Efficacy of total ankle replacement with meniscal-bearing devices: a systematic review and meta-analysis

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CRD summary
This review investigated the efficacy of total ankle replacement with three-component implants in individuals with end-stage arthritis. The authors concluded that ankle arthroplasty improved pain and joint mobility, but should be compared with the current reference standard in a well-designed randomised controlled trial. The authors' conclusion regarding the need for a trial is appropriate given the poor quality of the included studies.

Authors' objectives
To determine the evidence for ankle replacement with three-component implants, in terms of patient-centred end points such as improvement of joint mobility and pain, and to estimate the risk of typical complications of ankle arthroplasty.

Searching
The authors searched the electronic databases MEDLINE, EMBASE, CINAHL and the Cochrane CENTRAL Register, beginning with the first citation of ankle arthroplasty to July 2003; the search terms were provided. In addition, an internet search was carried out using the Google search engine, and the electronic contents of several key journals were searched. The Journal of Bone and Joint Surgery, Foot and Ankle International, the Lippincott Williams and Wilkens journal database, the European Journal of Trauma, Archives of Orthopedic and Trauma surgery, and Der Unfallchirurg were screened. No language restrictions were applied to the search. The bibliographies of all identified studies were checked for further relevant studies.

Study selection
Study designs of evaluations included in the review
Prospective and retrospective studies that enrolled at least 20 participants, and had a minimum follow-up of 1 year, were included in the review.

Specific interventions included in the review
Studies of primary total ankle joint replacement using three-component, meniscal-bearing implants were included. The specific implants included in the review were Scandinavian Total Ankle Replacement (STAR), Buechel-Pappas (B-P), LCS, RAMSES and ESKA. All but one of the included studies used cementless fixation.

Participants included in the review
Studies of participants with unilateral or bilateral ankle arthritis of post-traumatic, inflammatory, or any other origin, were eligible for inclusion. The most common cause of ankle replacement among the included participants was end-stage rheumatoid arthritis (37.5%), followed by post-traumatic arthrosis (27%) and osteoarthritis (24.6%). The mean age of the patients ranged from 48 to 64 years and the proportion of males ranged from 7.1 to 66.7%.

Outcomes assessed in the review
The studies were to provide at least one end point of clinical relevance (e.g. ankle scores such as the AOFAS hindfoot score or the Kofoed ankle score, ranges of motion (ROM), pain, quality of life, complication rates, or survival times) to be included. The main outcomes included in the review were ankle scoring, ROM, complications and survival rates.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Quality was assessed on an 8-point quality scale constructed from known assessment instruments. This involved an assessment of whether the data collection was prospective or retrospective, eligibility criteria, study profile (including number of participants enrolled and treated, and reasons for drop-outs), follow-up, end point definitions, demographic details, surgical techniques and rehabilitation programme. Two reviewers independently assessed the quality of the studies. Early inter-observer agreement for each item was measured using Cohen's kappa, and any inconsistencies were resolved by consensus.

**Data extraction**

Two reviewers extracted the data. Pre- and post-operative measurements of scales, ROM and survival rates were extracted. The reported numbers and proportions of superficial and deep wound infections, and implant loosening (which needed a statement of progressive lucency on radiographs), dislocation of components, intra- and post-operative fractures, need for revision surgery, impingement and salvage arthrodesis were also recorded.

**Methods of synthesis**

How were the studies combined?
The studies were pooled according to outcome in a random-effects meta-analysis. The studies were weighted by sample size. Relative outcome measures were regressed against sample sizes to assess publication bias.

How were differences between studies investigated?
A random-effects meta-regression with maximum likelihood estimation was used to assess the effects of fixation techniques (cemented or uncemented), different types of prostheses, causes of ankle arthritis and study quality on the results. Heteroscedasticity was assessed using the Cook-Weisburg test.

**Results of the review**

Eighteen studies (n=1,086) were included in the review, of which six had a prospective design (n=497).

Inter-observer agreement for individual quality items ranged from kappa 0.64 to kappa 1.00. The median quality score was 4 (interquartile range: 2 to 5) out of a maximum of 8. There was no evidence of publication bias.

Ankle scoring.
Following ankle replacement, global scores improved by a weighted average of 45.2 points on a 100-point scale (10 studies). This was mainly determined by pain ratings (28.6 points, 95% confidence interval, CI: 24.4, 32.8). Functional subscales improved by a mean of 12.5 points (95% CI: 5.9, 19.1). There appeared to be no association between the measure of ankle score used, type of implant, methodological issues, type of study design, or whether a publication was published in a peer-reviewed journal or not, and the results. The average scores increased with larger proportions of patients undergoing ankle replacement for osteoarthritis compared with patients suffering from rheumatoid arthritis.

Total ROM.
Based on 7 studies, there was a statistically significant improvement in ROM after ankle replacement. However, the overall gain in ROM was small (weighted mean difference 6.3 degrees, 95% CI: 2.2, 10.5). The results for STAR implants were similar to those for other types of prostheses used, and the underlying cause of ankle arthritis had no significant impact on gains in ROM. Prospective and retrospective studies produced similar results.

Complications.
Pooled estimates for the rate of complications were as follows: superficial infections, 10.8% (95% CI: 7.0, 14.7); deep infections, 1.6% (95% CI: 0.7, 2.5); loosening, 5.4% (95% CI: 1.3, 9.5); dislocation, 3.2% (95% CI: 2.1, 4.4); fractures, 13.4 (95% CI: 6.2, 20.7); revision surgery, 12.5% (95% CI: 5.6, 19.4); impingement, 14.7% (95% CI: 0.0, 33.5); arthrodesis, 6.3% (95% CI: 3.2, 9.5). There was a trend towards lower rates of deep infections with STAR implants (1.0%, 95% CI: 0.2, 1.8) compared with all other prostheses (3.8%, 95% CI: 1.5, 6.2). Retrospective studies found higher rates of superficial and deep infections (14.5% and 3.3%, respectively) than prospective studies (2.5% and 0.6%).
respectively). Patients with rheumatoid arthritis tended towards higher risks of implant loosening and dislocation of components, and patients with post-traumatic conditions developed deep wound infections more often.

Prosthesis survival rates (3 studies).

The weighted survival probability after 1 year was 96.9% (95% CI: 94.9, 98.8), and after 5 years 90.6% (95% CI: 84.1, 97.1).

Authors' conclusions
Ankle arthroplasty improves pain and joint mobility in end-stage ankle arthritis. Its performance in comparison with the current reference standard (ankle fusion) remains to be determined in a well-designed randomised trial.

CRD commentary
The authors set out a clear objective at the beginning of the review, and inclusion criteria were broadly defined in terms of the participants, interventions, outcomes and study design. A thorough search of several databases with no language restrictions will have helped to ensure that relevant studies were not missed. Publication bias was assessed. It was unclear how many reviewers selected papers for the review and, although two reviewers extracted the data, it was unclear whether this was done in duplicate. Study quality was assessed in duplicate, which helps reduce the risk of bias.

Individual study details were clearly tabulated. The data included in the review appears to have come from uncontrolled pre-post comparisons, which have a higher risk of bias and are less likely to be reliable than data from controlled studies. The methods used for the statistical analysis were unclear and might not have been appropriate. The authors' conclusion regarding the need for a trial is appropriate given the poor quality of the studies included in the review.

Implications of the review for practice and research
Practice: The authors stated that while associations between risk profiles such as age and aetiology are interesting, they should not produce potential differential indications for ankle replacement.

Research: The authors stated that a randomised controlled trial to compare ankle arthroplasty with ankle fusion is needed to produce valid estimates of efficacy. Generic tools, such as the Short Form 36 for outcome assessment, should be used.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.