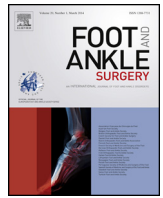




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A comparative prospective cohort health economic analysis comparing ankle fusion, isolated great toe fusion and hallux valgus surgery

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ABSTRACT

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

Methods: 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.

Results: 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 18.3–5.9), HV from 35.4 (CI 39.0–31.7) to 15.6 (CI 21.1–10.1). EQ-5D-5L: AF from 0.30 (CI 0.43–0.17) to 0.66 (CI 0.77–0.55), 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 <£5400) and MF at £1197 (threshold cost <£5780) and HV varying from £625 to £1688 (threshold cost <£1640).

Conclusions: 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.

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1. 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 speciality 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.

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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).

2. Patients and methods

Prospectively collected data was reviewed, 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 was the indication for either AF or MF and surgery involved joint debridement with compression by internal fixation. Symptomatic HV surgery consisted of soft tissue balancing with a first metatarsal osteotomy (scarf osteotomy) [10] and a proximal phalanx medial closing wedge osteotomy (akin osteotomy) [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 A). 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 £20,000 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.

3. Results

In total 143 patients referred to the Norfolk and Norwich University Hospitals received one of the three procedures in the study time period. After application of the exclusion criteria 85 patients were identified (Fig. 1). 76 patients had completed pre-operative questionnaires, and 63 of these went on to complete MOX-FQ 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.

3.1. 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) (Fig. 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 18.3–5.9), HV 15.6 (CI 21.1–10.1). However, there was no significant difference between the post-operative scores in each group ($p = 0.1041$).

3.2. 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) (Fig. 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 0.77–0.55), 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 ($p = 0.0678$).

3.3. 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).

3.4. 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

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