Total ankle replacement by the Ankle Evolution System

MEDIUM-TERM OUTCOME

S. S. Morgan,
B. Brooke,
N. J. Harris

From Chapel Allerton Hospital,
Leeds, England

We present the outcomes in 38 consecutive patients who had total ankle replacement using the Ankle Evolution System with a minimum follow-up of four years. Pain and function were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) score and regular standardised anteroposterior and lateral weight-bearing radiographs were obtained. Patient satisfaction and complications were recorded and the survival of the implants was demonstrated by the Kaplan-Meier method.

The mean follow-up was for 57.8 months (48 to 80). The cumulative survival rate at six years was 94.7% (95% confidence interval 80.3 to 98.7). The mean total AOFAS score was 88.1 (53 to 100). The mean score for pain was 35.8 (20 to 40). Ten patients presented with edge-loading of whom nine had corrective surgery. Two ankles were revised, one to an arthrodesis and the other to replace the tibial component. Nine patients showed radiological evidence of osteolysis. They had minimal non-progressive symptoms and further surgery was not undertaken. Nevertheless, the concerns about osteolysis led to the implant being withdrawn by the manufacturer.

The medium-term results of the ankle evolution system ankle replacement are satisfactory with high patient satisfaction, but the rate of osteolysis is of some concern. The long-term benefit of this procedure has yet to be determined.

The increased interest in total ankle replacement (TAR) developed after encouraging results had been achieved with second-generation, two-component implants.¹,² Third-generation designs consist of a three-part prosthesis with a mobile-bearing component similar to the Scandinavian total ankle replacement (STAR)³ and Buechal Pappas prostheses.⁴ The results using these meniscal-bearing implants have been encouraging and suggest that they give an acceptable risk-benefit ratio.⁵

We describe the medium-term outcome of the mobile-bearing, cementless Ankle Evolution System (AES) prosthesis at a minimum follow-up of four years.

Patients and Methods

The AES is a three-part mobile-bearing, unconstrained modular system. It is a cobalt chromium cementless prosthesis with a porous coat and hydroxyapatite coating to encourage bone growth on to the implant. It has a tibial keel to improve stability and a symmetrical talar dome to solve problems of the arched and flat foot (Fig. 1).

We included in the study 45 consecutive patients (30 men, 15 women) who had AES ankle replacement between 2002 and 2004. The indication for operation was primary osteoarthritis (OA) in 22 patients, post-traumatic OA in 18, inflammatory arthritis in four and haemorrhagic arthritis in one haemophiliac. The mean age at operation was 64.6 (50 to 77) years and the mean body index was 27 kg/m² (22 to 35). The past medical history included diabetes in three patients, asthma in two, a contralateral above-knee amputation because of a failed bypass in one and a total knee replacement in two.

All the operations were performed by the senior author (NJH) through an anterior approach between the tendons of tibialis anterior and extensor hallucis longus. The post-operative regime included a non-weight-bearing cast for two weeks followed by mobilisation in a walker boot for a further four weeks. All the patients had an annual clinical and radiological assessment. Those who were unable to attend had a telephone interview.

Pain and function were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) ankle and hind-foot score,⁶ which includes three main domains, pain, function and alignment. The maximum (best) score is
100 and the minimum 0. For pain the maximum score of 40 represents no pain and the minimum of 0 indicates severe, constant pain. Patients who had an exchange of either the talar or tibial component or conversion to an arthrodesis were considered to be failures, as were those with exchange of the polyethylene alone.

In order to assess overall satisfaction the patients were asked to choose if they were worse off, no better, better, much better or excellent after TAR.

At review anteroposterior and lateral weight-bearing radiographs were obtained, which were assessed for aseptic loosening (radiolucency of more than 2 mm), cavitation, migration, pre- and post-operative coronal alignment, and edge-loading indicating tilting of the talus into valgus or varus.

All the patients presenting with edge-loading were offered re-alignment which was done either in isolation or in combination with medial soft-tissue release, a lateral stabilising procedure incorporating peroneus brevis, a heel shift, a change of polyethylene insert and fibular osteotomy (Table I).

Post-operative complications, the walking distance and the use of walking aids were also recorded.

Statistical analysis. Revision of the tibial or talar component, conversion to an arthrodesis or the decision to revise were considered to be hard endpoints. Statistical analysis was performed using the statistical software package SPSS version 13.0 (SPSS Inc., Chicago, Illinois). The data were subjected to descriptive analysis and survival of the implants was determined by the Kaplan-Meier survival curve and life tables.

### Results

The mean follow-up for the 40 patients who were alive and available for follow-up at the final clinical review was 57.8 months (48 to 80). Three had died and two had emigrated, one at 49 months post-operatively and the other after 24 months. The three deaths occurred at 25, 36 and 42 months post-operatively. None of these patients had revision or recorded complications.

There were two patients who had a revision, one at four years post-operatively had revision of the tibial component for aseptic loosening and the other, who sustained a stress fracture of the talus after three years, to tibiocalcaneal fusion. Before the fracture the patient had been functioning well and radiographs showed satisfactory alignment of the prosthesis. The remaining 38 patients were available for clinical review, of whom 34 attended for clinical assessment and four had a telephone interview.

Functional outcome. The mean total AOFAS score was 88.1 (53 to 100). The mean score for pain was 35.8 (20 to 40).

The mean walking distance was two miles (1 to 7). A total of 28 patients could walk unaided, nine used one stick and one used a wheelchair because of rheumatoid arthritis affecting other joints.

Radiological assessment. Nine patients showed evidence of osteolysis (Fig. 2). They had minimal non-progressive symptoms and further surgery was not undertaken. Two had associated subsidence of the talar component.

Pre-operatively, ten patients had been in valgus alignment ranging from 7° to 30°, seven in varus ranging from 4° to 23° and 28 were in neutral. At the final clinical review, all including those who had re-alignment procedures, had neutral alignment except one with 10° of varus and edge-loading. His radiograph showed no osteolysis, his total AOFAS score was 87, and his AOFAS pain score was 40/40. He was offered re-alignment but declined.

Complications. Within the first year, ten patients had been in valgus alignment ranging from 7° to 30°, seven in varus ranging from 4° to 23° and 28 were in neutral. At the final clinical review, all including those who had re-alignment procedures, had neutral alignment except one with 10° of varus and edge-loading. His radiograph showed no osteolysis, his total AOFAS score was 87, and his AOFAS pain score was 40/40. He was offered re-alignment but declined.

Complications. Within the first year, ten patients had presented with edge-loading and nine had re-alignment procedures (Figs 3 and 4). Their outcome at the final clinical review is shown in Table II. After re-alignment and at the final clinical review these patients had a satisfactory functional and radiological outcome with high satisfaction (Table II).
Other complications included wound dehiscence in one patient who required skin grafting, and edge-loading as a result of a stress fracture of the tibia treated conservatively in another (Table III).

Survival analysis. With revision or decision to revise as the endpoint the cumulative survival rate at six years was 94.7% (Table IV, Fig. 5).

Patients satisfaction. A total of 33 patients chose either the ‘excellent’ or ‘much better’ category, two chose the ‘better’ category and three patients chose the ‘worse off’ category. Their total AOFAS scores were 53, 61 and 66, respectively. None required further surgery because the symptoms were not progressive and radiographs showed neutral alignment with no loosening. One ‘worse off’ patient showed osteolysis, which was non-progressive on subsequent radiographs.

Discussion
Our results were satisfactory in terms of functional outcome and patient expectations, but the high rate of osteolysis was of some concern. The survival rate at six years (94.7%) was better than or similar to that of other medium-term reports. For example, Carlsson9 reported a survival rate of 94%, Wood and Deakin10 of 93%, Anderson, Montgomery and Carlsson11 of 70% and Wood at al7 of 93% for the STAR prosthesis. A five-year survival of 80% was reported by Spirt, Assal and Hansen12 for the Agility prosthesis and an eight-year survival of 84% for the Low Contact stress and Buechel-Pappas prostheses by Doets, Brand and Nelissen.13 The medium-term results of the Swedish14 and New Zealand15 joint registries were 78% and 86%, respectively, for different types of third-generation prosthesis. A systematic review of the intermediate and long-term outcomes of TAR by Haddad et al16 showed a survival rate of 78% at five years. This paper reported the results associated with second generation implants including: Agility, Low contact stress, Buechel-Pappas, TNK (Kyocera, Kyoto, Japan), STAR and Salto (Tornier, Montbonnot, France) prostheses.

Three-part mobile-bearing unconstrained systems have overcome the problems such as cemented fixation, overconstraint, wound healing and pain in the first-generation implants. The Buechel-Pappas prosthesis which is similar to the AES design has shown good to excellent results in 88% of patients at ten and 12 years and survivorship rates of 93.5% and 92%, respectively.17,18

There has been much recent discussion as to the outcome of TAR in patients with significant pre-operative deformity.19-21 In our patients there was a high incidence of edge-loading resulting in the necessity for corrective
surgery. These patients achieved a satisfactory functional and radiological outcome and high satisfaction (Table II). Most had considerable pre-operative coronal malalignment which has been shown to contribute to the development of post-operative edge loading.7 We also believe that the AES implant is less stable in the coronal plane than other designs. One reason may be the width of the polyethylene insert which is significantly narrower than the talar implant. In other newer designs (Mobility; DePuy, Leeds, United Kingdom) the polyethylene insert extends the whole width of the talar component in the mid-coronal plane.

Most of those with osteolysis remained asymptomatic and the functional outcome was not affected. Wood et al7 reported a rate of aseptic loosening of 12.5% after STAR ankle replacement. Most of our patients had minimal non-progressive symptoms and no further surgery was indicated. Similar concerns have also recently been raised by Koivu et al22 who reported osteolytic lesions in 39% of 130 AES arthroplasties at a mean follow-up of 31.3 months. Nevertheless, because of concerns about osteolysis, this implant has been withdrawn by the manufacturer. It remains unclear whether polyethylene debris or the surface coating of the implant was the source of the increased osteolysis and this is the subject of further investigation.

Whereas arthrodesis was for many years the surgical method of choice for advanced OA of the ankle because there was no alternative, TAR now represents an attractive option.23 There is growing concern about the long-term effects of functional impairment and arthritis of the adjacent subtalar joint after arthrodesis.24 In a comparison between arthrodesis and TAR it has been shown that the

<table>
<thead>
<tr>
<th>Case</th>
<th>Pain score</th>
<th>Total AOFAS* score</th>
<th>Satisfaction</th>
<th>Pre-operative alignment (*)</th>
<th>Alignment at the final clinical review</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30/40</td>
<td>82</td>
<td>Much better</td>
<td>17 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>2</td>
<td>40/40</td>
<td>100</td>
<td>Excellent</td>
<td>12 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>3</td>
<td>40/40</td>
<td>100</td>
<td>Much better</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>4</td>
<td>40/40</td>
<td>87</td>
<td>Much better</td>
<td>Neutral</td>
<td>10° varus</td>
</tr>
<tr>
<td>5</td>
<td>40/40</td>
<td>100</td>
<td>Excellent</td>
<td>4 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>6</td>
<td>40/40</td>
<td>92</td>
<td>Much better</td>
<td>7 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>7</td>
<td>30/40</td>
<td>81</td>
<td>Excellent</td>
<td>12 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>8</td>
<td>40/40</td>
<td>94</td>
<td>Much better</td>
<td>14 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>9</td>
<td>20/40</td>
<td>74</td>
<td>Better</td>
<td>30 varus</td>
<td>Neutral</td>
</tr>
<tr>
<td>10</td>
<td>40/40</td>
<td>85</td>
<td>Excellent</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
</tbody>
</table>

* AOFAS, American Orthopaedic Foot and Ankle Society

<table>
<thead>
<tr>
<th>Radiological outcome*</th>
<th>No surgery (n = 34)</th>
<th>Corrective surgery because of edge-loading (n = 9)</th>
<th>Fusion/revision (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically satisfactory with no osteolysis</td>
<td>25</td>
<td>6</td>
<td>1 (patient developed stress fracture of the talus had tibiocalcaneal fusion)</td>
</tr>
<tr>
<td>Clinically satisfactory with osteolysis</td>
<td>6</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Clinically unsatisfactory with no osteolysis</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Clinically unsatisfactory with osteolysis or loosening</td>
<td>1</td>
<td>0</td>
<td>1 (revision of tibial component because of aseptic loosening and pain)</td>
</tr>
</tbody>
</table>

* clinically satisfactory, total American Orthopaedic Foot and Ankle Society (AOFAS) ≥ 5 and satisfaction category excellent, much better or better; clinically unsatisfactory, total AOFAS score < 75 and worse of satisfaction category

<table>
<thead>
<tr>
<th>Time (mths)</th>
<th>Total at start of 12-month interval</th>
<th>Failures during 12-month interval</th>
<th>Survivor function</th>
<th>95% confidence interval (CI) for survivor function</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>45</td>
<td>0</td>
<td>1.0</td>
<td>-</td>
</tr>
<tr>
<td>24</td>
<td>45</td>
<td>0</td>
<td>1.0</td>
<td>-</td>
</tr>
<tr>
<td>36</td>
<td>43</td>
<td>1</td>
<td>0.977</td>
<td>0.846 to 0.997</td>
</tr>
<tr>
<td>48</td>
<td>41</td>
<td>0</td>
<td>0.977</td>
<td>0.846 to 0.997</td>
</tr>
<tr>
<td>60</td>
<td>17</td>
<td>1</td>
<td>0.947</td>
<td>0.803 to 0.987</td>
</tr>
<tr>
<td>72</td>
<td>2</td>
<td>0</td>
<td>0.947</td>
<td>0.803 to 0.987</td>
</tr>
</tbody>
</table>
latter is associated with a decreased need for subtalar fusion. Also, by using gait analysis, Piriou et al showed an improved timing of gait and a restored pattern of ground-reaction-force in patients who had TAR compared with those with arthrodesis. Similarly, Zerahn and Kofoed showed that TAR can normalise gait and decrease the duration of foot contact.

To our knowledge this is the first medium-term report on the AES system. Our study is retrospective and we accept that the assessment of functional outcome would have been more robust if pre-operative AOFAS scoring had been available. The medium-term results in terms of survivorship, functional outcome and patient satisfaction are satisfactory, but we like others have our concerns about the high rate of osteolysis, which has led to the withdrawal of the prosthesis by the manufacturer.

The mobile-bearing system which was first used by Buechel, Pappas and Iorio is accepted by the orthopaedic manufacturers as a solution to the restoration of ankle biomechanics. As improvements in implants, instrumentation and training continues the success and survival rates of TAR will improve and it will become a more acceptable solution to end-stage OA of the ankle.

References