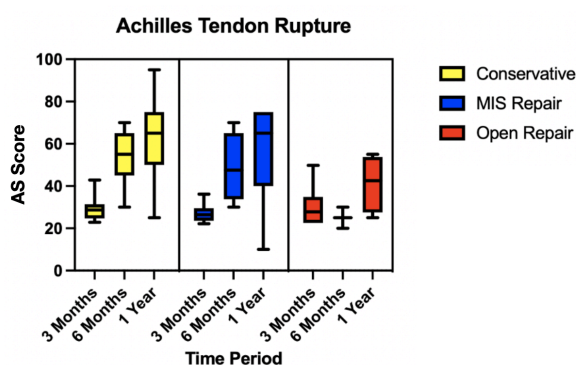


Figure 6.2 - ATRS Score for Achilles Tendon Ruptures

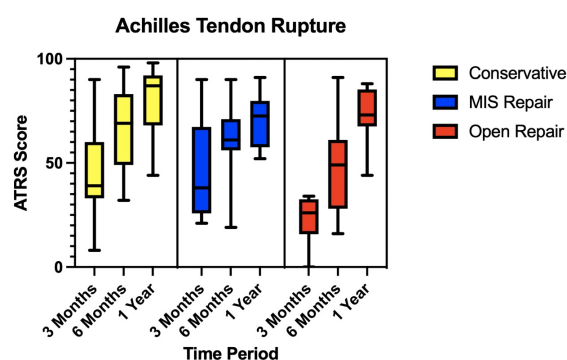


Table 6.1 - PROMS Scores for Achilles Tendon Rupture

| | | | 3 months | 6 months | 12 months | Wilcoxon Signed Rank Test |
|------------|--------------|-------------|----------|----------|-----------|---------------------------|
| | | Number | 55 | 57 | 59 | |
| AS Score | Open repair | Mean | 25 | 41.25 | 45 | NA |
| | | Lower bound | 12.58 | 19.34 | 27.81 | |
| | | Upper bound | 37.42 | 63.16 | 62.19 | |
| | Conservative | Mean | 54.62 | 61.25 | 56.3 | 0.205 |
| | | Lower bound | 50.42 | 55.53 | 49.65 | |
| | | Upper bound | 58.81 | 66.97 | 62.96 | |
| | MIS | Mean | 48.75 | 56.43 | 58 | 0.108 |
| | | Lower bound | 22.46 | 34.46 | 35.36 | |
| | | Upper bound | 75.04 | 78.4 | 80.64 | |
| ATRS Score | Open repair | Mean | 27.33 | 42.75 | 70.5 | 0.083 |
| | | Lower bound | 11.17 | 12.38 | 64.34 | |
| | | Upper bound | 43.5 | 73.12 | 76.66 | |
| | Conservative | Mean | 48.69 | 66.28 | 79.61 | <.001 |
| | | Lower bound | 42.5 | 59.81 | 72.47 | |
| | | Upper bound | 54.89 | 72.75 | 86.75 | |
| | MIS | Mean | 55.75 | 57.71 | 72.2 | 0.028 |
| | | Lower bound | 9.66 | 38.58 | 54.5 | |
| | | Upper bound | 101.84 | 76.85 | 89.9 | |

Section 7: Adult Foot and Ankle

The “Adult Foot and Ankle” pathway is the largest collection of pathways within the BOFAS registry database. This pathway is set up to collect outcomes on all foot and ankle procedures which are not covered by the other specific pathways. In this report we have focused on four of the procedures with the best follow up and completion rates: hallux valgus correction, Morton’s neuroma excision, first MTPJ cheilectomy and ankle ligament reconstruction.

The most common data point related to a foot and ankle

pathology reported in the registry was the primary diagnosis. In total, there were 239 unique primary diagnoses recorded within the registry. The top 19, most common diagnoses are displayed in table 7.1 below. There are still improvements to the coding of diagnosis and procedure needed which will allow more data analysis and potentially enable better long term outcomes.

Compared to last year, the biggest increase in the number of pathways was seen in adult Hallux Valgus which increased by 281.

| Diagnosis | Pathway Count |
|--|---------------|
| Hallux Valgus (Adult) | 727 |
| Primary Osteoarthritis (Joint other than Ankle or 1st MTPJ) | 235 |
| Hallux Rigidus | 203 |
| Acquired Toe Deformity | 166 |
| Ankle Instability (Chronic) | 165 |
| Osteochondral Defect | 151 |
| Morton's Neuroma | 120 |
| Osteoarthritis (Joint other than Ankle or 1st MTPJ) - Secondary to Trauma Malunion | 84 |
| Achilles Tendinopathy (Insertional) | 81 |
| Plantar Fasciitis | 75 |
| Hallux Valgus (Adolescent) | 70 |
| Acquired Flat Foot [Pes Planus] | 58 |
| Primary Osteoarthritis of the Ankle | 51 |
| Anterior Impingement of Ankle Osteophytes | 47 |
| Primary Osteoarthritis of the 1st MTPJ | 47 |
| Metatarsalgia | 45 |
| Achilles Tendinopathy (Non-Insertional) | 45 |
| Hardware/Metalwork Problem | 44 |
| Impingement Syndrome of the Ankle | 42 |

Table 7.1 - Most common general foot and ankle pathways

Hallux Valgus

A total of 519 patients have been enrolled in this pathway with 6 month data being recorded for 294, and results at one year in 205.

A variety of operative strategies were recorded, with open metatarsal osteotomy being the most common (Table 7.2). Improvement in scores was highly significant in all

MOXFQ domains, EQ5D and the VAS pain score (Table 7.3, Figs 7.1 and 7.2).

Using independent Kruskal-Wallis test, the MIS metatarsal osteotomy was best performing at 12 months and Lapidus fusion worst performing, although there maybe significant selection bias across groups.

Table 7.2 - HV reconstruciton variability

| | Frequency | Percent |
|------------------------------------|-----------|---------|
| Open Metatarsal Osteotomy +/- Akin | 378 | 49.3 |
| Isolated Akin | 16 | 2.1 |
| Lapidus | 40 | 5.2 |
| MIS Metatarsal osteotomy +/- Akin | 137 | 17.9 |
| Unknown | 176 | 23 |
| MTPJ Arthrodesis | 19 | 2.5 |

Table 7.3 - PROMS relating to hallux valgus procedures in total

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 519 | 294 | 205 | |
| MOXFQ Pain | Mean | 53.73 | 27.17 | 23.38 | <.001 |
| | Lower | 51.47 | 24.09 | 19.78 | |
| | Upper | 55.99 | 30.24 | 26.97 | |
| MOXFQ Walking/Standing | Mean | 49.51 | 23.32 | 20.86 | <.001 |
| | Lower | 46.8 | 19.91 | 16.65 | |
| | Upper | 52.21 | 26.72 | 25.06 | |
| MOXFQ Social | Mean | 46.89 | 19.34 | 16.82 | <.001 |
| | Lower | 44.41 | 16.11 | 13.28 | |
| | Upper | 49.38 | 22.57 | 20.35 | |
| EQ5D Index | Mean | 0.6809 | 0.79 | 0.82 | <.001 |
| | Lower | 0.6616 | 0.76 | 0.79 | |
| | Upper | 0.7002 | 0.82 | 0.85 | |
| VAS Pain | Mean | 44.1264 | 20.54 | 17.22 | <.001 |
| | Lower | 41.5832 | 17.56 | 13.61 | |
| | Upper | 46.6697 | 23.52 | 20.83 | |
| EQ5D VAS | Mean | 76.7495 | 80.65 | 80.76 | 0.023 |
| | Lower | 75.1979 | 78.6 | 78.27 | |
| | Upper | 78.3011 | 82.7 | 83.25 | |

Figure 7.1 - MOXFQ hallux valgus

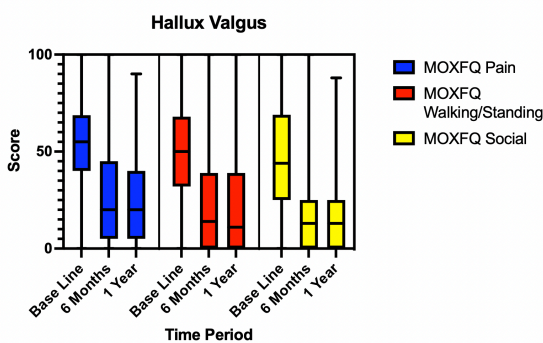
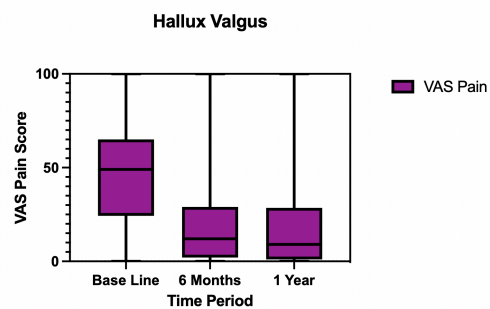


Figure 7.2 - VAS Pain hallux valgus



Metatarsophalangeal Joint Cheilectomy

A total of 123 pathways were recorded for 1st metatarsophalangeal joint cheilectomy on the registry. At baseline 96 recorded PROMS, 51 recorded PROMS at 6 months and 28 at 12 months.

The PROMS scores are summarised in table 7.4. Although the numbers are small, a statistically significant improvement was seen in all domains of the MOXFQ, the EQ5D and VAS Scores (Table 7.4 and Figs 7.3 and 7.4).

Although the numbers are small, functional scores on 1st MTPJ cheilectomy with additional microfracture and Moberg osteotomies is illustrated in figure 7.5.

Figure 7.3 - MOXFQ cheilectomy

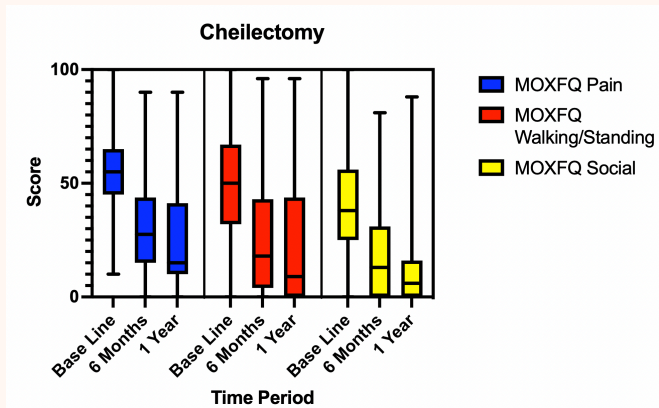


Figure 7.4 - VAS Pain cheilectomy

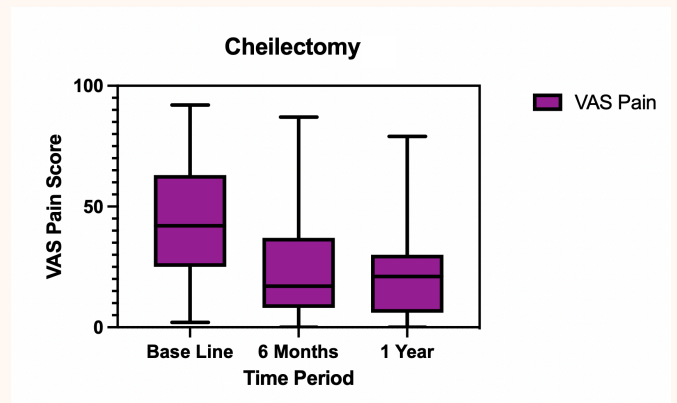


Figure 7.5 - VAS Pain with additional procedures

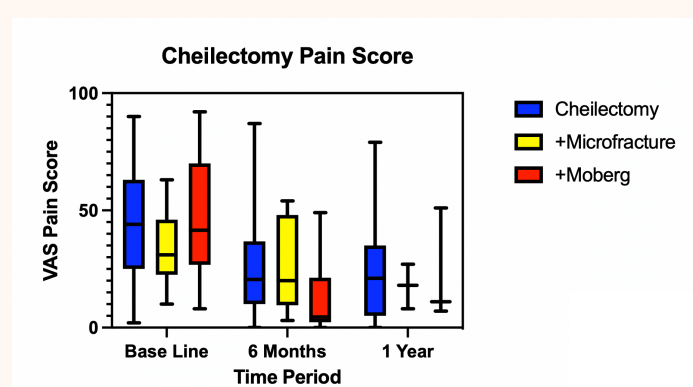


Table 7.4 - PROM scores for 1st MTPJ Cheilectomy

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|-------------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 96 | 51 | 28 | |
| MOXFQ Pain | Mean | 53.44 | 29.12 | 24.11 | <.001 |
| | Lower | 49.36 | 23.54 | 14.88 | |
| | Upper | 57.52 | 34.69 | 33.34 | |
| MOXFQ Walking/Standing | Mean | 48.26 | 22.57 | 21.61 | <.001 |
| | Lower | 43.3 | 16.59 | 11.05 | |
| | Upper | 53.22 | 28.55 | 32.16 | |
| MOXFQ Social | Mean | 41.02 | 16.88 | 11.64 | <.001 |
| | Lower | 36.49 | 12.35 | 3.97 | |
| | Upper | 45.55 | 21.41 | 19.31 | |
| EQ5D Index | Mean | 0.7 | 0.78 | 0.82 | <.001 |
| | Lower | 0.67 | 0.74 | 0.77 | |
| | Upper | 0.72 | 0.82 | 0.87 | |
| VAS Pain | Mean | 42.33 | 21.02 | 20.5 | <.001 |
| | Lower | 37.79 | 15.76 | 13.57 | |
| | Upper | 46.87 | 26.28 | 27.43 | |
| EQ5D VAS | Mean | 75.39 | 77.57 | 78.86 | 0.015 |
| | Lower | 67.45 | 70.89 | 70.36 | |
| | Upper | 83.34 | 84.25 | 87.35 | |

Morton's Neuroma

There were 94 patients registered with Morton's Neuroma excision on the registry. At baseline, 50 patients had recorded PROMS, 26 recorded provided data at 6 months and 18 at one year. The PROMS data are illustrated in figures 7.6 and 7.7 and table 7.5.

Even with the small numbers, there was statistically significant differences from base line to 12 months in all PROMS apart from EQ5D VAS.

Figure 7.7 - MOXFQ Morton's Neuroma

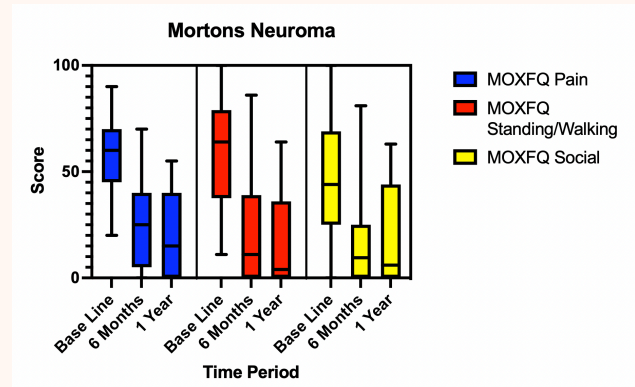


Figure 7.6 - VAS Pain Morton's Neuroma

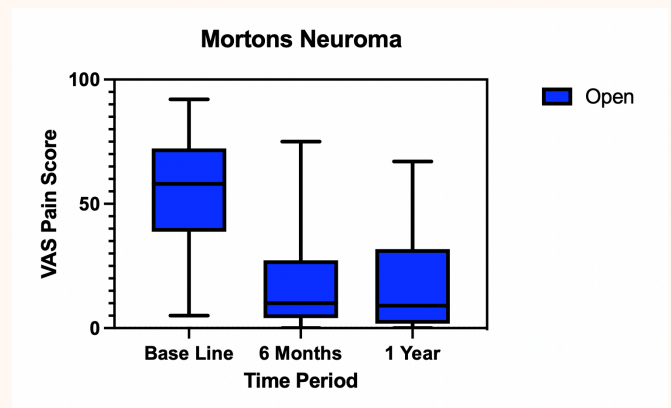


Table 7.5 - PROM scores for Morton's Neuroma

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|-------------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 50 | 26 | 18 | |
| MOXFQ Pain | Mean | 55.3 | 23.65 | 20.56 | .003 |
| | Lower | 50.05 | 15.67 | 10.22 | |
| | Upper | 60.55 | 31.64 | 30.89 | |
| MOXFQ Walking/Standing | Mean | 56.92 | 19.38 | 20.5 | .003 |
| | Lower | 49.89 | 9.67 | 8.07 | |
| | Upper | 63.95 | 29.1 | 32.93 | |
| MOXFQ Social | Mean | 45.26 | 18.81 | 19.22 | .008 |
| | Lower | 38.38 | 9.36 | 7.56 | |
| | Upper | 52.14 | 28.25 | 30.89 | |
| EQ5D Index | Mean | 0.59 | 0.82 | 0.8 | .011 |
| | Lower | 0.53 | 0.76 | 0.67 | |
| | Upper | 0.65 | 0.88 | 0.92 | |
| VAS Pain | Mean | 51.38 | 12.81 | 16.56 | <.001 |
| | Lower | 44.29 | 6.65 | 6.6 | |
| | Upper | 58.47 | 18.96 | 26.51 | |
| EQ5D VAS | Mean | 69.2321 | 75.15 | 78.17 | .286 |
| | Lower | 63.8395 | 67.98 | 72.01 | |
| | Upper | 74.6248 | 82.32 | 84.34 | |

Ankle Ligament Repair

There were 119 patients registered as ankle ligament reconstruction pathways on the registry. At baseline there were 92 patients who completed PROMS, 41 at 6 months and 24 at 12 months.

Although the numbers are small, there is a statistically significant improvement in all the domains of the MOXFQ, EQ5D and VAS scores (Figure 7.7 and Table 7.6). The baseline pain scores were lower than other pathways, however the pain relief was still statistically significant although not MIC.

Of the 119 procedures, 46.2% were performed open and 53.8% were performed arthroscopically. There was not enough data to reliably determine if one option was superior.

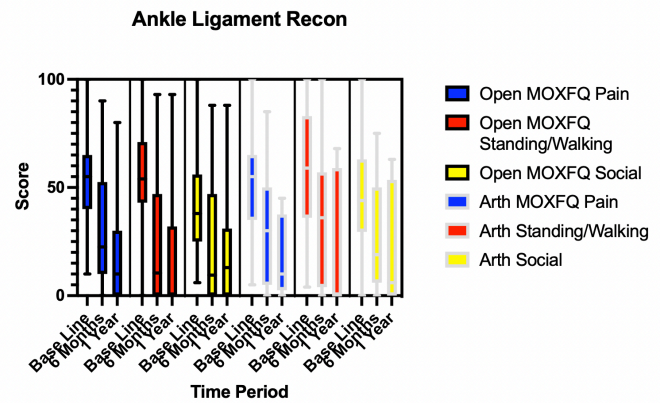


Figure 7.7 - MOXFQ Ankle Ligament reconstruction

Table 7.4 - PROM scores for Ankle Ligament Repair

| | | Base Line | 6 Months | 12 Months | Wilcoxon Signed Rank Test |
|------------------------|-------|-----------|----------|-----------|---------------------------|
| Number | | 92 | 41 | 24 | |
| MOXFQ Pain | Mean | 52.8977 | 31.84 | 23.96 | 0.002 |
| | Lower | 48.4183 | 23.15 | 12.72 | |
| | Upper | 57.3772 | 40.53 | 35.2 | |
| MOXFQ Walking/Standing | Mean | 57.1136 | 30.16 | 21.92 | <.001 |
| | Lower | 51.7203 | 19.7 | 8.1 | |
| | Upper | 62.507 | 40.62 | 35.73 | |
| MOXFQ Social | Mean | 43.6591 | 25.55 | 22.75 | 0.002 |
| | Lower | 38.6885 | 16.38 | 11.52 | |
| | Upper | 48.6297 | 34.72 | 33.98 | |
| EQ5D Index | Mean | 0.5969 | 0.7831 | 0.79 | 0.002 |
| | Lower | 0.545 | 0.7252 | 0.69 | |
| | Upper | 0.6487 | 0.841 | 0.9 | |
| VAS Pain | Mean | 39.0989 | 24.4146 | 22.62 | 0.003 |
| | Lower | 34.0501 | 17.1067 | 12.98 | |
| | Upper | 44.1477 | 31.7225 | 32.25 | |
| EQ5D VAS | Mean | 70.6882 | 76.2619 | 77.88 | 0.028 |
| | Lower | 66.8208 | 71.4034 | 70.61 | |
| | Upper | 74.5555 | 81.1204 | 85.16 | |



Outcome Committee Chair - Lyndon Mason

"The landscape in the NHS regarding registries is changing very quickly. The political developments, due to the Cumberlege report and the government's response this year, appear to be in favour of the creation of an all-specialty PROMS registry for all surgical interventions. The BOFAS registry is well placed to share experience in the development of a national implant registry, especially the pitfalls in data capture in real-life clinical environments."

Summary

The BOFAS Registry is progressing well. Compliance has improved from previous years, currently averaging 60% across all pathways currently. The registry moved to use additional text message data collection last year which has improved the PROMS collection by approximately 10-15%. The general data has supported the success of the procedures in all PROMS, even with very variable nature the procedures that have been performed. Unlike arthroplasty surgery, where techniques can be relatively standardised, foot and ankle surgery encompass many diverse procedures, and standardisation is difficult to achieve.

The registry has also been incorporated into national guidelines. In 2022, the National Institute for Health and Care Excellence published new guidelines which state that any consultant performing 1st MTPJ Arthroplasty procedures must add their patients to the BOFAS Registry, to ensure clinical scores are collected and to facilitate the local review of clinical outcomes. It is believed that once patients have been added to the BOFAS Registry, Consultants will be able to discuss the outcomes of the procedure during their annual appraisal to reflect, learn

and improve. This means that any Consultants who perform 1st MTPJ Arthroplasty procedures, whether that is within the NHS or private healthcare sector, will need to adopt BOFAS data entry as part of their normal working routine if performing 1st MTPJ arthroplasty.

The new pathways which incorporate trauma, including the adult ankle fracture pathway, are as yet too immature to report on. We expect over the next 2 years to be able to include the trauma pathways and revision ankle arthroplasty on to the annual report.

With the government publishing their response to the Cumberlege report in 2021, accepting the recommendation number 7, legislation through the Medicines and Medical Devices Act 2021, has given power to the secretary of state to regulate for the establishment of a UK-wide Medical Device Information System (MDIS). Central to the development of the MDIS are PROMS. The BOFAS registry is showing the utility in data collection across multiple procedures, and its continued use will only see it grow and become more useful.

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