TITLE: Total Ankle Replacements: Clinical Effectiveness and a Review of the Guidelines

DATE: 20 October 2008

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of total ankle replacements?
2. What are the guidelines regarding total ankle replacements?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, the Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Results include articles published between 2003 and October 2008, and are limited to English language publications only. No filters were applied to limit the retrieval. Internet links are provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS:

The literature search identified two systematic reviews, three controlled clinical trials, and thirty-four observational studies. Of the observational studies, two have been included in the main report. The remainder, which did not directly compare ankle replacement with ankle arthrodesis or were not specific to the Hintegra® prosthesis, are listed in the appendix with other articles of potential interest. The literature search did not identify any health technology assessments, randomized controlled trials, or evidence-based guidelines.
HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, controlled clinical trials, observational studies, and evidence-based guidelines.

OVERALL SUMMARY OF FINDINGS:

Two systematic reviews were identified. Haddad et al. (2007) performed a systematic review comparing total ankle arthroplasty with ankle arthrodesis. The review included 49 studies; 10 studies of ankle arthroplasty and 39 studies of ankle arthrodesis. The comparative results are shown in Table 1.

Table 1: Comparison of ankle arthroplasty and ankle arthrodesis outcomes, Haddad et al.¹

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Ankle arthroplasty (n=852 patients)</th>
<th>Ankle arthrodesis (n=1,262 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOFAS Ankle-Hindfoot Scale score</td>
<td>78.2 points (95%CI, 71.9-84.5)</td>
<td>75.6 points (95%CI, 71.6-79.6)</td>
</tr>
<tr>
<td>Rating of results (% of patients)</td>
<td>Excellent: 38%</td>
<td>Excellent: 31%</td>
</tr>
<tr>
<td></td>
<td>Good: 30.5%</td>
<td>Good: 37%</td>
</tr>
<tr>
<td></td>
<td>Fair: 5.5%</td>
<td>Fair: 13%</td>
</tr>
<tr>
<td></td>
<td>Poor: 24%</td>
<td>Poor: 13%</td>
</tr>
<tr>
<td>Revision rate</td>
<td>7% (95%CI, 3.5-10.9)</td>
<td>9% (95%CI, 5.5-11.6)</td>
</tr>
<tr>
<td>Percentage of patients requiring below-the-knee amputation</td>
<td>1%</td>
<td>5%</td>
</tr>
</tbody>
</table>

AOFAS=American Orthopaedic Foot and Ankle Society; CI=confidence interval

The five-year implant survival rate was 78% (95%CI, 69.0-87.6), and the 10-year survival rate was 77% (95%CI, 63.3-90.8). The authors noted that data were sparse and more comparative studies were needed to strengthen the conclusion. However, they stated that the intermediate outcomes of total ankle arthroplasty and ankle arthrodesis appeared to be similar.

Stengel et al. (2005)² conducted a systematic review/meta-analysis to investigate the efficacy of three-component ankle implants in patients with end-stage arthritis. The review included 18 studies (n=1,086 patients) of five implants: Scandinavian Total Ankle Replacement (STAR), Buechel-Pappas, LCS, RAMSES, and ESKA implants. The pooled outcomes reported in the review were:

- standardized 100-point ankle and hindfoot scores pooled from 10 trials (n=497) showed a mean improvement of 45.2 points (95%CI, 39.3-51.1)
- overall range of motion improved slightly; 6.3 degrees (95%CI, 2.2-10.5)
- weighted complication rates ranged from 1.6% (deep infections) to 14.7% (impingement)
- secondary surgery was required in 12.5% of cases and secondary arthrodesis was required in 6.3% of cases
- weighted five-year prosthesis survival rate averaged 90.6%

The authors concluded that ankle arthroplasty improved pain and joint mobility in end-stage ankle arthritis. However, due to the poor quality of the included studies, further comparison of ankle fusion with total ankle replacement should be conducted with a well-designed, randomized trial.

Three controlled clinical trials, all addressing gait, were identified. Houdijk et al. (2008)³ compared mechanical load and quasi-stiffness of the ankle joint in 10 total ankle replacement (TAR) patients and 10 age-matched healthy control subjects, walking barefoot on an indoor track, at self-selected walking speeds. No differences were observed between the two groups in peak moments or in the stiffness coefficient. Internal work at the ankle during the step was
considered to be significantly different (p=0.02) for TAR [-0.078 (0.088) J kg(-1)] versus control [0.005 (0.048) J kg(-1)], but it was thought this might be due to minor differences in walking speeds between the two groups. The authors concluded that, although there was a small difference in internal work at the ankle, the difference in mechanical loading of the ankle after TAR was not significantly different compared with normal subjects.

Piriou et al. (2008) compared before and after gait analyses of 12 patients who received ankle arthroplasty to 12 patients who received ankle arthrodesis, and to a control group of 12 healthy subjects. Time of analysis post-surgery, and a comparison of pre- and post-intervention outcomes were not reported in the abstract. No data from comparisons of either intervention to the control group was reported in the abstract. Patients with ankle arthrodesis demonstrated a faster gait and longer step length compared with ankle replacement. Ankle replacement patients showed restored ground reaction force pattern, greater symmetry in gait, and greater movement at the ankle than the arthrodesis group. The authors concluded that ankle replacement resulted in a significantly slower gait, but the improved symmetry (timing) resulted in limp reduction.

Doets et al. (2007) compared gait analysis of 10 patients who received uneventful total ankle replacements (time of analysis post-surgery not reported) with 10 healthy control subjects, during barefoot walking. Compared with the control group, the ankle replacement group showed:

- 6% lower velocity
- reduced dorsiflexion (p<0.001)
- no differences in the joint angular pattern of the knee joint
- minimal changes at the hindfoot-to-tibia and forefoot-to-hindfoot levels
- increased ground reaction force at midstance (p=0.005)
- decreased magnitude of the vertical peak at terminal stance (p<0.001)
- electromyographic (EMG) activity patterns not fully normalized

The authors concluded that, although ground reaction forces and EMG activity did not fully normalize, the remainder of the gait pattern was near normal, following uneventful total ankle replacement.

One comparative observational study and one observational study specific to the Hintegra® device were identified by the literature search. SooHoo et al. (2007) retrospectively compared re-operation rates following 480 ankle replacements and 4,705 ankle fusions, over a 10-year period. Outcomes reported were:

- rates of major revision surgery were significantly higher (p<0.001) for ankle replacement than ankle arthrodesis; 9% for ankle replacement and 5% for ankle arthrodesis at one year; 23% for ankle replacement and 11% for ankle arthrodesis at five years
- rates of subtalar fusion were lower with ankle replacement (p=0.03); 0.7% for ankle replacement and 2.8% for ankle arthrodesis

The authors concluded that ankle replacement was associated with a higher rate of complications than ankle arthrodesis, but showed a decreased risk of the patient requiring subtalar joint fusion.

Hintermann et al. (2004) describe a study of short-term outcomes in 116 patients (122 ankles) receiving the Hintegra® ankle prosthesis. The average length of follow-up was 18.9 months (range 1-3 years). Eight ankles required revision. The clinical result was rated as excellent or good in 82% of the cases, and 84% of patients were satisfied. AOFAS hindfoot score improved from 40 points pre-operatively to 85 points post-operatively. Eighty-three ankles (68%) were pain-free. The tibial component was stable in all ankles, and with no tilting since surgery. Two
ankles showed migration of the talar component. The authors concluded that the outcomes of function, pain relief, and patient satisfaction were promising and mostly superior to those outcomes with other devices.

In summary, outcomes for total ankle replacement were comparable to and, in some cases, superior to those for ankle arthrodesis. However, most authors stated that good quality, comparative trials are necessary to confirm their conclusions. The single observational study on the Hintegra® ankle (2004)\(^7\) concluded that this device may be successful as a total ankle replacement.
REFERENCES SUMMARIZED:

Health technology assessments
No literature identified

Systematic reviews and meta-analyses


Randomized controlled trials
No literature identified

Controlled clinical trials


Observational studies


Guidelines and recommendations
No literature identified
APPENDIX – FURTHER INFORMATION:

Economic analyses and cost information


Observational studies (non-comparative or non-Hintegra®)


**Review articles**


**Additional references**

