

Registry Report 2020

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INTRODUCTION

The data presented in this report cover procedures entered into the British Orthopaedic Foot & Ankle Society (BOFAS) Registry from 2014 until April 2020. The 1st Metatarsophalangeal Joint Arthrodesis Pathway (1st MTPJAP) and the Ankle Arthrodesis Pathway (AAP) have been open since the registry started, however the Foot and Ankle General Pathway (FAG) was only opened towards the end of 2016.

Over this period of time 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. The majority of the information in this report is summary data, it is anticipated that as the number of cases increase, we will be able to analyse the outcomes statistically.

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.

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.

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 form 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: Paul Halliwell
- Member: Nick Harris
- Member: Lyndon Mason
- Member: Nilesh Makwana
- Member: James McKenzie
- Member: Ed Wood

- Caldicott Guardian: Stephen Bendall
- President: James Davies
- Treasurer: Hiro Tanaka
- Secretary: Mark Davies
- Co-opted: Andy Goldberg
- Co-opted: Karan Malhotra

OF CONTRIBUTING SURGEONS / UNITS

Adam Devany Andrea Sott Andrew Gower

Andrew Riddick Arshad Khaleel Ashok Acharya **Barry Rose Billy Jowett Claire Topliss Cliff Butcher Daniel Marsland** James Davenport D Mahadevan Edward Wood Heath Taylor Iain Bissell Jamie McKenzie Joel Humphrey John Stuart Moir Greater Glasgow & Clyde YDH Julian Grundy Kar Teoh Princess Alexandra hospital, Harlow 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 Maurice O'Flaherty Musgrave Park Hospital Melwyn Pereira Joint Clinic, Droitwch

Michael Butler

Robert Jones and Agnes Hunt Epsom St Helier NHS Trust County Durham and Darlington NHS **Foundation Trust** Southmead Hospital

Eastbourne District General Hospital

ABMU HB University Hospital Aintree Hampshire Wrightington Hospital Reading Foot & Ankle Unit **Countess of Chester Hospital Royal Bournemouth Hospital Royal Orthopaedic Hospital** Birmingham Milton Keynes

Michael Karski Neal Jacobs Nicholas Savva Nilesh Makwana Osmond Thomas Paul Halliwell Paul Hamilton Peter Robinson Phil Vaughan Raghu Kankate **Robbie Ray Robert Smith** Robin Elliot **Robin Rees** Sanjeev Goswami Simon Henderson **Stephen Hepple** Steve Milner Sue Kendall S Chandrashekar **Tim Clough** Tim Millar **Tim Sinnett Timothy Williams** Togay Koc Tristan Barton **Turab Syed** Vivek Dhukaram Williams Harries

Wrightington Hospital Salisbury **Dorset County Hospital** RJAH **NewCross Hospital Royal Surrey County Hospital NHS** Epsom & St. Helier Southmead Hosptial, Bristol West Suffolk **High Wycombe** Kings College London NHS Trust

Hampshire Hospital University Hospital of North Midlands Walsall Healthcare NHS Trust **Musgrave Park Hospital** Southmead Hospital Bristol **Royal Derby Hospital**

Homerton

Wrightington Hospital University Hospitals of Morecambe Bay Chelsea and Westminster NHS FT **Colchester General Hospital** Queen Alexandra Hospital Royal United Hospital Bath, NHS FT **Royal Free London Hospital** University Hospitals Coventry & Warwickshire Southmead Hospital Bristol

*Where Organisation is blank - information not available from individual's BOFAS Profile.

Cornwall

UPTAKE & COMPLIANCE

The degree of uptake of the registry by the BOFAS membership is increasing with time. 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.

BARRIERS TO UPTAKE

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

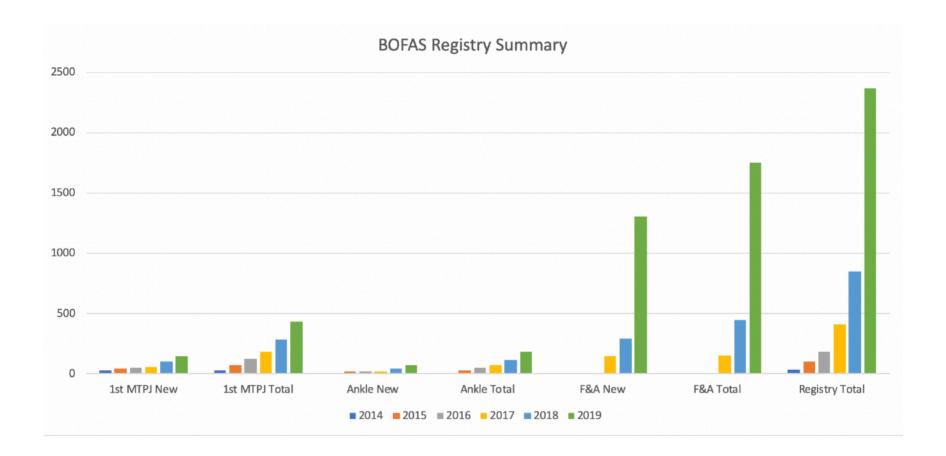


Fig 1: BOFAS Registry Summary Growth Figures.

regarding data use. As the registry is not currently mandated, support from Trusts regarding data collection & input is widely variable. We believe this will be a valuable tool for our members for revalidation & appraisal and may 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 pathways (≥95%). 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 paper consent and file this in their casenotes.

Between 15% and 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. Making use of telephone review streams can be a good solution.

We have also seen a significant proportion of patients registered but with no initial PROMS entered (18% - 39% 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 PROM SCORES

The BOFAS registry allows foot and ankle surgeons to use the outcome scores to assess patients both pre and post operatively. The Outcomes committee, following a review defined that the following scores would be collected as the Minimum Dataset:

- 1. MOXFQ
- 2. EQ- 5D-5L
- 3. EQ-5D Health VAS

The database is hosted by Amplitude. Other scores may be available depending on surgeon choice. Scores are recorded pre-operatively then routinely, via email or in person, at six months and one year post-operatively.

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.

MOXFQ

The Manchester-Oxford Foot Questionnaire 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 consist of three domains/scales:

- 1. Walking/standing 7 items. (MOxFQ-W)
- 2. Pain 5 items. (MOxFQ- P)
- 3. 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.

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)

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.

METATARSOPHALANGEAL JOINT ST **ARTHRODESIS PATHWAY**

Within the registry, 487 1st MTPJ Arthrodesis pathways (469 Patients) have been instituted since it went live in 2016, an increase of 199 over the course of the year. There was reasonable compliance with completion of PROMS preoperatively with completion rates of 88% for EQ-5D, 85% VAS, 87% MOXFQ. The completion rates at 6 months were lower with 76%, 70% and 73% and lower again at 12 months with 65%, 57% and 64% for the EQ-5D, VAS and MOXFQ scores respectively.

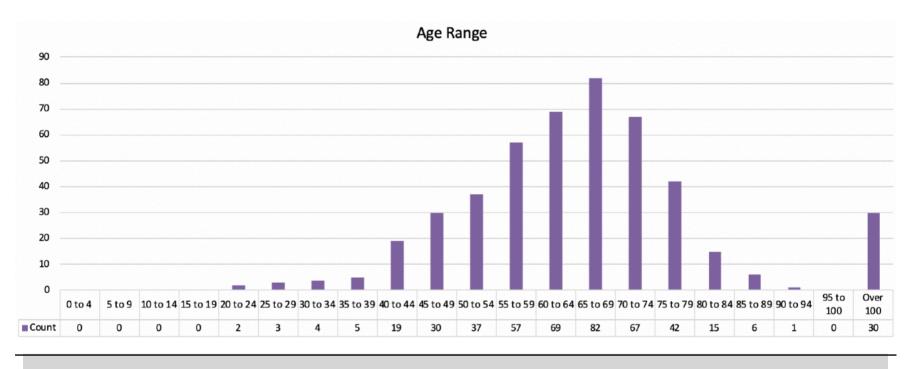


Fig 2: 1st MTPJ Age Distribution

The average age was 67 and the range for this patient cohort is illustrated in figure 2. The patients aged over 100 are likely to represent an incorrect date submitted. The BMI range is illustrated in figure 3, with the majority of patients being

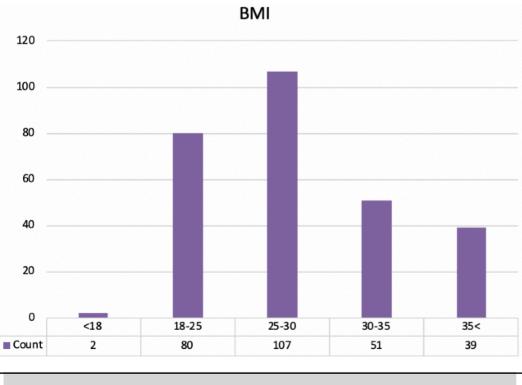


Fig 3: 1st MTPJ BMI

overweight or obese. The operation was undertaken on the right foot in 48% of individuals and left side in 44% of individuals, 8% the side was not recorded. Smoking was recorded in 6% of individuals, ex-smoker in 20% of individuals and non-smoker in 74% of individuals. The numbers for smoking was too small to make any comparison in outcomes.

93% of patients were classed as primary procedures, with only 3% revision procedures and 1% conversion of arthroplasty on the database.



EQ-5D Health VAS Mean StdDev n (

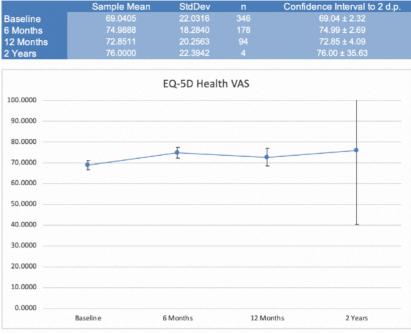


Fig 4: EQ-5D Index score

Fig 5: EQ-5D Health VAS

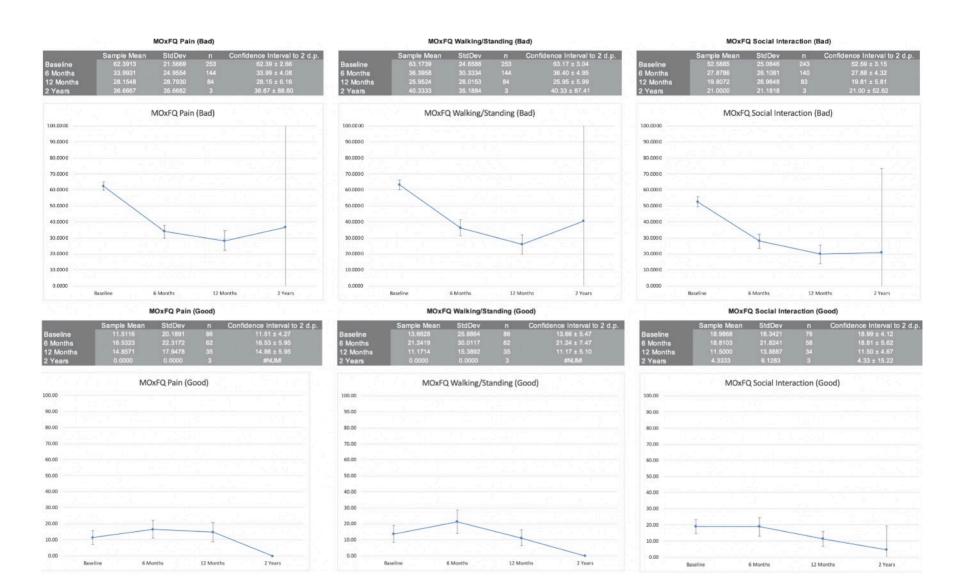
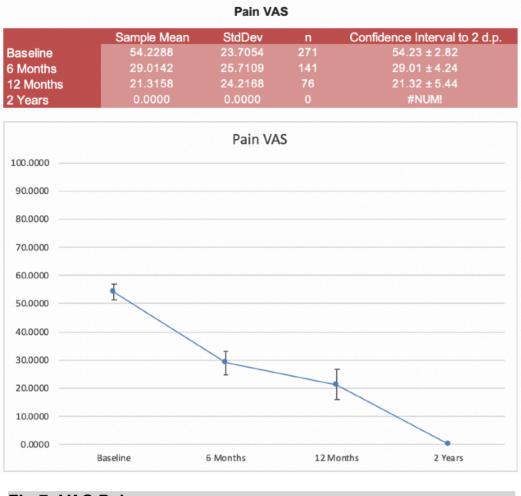


Fig 6: MOXFQ Scores



The average increase in the EQ-5D Index was from 0.57 preoperative to 0.70 and 0.74 at 6 and 12 months post operative respectively (Fig 4). 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 5), at 12 months there was no change seen. The number of patients with scores at 2 years is too small for analysis.

Fig 7: VAS Pain

The MOXFQ components all revealed a clinically relevant improvement in symptoms at 12 months post-operative (Fig 6). The Pain scores improved from a pre-operative baseline of 62.39 to 28.15 at 12 months post-operative, the Walking/Standing scores improved from 63.17 to 25.95 and the Social Interaction scores from 52.59 to 19.81. The Pain and Walking/Standing scores showed a trend towards normal at 12 months and the Social Interaction score had normalised. The number of patients with scores at 2 years is too small for analysis.

The VAS pain score again showed continued improvement up to 12 months post-operative (Fig 7).

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.

ANKLE ARTHRODESIS PATHWAY

Within the registry, 201 Ankle Arthrodesis pathways have been instituted since the pathway went live in 2016. There are twice as many males as females. Of the 201 pathways, 64 have completed 6 month follow up scores and 31 patients have completed follow up MOxFQ scores to 12 months. The age range for this patient cohort is illustrated in figure 8.

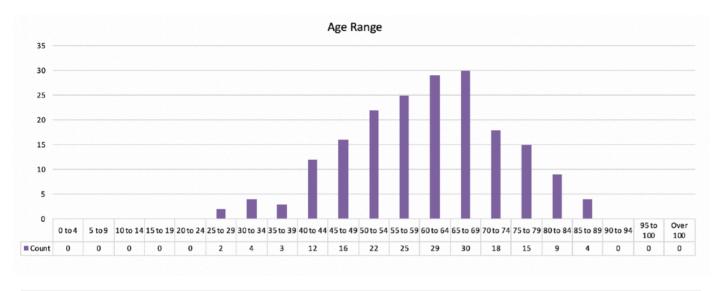


Fig 8: Age demographics of ankle arthrodesis pathway

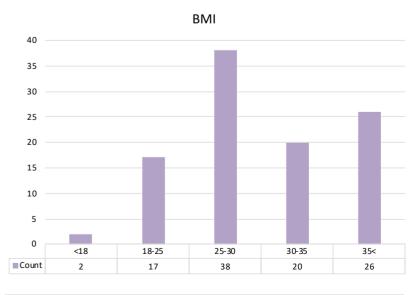
The BMI range is illustrated in figure 9. Smoking was recorded in 7% of individuals, ex-smoker in 20% of individuals and non-smoker in 73% of individuals. The numbers for smoking was too small to make any comparison in outcomes.

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

Arthroscopic fusions accounted for 52% of the recorded pathways and 47% were open. The number of 1 year postoperative completed scores are too small to make comparisons between the approaches. Ankle fusion fixation was undertaken using cannulated screws in 87% of patients. The other forms of fixation include plates, an external fixator and

staples. In those individuals undergoing fusion using screws, 2 screws were used in 82% and 3 screws in 15%.

The average increase in the EQ-5D index was from 0.43 preoperative to 0.75 at 1 year post operative(Fig 10). In comparison to population norms (Kind P 1999), this is favourable as the mean EQ-5D index is 0.713 for England. The pain scores improved in both the VAS pain and MOxFQ pain, walking and standing, and social interaction indices as illustrated in figures 11 and 12.





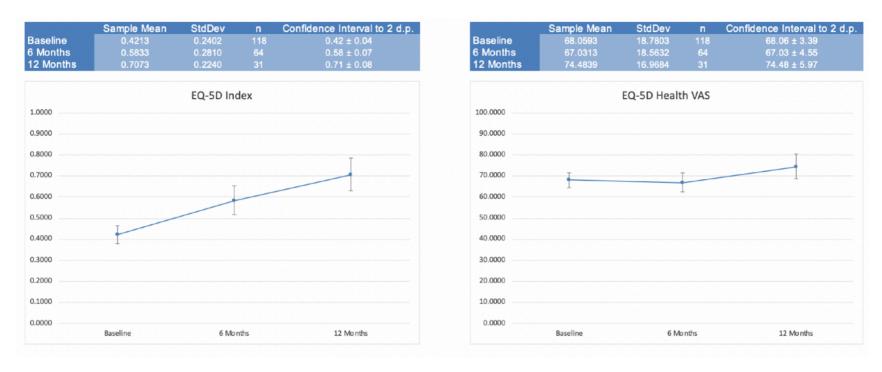


Fig 10: Ankle arthrodesis EQ-5D

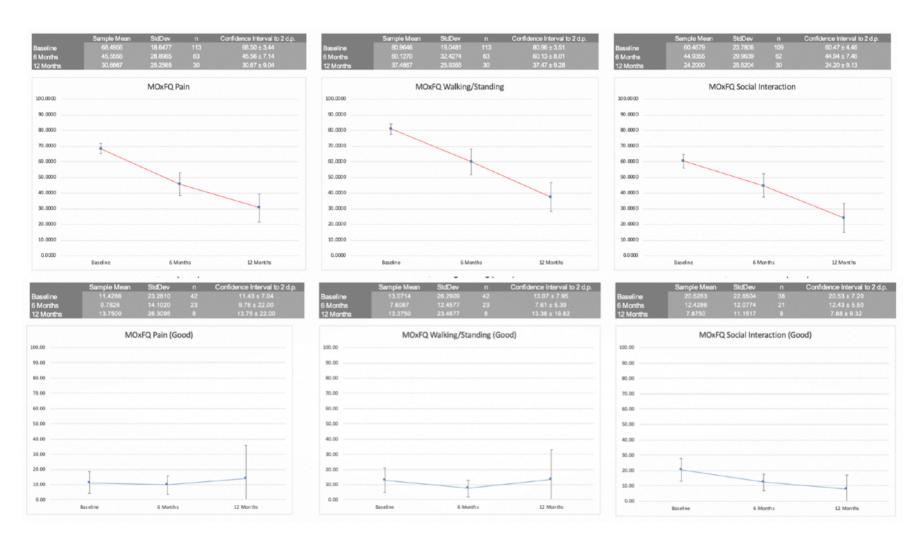


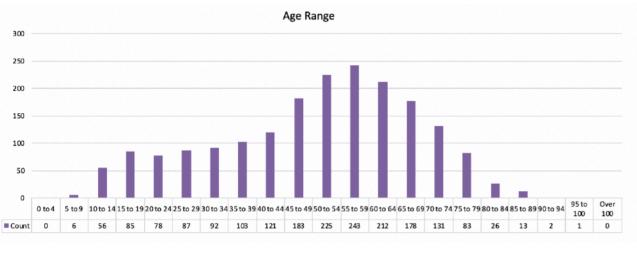
Fig 11: Ankle arthrodesis MOxFQ

	Sample Mean	StdDev	n	Confidence Interval to 2 d.p
Baseline	62.4000	23.8859	95	62.40 ± 4.80
6 Months	38.3958	31.4111	48	38.40 ± 8.89
2 Months	19.8095	22.3854	21	19.81 ± 10.19
		PainVAS	5	
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	Baseline	6 Mo	ntns	12 Months

Fig 12: Ankle arthrodesis VAS Pain Score

AND ANKLE GENERAL Ο Ο PATHWAY

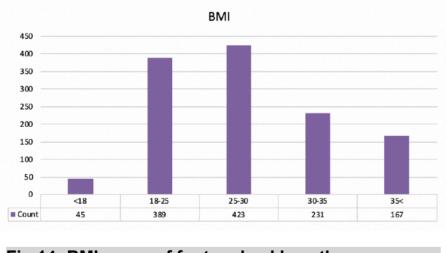
Within the registry, 4936 FAG pathways have been instituted since the pathway went live in 2017 a ten fold increase from the 451 pathways reported in the last report. This is largely due to the inclusion of a large Hospital dataset. Of the 4936 pathways, 1387 pathways have a preoperative score and 200 have completed to 1 year. The age range for this patient cohort is much more diverse than the previous pathways, as illustrated in figure 13. The BMI range for the foot and ankle







The most common diagnoses in this pathway were: hallux valgus (n=253), arthritis (n=204), hallux rigidis (n=72), toe deformity (n=103) and Achilles tendon disorders (n=64). The surgical coding in the FAG pathway is currently under review, as little can be drawn from the individual coding of procedure by each individual surgeon.

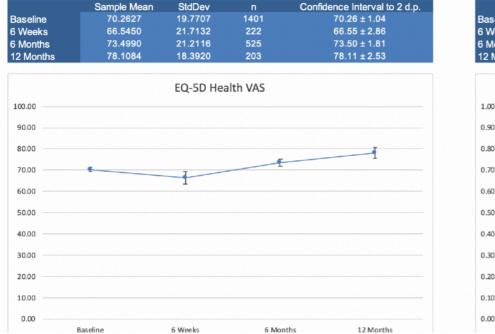




It is possible look at the amalgamated overall outcomes for the Foot and Ankle General pathway. The EQ-5D, VAS Pain & MOxFQ are shown below (figures 15, 16 and 17). The EQ-5D Health VAS shows a subtle improvement at 6 months becoming more evident at 12 months. The EQ-5D index scores reveal improvements in outcomes at 6 & 12 months compared to the baseline scores. The VAS Pain scores reveal a progressive improvement in symptoms from a baseline of 50.17 to 24.84 at 12 months

pathway is shown in figure 14.

post operative. The MOxFQ domains show improvements in outcomes at 6 and 12 months post operative in comparison with baseline scores in all domains.



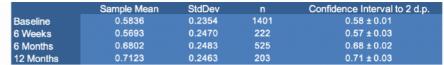




Figure 14: EQ-5D results for foot and ankle pathway.

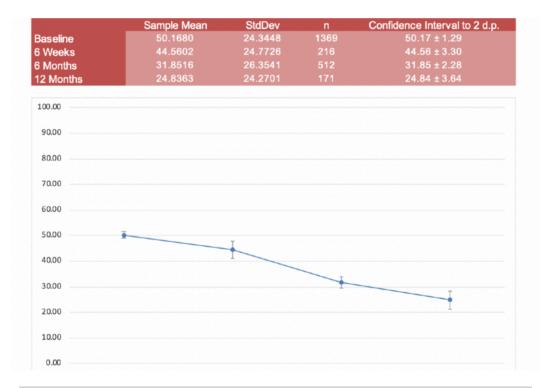


Fig15: VAS pain score for foot and ankle pathways

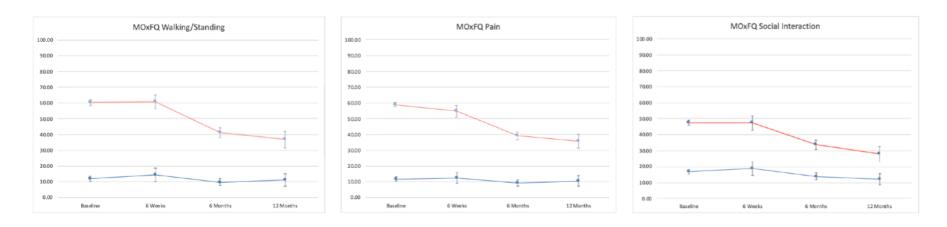


Fig 16: MOxFQ, FAG pathway. Red illustrates treated limb, blue illustrates untreated limb.

QUALITY ASSURANCE

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 report concluded that whilst data completeness was good for some variables such as gender, baseline BMI and medication and 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.

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 will review these conclusions and work with Amplitude to improve the data quality and capture as well as reducing missing data.

FUTURE PATHWAYS

This year the following new pathways have already been launched:

- Ankle (Primary Arthroplasty) with option to link to NJR
- · Ankle (Revision Arthroplasty) with option to link to NJR
- · Achilles Tendinopathy
- Achilles Rupture
- · Paediatric foot and ankle

Later this year, a foot and ankle trauma and ankle fracture pathways will also be available.

SUMMARY

The BOFAS Outcomes Registry has been conceived and developed by working clinicians with minimal funding, motivated by the wish and professional requirement to improve patient outcomes by data collection. This 2020 Annual Report demonstrates how much has been achieved already, but also highlights the limitations of data quality in the absence of resources to increase compliance and volume. The generic pathway was deliberately intended to collect basic PROMS across many procedures. Despite the intrinsic coding complexities, it shows just how much our interventions are improving the quality of life of our patients. We now wish to increase data capture with the expanded dedicated pathways so as to more accurately reflect national activity and enable valid analysis of outcomes, especially where variation in practice exists. At the time of writing, the NHS is facing recovery from Covid-19's impact. We will actively seek ways of using our established system to monitor and inform the process in our field.

The 2020 Annual Report shows that the BOFAS Registry fundamentally works and tantalisingly hints at its true potential for patient benefit. BOFAS will continue to lobby for central NHS England support via its Outcomes Committee, as it did last year working with the National Joint Registry and Trauma and Orthopaedic Registries Unified Structure (TORUS). Meanwhile I commend BOFAS members who have engaged with the Registry and thank my Committee for their work in preparing this Report.

Paul Halliwell

Chairman, BOFAS Outcomes Committee

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