Cost-effectiveness comparison of three methods of internal fixation for arthrodesis of the first metatarsophalangeal joint

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Fixation devices for first metatarsophalangeal joint arthrodesis.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Patients undergoing arthrodesis of the first metatarsophalangeal joint.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Clinical data were collected between May 1984 and November 1993; 1984-1989 for Herbert screws, 1988-1994 for AO screws, and 1991-1994 for Luhr plates. Resource use data and corresponding dates of data collection were not specifically reported (although this seems to correspond with the time span of the effectiveness data). The price year was not explicitly specified.

Source of effectiveness data
Evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was retrospectively undertaken on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were not used to determine the sample size. The 3 groups were roughly consecutive, but this occurred fortuitously because the surgeon used Herbert screws between 1984 and 1989, AO screws between 1988 and 1994 and Luhr plates between 1991 and 1994. Where there was a time overlap the authors did not explain the choice of method. The unit of study was the foot. The sample consisted of feet operated on by the same surgeon at 2 hospitals over the study period whose owners could be traced. Feet which had required structural bone graft were excluded. A total of 104 feet in 89 patients were operated on in the study period. 15 feet in 13 patients could not be traced and 14 feet in 12 patients were excluded because they required structural bone graft. This left 75 feet belonging to 64 patients
who formed the study sample. 23 feet had crossed Herbert screw fixation, 27 had crossed cannulated cancellous AO screw fixation and 25 had Luhr plate fixation.

**Study design**
This was a retrospective cohort study. The study was multi-centred. Two hospitals were used, but the same senior surgeon performed all operations. Duration of follow-up was from 24 to 101 months with an average duration of 27 months. Loss to follow-up consisted of 15 feet belonging to 13 patients who could not be traced.

**Analysis of effectiveness**
The analysis was based on treatment completers only. Primary health outcomes were:

1. union of the joint;
2. complications;
3. additional intervention (including hardware removal, wound care, and fixation revision); and
4. the patient's satisfaction with the procedure expressed as one of three statements: "satisfied", "satisfied with reservation" and "unsatisfied".

A standard gamble method was used to assign a value to an intermediate utility. These judgements were obtained by questionnaire at latest follow-up. No details were given regarding the age of patients. Details of the diagnoses of the cause of pain and of whether the feet had had previous surgery were given by treatment group. There was no statistical difference between groups in the incidence of previous surgery.

**Effectiveness results**
Union occurred in the HS group in 10 feet (61%), in the AO group in 24 feet (89%), and in the LP group in 23 feet (92%). Differences between the HS group and the other groups were significant but differences between the AO and LP groups were not. Details of significance levels were not given.

In the HS group patients rated 8 feet (35%) as satisfied, 8 feet (35%) as satisfied with reservation and 7 feet (30%) as unsatisfied.

In the AO group patients rated 15 feet (56%) as satisfied, 9 feet (33%) as satisfied with reservation and 3 feet (11%) as unsatisfied.

In the LP group patients rated 15 feet (60%) as satisfied, 8 feet (32%) as satisfied with reservation and 2 feet (8%) as unsatisfied.

Group and pair-wise differences were not statistically significant. Complications other than non-union occurred with 4 (17%) feet in the HS group, 2 (7%) in the AO group and 1 (4%) in the LP group. The differences were not significant. The percentage of additional interventions was 22% in the HS group versus 33% in the AO group and 12% in the LP group. The differences were not statistically significant.

**Clinical conclusions**
Use of the Luhr plate has led to a marginally improved union rate, a decreased revision rate, and decreased incidence of hardware removal.

**Modelling**
A decision tree was used to model group utilities and costs. Costs and utility values of each branch were rolled back to produce weighted average values for each group.
Measure of benefits used in the economic analysis
Units of utility were used as the measure of benefit based on the 3 levels of satisfaction reported by patients in the clinical study. The answer "satisfied" was assigned a value of 1 and the answer "Unsatisfied" the value 0. "Satisfied with reservation" was established as 0.589 by using a standard gamble technique. After a pilot interview with 10 individuals which was not used in establishing value, 30 individuals without lower extremity complaints were presented with metatarsophalangeal joint symptom scenarios and asked whether they would undergo surgery with various probabilities of success and complications until indifference between options was reached. Each individual gave 6 interviews, a total of 180. No details were given of the interviewees' characteristics.

Direct costs
Costs were not discounted (despite a mean follow-up of 27 months), and quantities and costs were not analysed separately. Charges for each patient were obtained from hospital finance departments and from the surgeon's office. All charges, for the index surgery, outpatient or inpatient wound care, hardware removal and revision where necessary, were included covering the entire treatment course. Where an operation included lesser toe procedures, only charges relating to the first joint were included. Within each fixation group there were 4 or 5 (4 in the Herbert screw group and 5 in the other 2 groups) possible courses of clinical events. The charges for each subgroup were averaged and used as the charge expected on that branch of the decision tree. The cost boundary was that of the patient. No unique price date was given and the charges were those actually made over the 10 year study period.

Statistical analysis of costs
Multivariate regression analysis was performed to identify the most important confounding cost variables influencing the total cost differences among the fixation groups.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
Simple one-way sensitivity analysis was carried out on each variable (cost, union rate, complication rate, incidence of additional intervention, and value of intermediate utility) to determine the influence of each on the cost-effectiveness results. Threshold values were calculated for sensitive parameters of the model.

Estimated benefits used in the economic analysis
The group utility value for Herbert screws was 0.504, for the AO screw was 0.720 and for the Luhr plate was 0.766.

Cost results
The weighted average cost for the Herbert screw group was $8,226, for the AO screw was $6,046 and for the Luhr plate was $6,757.

Synthesis of costs and benefits
The average cost of utility was calculated as the measure of cost-utility analysis. For Herbert screws this was $16,321, for AO screws it was $8,397 and for Luhr plates it was $8,821. Herbert screws were in any case dominated by the other two options, being both more expensive and having a lower utility value than either. The incremental cost of utility of the Luhr plate over AO screws was given as $15,457 (the theoretical cost to yield one more "satisfied"
outcome from a patient). Cost-utility results were most strongly influenced by operating room costs and union rate.

Authors' conclusions
AO screws had the lowest average cost of utility and are therefore the most cost-effective fixation device even though utility is highest with the Luhr plate.

CRD COMMENTARY - Selection of comparators
None of the three health technologies studied was specifically regarded as the comparator.

Validity of estimate of measure of benefit
The internal validity of the estimate of effectiveness and benefit can not be reasonably guaranteed due to the small sample size. Furthermore, the operating skill of the surgeon may have changed over the 10 years of the study. The overlap in the time periods during which the devices were used may have led to selection bias arising from the surgeon's opinion as to which was the more appropriate device for each foot.

Validity of estimate of costs
The costs were not inflated or discounted and, over 10 years, this could have caused important variation and bias. Insufficient details of resources used and prices were provided. Furthermore, the use of charge data rather than true costs might have adversely affected the internal validity of the cost results.

Other issues
Notwithstanding the limitations regarding the sample size (which the authors themselves as acknowledged) and cost calculations, the authors’ conclusions appear to be justified given the relatively extensive set of sensitivity and threshold analyses which were performed. The issue of generalisability to other settings or countries was addressed by performing sensitivity analysis and appropriate comparisons were made with other studies.

Implications of the study
A valid, reliable scale which accounts for patient expectations such as the Patient-Specific Index would be more useful for decision-analysis modelling as the scores could be used instead of arbitrary utility values.

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