Is the artificial total talar prosthesis applicable for the total ankle arthroplasty?-A comparative study against the standard total ankle arthroplasty-

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Abstract

Background: Total ankle arthroplasty (TAA) has been the reliable solution for patients with end-stage ankle arthritis in cases resistant to conservative treatment. Aseptic loosening of the talar component has been reported as the most frequent complication. A custom-made artificial talus could be used as the talar component and combined with TAA (Combined TAA) for patients with poor bone stock of the talus. The purpose of this study was to investigate the functional and clinical outcomes of combined TAA. Methods: 10 patients (10 ankles) treated by combined TAA between 2009 and 2013 were investigated, while age, gender and follow-up period matched 12 patients(12 ankles) were investigated as the standard TAA group. All patients had end-staged ankle arthritis. Combined TAA features a tibial component of the TNK ankle and an alumina ceramic artificial talus, designed using computed tomography (CT) data from each individual patient. The average follow-up period for the combined TAA and standard TAA groups were 58 and 64 months, and the mean age at the time of surgery were 71 and 75 years. The Japanese Society for Surgery of the Foot (JSSF) ankle-hindfoot

scale and the ankle osteoarthritis scale (AOS) were used. Results: The preoperative JSSF scale of the combined TAA and standard TAA were 44 ±11 and 49±10. Postoperative JSSF scales were 89±6.1 and 72±15. The postoperative score of the combined TAA was significantly higher (p=0.0034). Preoperative AOS scores of pain and function for the each group was 5.8±3.3, 5.5±3.1, 8.6±1.3 and 7.1±2.9. Postoperative AOS scores were 2.5±2.5, 2.2±1.9, 2.5±3.3 and 3.4±2.9. There were no significant differences between the two groups in terms of postoperative AOS scores. Conclusions: Combined TAA resulted in better clinical and functional results than standard TAA. Combined TAA is therefore thought to represent an appropriate treatment for patients with end-stage ankle arthritis with poor bone stock.

Level 3

Introduction

Ankle arthritis affects approximately 6% of the population[1]. Furthermore, functional disability and the diminished quality of life associated with end-

stage ankle arthritis have been reported to be comparable with those associated with end-stage hip or knee arthritis[2,3]. Ankle arthrodesis (AA) and total ankle arthroplasty (TAA) have been the most reliable solution for patients with end-stage ankle arthritis in cases resistant to conservative treatment. However, the indications for AA and TAA have not been clearly defined, and depend largely upon the surgeon's experiences.

In the past, AA was considered the gold standard treatment for end-stage ankle arthritis[4]. Although AA results in marked relief in pain, disadvantages such as loss of range of motion, the risk of arthritis advancement in the adjacent joints, and non-union leading to revision surgery still remain[5]. Recent reports have clarified comparative mid-term results of AA with TAA along with the development of implantation and surgical techniques[6]. The most significant advantage of TAA is preserving ankle motion[6,7]. However, the major problem of TAA is the higher rate of revisions compared with those for total hip arthroplasty (THA) or total knee arthroplasty (TKA). According to a previous report, complication rates for TAA can be as high as 19%[6]. While the ten-year-survival rates

for THA and TKA are both around 96%[8-11], the survival rates for TAA were reported to range from 70% to 98% at three to six years and from 80% to 95% at eight to twelve years[12].

Aseptic loosening of the talar component has been reported as the most frequent complication of TAA[13]. Subsidence of the talar component is one of the most serious complications following TAA that physicians should be aware of. In recent years, a custom-made artificial talus has been produced, and subsequent reports have shown favorable clinical results following replacement of the talus with these new devices. Furthermore, there have not been any reports of major complications, such as subsidence, or mismatch of the implant, and clinical outcomes have been good[14]. This type of implant could be used as the talar component and combined with total ankle arthroplasty (Combined TAA) for patients with poor bone stock or severe deformity of the talus.

The purpose of this study was to investigate the functional and clinical outcomes of combined TAA and compare these outcomes with those derived from cases involving standard TAA.

Materials and Methods

This study investigated 10 patients (10 ankles) treated by total ankle arthroplasty combined with artificial talus (combined TAA group) between 2009 and 2013. While 66 ankles were treated standard total ankle arthroplasty in this study period, age, gender and follow-up period matched 12 patients (12 ankles) were investigated as the standard TAA group. For the patient with severe collapse or large size of bony cyst in the talus, artificial total talar prosthesis was applied instead of talar component, because it was thought to be difficult to replace the surface of the talar dome**(Figure 1)**. All patients had end-staged ankle arthritis (stage 3b and stage 4). Combined TAA features a tibial component of the TNK ankle® **(Kyocera, Kyoto, Japan)** and an alumina ceramic artificial talus **(Kyocera, Kyoto, Japan)**, designed using computed tomography (CT) data from each individual patient **(Figure 2)**.

The average follow-up period for the combined TAA group was 58 months (range: 43 to 81 months), and the mean age at the time of surgery was 71 years (range: 61 - 82 years). The mean follow-up period for the standard TAA group was 64 months (range: 48 to 88 months), and the

mean age at the time of surgery was 75 years (range: 62 to 82 years). In both groups, surgical intervention was performed through an anterior approach. In the standard TAA group, osteotomies for the distal tibia and talar dome were performed using osteotomy guides.

The talar component was fixed with bone cement, and the tibial component was fixed without bone cement. Small cement beads were originally mounted on the surface of the tibial component facing towards the tibia, and bone marrow was placed on the surface of the implant after application of calcium phosphate paste to induce bone bonding to the implant. **In the combined TAA group, osteotomy of the distal articular surface of the tibia was performed through the anterior approach for replacement with the tibial component. Subsequently, the talus was separated into several segments and removed following dissection of the attached ligaments. After placement of the artificial talus, osteotomy of the tibia was finalized. The tibial component was placed according to the standard TAA procedure. As ankle stability was obtained after implantation, ligament reconstruction was not performed.**

In both groups, a short leg cast was applied in the neutral position for three weeks. Weight bearing was avoided during the next two weeks, and partial weight-bearing was allowed in the third week according to the control of pain. The Japanese Society for Surgery of the Foot (JSSF) ankle-hindfoot scale was used for subjective evaluation. This is composed of three sub-categories of pain, function, and alignment. We also used the ankle osteoarthritis scale (AOS) and the Self-Administered Foot Evaluation Questionnaire (SAFE-Q) for objective evaluation, which is composed of five sub-scales: 'Pain and Pain-Related'; 'Physical Functioning and Daily Living'; 'Social Functioning'; 'Shoe-Related' and 'General Health and Well-Being.' The AOS score was measured before surgery and at the final follow up, while the SAFE-Q was given to the patient at the final follow up. Data arising from these two assessments were then compared between the two groups. Standard statistical procedures were used to analyze data. The Student's t test was used to compare data between groups. A P value < 0.05 was considered to be statistically significant. This research has been approved by the IRB of our affiliated institutions.

Source of Funding

We received no external funding for this study

Results

The preoperative JSSF scale was 44±11 in the combined TAA group and 49±10 in the standard TAA group; there was no significant difference between the two groups. Postoperative JSSF scale for the combined TAA and standard TAA groups were 89±6.1 and 72±15, respectively, and were significantly improved compared to preoperative scores($p<0.001$, $p<0.001$). Furthermore, the postoperative score of the combined TAA group was significantly higher than that of the standard TAA group ($p=0.0034$). According to the AOS scale, the score for pain and function improved significantly from 5.8 ± 3.3 preoperatively to 2.5 ± 2.5 postoperatively ($p=0.019$), and from 5.5±3.1 to 2.2±1.9 ($p=0.011$), respectively, in the combined TAA group. In the standard TAA group, the AOS score also improved significantly from 8.6 ± 1.3 to 2.5 ± 3.3 ($p=0.000032$) and from 7.1±2.9 to 3.4±2.9 ($p=0.0069$), respectively.

By comparing AOS scores between the two groups, it was clear that preoperative pain score in the standard TAA group was significantly worse than that in the combined TAA group (p=0.024). There were no significant differences between the two groups in terms of preoperative function, postoperative pain, and function (Table 1).

Each score of the SAFE-Q is given in Table 2. There were no significant differences in terms of postoperative SAFE-Q scores between the two groups; however, all subscale points were higher in the combined TAA group than in the standard TAA group.

Discussion

Currently, the predominant treatment option for end-stage ankle arthritis is TAA or AA. Although AA is known to provide favorable pain relief, TAA has become the first line option due to preservation of ankle motion, which helps to prevent arthritis in the adjacent joints[15,16]. TAA has become the standard option due to improvements in component design and surgical instruments. However, the rate of complications following TAA is still higher than those of TKA and THA, and the survival rate

163 remains lower[8-11]. It has been reported that the main reason for lower
164 survival rates for TAA is the technical demands made upon surgeons. [17,18].
165 The dominant risk factors for revision surgery are coronary artery disease,
166 peripheral vascular disease, and a history of smoking. It is also important
167 to take great care to identify indications in obese and young
168 patients[19,20,21]. The main reason for revision surgery is aseptic loosening
169 and subsidence of the talar component. According to radiographic studies,
170 osteonecrosis, collapse and deformity of the talus, along with poor bone
171 stock, are likely to be the most important risk factors for revision
172 surgery[19].
173 In total ankle systems, the talar component is designed as a surface
174 replacement implant. As such, particular attention should be paid to the
175 cuts of the talar dome in patients with poor bone stock. Although Haskell
176 et al. reported that perioperative complications of TAA could be reduced
177 by increased levels of surgical experience, Braito et al. reported that mild
178 malalignment of TAA with radiographs did not affect midterm clinical
179 outcome following TAA[18,22]. Consequently, identifying indications for TAA
180 is critical in obtaining a better result, and considerable care should be

paid to patients with osteonecrosis of the talus and poor bone stock[19].

In case of failed TAA, arthrodesis, using allograft, or revision TAA, could be selected as a means of salvage surgery. However, arthrodesis impairs ankle motion and leads to functional deterioration. **Wagener et al. reported favorable clinical results following revision TAA using customized talar body prosthesis[23]. However, revision TAA remains particularly challenging in cases involving subsidence of the talar component[24].**To avoid subsidence of the talar component, we recommend that the whole talus should be replaced by an artificial implant. In 1997, Harnroongroj reported the use of a stainless steel talar body prosthesis. However, this was only a case series on the replacement of the talar body[25]. Alumina ceramic talar body prostheses were subsequently developed and applied for idiopathic talar necrosis[26,27], and then total talar prostheses were developed as customized implant[14]. This customized total talar prosthesis could be combined with the tibial component of the total ankle prosthesis and adopted for subsidence after total ankle arthroplasty[28]. By replacing the customized total talar prosthesis, TAA could be adopted for patients with severe talar deformity

or extremely poor bone stock without major complications such as migration of the total talar prosthesis to the calcaneus.

This study was limited by the fact that it involved a small case series and a short follow-up period. However, this small case series is sufficient to highlight the current status of total ankle arthroplasty.

Conclusion

In conclusion, combined TAA resulted in better clinical and functional results than standard TAA. Combined TAA is therefore thought to represent an appropriate treatment for patients with end-stage ankle arthritis with poor bone stock.

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304
305 Figure legends:
306

Figure 1. Combined TAA was performed for patients with ankle arthritis with poor bone stock or severe deformity of the talus.

Figure 2. Total Ankle Arthroplasty (TAA) with an artificial talus (combined TAA) and standard TAA.

Table 1: Preoperative clinical data compared to final follow-up.

Table 2: Postoperative results of the Self-Administered Foot Evaluation Questionnaire (SAFE-Q).