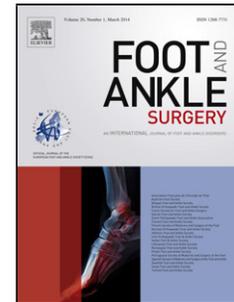


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A comparative prospective cohort health economic analysis comparing ankle fusion, isolated great toe fusion and hallux valgus surgery.

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Highlights

- Improvements in outcomes for all three common foot and ankle operations.
- The greatest outcome score improvements were with ankle fusion and 1st MTP joint fusion compared to hallux valgus.
- Health economics analysis suggested all three procedures were favourable compared to threshold levels of cost-effectiveness.
- The costs of ankle fusion and 1st MTPJ fusion were easily within threshold costs per QALY whereas hallux valgus had varying costs making it just favourable.

ABSTRACT

This study assessed the health economics and outcomes of three common foot and ankle operations.

Between July 2013 and October 2014 all patients undergoing ankle fusion (AF) for osteoarthritis, first metatarsophalangeal joint fusion for osteoarthritis (MF) or hallux valgus surgery (HV) were included. Patients having additional procedures were excluded. Patients completed the Manchester-Oxford Foot Questionnaire (MOX-FQ), the EuroQol EQ-5D-5L questionnaire and the EQ-VAS on presentation and at least 6 months post-operatively.

63 patients undergoing AF (n=22), MF (n=22), or HV (n=32) completed preoperative and postoperative questionnaires. 76 completed preoperative questionnaires and 63 completed the follow up questionnaires. The follow up questionnaires were completed at a median of 12 months (range 6-24 months) following surgery. The mean age at surgery was 59 years (range 26-85 years). Pre-operative MOX-FQ and EQ-5D-5L scores differed significantly between the three groups with AF and MF patients reporting worse scores compared to HV patients. MOX-FQ and EQ-5D-5L significantly improved in all groups from pre-operative levels. MOX-FQ: AF from 53.8 (CI 56.8 – 50.8) to 22.9 (CI 30.9 – 14.9), MF from 43.0 (CI 46.4 – 39.6) to 12.1 (CI 5.9 – 18.3), HV from 35.4 (CI 39.0 – 31.7) to 15.6 (CI 21.1 to 10.1). EQ-5D-5L: AF from 0.30 (CI 0.43 – 0.17) to 0.66 (CI 0.55 – 0.77), MF from 0.45(CI 0.52 – 0.38) to 0.83 (CI 0.07 – 0.07), HV from 0.71(CI 0.74 – 0.68) to 0.82 (CI 0.88 – 0.76). There was no significant difference in the EQ-VAS suggesting it may not be representative of foot and ankle health. Health economics analysis using the EQ-5D-5L data to estimate quality-

adjusted life years (QALYs) suggested all three procedures were favourable compared to threshold levels of cost-effectiveness. There were differences in estimated costs between the three operations with AF at £2950 (threshold cost <£5,400) and MF at £1197 (threshold cost <£5,780) and HV varying from £625 to £1688 (threshold cost <£1640).

This study reveals that the joint-specific (MOX-FQ) and generic health (EQ-5D-5L) outcome scores of patients improved after AF, MF and HV. The greatest benefit from surgery was gained in the arthritic patient groups. In the future, the use of large population patient reported outcome measures data may also potentially have implications for prioritisation of healthcare provision, acting as an indicator of foot and ankle surgical procedures that produce the most benefit to patients.

INTRODUCTION

In recent years Patient Reported Outcome Measures (PROMs) have become an important tool both in clinical practice and in healthcare provision. They are seen as a key measure both in clinical research, and in evaluating surgical outcomes and service quality. Many of the specialty societies, including the British Society for Surgery of the Hand (BSSH), and the British Association for Spinal Surgery (BASS), have set up registries where their members can audit patient outcomes for the most common procedures. A central UK registry for foot and ankle surgery has been proposed (1), initially recording surgeons' outcomes for AF and MF. This study has also included HV as it is probably the commonest patient group in foot and ankle surgery.

Many scoring systems exist which relate specifically to the foot and ankle. One study found 139 different outcome scales in use in the foot and ankle literature (2). A commonly used score in the UK is the Manchester-Oxford Foot Questionnaire (MOX-FQ) which was originally validated for use in hallux valgus (3), but has subsequently been validated for use in all regions of the foot and ankle (4). The MOX-FQ consists of 16 questions covering the three domains of function (standing and walking), pain, and social interaction. Pain and function have been shown to be strong predictors of patient satisfaction post-operatively (5,6). The three MOX-FQ domains are combined to form a MOX-FQ index (7), with higher scores indicating more severe symptoms. The EuroQol EQ-5D-5L index (8) is a standardised generic measure of health developed by the EuroQol group. It includes five domains of mobility, self-care, daily activities, pain, anxiety or depression. Each domain has 5 levels. The EQ-5D-5L index scores range from -0.594 to 1 (full health) with negative values representing health states worse than death, which is assigned a score of zero (9). The EQ-5D visual analogue

scale (EQ-VAS) is a measure of overall health, with patients marking their health on a scale from 0 (worst health you can imagine) to 100 (best health you can imagine).

The primary aim of this study was to compare health economy outcomes using quality-adjusted life years (QALY) between isolated MF, isolated AF, and isolated HV. Secondary outcomes included comparison of three different outcome scores between the three procedures (MOX-FQ, EQ-5D-5L, and EQ-VAS).

PATIENTS & METHODS

Prospectively collected data was reviewed retrospectively, up to December 2015, on all patients who underwent AF, MF, or HV between 4th July 2013 and 31st October 2014. The operations were performed by either of the two senior authors (GS and DL), or under their direct supervision. Symptomatic arthritis affecting the particular joint was the primary indication for either AF or MF. HV correction consisted of a scarf osteotomy plus lateral soft tissue release (10) and an Akin osteotomy of the proximal phalanx (11) if indicated perioperatively. Subjects attending the out-patient clinic pre-operatively completed a paper questionnaire consisting of the MOX-FQ, the EQ-5D-5L, and the EQ-VAS. At a minimum of 6 months post-operatively, the patients were initially contacted via post and asked to complete the same questionnaires. The few patients who did not reply by post were then contacted by telephone. Patients undergoing concurrent ipsilateral forefoot surgery such as Weil's osteotomy or a proximal interphalangeal joint fusion were excluded. Those undergoing revision surgery or simultaneous bilateral surgery were also excluded, as were those who had rheumatoid arthritis.

For health economic evaluation the quality-adjusted life year (QALY) is routinely used. The QALY seeks to combine effects in terms of both quality of life and length of life, enabling the benefits of different interventions to be compared on the same scale(12). The National Institute for Health and Care Excellence (NICE) (13) recommends that EuroQol EQ-5D (14) is used to estimate QALYs. The QALY can be calculated using the area-under-curve method (15) with linear interpolation (this assumes a straight-line change between points, rather than an immediate improvement). In line with previous work (16), we estimated the QALY gain between the individual pre- and post-operation EQ-5D-5L scores, based on the assumption of a 6 month follow up period and that without the procedure in question the pre-operative score would have been maintained (see Appendix 1). Threshold analysis (12) was then conducted on the mean QALY gain for each procedure in order to estimate the maximum cost at which the procedure is likely to be cost-effective based on the threshold value of £20000 per QALY (13). Indicative costs were subsequently identified for each procedure and compared to these maximum costs in order to assess whether the procedures were likely to have favourable levels of cost-effectiveness.

A one-way ANOVA was used for between groups statistical analysis, and a paired student's *t*-test for the pre- and post-operative score analysis. A *p*-value of <0.05 was accepted as being statistically significant. Local audit committee approval was obtained for the study.

RESULTS

In total 143 patients referred to the Norfolk and Norwich University Hospital received one of the three procedures in the study time period. After application of the exclusion criteria 85

patients were identified (figure 1). 76 patients had completed pre-operative questionnaires, and 63 of these went on to complete MOXFQ and EQ-5D post-operative questionnaires at a median of 12 months following surgery (range 6-24 months). However all data from the 76 patients completing pre-operative questionnaires was used in statistical analysis. The average age was 59 years (range 26-85 years) and 53 (70%) patients were female (table 1). The HV group was mainly female and had a wider age range compared to the AF and MF groups.

MOX-FQ

Mean pre-operative MOX-FQ scores were AF 53.8 (CI 56.8 – 50.8), MF from 43.0 (CI 46.4 – 39.6), HV from 35.4 (CI 39.0 – 31.7) (figure 2). These differed significantly between the three groups ($p < 0.0001$) with AF patients reporting the worst scores, and HV patients the best scores. There was significant improvement in the MOX-FQ in all groups ($p < 0.0001$). The mean post-operative scores were AF 22.9 (CI 30.9 – 14.9), MF 12.1 (CI 5.9 – 18.3), HV 15.6 (CI 21.1 to 10.1). However, there was no significant difference between the post-operative scores in each group ($p = 0.1041$), AF 0.66 (CI 0.55 – 0.77), MF 0.83 (CI 0.07 – 0.07), HV 0.82 (CI 0.88 – 0.76).

EQ-5D-5L

Mean pre-operative EQ-5D-5L were AF 0.30 (CI 0.43 – 0.17), MF 0.45 (CI 0.52 – 0.38), HV 0.71 (CI 0.74 – 0.68) (figure 3). These scores differed significantly between the groups ($p < 0.0001$), again with ankle fusion patients reporting the worst scores, and hallux valgus patients the best scores. Mean post-operative scores were AF 0.66 (CI 0.55 – 0.77), MF 0.83 (CI 0.07 – 0.07), HV 0.82 (CI 0.88 – 0.76). EQ-5D-5L showed a statistically significant

improvement following surgery in all three conditions (MTPJ $p < 0.0001$; ankle $p = 0.00013$; hallux valgus $p = 0.0027$). Post-operative EQ-5D-5L did not differ between groups ($p = 0.0678$).

EQ-VAS

The EQ-VAS showed a significant difference between the surgical groups pre-operatively ($p = 0.0448$), with AF 73.5 (CI 80.9 – 66.1), MF 72.2 (CI 81.5 – 62.9), HV 83.5 (CI 88.4 – 78.6).

There was no significant difference between the groups post-operatively with AF 72.8 (CI 83.1 – 62.5), MF 78.4 (CI 85.0 – 71.8), HV 81.8 (CI 86.4 – 77.2), and there was no significant improvement between pre- and post-op scores for each type of surgery (Table 2).

Clinical Outcomes

None of the patients in the study population underwent revision surgery or had removal of metalwork during the study period. A total of 4 out of the 22 AF patients had post operative computer tomography (CT) scans for ongoing pain. Two had non unions and two had solid fusions. One AF patient sustained a stress fracture at the proximal screw four months post-operatively. This was managed conservatively and healed by 7 months post-operation. There were no MF non-unions, although one patient with a poor MOX-FQ score had a CT scan demonstrating union.

Health Economics

Threshold analysis was used to determine the cost below that an intervention would look to have a favourable cost per QALY, given the estimated QALY gain [12] (Table 3). NICE recommends a cost of £20,000 per QALY.

For the cost of the intervention in England the NHS National Schedule of Reference Costs 2013-14 was used (Table 4). For this the ICD-10, OPCS-4, HRG4 codes were required. The International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10) is a World Health Organisation medical classification for diseases. The Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures 4th revision (OPCS-4) is a NHS England classification translating surgical procedures into codes. The Healthcare Resource Group 4 (HRG4) is a NHS England classification of patient activity, based on procedures and diagnosis, to determine reimbursement for providers.

For AF there is a cost of £2950 and in this study's patient group a QALY gain of 0.270 (compared to what would have happened without the intervention). As the incremental cost of the intervention is <£5,400 then the cost per QALY is likely to be favourable.

For MF there is a cost of £1197 and in this study's patient group a QALY gain of 0.289 (compared to what would have happened without the intervention). As the incremental cost of the intervention is <£5,780 then the cost per QALY is likely to be favourable.

For HV the costing is not as clear due to the variations in surgery and coding requirements. OPCS-4 and HRG4 codes stipulate if a soft tissue procedure is performed with hallux valgus surgery then this code has to be listed first. This leads to a considerable reduction in the

costing. For hallux valgus surgery there is a cost ranging from £625 to £1688 and in this study's patient group a QALY gain of 0.082 (compared to what would have happened without the intervention). As the incremental cost of the intervention, £1640, is similar to the top end cost then the cost per QALY is just likely to be favourable.

DISCUSSION

The results of this study show that both foot and ankle specific (MOX-FQ), and generic (EQ-5D-5L) scores differ between patients who have different pathologies of the foot and ankle. Arthritic conditions affecting the ankle joint (AF group) lead to the worst MOX-FQ and EQ-5D-5L scores followed by arthritis of the first MTP joint (MF group), with hallux valgus patients (HV group) recording the best scores of the three study groups. Both MOX-FQ and EQ-5D-5L show a statistically significant improvement following surgery in the three groups. These results are broadly in line with previous studies which have suggested that the MOXFQ is the best disease-specific score for hallux valgus patients (17), and that it is more responsive in foot and ankle patients than EQ-5D-5L and other generic scoring systems (18).

The minimum change for a MOX-FQ score to be considered significant is 7 points (19). In this study, the mean change in each of the three groups was greater than 7. However, there were ten patients who did not achieve this level: 3 AF, 2 MF and 5 HV. The EQ-VAS showed a difference in pre operative scores, but there was no significant change from pre-op to post-op in any of the three groups (the post operative scores did not differ significantly between the groups). This suggests the EQ-VAS may not be responsive to foot and ankle health.

Patients may perceive their overall health as representing something different than a specific problem related to foot and ankle pain and mobility.

From the health economics analysis using the EQ-5D-5L the three interventions can be judged to be cost-effective procedures. Hallux valgus surgery emerges as having a cost that is similar to the threshold cost. However coding requirements demand if a soft tissue procedure is involved then this has to be coded first. This leads to the cost of the procedure to be much less than the threshold cost. Most surgeons would agree that a first metatarsal osteotomy for hallux valgus always requires release of the tight lateral tissue and reefing of the medial soft tissues. Therefore all hallux valgus surgery will be coded at a lower cost. There are a number of potential criticisms of this analysis. It is assumed the quality of life would not have changed without intervention. For the three interventions listed surgery is only advised when patients are unable to manage their symptoms with painkillers, altered footwear or altered activities. All three conditions have a slow onset and it is likely patients have lived with their symptoms for sometime prior to presentation. The three conditions affect mobility and unless the patients stop walking (highly unlikely) they are likely to have continued symptoms without an intervention. For these interventions only the cost associated with the initial procedure have been considered. Other costs e.g. physiotherapy and medication costs, might differ between groups and the analysis makes the assumption that all other costs are the same in both groups. Though this might be a simplification it is recognised that cost-effectiveness studies should concentrate on those resources that are expected to differ between groups, and that healthcare resource groupings are often used to estimate unit costs [20].

The limitations for this study are the relatively small number of patients with a variable follow up. There is a risk of bias from the patients lost to follow up. In total 63 out of the 76 (83%) patients meeting the inclusion criteria with pre-operative data were contactable for post-operative scores. Excluding those patients who had rheumatoid arthritis, multiple surgical procedures, revision procedures and bilateral procedures strengthens the study enabling the particular disease process to be studied in isolation.

Patient reported outcome measures are undoubtedly of use for clinical audit, quality improvement, and identification of surgeon outliers (21, 22). However, the quality of their measurement properties (23), and hence their use in rationalising surgical services and predicting patients' post-operative outcomes have been shown to be limited for other orthopaedic conditions (24); this is also likely to be the case for foot and ankle conditions. Further research needs to be undertaken to ascertain the best outcome measure for foot and ankle patients' general health, and disease-specific health. Introduction of the proposed national database of foot and ankle outcomes will allow analysis of much larger patient numbers and more valid conclusions may then be drawn regarding the relevant benefits of various foot and ankle procedures.

CONCLUSIONS

The results in this study show that patients with arthritic conditions of the ankle (AF group) and great toe (MF group) score significantly worse pre-operatively than those with hallux valgus (HV group). Surgical management of the three conditions studied improved the patients' joint-specific (MOX-FQ) and generic health (EQ-5D-5L) outcome measures in all groups. The greatest benefit from surgery was gained in the AF and MF groups. In the

future, the use of large population patient reported outcome measures data will aid foot and ankle surgeons when counseling patients regarding likely post-operative outcomes, and serve to inform patients' expectations of surgery. They may also potentially have implications for prioritisation of healthcare provision, acting as an indicator of foot and ankle surgical procedures that produce the most benefit to patients.

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Figure 1.

Flowchart showing patient inclusion and exclusion criteria

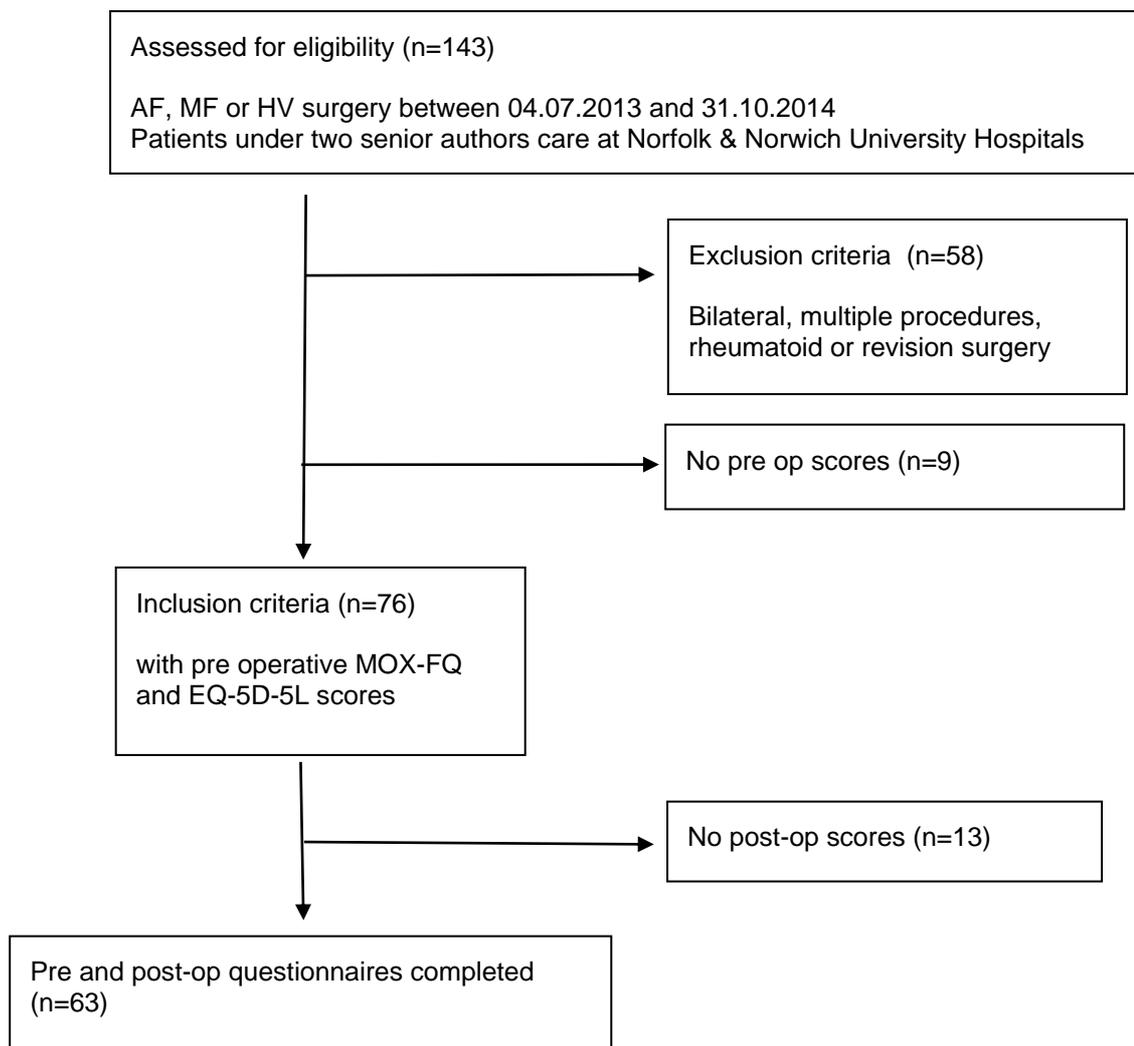


Figure 2.

Mean pre- and post-operative MOX-FQ scores showing 95% confidence intervals for each group.

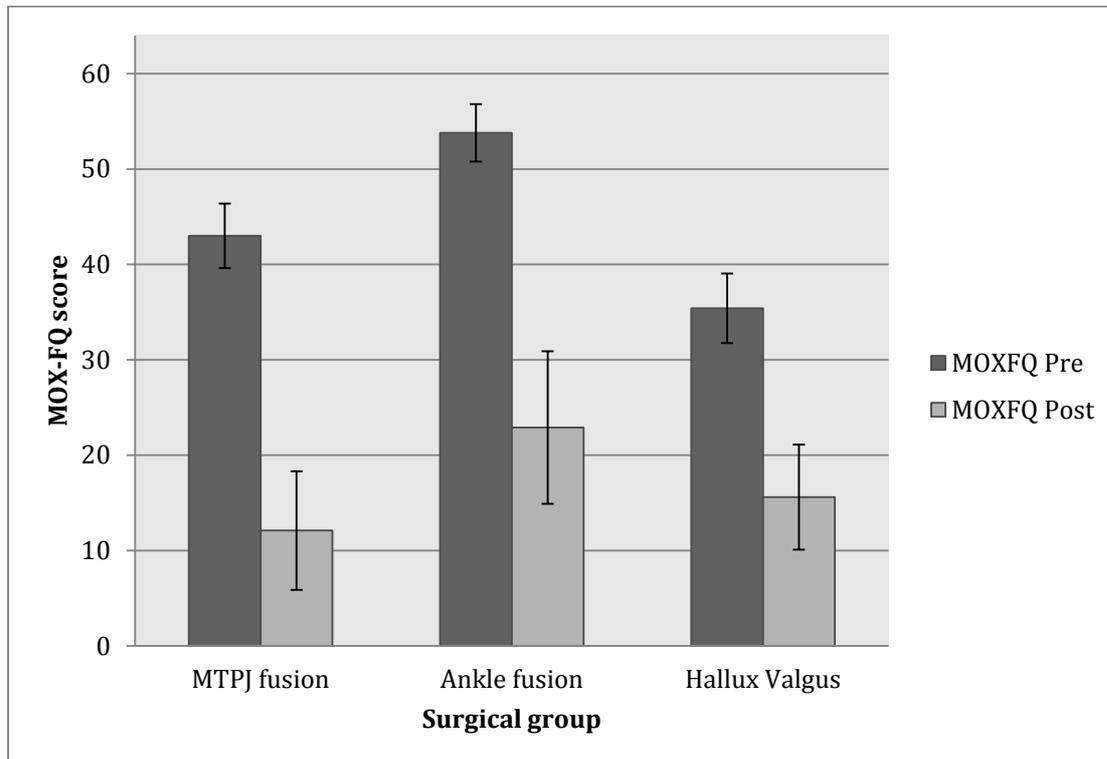


Figure 3.

Mean pre- and post-operative EQ-5D scores showing 95% confidence intervals for each group.

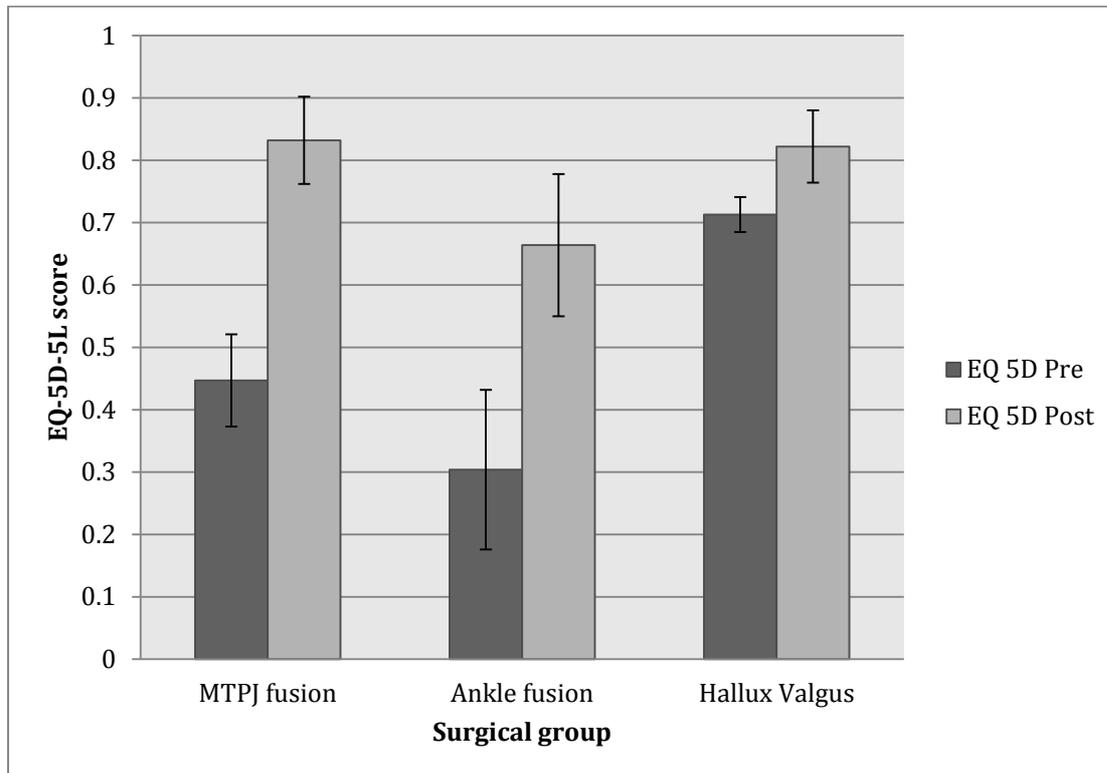


Table 1.

Demographics of patients included in the three surgical groups

	1 st MTPJ fusion	Ankle Fusion	Hallux Valgus Surgery
Patients (Total 76) (Complete datasets 63)	22 (17)	22 (19)	32 (27)
Male:Female	10:12	11:11	2:30
Mean Age at time of surgery (yrs) (range)	62 (43-85)	68 (41-81)	56 (26-78)
Median time post-op (months) (range)	12 (6-24)	15 (7-24)	8 (6-21)

Table 2.

Mean EQ-5D VAS pre and post operative scores for the three surgical groups.

	1st MTPJ fusion	Ankle fusion	Hallux Valgus correction	p-value (one way ANOVA)
Pre-op EQ-5D VAS mean (SD)	72.16 (22.20)	73.50 (17.71)	83.52 (14.09)	0.0448
Post-op EQ-5D VAS mean (SD)	78.42 (15.83)	72.76 (24.62)	81.80 (14.38)	0.2194
p-value (paired t-test)	0.06	0.8178	0.7668	

Table 3.

Threshold analysis

	QALYs for standard care	QALYs for intervention	Incremental QALY gain	Threshold cost
1st MTPJ fusion	0.447	0.736	0.289	£5,780
Ankle fusion	0.304	0.574	0.270	£5,400
Hallux valgus	0.713	0.795	0.082	£1,640

Table 4.

Codes with descriptions

Operation	ICD-10	OPCS-4	HRG4
1 st MTPJ fusion	HB34E Minor foot procedure non trauma 19 years & over Category 2 £1197	W593 Fusion of first metatarsalphalangeal joint NEC	M202 Hallux rigidus
Ankle fusion	HB32A Intermediate foot procedure non trauma 19 years & over Category 2 £2950	W621 Primary arthrodesis and internal fixation of joint	M1997 Arthrosis unspecified: Ankle and foot joint
Hallux valgus	HB33E Intermediate foot procedure non trauma 19 years & over Category 1 £1688	W153 Osteotomy of first metatarsal bone NEC	M201 Hallux Valgus (acquired)
Hallux valgus	HB35C - Minor Foot Procedures for Non- Trauma category 1 without CC £625	W791 Soft tissue correction of hallux valgus W153 Osteotomy of first metatarsal bone NEC	M201 Hallux Valgus (acquired)

Appendix 1.

QALY calculations with EQ-5D-5L

1st 6 month

standard (i.e. do nothing) = (((mean eq5d score before surgery + mean eq5d score before surgery) / 2) x (6/12)

intervention (i.e. operate) = (((mean eq5d score before surgery + mean eq5d score after surgery at 6 months) / 2) x (6/12)

2nd 6 months

standard (i.e. do nothing) = (((mean eq5d score before surgery + mean eq5d score before surgery) / 2) x (6/12)

intervention (i.e. operate) = (((mean eq5d score after surgery at 6 months + mean eq5d score after surgery at 6 months) / 2) x (6/12)

Threshold cost

£20,000 x Incremental QALY gain