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Total ankle arthroplasty – Total ankle arthroplasty in Western France: Influence of volume on complications and clinical outcome

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KEYWORDS
Arthroplasty; Ankle; Osteoarthritis

Summary
Introduction: Total ankle arthroplasty (TAA) has become an alternative to ankle arthrodesis in the treatment of advanced osteoarthritis. "The difficulty of performing a total ankle replacement and the corresponding steep learning curve" has resulted in a proposal "to limit ankle replacement to centers that have performed at least ten total ankle replacements for at least 3 years". The aim of this study was to evaluate the influence of the frequency of TAA procedures on the complications and outcome of these arthroplasties.

Materials and methods: This retrospective series included 183 cases who underwent surgery between 1997–2010 in eight centers: three high volume centers performed at least five TAA per year (100 cases) and six low volume centers performed less than five TAA per year (78 cases).

Results: The clinical assessment was performed in 133 cases that were reviewed after a mean 39 months ± 29 of follow-up. The preoperative AOFAS score was 33 ± 4 and 77 ± 15 at the final follow-up. The five-year survival rate was 86%. No significant difference was found between the groups for the AOFAS score or implant survival at the final follow-up. The high volume centers experienced more complications (45% versus 13%) but fewer implant failures (8% versus 13%) overall compared to the low volume centers.

Discussion: The outcome of TAA depends mainly upon the pertinence of the indication and the associated procedures that may be necessary. Rather than limiting TAA to high volume reference centers, we suggest that the assessment of each case within a predetermined area should be done in a network. This would determine the degree of specialization required for each TAA case and provide all patients with safe and equal access to this therapeutic option.

Level of evidence: IV – Retrospective study.

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Introduction

Preservation of ankle range of motion by total ankle arthroplasty (TAA) results in a more physiological gait pattern and limits overloading of adjacent joints [1,2]. Nevertheless, this procedure is still fairly rare, as confirmed by the 516 TAA performed in France in 2009 compared to 1331 ankle arthrodesis during the same period (PMSI 2009 data). In the decision rendered on March 23rd, 2010, in response to the request to renew registration of the Total Ankle Replacement Salto® on the list of products and services mentioned in article L 165-1 of the Social Security code, The National Commission for the Evaluation of Medical Devices and Healthcare Technologies (la Commission nationale d’évaluation des dispositifs médicaux et des technologies de santé) emphasized “the difficulty of performing TAA and the corresponding steep learning curve”. It therefore suggested “limiting TAA to centers that had performed at least ten TAA per year for the past 3 years” [3]. We evaluated the influence of the volume of TAA performed by surgeons and/or centers on complications and the outcome of these procedures for the TAA symposium organized by the French Western Orthopedic Society (Société d’orthopédie de l’Ouest) during its 2011 annual meeting.

Materials and methods

This was a retrospective, multicenter, multisurgeon study of 183 cases (175 patients, eight bilateral cases) who underwent surgery between 1997 and 2010 in eight centers (private and public) in the western part of France. Minimum follow-up was 6 months. There were 107 males, 72 females. Mean age at surgery was 64 years old (±12 (27–88). The initial diagnosis was ankle osteoarthritis (OA) in 87% of the cases: primary OA in 22%, post-traumatic OA in 39% and OA secondary to ankle instability in 16% of the cases (other causes of OA in 10%). Thirteen percent of the cases were due to a rheumatoid arthropathy. The series included 91 Salto®, 39 HingeTect®, 20 AEST®, 17 Coppelia®, 11 STAR®, four Ramses® and one Akile® arthroplasty systems. All implants were 3-component mobile bearing implants. Fixation was cementless in all systems except the Coppelia® and Ramses® which were cemented.

We divided the centers into two groups depending on whether they had performed five or more TAA per year during the study period. The three high volume centers performing more than five TAA per year (100 cases) were: Bordeaux Polyclinic (Polyclinique de Bordeaux—Dr. Toulouse), Tours Regional University Hospital Center (CHRU de Tours—Dr. Brillault) and Trelazé Saint-Leonard Clinic ( Clinique Saint-Leonard de Trelazé—Dr. Chomarat). The six low volume centers performing less than six TAA per year (78 cases) were: University Hospital (CHU) of Angers, Brest, Limoges and Nantes, the Polyclinic of Blois and Poitiers and the Saint-Leonard Clinic of Trézé (two surgeons).

Patients were evaluated at follow-up. They were asked to fill out a questionnaire about their level satisfaction, and to choose between “very satisfied”, “satisfied”, “fairly satisfied”, “disappointed” or “very disappointed”. The clinical assessment was then performed using the French translation of the forefoot and ankle questionnaire of the American Orthopaedic Foot and Ankle Society [4]. This is a 100 point score (40 points for pain, 50 points for function and 10 points for alignment). The preoperative score was calculated from clinical data found in the patient’s file. A score above 85 points was considered to be “excellent”, 75–85 points “good”, 50–75 points “acceptable” and below 50 points “poor”. Finally patients were proposed standing X-rays including: a AP and lateral view of the ankle, a Meary view as well as dynamic lateral weight bearing views in plantar flexion and dorsiflexion.

Implant survival was analyzed by the Kaplan Meier method. Failure was defined as “any revision surgery that involved all or part of the implant”. The statistical analysis was performed with parametric and non parametric tests depending on the size of the samples studied. P < 0.05 was considered to be significant.

Results

The study included 183 TAA procedures. The data are described in Table 1. The population included 105 males and 70 females (eight bilateral cases), mean age 64 years old (±12; 32–88). Sixty-one cases (33%) presented with at least one complication. There were 22 perioperative malleolar fractures (12%): 15 medial malleolus, four lateral malleolus, one posterior malleolus and two malleolar fractures whose location was not defined. Twenty cases (11%) presented with wound healing complications including four cases requiring additional surgery: three debridements and one flap cover. Ten cases (5%) developed neurological complications: five tarsal tunnel syndromes (four cases with secondary neurolysis), two cases of posterior tibial nerve injury (one case requiring secondary suture of the nerve). Four patients died, 11 patients were lost to follow-up, 12 clinical files were incomplete and there were 23 failures. The clinical assessment included 133 cases. The mean follow-up at consultation was 39 months (±29; 6–132).

The mean preoperative AOFAS score was 33 points (±4; 7–83) including four points (±8; 0–40) for “pain” and 22 points (±9; 10–41) for “function”. The mean score at final follow-up was 77 points (±15; 10–100) for the global score, 30 points (±9; 0–40) for “pain” and 38 points (±8; 10–50) for “function”. All items improved significantly, in particular pain. At final follow-up, 65% of the cases reported “excellent or good” results, 33% “average” results and 4% “poor” results. Eighty-four percent of the cases were “very satisfied” or “satisfied” with the functional results, while 52% were “fairly satisfied” or “disappointed”. The overall implant survival rate at five years was 86% (Fig. 1).

Care performed in high volume centers included 97 cases in 93 patients (40 females, 53 males, four bilateral cases) mean age 63 years old (±12; 32–85). The initial diagnosis and indication for TAA was primary OA in 15 cases, OA secondary to ankle instability in 22 cases, post-traumatic OA in 44 cases, and other etiologies of osteoarthritis in five cases. Diagnosis was rheumatoid arthritis in 11 cases. There were eight failures in this group (revision surgery for TAA) and there were one or more complications in 44 cases:...
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Table 1  Analysis between high and low volume centers.

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>High volume centers (over 5 TAA/year)</th>
<th>Low volume centers (5 TAA or less/year)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>183 cases</td>
<td>97 cases (93 patients)</td>
<td>86 cases</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>70 F/105 M</td>
<td>40 F/53 M</td>
<td>30 F/52 M</td>
<td>0.476</td>
</tr>
<tr>
<td>Age at surgery</td>
<td>64 years</td>
<td>(± 12; 32–88)</td>
<td>67 years</td>
<td>0.054</td>
</tr>
<tr>
<td>Initial Diagnosis</td>
<td>OA: 86 cases</td>
<td>OA: 74 cases</td>
<td>RA: 12 cases</td>
<td>0.757</td>
</tr>
<tr>
<td>Cases with at least one complication</td>
<td>56 cases</td>
<td>44 cases (45%)</td>
<td>12 cases (13%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Perioperative fractures</td>
<td>22 cases</td>
<td>13 cases (13%)</td>
<td>9 cases (10%)</td>
<td>0.702</td>
</tr>
<tr>
<td>Infectious and cutaneous complications</td>
<td>20 cases</td>
<td>16 cases (16%)</td>
<td>4 cases (5%)</td>
<td>0.015</td>
</tr>
<tr>
<td>Implant failures</td>
<td>23 cases</td>
<td>8 cases (8%)</td>
<td>15 cases (17%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Died or lost to follow-up</td>
<td>15 cases</td>
<td>9 cases (9 patients) (9%)</td>
<td>6 cases (6 patients) (7%)</td>
<td>0.766</td>
</tr>
<tr>
<td>Cases evaluated in consultation</td>
<td>133 cases</td>
<td>71 cases</td>
<td>62 cases</td>
<td>0.999</td>
</tr>
<tr>
<td>Mean final follow-up</td>
<td>39 months</td>
<td>(± 29; 6–132)</td>
<td>43 months</td>
<td>0.100</td>
</tr>
<tr>
<td>Preoperative score</td>
<td>33 points</td>
<td>31 points (± 4; 7–83)</td>
<td>34 points</td>
<td>0.269</td>
</tr>
<tr>
<td>Score at final follow-up</td>
<td>77 points</td>
<td>75 points (± 13; 7–61)</td>
<td>79 points</td>
<td>0.135</td>
</tr>
<tr>
<td>5-year survival</td>
<td>86%</td>
<td>88.4%</td>
<td>84.9%</td>
<td>0.245</td>
</tr>
</tbody>
</table>

TAA: total ankle arthroplasty; M: male; F: female; OA: osteoarthritis; RA: rheumatoid arthritis; P: results of the statistical comparison.

Figure 1  Overall survival curve. Exclusion occurred when implant was removed.

- nine neurological complications: four tarsal tunnel syndromes, two posterior tibial nerve injuries, two cases of neuralgia of the superficial fibular nerve and one lumbar sciatica;
- the other complications in this group included: four equinus deformities, two deep infections, one complex regional pain syndrome, one unexplained joint stiffness, one allergy to the implant metal.

Functional results were evaluated in 71 cases who still had their original implants at final follow-up and who were assessed at the final follow-up consultation with a complete file. There were seven lost to follow-up, two patients who died for reasons not related to TAA, and 11 incomplete files. A clinical assessment was performed in 77 cases at the final follow-up consultation. At the final consultation the mean follow-up was 35 months (± 25; 6–120). The preoperative AOFAS score was 31 points (± 13; 7–61), which had increased significantly to 75 points (± 17; 10–100) at final follow-up. Five-year implant survival for this group was 88.4% (Fig. 2).

Care performed in the low volume centers included 86 cases in 82 patients (30 females, 52 males, four bilateral cases) mean age 67 years old (± 11; 32–88). The initial diagnosis was primary OA in 25 cases, OA due to ankle instability in eight cases, post-traumatic OA in 27 cases, rheumatoid arthritis in 12 cases and another pathology in 14 cases. There were four lost to follow-up, two patients who died for reasons not related to TAA and three incomplete patient files. There were 15 failures and 12 complications in this group:

- 13 perioperative fractures: 10 medial malleolus, two lateral malleolus and one case in which the fracture site was not documented;
- 16 cases with delayed wound healing;
- other complications:
  - nine neurological complications: four tarsal tunnel syndromes, two posterior tibial nerve injuries, two cases of neuralgia of the superficial fibular nerve and one lumbar sciatica;
  - the other complications in this group included: four equinus deformities, two deep infections, one complex regional pain syndrome, one unexplained joint stiffness, one allergy to the implant metal.

• five medial malleolar fractures, two lateral malleolar fractures, one fracture of the posterior malleolus, one in which the fracture site was not documented;
• three delayed wound healing;
• one posterior tibial nerve injury;
• two deep infections.

Functional results were evaluated in 62 cases who still had their original implants at final follow-up and who were assessed at the follow-up consultation with a complete file. The mean follow-up at the final consultation was 43 months (± 33; 6–132). The preoperative AOFAS score was 34 points (± 15; 12–83), which had increased significantly to 79 points (± 13; 51–100) at final follow-up. Implant survival in this group was 84.9% at 5 years (Fig. 2).

No differences were observed between the two groups in terms of demographic data diagnosis, preoperative AOFAS score and the number of lost to follow-up. We did not find any significant difference between the groups for AOFAS score at final follow-up or 5-year implant survival. There were more complications (44/97 cases; 45%) in the high volume centers than in the low volume centers (12/86 cases; 13%). On the other hand, there were fewer implant failures in the high volume centers (8/97 cases; 8%) than in the low volume centers (15/86 cases; 17%). No diseases or comorbidities were identified that could explain either of these differences.

Discussion

We did not find any significant difference in functional results or implant survival according to TAA volume performed in this study. The rate of complications was higher, and the rate of implant failure was lower in high volume centers that have more experience with TAA care. This suggests that the indications for TAA were extended in these high volume centers, resulting in more complications, which were nevertheless successfully managed, since they did not result in an increase number of failures. The TAA learning curve has been studied by several authors, showing that 25 TAA must be performed to reduce the rate of malalignment and peri-operative complications [5,6]. However, while some complications such as malleolar fractures are unfortunate, they do not affect the long-term functional outcome [7]. Although the surgeon’s experience does not seem to influence the final functional results, this is not the case for implant survival, as reported by Reuver et al. [8] who has shown that TAA survival is significantly better for implants performed in centers that have more experience with this type of surgery. This raises the question of whether it is the technical performance of the surgical team or the surgical indication that makes the difference. Ankle arthroplasty is still a rare surgical procedure in France, and there are very few centers that perform more than 10 per year. It is therefore difficult to evaluate our learning curve. The “threshold” of performing five TAA per year that we used in this study did not reveal any difference in final functional results or implant survival at 5 years.

The limitations to this study are its retrospective design, and its heterogeneity due to the many types of TAA systems and surgical techniques used. The number of incomplete patient files (13) the geographic distribution of patients, made it difficult to review the cases and exploit the clinical data. Nevertheless, the study population was large, and there were very few lost to follow-up. Finally, this is an independent study, as none of the TAA manufacturers or TAA designers participated in the study.

The outcome of TAA depends mainly upon the pertinence of the indication and the associated procedures that may be necessary. The role of patient co-morbidities and ankle deformities in the prognosis of TAA have already been described. [9–11]. This suggests that there are TAA that can be performed by most orthopedic surgeons, and TAA requiring associated procedures that necessitate more experience in foot and ankle surgery. Thus, rather than limiting TAA to high volume reference centers, we suggest that the assessment of each case within a predetermined area should be done in a network. This would determine the degree of specialization required for each TAA case and provide all patients safe and equal access to this therapeutic option.

Disclosure of interest

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References


