British Orthopaedic Foot & Ankle Society

British Orthopaedic Foot and Ankle Society

Registry Report 2021

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Introduction

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The data presented in this report cover procedures entered into the British Orthopaedic Foot & Ankle Society (BOFAS) Registry from 2014 until December 2020. The 1st Metatarsophalangeal Joint Arthrodesis Pathway (1st MTPJAP) and the Ankle Arthrodesis Pathway (AAP) have been active since the registry started, however the Foot and Ankle General Pathway (FAGP) was only launched towards the end of 2016. This year has also seen the introduction of the Achilles Rupture Trauma Pathway, Achilles Tendinopathy Pathway and Ankle Primary & Revision Arthroplasty pathways. The new trauma pathways (foot and ankle trauma and ankle fracture pathways) are new for 2021, so are not included in this report.

Since the creation of the BOFAS Registry in 2014 we have seen a steady increase in data entry. However, as it currently stands, the Registry only captures a small proportion of national activity, both in the Private and 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 different, established systems such as those used in Wales and Scotland. The majority of the information in this report is summary data, and it is anticipated that as the number of cases increase, we will be able to statistically analyse patient outcomes in the future.

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 help direct practice 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. In addition, a National Consultant Information Programme (NCIP), run by GIRFT and NHSEI, and in conjunction with surgical specialties is likely to be introduced. This will enable local clinical practice to be compared with national benchmarks and provide better quality data at a local level.

This year we have seen some major developments in the quest for national data collection. On the 8th July 2020, the **First Do No Harm** (Otherwise known as the **Cumberlege Report**) was published. For access, use the link https:// www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf. One particular recommendation from this report (recommendation number 7) stated that *"A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes in terms of both the device safety and patient reported outcomes measures"*. This recommendation is important due to its need for centralised data collection on all patients with implantable devices with the prospective collection of PROMS data. The BOFAS Registry is perfectly placed to provide the tools for central data collection as set out by the Cumberlege report. As a consequence of the report, mandation of PROMS collection is a possibility in the future, as is the creation of an all encompassing Musculoskeletal Registry.

Aims

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:

- Monitoring the progress of Registry activity
- Production of an annual Registry Report
- Furthering use of the Registry by communication with BOFAS members
- Working to improve data quality, especially with respect to improving data capture across the country
- Supporting BOFAS members in setting up with their Trusts
- Exploring new ways to advance and apply Registry functionality, including ongoing discussions with other orthopaedic registries and with the National Joint Registry
- Liaising with the platform providers, Amplitude
- Maintaining data security with respect to both the Registry and BOFAS as a whole
- Liaising with the other BOFAS Committees, especially the Scientific Committee, when outcome-data dependent research or publications are ongoing

Background

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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.

Membership of the Outcomes Committee

Chair:	Paul Halliwell	Caldicott Guardian:	Stephen Bendall
Chair Elect:	Lyndon Mason	President:	James Davies
Member:	Nick Harris	Treasurer:	Hiro Tanaka
Member:	Nilesh Makwana	Secretary:	Mark Davies
Member:	James McKenzie	Co-opted:	Andy Goldberg
Member:	Ed Wood	Co-opted:	Karan Malhotra

Contributing Surgeons / Units

- Adam Devany - Robert Jones and Agnes Hunt
- Andrea Sott - Epsom St Helier NHS Trust
- Andrew Gower - County Durham and Darlington
- Andrew Riddick - Southmead Hospital
- Arshad Khaleel - St Peters Hospital, Chertsey
- Ashok Acharya - Barking Havering Redbridge Trust
- Barry Rose - Eastbourne DGH
- Billy Jowett - Queen Alexandra Hospital
- Claire Topliss - ABMU HB
- Cliff Butcher - University Hospital Aintree
- Daniel Marsland - Hampshire
- James Davenport - Wrightington Hospital
- D Mahadevan - Reading Foot & Ankle Unit
- Edward Wood - Countess of Chester Hospital
- Heath Taylor - Royal Bournemouth Hospital
- Iain Bissell - Wye Valley NHS Trust, Hereford
- Jamie McKenzie - Royal Orthopaedic Hospital, Birmingham
- Joel Humphrey - Milton Keynes
- John Stuart Moir - Greater Glasgow & Clyde
- Julian Grundy - YDH
- Kar Teoh - Princess Alexandra hospital
- Kate Thomason - Countess of Chester Hospital
- Lyndon Mason - University hospital Aintree
- Lynne Barr - Colchester
- Mark B Davies - Sheffield Teaching Hospital NHS
- M Henderson - Gloucester
- Matthew Solan - Guildford
- M O'Flaherty - Musgrave Park Hospital
- Melwyn Pereira - Joint Clinic, Droitwch
- Michael Butler - Cornwall
- Michael Karski - Wrightington Hospital
- Neal Jacobs - Salisbury
- Nicholas Savva - Dorset County Hospital
- Nilesh Makwana - RJAH
- Osmond Thomas - New Cross Hospital
- Paul Halliwell - Royal Surrey County Hospital NHS
- Paul Hamilton - Epsom & St. Helier
- Peter Robinson - Southmead Hosptial, Bristol

Registry Membership

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Contributing Surgeons / Units

- Phil Vaughan - West Suffolk
- Raghu Kankate - High Wycombe
- Robbie Ray - Kings College London
- Robert Smith - Wrightington
- Robin Elliot - Hampshire Hospital
- Robin Rees - North Midlands
- S Goswami - Walsall Healthcare NHS Trust
- S Henderson -Musgrave Park Hospital
- Stephen Hepple - Southmead Hospital
- Steve Milner - Royal Derby Hospital
- S Chandrashekar - Homerton
- Tim Clough - Wrightington Hospital
- Tim Millar - Morecambe Bay
- Tim Sinnett - Chelsea and Westminster
- Timothy Williams - Colchester
- Togay Koc - Queen Alexandra Hospital
- Tristan Barton - Royal United Hospital Bath
- Turab Syed - Royal Free London Hospital
- Vivek Dhukaram - Coventry & Warwickshire
- Williams Harries - Southmead Hospital Bristol

Uptake

The degree of uptake of the Registry by the BOFAS membership is increasing with time. However, active data submission is still only achieved by a minority of members. Over the last two years we have seen an almost exponential increase in the total number of cases in the combined pathways (Fig 1): this is still however only a small proportion of the national figures.

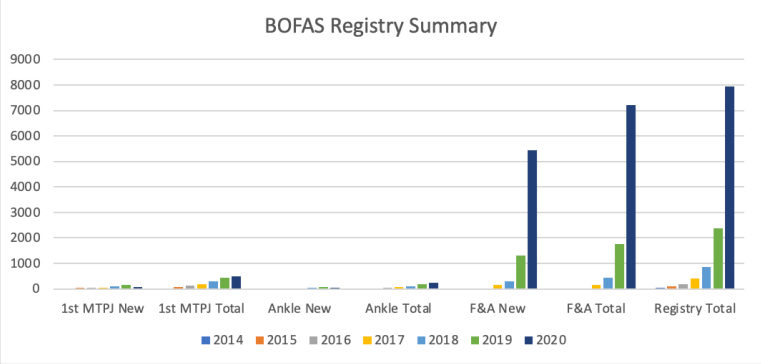


Figure 1: Summary of New & Total pathway numbers.

Impact of the COVID-19 pandemic

The impact of the Covid pandemic on clinical activity is clearly reflected in the reduced numbers of new pathways generated. This is particularly associated with the lockdown periods and is illustrated in figure 2. On average 76 new pathways were added each month in the 3 months prior to the first lockdown, falling to an average of 8 per month in the following 3 months.

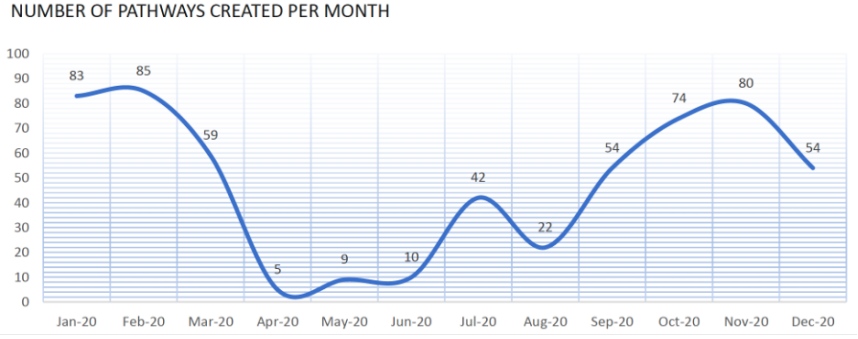


Figure 2: Impact of COVID-19 Pandemic

Separate to the Registry, as part of a collaboration between the Scientific and Outcomes committees, work has been completed looking at the outcome of patients in the UK who underwent foot and ankle surgery during the COVID-19 crisis. This is detailed in the UK-FAICoN Audit report, available on the BOFAS website (https://www.bofas.org.uk/clinician/research/bofas-national-audits).

Barriers to uptake

A number of factors may prevent surgeons from registering and entering cases: time pressure, unfamiliarity, concern regarding data use. As the registry is not currently mandated, support from Trusts regarding data collection and input is widely variable. We believe the Registry will be a valuable tool for our members for revalidation and appraisal and is likely to become something that Responsible Officers look to. Videos on how to use the registry are now available on the BOFAS website.

Compliance

Compliance for consent is high across the three main pathways (≥94%). Where consent has been gained, surgeons can look back at individual outcomes. Where consent is absent, the record has to be 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. Even though patients confirm consent online when they first log in, it is still necessary to take consent on paper and file this in their case-notes to remain GDPR compliant.

Between 15-34% of patients either do not use or do not have access to email. In this scenario, automated data collection is not possible and different strategies for post-op PROMS collection need to be put in place. Alternative strategies, such as making use of telephone clinic review streams, should be considered. The Outcomes committee have implemented a number strategies to improve this. These include the mandating of email and or mobile phone number at initial data entry and the commissioning of a SMS texting service which will commence in March/April 2021. We hope this will help improve compliance.

We have also seen a significant proportion of patients registered but with no initial PROMS entered (12-33% depending on pathway). 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.

Overview of PROMS

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 outlined below.

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

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 or in person, at regular intervals post-operatively, depending on the pathway. Other scores collected by the surgeon outside of the scores detailed in the above table, would not enter the national reporting data.

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

EQ-5D is a standardised measure of health status developed by the EuroQol Group in order 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 (MOxFQ)

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 summating 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.

Olerud and Molander Ankle Score (OMAS)

The Olerud and Molander Ankle Score 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 and Molander, 1984). There is evidence for test-retest reliability and construct validity for the English, Swedish and 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 Minimally Important Change (MIC) for OMAS has yet to be defined.

The Achilles Tendon Total Rupture Score (ATRS)

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 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).

Achilles Tendon Rupture Repair Score (AS)

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.

Victorian Institute of Sports Assessment – Achilles (VISA-A)

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).

Confidence Intervals

Where expressed, a 95% confidence interval has been used.

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). Similarly, MCID estimates for VAS pain ranged from 1.8 to 5.2 (Sutton *et* al, 2019). 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 & Ankle Fusion pathways the criteria are clearly defined and analysis of the variables should be easily achieved. The more generic Foot & Ankle pathway will be more difficult to analyse because of the sheer variety of procedures undertaken. We are working with Amplitude to try to achieve consistency, particularly with definition of procedures, to help us achieve this in the future.

Pathway Reports

British Orthopaedic Foot & Ankle Society

1. 1st MTPJ Arthrodesis
2. Ankle Arthrodesis
3. Foot & Ankle General
4. Total Ankle Replacement (Primary)
5. Total Ankle Replacement (Revision)
6. Achilles Rupture
7. Achilles Tendinopathy

1st MTPJ Arthrodesis

Within the registry, 510 1st MTPJ Arthrodesis pathways have been instituted since it went live in 2016, an increase of only 23 over the course of the last year. There was reasonable compliance of preoperative completion of PROMS, with completion rates of 88% for EQ-5D and 85% VAS. Unfortunately the completion rate for preoperative MOXFQ scores has fallen from 87% to 76% compared with the previous year. The completion rates at 6 months were lower with 75%, 70% and 61% and lower again at 12 months with 62%, 56% and 48% for the EQ-5D, VAS and MOXFQ scores respectively.

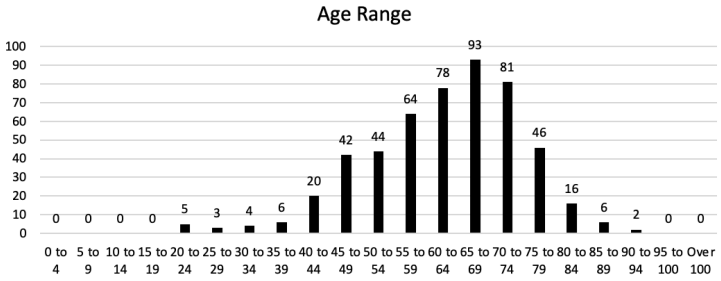


Figure 3: Age distribution, 1st MTPH Arthrodesis Pathway

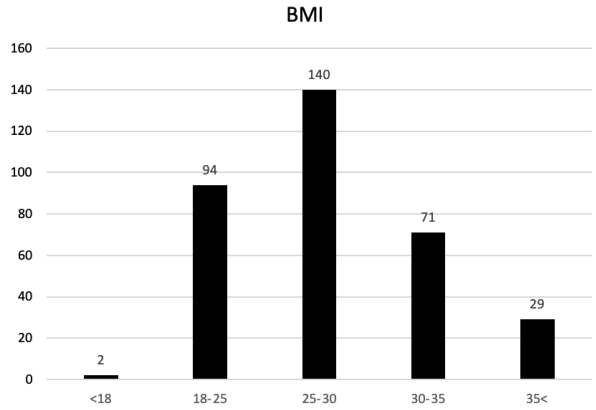


Figure 4: BMI Range MTPJ Pathway

The average age was 67 (SD 21.49) and the range for this patient cohort is illustrated in figure 3. Gender was 37% male and 63% female. The BMI range is illustrated in figure 4, with the majority of patients being either overweight or obese (BMI ≥25). The operation was undertaken on the right foot in 51% of individuals and left side in 43% of individuals, in 6% the side was not recorded. Smoking was recorded in 7% of individuals, ex-smoker in 20% of individuals and non-smoker in 73% of individuals. The numbers for smoking were too small to make any comparison in outcomes. Primary procedures were classed in 93% of patients, with only 4% revision procedures, 1% conversion of arthroplasty and 2% other indication.

The average increase in the EQ-5D Index was from 0.58 preoperative to 0.71 and 0.76 at 6 and 12 months post-operative respectively (fig 5). 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 (fig 6), at 12 months there was no change seen. The number of patients with scores recorded at 2 years is too small for meaningful analysis.

EQ-5D Index

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	0.5771	0.2251	393	0.58 ± 0.02
6 Months	0.7108	0.2086	226	0.71 ± 0.03
12 Months	0.7614	0.1974	129	0.76 ± 0.03

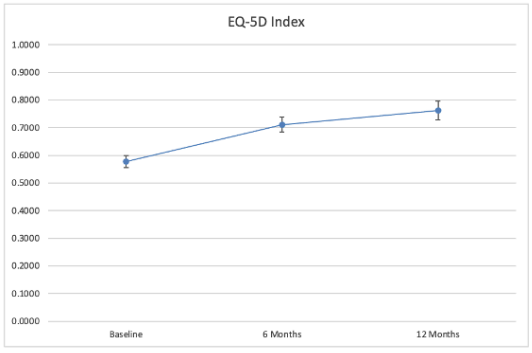


Figure 5: EQ-5D Index Scores, 1st MTPJ Arthrodesis Pathway

The MOXFQ components all revealed a clinically relevant improvement in symptoms at 12 months post-operative, with changes greater than the MIC in all domains. The Pain scores improved from a pre-operative baseline of 62.32 to 28.64 at 12 months post-operative, the Walking/

Standing scores improved from 62.90 to 25.73 and the Social Interaction scores from 52.59 to 20.93 (figs 7-9). The MOXFQ scores showed a trend towards normal at 12 months with the Social Interaction score confidence intervals overlapping. The number of patients with recorded scores at 2 years is too small for meaningful analysis. The VAS pain score again showed improvement from 54.58 to 23.66 at 12 months post-operative (fig 10).

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.

EQ-5D Health VAS

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	69.7888	21.5978	393	69.79 ± 2.14
6 Months	75.3717	18.4442	226	75.37 ± 2.40
12 Months	74.3178	20.1317	129	74.32 ± 3.47

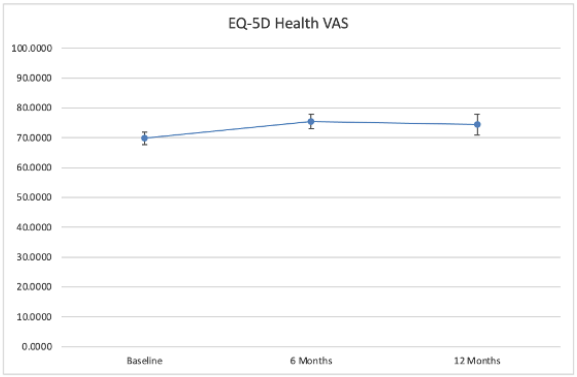
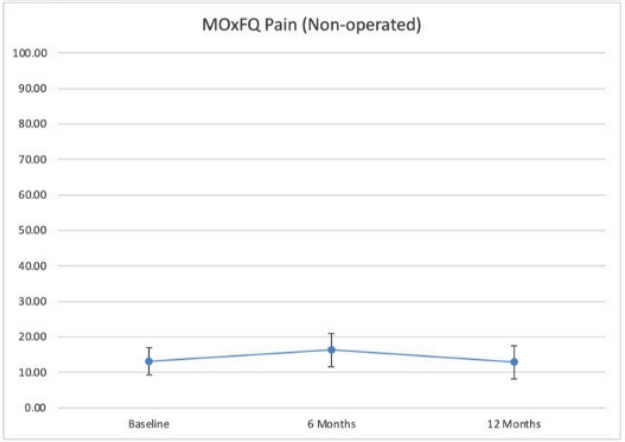


Figure 6:EQ-5D VAS Scores, 1st MTPJ Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	13.0769	21.2419	117	13.08 ± 3.85
6 Months	16.3131	23.5872	99	16.31 ± 4.73
12 Months	12.8226	18.9996	62	12.82 ± 4.73



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	62.3239	21.2477	284	62.32 ± 2.47
6 Months	34.4382	25.8011	178	34.44 ± 3.79
12 Months	28.6486	28.9450	111	28.65 ± 5.38

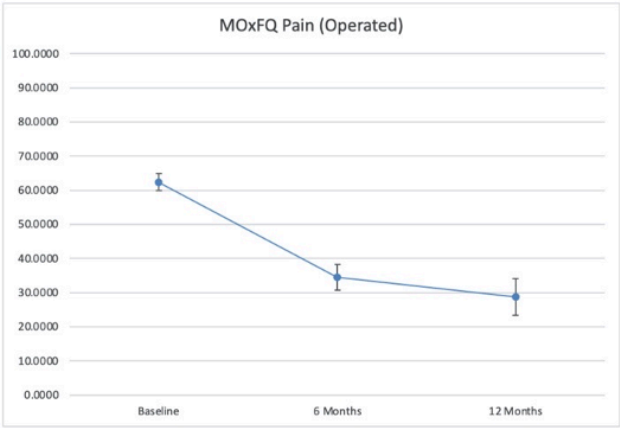
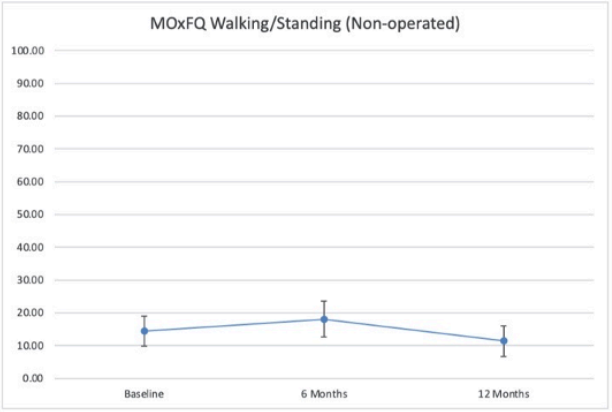


Figure 7: MOxFQ Pain, 1st MTPJ Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	14.4530	25.4026	117	14.45 ± 4.60
6 Months	18.0303	27.5869	99	18.03 ± 5.43
12 Months	11.3871	18.7215	62	11.39 ± 4.66



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	62.8979	24.5705	284	62.90 ± 2.86
6 Months	36.1236	30.8021	178	36.12 ± 4.53
12 Months	25.7297	28.2664	111	25.73 ± 5.26

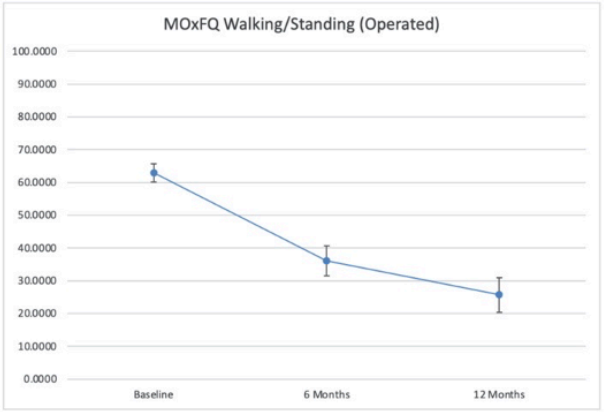
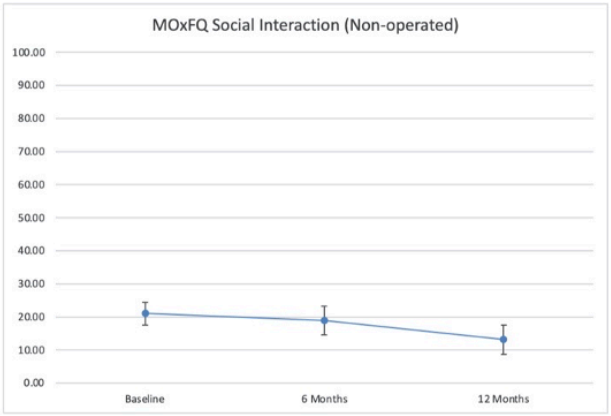


Figure 8: MOxFQ Walking/Standing, 1st MTPJ Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	21.0459	18.5281	109	21.05 ± 3.48
6 Months	18.9158	21.8018	95	18.92 ± 4.38
12 Months	13.1967	17.6977	61	13.20 ± 4.44



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	52.5906	24.6831	276	52.59 ± 2.91
6 Months	28.3851	27.1982	174	28.39 ± 4.04
12 Months	20.9273	26.9088	110	20.93 ± 5.03

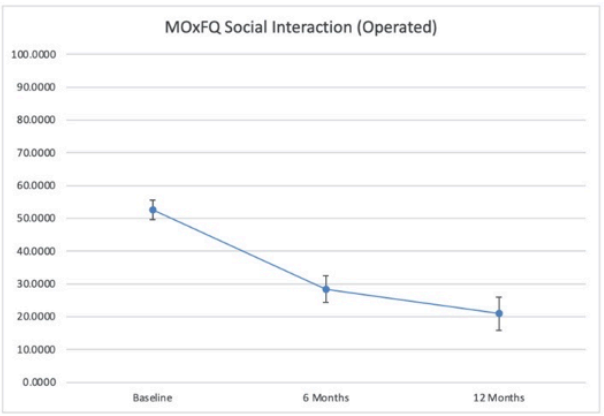


Figure 9: MOxFQ Social Interaction, 1st MTPJ Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	54.5788	23.7039	311	54.58 ± 2.63
6 Months	28.6075	25.9976	186	28.61 ± 3.74
12 Months	23.6577	25.9818	111	23.66 ± 4.83

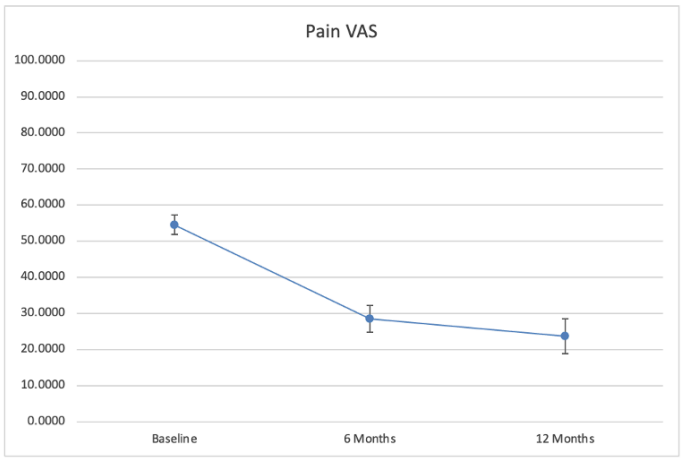


Figure 10: VAS Pain, 1st MTPJ Arthrodesis Pathway

Within the registry, 242 AA pathways have been instituted since the pathway went live in 2016. This is a 20% increase since last year and reflects the impact on elective surgery due to the COVID-19 pandemic. Completed procedure forms were available for 144 cases. There are nearly twice as many males as females. The MOXFQ score was completed at baseline in 135 patients, 83 have completed 6 month and 47 patients have completed 12 months. The age range for this patient cohort is illustrated in figure 1. The BMI range is illustrated in figure 2. Smoking was recorded in 7% of individuals, ex-smoker in 18% of individuals and non-smoker in 74% of individuals. The numbers for smoking were too small to make any comparison in outcomes. The most common indications for fusion were primary arthritis and post-traumatic arthritis. Other indications included inflammatory arthritis, and avascular necrosis of talus. Arthroscopic fusions accounted for 54% of the recorded pathways and 43% were open. The number of 1 year post-operative completed scores are too small to make comparisons between the approaches. Ankle fusion fixation was undertaken using cannulated screws in 86% of patients. The other forms of fixation include plates, an external fixator, IM nail and staples. In those individuals undergoing fusion using screws, 2 screws were used in 83% and 3 screws in 14%

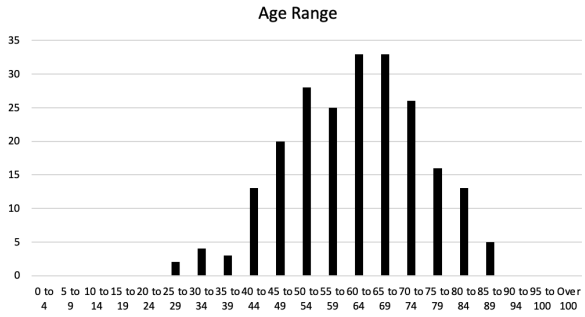


Figure 11: Age distribution, Ankle Arthrodesis Pathway

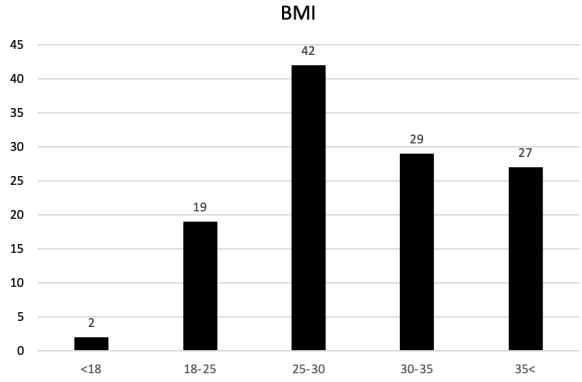


Figure 12: BMI distribution, Ankle Arthrodesis Pathway

The average increase in the EQ-5D index was from 0.43 preoperative to 0.71 at 1 year post-operative (fig 13). In comparison to population norms (Kind P, Hardman G, Macran S 1999. "UK population norms for EQ-5D," Working Papers 172chedp, Centre for Health Economics,

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	0.4290	0.2362	144	0.43 ± 0.04
6 Months	0.6013	0.2696	85	0.60 ± 0.06
12 Months	0.7071	0.2186	47	0.71 ± 0.06

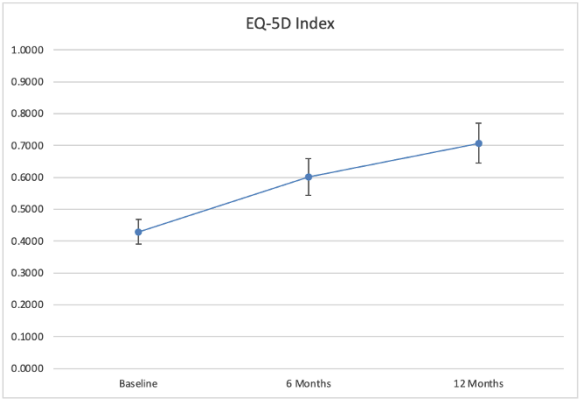


Figure 13: EQ-5D Index, Ankle Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	66.8333	18.5659	144	66.83 ± 3.03
6 Months	68.6941	18.2067	85	68.69 ± 3.87
12 Months	72.9149	17.5691	47	72.91 ± 5.02

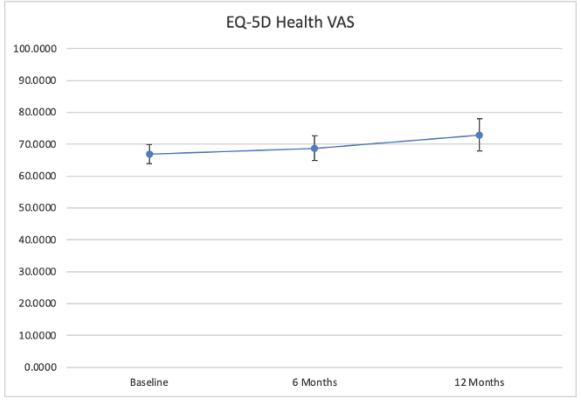


Figure 14: EQ-5D Health VAS, Ankle Arthrodesis Pathway

University of York), this is favourable as the mean EQ-5D index is 0.713 (Std Dev 0.229, Median 0.786) for England. EQ5D Health VAS similarly improved at 1 year (fig 14). The scores improved in both the VAS Pain and MOxFQ Pain, Walking and Standing, and Social Interaction indices, as illustrated in figures 15 to 18. In all domains of the MOXFQ the MIC was exceeded when comparing the baseline and 12 month post-operative figures.

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	61.9500	23.1206	120	61.95 ± 4.14
6 Months	37.4366	29.9820	71	37.44 ± 6.97
12 Months	22.8378	22.4084	37	22.84 ± 7.22

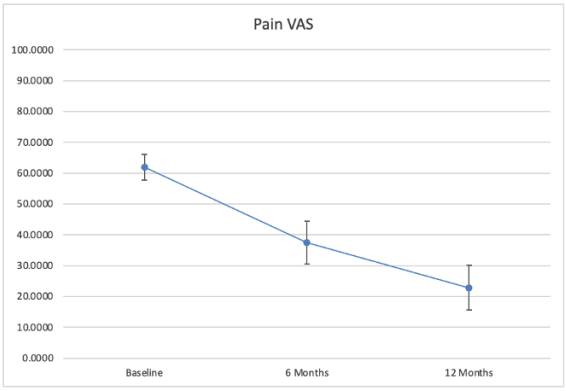
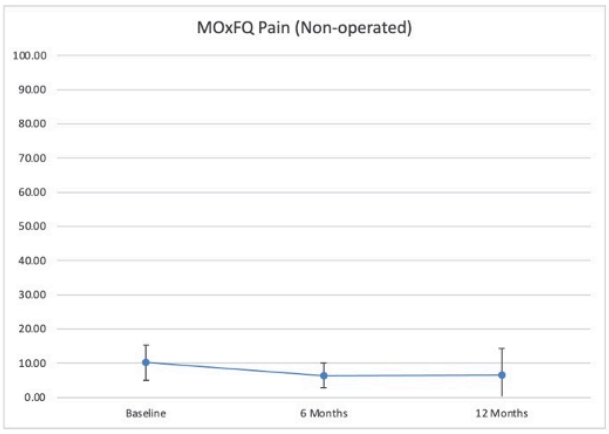


Figure 15: VAS Pain, Ankle Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	10.1493	21.9050	67	10.15 ± 5.25
6 Months	6.4286	11.7659	42	6.43 ± 7.90
12 Months	6.5217	18.2635	23	6.52 ± 7.90



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	67.8519	18.7631	135	67.85 ± 3.17
6 Months	43.0723	28.0365	83	43.07 ± 6.03
12 Months	33.0435	27.2564	46	33.04 ± 7.88

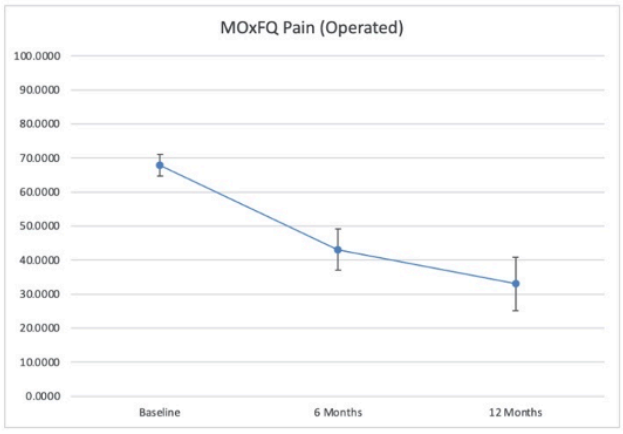
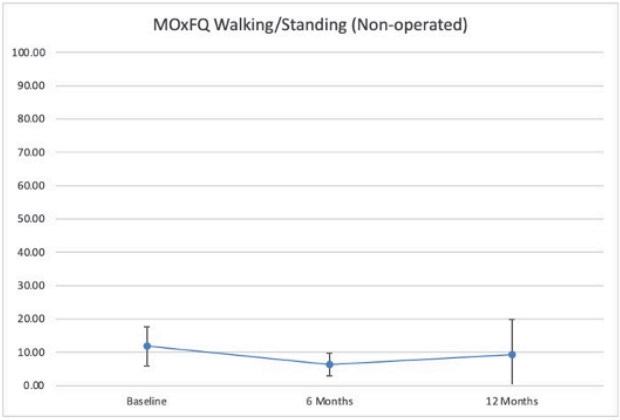


Figure 16: MOxFQ Pain, Ankle Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	11.7761	24.6920	67	11.78 ± 5.91
6 Months	6.3095	11.2196	42	6.31 ± 3.39
12 Months	9.1739	24.5988	23	9.17 ± 10.64



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	80.5926	19.4416	135	80.59 ± 3.28
6 Months	57.8554	32.5555	83	57.86 ± 7.00
12 Months	40.1522	29.9565	46	40.15 ± 8.66

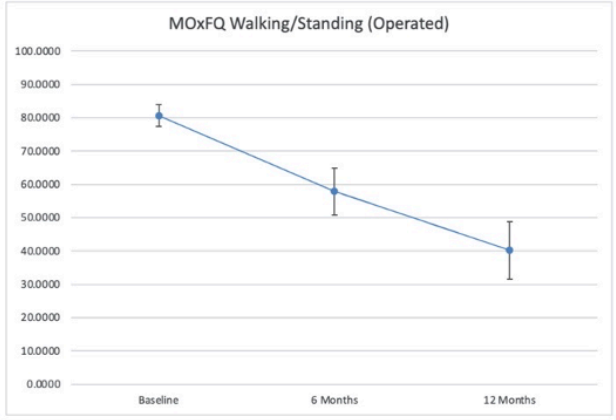
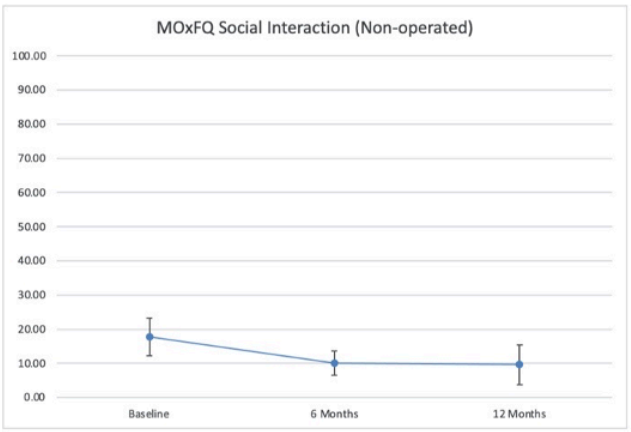


Figure 17: MOxFQ Walking/Standing, Ankle Arthrodesis Pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	17.7742	22.3292	62	17.77 ± 5.56
6 Months	10.1026	11.1420	39	10.10 ± 3.50
12 Months	9.6087	13.5157	23	9.61 ± 5.84



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	58.9846	24.1259	130	58.98 ± 4.15
6 Months	42.1358	30.1305	81	42.14 ± 6.56
12 Months	29.8478	29.3287	46	29.85 ± 8.48

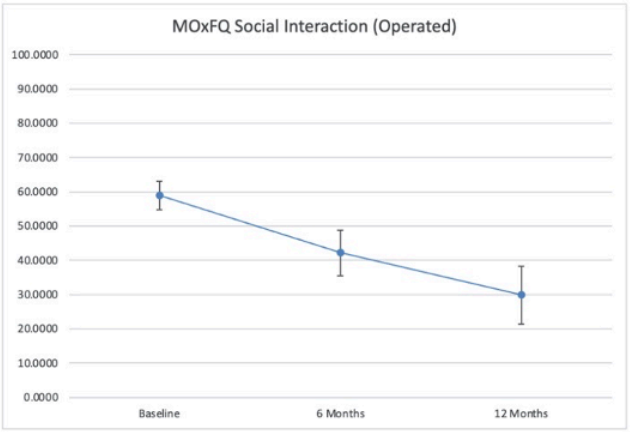


Figure 18: MOxFQ Social, Ankle Arthrodesis Pathway

Within the registry, 7284 FAG pathways have been instituted since the pathway went live in 2017, an almost 50% increase from the 4936 pathways reported in the last report. This is largely due to the importing of an established large Hospital dataset (Royal Orthopaedic Hospital, Birmingham) of the 7284 pathways, 2123 pathways have a pre-operative score and 737 have completed to 1 year. The age range for this patient cohort is much more diverse than the previous pathways, as illustrated in figure 19. The BMI range for the foot and ankle pathway is shown in figure 20. Most were non-smokers and most had a primary procedure.

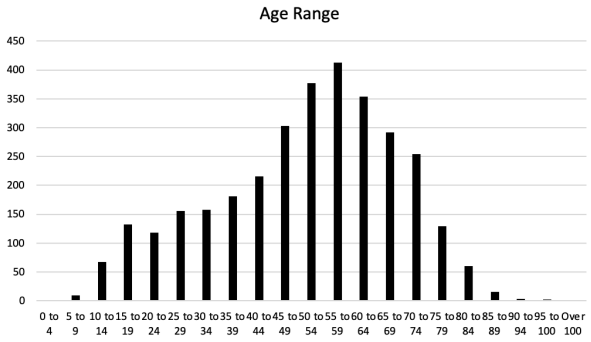


Figure 19: Age distribution, Foot and Ankle General pathway

The most common diagnoses in this pathway were: hallux valgus (n=347), arthritis (n=238), hallux rigidis (n=105), Achilles tendon disorders (n=102) and toe deformity (n=99). Following the addition of new pathways in the registry some of the procedures coded in this pathway will be added to these new pathways. This will enable better data collection and make future analysis easier.

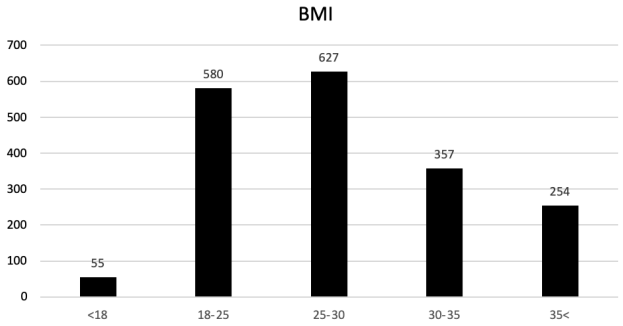


Figure 20: BMI distribution, Foot and Ankle General pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	69.8610	19.9085	1906	69.86 ± 0.89
6 Weeks	65.2893	22.3716	197	65.29 ± 3.12
6 Months	72.8960	20.7823	971	72.90 ± 1.31
12 Months	76.1054	19.5664	408	76.11 ± 1.90
2 Years	75.7208	17.6791	154	75.72 ± 2.79

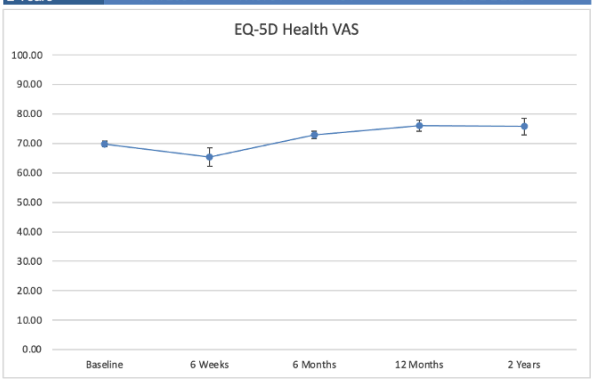


Figure 21: EQ-5D VAS, Foot and Ankle General pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	0.5807	0.2391	1906	0.58 ± 0.01
6 Weeks	0.5813	0.2526	197	0.58 ± 0.04
6 Months	0.6677	0.2508	971	0.67 ± 0.02
12 Months	0.7046	0.2612	408	0.70 ± 0.03
2 Years	0.6934	0.2528	154	0.69 ± 0.04

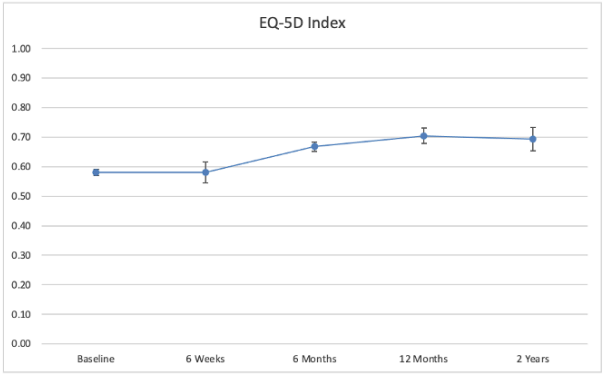


Figure 22: EQ-5D Index, Foot and Ankle General pathway

With the diversity of data little can be drawn from the individual data for each individual surgeon. It is possible look at the amalgamated overall outcomes for the Foot and Ankle General pathway. The EQ-5D, VAS Pain and MOxFQ outcomes are shown below (figures 21 to 26).

The EQ-5D Health VAS shows a subtle improvement at 6 months becoming more evident at 12 months. The EQ-5D index scores reveal improvements in outcomes at 6 and 12 months compared to the baseline scores. The VAS Pain scores reveal an improvement in

symptoms from a baseline of 49.89 to 25.65 at 12 months post-operative. The MOxFQ domains show improvements in outcomes at 6 and 12 months post-operative, in comparison with baseline scores, in all domains. Two year data has been included.

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	49.8801	24.2796	1851	49.88 ± 1.11
6 Weeks	44.3724	26.4119	196	44.37 ± 3.70
6 Months	33.4695	26.6988	952	33.47 ± 1.70
12 Months	25.6517	25.7593	333	25.65 ± 2.77
2 Years	25.3036	26.5424	112	25.30 ± 4.92

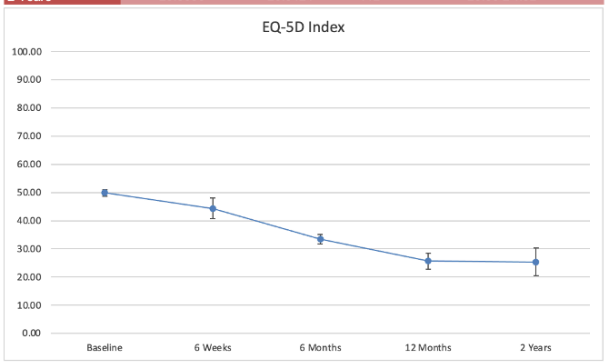
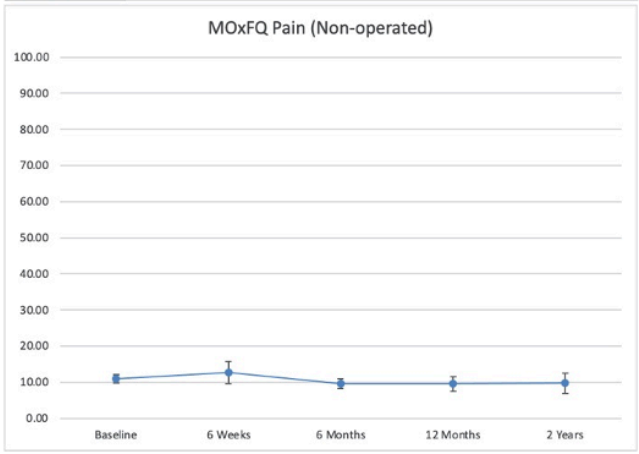


Figure 23: VAS Pain, Foot and Ankle General pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	10.9225	18.4901	1084	10.92 ± 1.10
6 Weeks	12.6393	17.6612	122	12.64 ± 3.13
6 Months	9.5808	16.8271	656	9.58 ± 1.29
12 Months	9.5341	17.1275	279	9.53 ± 2.01
2 Years	9.7177	16.0682	124	9.72 ± 2.83



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	58.7826	21.7115	1463	58.78 ± 1.11
6 Weeks	55.3742	23.5060	155	55.37 ± 3.70
6 Months	40.7810	26.8898	767	40.78 ± 1.90
12 Months	36.5805	27.7194	329	36.58 ± 3.00
2 Years	36.9600	28.6768	125	36.96 ± 5.03

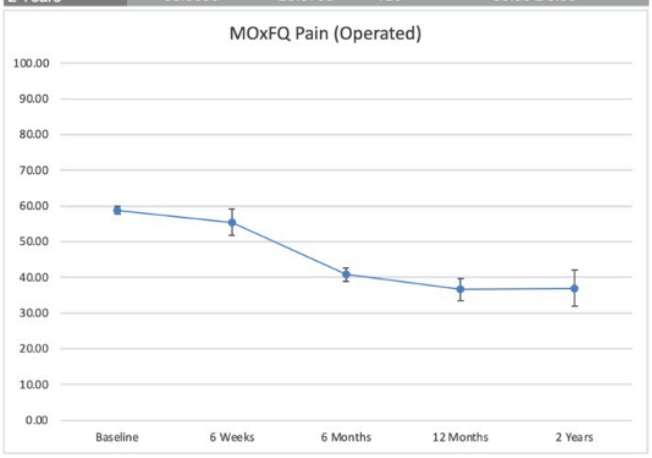
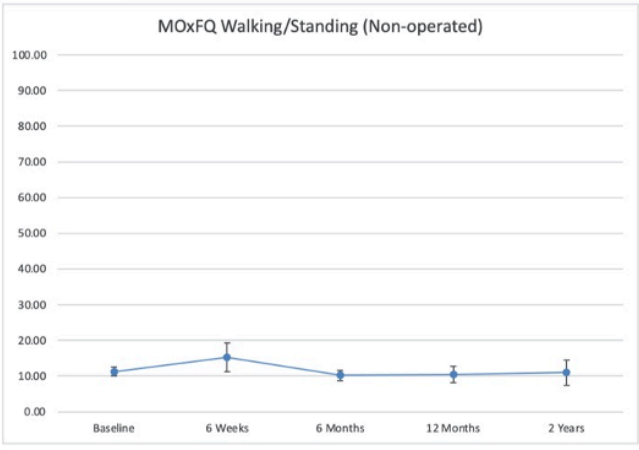


Figure 24: MOxFQ Pain, Foot and Ankle General pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	11.2973	20.8030	1083	11.30 ± 1.24
6 Weeks	15.2459	22.9151	122	15.25 ± 4.07
6 Months	10.2061	19.5149	655	10.21 ± 1.49
12 Months	10.4086	19.8080	279	10.41 ± 2.32
2 Years	10.9597	20.0706	124	10.96 ± 3.53



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	60.5899	27.1226	1463	60.59 ± 1.39
6 Weeks	62.4774	26.3604	155	62.48 ± 4.15
6 Months	42.7223	32.4689	767	42.72 ± 2.30
12 Months	37.5471	33.6856	329	37.55 ± 3.64
2 Years	39.6480	33.3242	125	39.65 ± 5.84

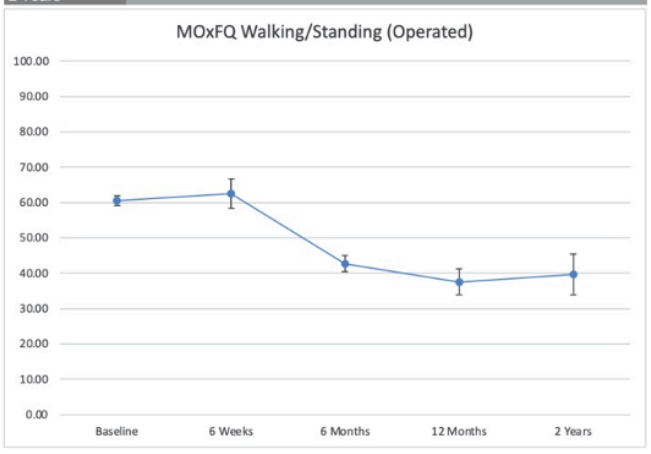
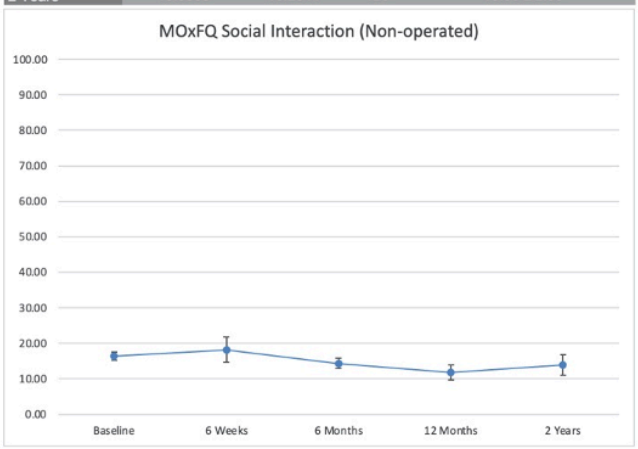


Figure 25: MOxFQ Walking/Standing, Foot and Ankle General pathway

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	16.4246	17.9295	1008	16.42 ± 1.11
6 Weeks	18.1731	18.3447	104	18.17 ± 3.53
6 Months	14.3720	18.0803	629	14.37 ± 1.41
12 Months	11.8561	17.7882	264	11.86 ± 2.15
2 Years	13.9583	16.2041	120	13.96 ± 2.90



	Sample Mean	StdDev	n	Confidence Interval to 2 d.p.
Baseline	48.2121	25.1349	1386	48.21 ± 1.32
6 Weeks	47.9708	25.7083	137	47.97 ± 4.30
6 Months	35.1284	30.0875	740	35.13 ± 2.17
12 Months	28.4825	29.0148	315	28.48 ± 3.20
2 Years	33.5950	31.4466	121	33.60 ± 5.60

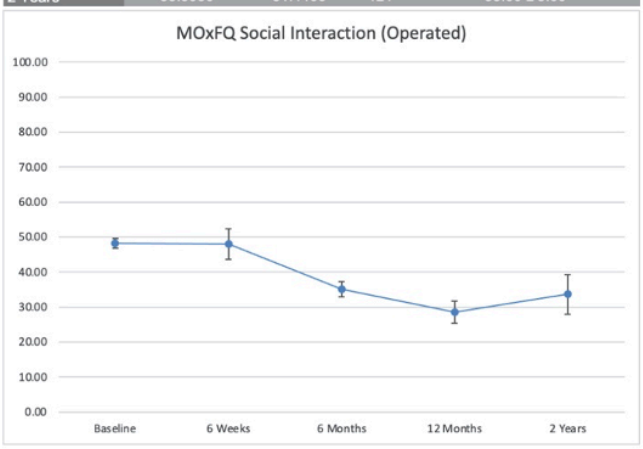


Figure 26: MOxFQ Social, Foot and Ankle General pathway

Total Ankle Replacement (Primary)

The Total Ankle Replacement (Primary) pathway has only recently been introduced and the number of cases are therefore small. There are currently 21 active pathways by 5 surgeons. In comparison to the National Joint Registry (NJR Annual Report 2020), between 2015 and 2019, the number of procedures each year ranged from 618-974. The number of cases increased year on year. We are therefore only recording between 2-3% of cases performed on the registry.

The primary diagnosis was primary osteoarthritis in 14 ankles, osteoarthritis secondary to trauma in 5 cases, and rheumatoid arthritis in 2 cases.

All cases used the anterior approach. Ankle dorsiflexion pre-operative ranged from neutral to 20 degrees. The ASA grades ranged from 1 to 3, with one ASA 1, thirteen ASA 2 and seven ASA 3. The subtalar joint had been fused in 3 cases and a further 14 reported the joint to be stiff.

Regarding implants used, there were 17 STAR (Stryker) implants and 5 Infinity (Wright Medical). In comparison the 2019 NJR data showed that the STAR implant was performed in 9% of cases and the Infinity implant was used in 63% of cases.

The data is not yet sufficient for meaningful analysis of PROMS but in a short time, the Registry has demonstrated its potential for capturing PROMS on all ankle replacements performed in the UK, giving sufficient support to enable ubiquitous usage

Total Ankle Replacement (Revision)

Again, this pathway has only just been introduced. There are currently no pathways on the registry for revision Total Ankle Replacement.

Achilles Pathways

British Orthopaedic Foot & Ankle Society

Achilles Tendon Rupture Pathway

The Achilles Tendon Rupture pathway has only recently been introduced and the numbers of cases are therefore small. The 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) although other scores, such as MOXFQ or EQ-5D, may be added in the pathway owner's registry settings, if desired.

Only 17 cases have been entered so far. Their mean age was 42.8 years (range 26-81), 8 left and 9 right. Injury during sport was recorded in 8 cases: 5 Football (Soccer), 2 Tennis and 1 Netball. 5 Cases were managed surgically with a primary repair and the remaining cases were managed non-operatively with functional rehabilitation.

There is insufficient data for meaningful analysis of PROMS at this stage.

The pathway allows for detailed recording of the ultrasound findings, with the ankle in different positions, gap size and rupture site. Registry users are encouraged to review the parameters with their radiologists and radiographers to ensure reporting is standardised.

Achilles Tendinopathy Pathway

Again, this pathway has only just been introduced and uptake is limited to only 4 cases so far. Analysis of these has not been undertaken.

The standard PROMS are EQ-5D and VISA-A, although additional PROMS may be used as the pathway owner's discretion.

Quality Assurance

BOFAS
British Orthopaedic Foot & Ankle Society

BOFAS was successful in a competitive bid for Amplitude to quality assure the BOFAS registry. The study commissioned by Amplitude was undertaken by Dr Alison Rushton, Reader in Musculoskeletal Rehabilitation Sciences at Birmingham University (Ethical approval ERN_19-1274AP2). The Objectives of the study were to evaluate data quality and capture, to evaluate accuracy of the data and to evaluate the pre and post patient reported outcome measures (PROMs) and associated clinical data of the three pathways within BOFAS (First metatarsophalangeal joint arthrodesis, Ankle Arthrodesis and Foot and Ankle pathway).

The draft reports for the three pathways have been reported: The reports included data from August 2014 to May 2019. The reports concluded that whilst data completeness was good for some variables such as gender, baseline BMI and medication it was generally poor for other variables such as smoking, previous surgery and type of surgery. MOxFQ (pain, walking-standing and social interaction) VAS, and EQ5D scores were improved compared to baseline values following surgery at 12 months for each pathway.

The reports highlighted the following issues, missing data, unrealistic data input (e.g. BMI of 4500), and staggered data in one field (co-morbidities) rendering analysis in that field implausible.

The Outcomes committee have reviewed these reports and a number of changes have been made to the registry. These include mandating e-mail and/or mobile phone number for all patients. BOFAS has also commissioned an SMS service through Amplitude to increase data capture. These changes will improve the data quality and provide reliable data allowing future analysis and research.

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Summary

The previous BOFAS Registry Report in 2020 clearly demonstrated the potential for the Registry to provide a real-word picture of foot and ankle surgery across the nation and its clinical outcomes. The introduction of additional dedicated pathways and an almost-tripling of total patient numbers illustrated in this 2021 Report validate that contention. Introduction of SMS texting in April 2021 should increase follow-up data capture substantially, but two major obstacles remain:

- Increasingly onerous and inconsistent demands from Trust Information Governance Officers (required for sign-up).
- Inadequate support for members "at the coal-face" to collect and enter data.

These two limitations are the keys to the Registry becoming a truly National Foot and Ankle Registry. Your Committee recognises them and is lobbying at the highest levels for solutions.

"This is my final Report as Chair of the Outcomes Committee, having come to the end of my 6 year tenure. I wish to thank my talented Committee for their drive, expertise and support. It is their hard work which has achieved the results outlined in the Report. I pass the Committee with total confidence to Lyndon Mason's safe hands. I also congratulate all the BOFAS Members who contribute to the Registry and encourage those who are yet to sign up to visit BOFAS' hugely improved website to do so."

Paul Halliwell
Chair, BOFAS Outcomes Committee