Short-Term Clinical Outcomes Following Total Ankle Arthroplasty Without Concomitant Osteotomy in Ankles with Severe Preoperative Varus Deformity

Comparison to Ankles with Preoperative Neutral Alignment

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Background: It remains controversial whether satisfactory outcomes can be obtained following total ankle arthroplasty (TAA) without osteotomy in patients with severe varus ankle deformities. This study aimed to examine outcomes following TAA without concomitant osteotomies in patients with severe varus ankle alignment by comparing them with those in patients with neutral alignment.

Methods: Fifty-one patients (53 ankles; mean age, 71.4 ± 5.6 years) who underwent TAA using the TNK ankle prosthesis were examined (mean follow-up, 36.8 ± 17.8 months). Patients were allocated into groups according to the preoperative talar tilt (TT) angle: the neutral group (preoperative TT angle $<10°$; n = 37) and the varus group (preoperative TT angle $\geq 10°$; n = 16). Outcome measures, including the Japanese Society for Surgery of the Foot scale, Self-Administered Foot Evaluation Questionnaire, ankle range of motion, and radiographic parameters, were assessed before surgery and at the final follow-up.

Results: Significant improvements were observed in clinical and radiographic outcomes in both groups after surgery. Postoperative Japanese Society for Surgery of the Foot scale and subscale scores of pain and shoes in the Self-Administered Foot Evaluation Questionnaire were not significantly different between the groups, whereas subscale scores of function, social, and health were greater in the varus group than in the neutral group at the final follow-up. Radiographic parameters, including TT angle and tibial axis-medial malleolus (TMM) angle, improved postoperatively and were not significantly different between the neutral (mean TT angle, 0.5 ± 0.7°; mean TMM angle, 16.0 ± 4.6°) and varus (meanTT angle, 0.4 ± 0.7°; meanTMM angle, 17.0 ± 5.3°) groups at the final follow-up. To achieve neutral alignment, adjunctive procedures were required more often in the varus group.

Conclusions: Outcomes of TAA using the TNK ankle prosthesis were favorable in patients with severe varus ankle and in those with neutral ankle without concomitant osteotomy. Satisfactory outcomes could be achieved in patients with severe varus ankle alignment after TAA without concomitant osteotomy. (J Am Podiatr Med Assoc 112(6), 2022)

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Modern total ankle arthroplasty (TAA) has been shown to have satisfactory outcomes with better function and equivalent pain relief compared to ankle arthrodesis in patients with ankle osteoarthritis or rheumatoid arthritis (RA).[1-4] This could be attributable to many factors, including improvement of prosthetic design, development of surgical technique, achievement of soft-tissue balancing, careful patient selection, and severity of preoperative deformity.[5,6] However, experts have yet to arrive at a consensus on whether preoperative coronal deformity is associated with postoperative poor outcomes. Some authors reported that preoperative coronal malalignment was associated with poor outcomes,[7,8] and others reported no association between preoperative coronal varus deformity and postoperative clinical outcomes.[2,9-12]As a limitation, most previous studies performed simultaneous osteotomy at the time of TAA for ankles with severe varus coronal deformity.

The TNK ankle prosthesis (Kyocera Medical Technologies Inc, Kyoto, Japan), which was originally developed by Takakura et al,[13] has a medial wall in its tibial insert (Fig. 1). This shape of the tibial insert is unique, and this may stabilize the medial part of the ankle more than other prostheses; however, to date, only a few studies have reported the clinical outcomes following TAA using the TNK ankle prosthesis.[13-15] Thus, it remains unclear whether preoperative coronal varus malalignment is associated with postoperative poor outcomes following TAA using the TNK ankle prosthesis. Therefore, this study aimed to investigate the postoperative outcomes following TAA using the TNK ankle prothesis and to compare the outcomes between a neutral group (preoperative coronal alignment $<10^{\circ}$) and a varus group (preoperative coronal alignment $\geq 10^{\circ}$). As a hypothesis, both groups would show significant improvement following TAA and the neutral group would have better clinical outcomes than the varus group.

Methods

This study was a retrospective analysis of prospectively collected data of primary TAA performed in our institution. Fifty-three arthritic ankles of 51 patients (mean age at surgery, 71.4 ± 5.6 years; 16 men and 35 women) who underwent TAA were included in this study. The average follow-up period after surgery was 36.8 ± 17.8 months. This analysis included 48 ankles with osteoarthritis and five

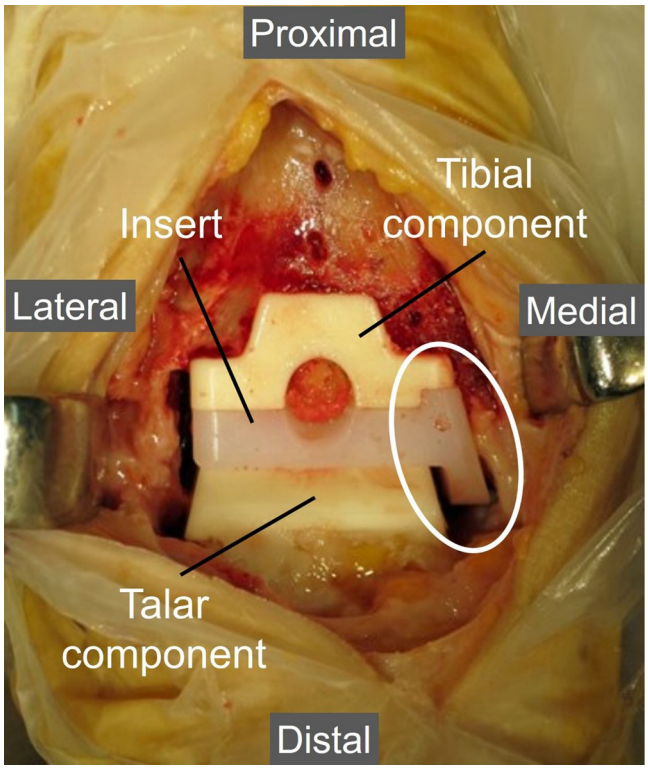


Figure 1. TNK ankle prosthesis. Total ankle arthroplasty using the TNK ankle prosthesis were performed by means of an anterior approach. The insert has a medial wall (white circle).

ankles with RA. Inclusion criteria were patients who underwent TAA from May of 2012 to November of 2018 performed by a single surgeon. Exclusion criteria were patients who received less than 1-year follow-up after the surgery; no cases were excluded in the present study. The study was conducted in accordance with the Declaration of Helsinki and the Guidelines for Good Clinical Practice. The institutional review board approved this study (No. 180053), and informed consent was obtained from all patients.

The ankles were allocated into two groups according to the preoperative talar tilt (TT) angle: the control group ($<10^{\circ}$; 37 ankles) and the varus group ($\geq 10^{\circ}$; 16 ankles). The TT angle was defined as the angle between the tibial articular surface and the talar articular surface by using an anteroposterior weightbearing radiograph of the ankle as previously reported.[16] The demographic data of the two groups are listed in Table 1. Two patients underwent bilateral TAA at different times. One patient had neutral alignment on both sides of the ankles, and one patient had varus alignment of greater than or equal to 10° on both sides. These four ankles were allocated to the control and varus groups accordingly and were evaluated independently.

Surgical Procedure

The third-generation TNK ankle prosthesis was used for all patients. The TNK ankle was originally developed by Takakura et al.[13,14] The third-generation TNK ankle is made of alumina ceramic and comprises tibial and talar components with a polyethylene insert, which has a medial wall (Fig. 1). This insert is attached to the tibial component; thus, the TNK ankle is called a two-component type.

All procedures were performed through an anterior approach between the extensor hallucis longus and tibialis anterior tendon to the ankle joint. Capsulectomy was performed and all osteophytes were removed piece by piece. In cases where the inner tightness was marked at the medial part of the ankle, the deep layer of the deltoid ligament was dissected and elongation of the superficial layer was performed. Thereafter, tibial cutting was performed based on the preoperative planning, following talar cutting. The talar component was fixed with cement, and the tibial component was fixed with a small cancellous screw (DePuy Synthes, West Chester, Pennsylvania). Small beads of cement were initially placed on the surface of the tibial component facing the tibia, and bone marrow was placed on its surface after the application of a calcium phosphate paste to induce osseous bonding (HOYA, Tokyo, Japan). Simultaneous concomitant procedures during TAA were documented.

Postoperative Rehabilitation

The same postoperative rehabilitation protocol was used in both groups. The short leg splint was

Table 1. Demographic Data

Characteristic	Neutral Group	Varus Group	*P* Value
No. of patients	37	16	
Sex			.98
Male	12	5	
Female	25	11	
Age at surgery (years)[a]	71.7 ± 4.5	70.7 ± 7.6	.39
Follow-up (months)[a]	40.0 ± 18.7	29.1 ± 12.3	.04[b]
Preoperative diagnosis (OA/RA)	33/4	15/1	.63
Preoperative talar tilt angle (°)			<.001[b]
Mean ± SD	2.6 ± 3.6	13.9 ± 8.7	
Range	0–9	10–30	
Takakura OA classification[c]			
Stage 3a	4	0	
Stage 3b	13	15	
Stage 4	16	0	

Abbreviations: OA, osteoarthritis; RA, rheumatoid arthritis.

[a]Mean ± SD.

[b]Significant difference.

[c]From Takakura Y, Tanaka Y, Kumai T, et al: Low tibial osteotomy for osteoarthritis of the ankle. Results of a new operation in 18 patients. J Bone Joint Surg Br **77:** 50, 1995; and Doets HC, van der Plaat LW, Klein JP: Medial malleolar osteotomy for the correction of varus deformity during total ankle arthroplasty: results in 15 ankles. Foot Ankle Int **29:** 171, 2008.

applied, and weightbearing was not permitted for the first 2 weeks after surgery. Range-of-motion exercises were started 3 days after surgery during physical therapy. From 2 weeks after surgery, a soft brace with a stay was applied, and full weightbearing was allowed. Range-of-motion exercises were performed without limitations 2 weeks after surgery. The stay of the brace was removed 6 weeks after the surgery, and the brace was applied without the stay until 3 months after surgery.

Clinical Outcomes

The Japanese Society for Surgery of the Foot (JSSF) ankle-hindfoot scale[17,18] was used for objective evaluation, and the Self-Administered Foot Evaluation Questionnaire (SAFE-Q)[19] was used for subjective assessment before surgery and at the final follow-up. Dorsiflexion and plantarflexion angles of the ankle were measured using a goniometer before surgery and at the final follow-up. Concomitant procedures and complications related to the operation were documented.

Radiographic Evaluation

Before surgery and at the final follow-up, the tibial anterior surface (TAS) angle, tibial axis–medial malleolus (TMM) angle, TT angle, and tibial lateral surface (TLA) angle were measured using plain radiographs of the ankle under weightbearing conditions by one examiner, as described previously.[20] The TMM angle was defined as the angle between the distal one-third of the tibial shaft and the joint surface of the medial malleolus. The postoperative TMM angle was defined as the angle between the tibial shaft axis and the surface of the component at the medial malleolus (Fig. 2).

Statistical Analysis

All measurements were expressed as mean ± standard deviation. Data analyses were performed using Excel Statistics version 7 (ESUMI Co., Ltd, Tokyo, Japan). A paired t test was performed to explore preoperative and postoperative differences in clinical scores and radiographic parameters in each group. The Mann-Whitney U test was performed to explore the differences in clinical scores and radiographic parameters between the neutral group and the varus group. The χ^2 test was used to explore the differences in concomitant procedures and complications between the groups. The significance level was set as $P < .05$.

To evaluate intraobserver and interobserver intraclass correlation coefficients (ICCs) in radiographic measurements, all measurements were performed

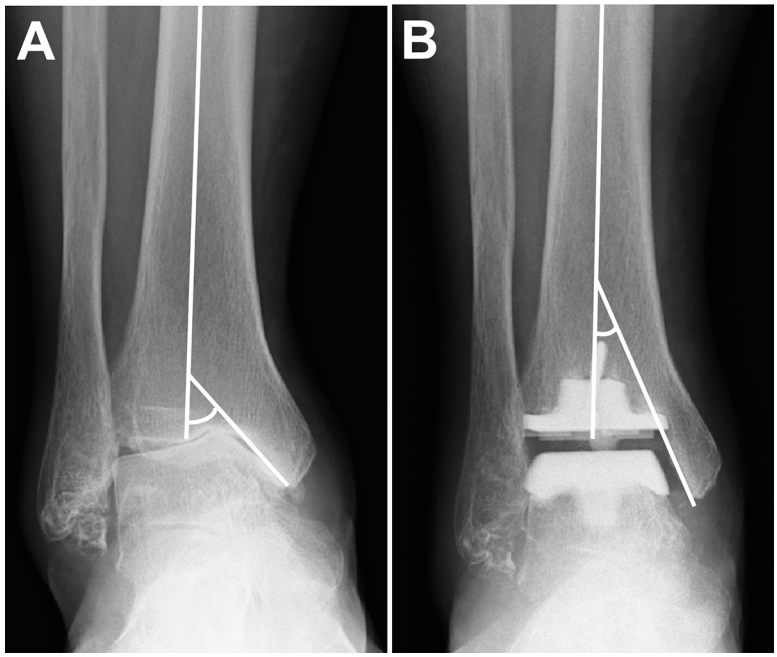


Figure 2. The measurement of the tibial axis–medial malleolus (TMM) angle (A) preoperatively and (B) postoperatively. The TMM angle is the angle between the distal third of the tibial shaft and the joint surface of the medial malleolar joint surface.

twice by the same examiner with a greater than 2-week interval, and another examiner measured once. Intraobserver ICCs were 0.94, 0.96, 0.96, and 0.94 for TAS, TMM, TT, and TLS angles, respectively. Interobserver ICCs were 0.90, 0.96, 0.95, and 0.91 for TAS, TMM, TT, and TLS angles, respectively, indicating excellent reproducibility. A priori power analysis showed that at least 31 and 15 cases, respectively, were required to determine a significant difference between two independent means with two tails, an effect size of 0.9, a power of 0.80, and an alpha error of 0.05.

Results

Postoperative JSSF and SAFE-Q scores were significantly greater than the preoperative scores in each group (Tables 2 and 3). In terms of the JSSF scale, no significant differences were found between the

Table 2. Results of the Japanese Society for Surgery of the Foot Ankle-Hindfoot Scale

	Neutral Group	Varus Group	*P* Value
Total			
Preoperative	52.3 (13.8)	56.9 (5.5)	.38
Last follow-up	88.7 (10.3)	94.3 (7.1)	.07
P value	<.001[a]	<.001[a]	
Pain			
Preoperative	15.0 (9.1)	20.0 (0.0)	.07
Last follow-up	33.4 (6.6)	36.3 (6.0)	.13
P value	<.001[a]	<.001[a]	
Function			
Preoperative	30.5 (8.4)	31.9 (6.1)	.57
Last follow-up	45.4 (6.4)	48.1 (3.2)	.11
P value	<.001[a]	<.001[a]	
Alignment			
Preoperative	7.0 (3.4)	5.0 (1.9)	.025[a]
Last follow-up	9.9 (0.8)	10.0 (0.0)	.52
P value	<.001[b]	<.001[a]	

Note: Values indicate mean (SD).
[a]Significant difference.

Table 3. Results of the Self-Administered Foot Evaluation Questionnaire

	Neutral Group	Varus Group	*P* Value
Pain			
Preoperative	39.0 (17.5)	36.3 (19.1)	.74
Last follow-up	75.7 (17.7)	82.3 (12.6)	.17
P value	<.001[a]	<.001[a]	
Function			
Preoperative	36.0 (20.0)	46.8 (17.0)	.023[a]
Last follow-up	69.5 (19.6)	79.1 (16.9)	.049[a]
P value	<.001[a]	<.001[a]	
Social			
Preoperative	34.9 (29.0)	51.1 (30.1)	.041[a]
Last follow-up	72.7 (30.0)	91.9 (13.4)	.008[a]
P value	<.001[a]	<.001[a]	
Shoes			
Preoperative	47.8 (27.1)	41.7 (24.1)	.91
Last follow-up	74.1 (20.8)	81.3 (18.3)	.26
P value	<.001[a]	<.001[a]	
Health			
Preoperative	39.6 (24.6)	44.0 (21.1)	.42
Last follow-up	74.1 (22.5)	90.1 (9.1)	.01[a]
P value	<.001[a]	<.00[a]	

Note: Values indicate mean (SD).
[a]Significant difference.

groups, except in preoperative alignment (Table 2). Regarding the SAFE-Q, no significant differences were noted in pain, shoes, and preoperative health subscale scores between the groups, whereas function, social, and postoperative health subscale scores were greater in the varus group than in the neutral group (Table 3). However, no significant differences were noted in the improvement of function, social, and postoperative health subscale scores between the groups.

Regarding the range of motion of the ankle, no significant differences were observed in dorsal flexion and plantarflexion between the groups preoperatively versus postoperatively (Table 4). Concerning the radiographic parameters, no significant differences were found between the groups at the final follow-up (Table 5).

Concomitant procedures during TAA are shown in Table 6, and deltoid ligament release was more often performed in the varus group than in the neutral group. Complications are summarized in Table 7; no significant differences in the complication rates were observed between the groups. Moderate talar component subsidence occurred in two ankles in each group, and total talar replacement was performed in those cases using total talar prostheses.

Discussion

The main findings of this study were as follows: 1) significant improvements in clinical outcomes and radiographic outcomes occurred in each group following TAA using the TNK ankle prosthesis, and 2) the outcomes in the varus group were similar to those of the neutral group. These findings suggest that the postoperative outcomes following TAA were favorable even in patients who had preoperative varus coronal malalignment greater than 10°, which is in line with the previous studies showing satisfactory outcomes after TAA in the ankles with preoperative substantial coronal deformity.[4,9-12] Importantly, neutral coronal alignment was achieved only by performing soft-tissue balancing without osteotomies even in the varus group in the present study. The tibial insert of the TNK ankle prosthesis has a medial wall, which could stabilize the mortise and might be an advantage of this prosthesis; however, further comparative studies will be needed to investigate whether this unique prosthetic design could contribute to better outcomes after TAA.

Previous studies have shown that preoperative coronal malalignment is considered a risk factor for early prosthesis failure.[6-8] Therefore, it is considered essential to establish a neutrally aligned ankle after TAA for successful long-term outcomes and to prevent complications.[4,11,21] Recently, several studies have shown that satisfactory outcomes can be obtained following TAA even in ankles with substantial preoperative coronal deformity.[4,9-12] The key to achieving postoperative neutral alignment appears to be associated with additional procedures at the time of TAA. Similar to previous studies, in the present study, additional procedures were performed at the time of TAA to obtain appropriate soft-tissue balancing and neutral alignment, resulting in outcomes comparable to those in previous reports. The present findings support the suggestion that preoperative deformity does not diminish clinical outcomes if a well-aligned stable ankle is obtained after TAA.[4,11]

No concomitant osteotomies were performed in the present study, even in the varus group; however, the postoperative TT and TMM angles were improved in both groups and were not significantly different between the neutral and coronal groups. This finding suggests that postoperative neutral coronal alignment was achieved by performing proper soft-tissue balancing, such as deltoid ligament release, alone. Several studies reported that

Table 4. Results of the Ankle Range of Motion[a]

Parameter	Neutral Group	Varus Group	*P* Value
Dorsiflexion (°)			
Preoperative	9.6 (6.2)	9.4 (5.6)	.98
Last follow-up	12.8 (5.1)	12.1 (4.7)	.73
P value	<.001[a]	.06	
Plantarflexion (°)			
Preoperative	33.9 (11.6)	28.1 (9.5)	.07
Last follow-up	37.4 (11.8)	33.8 (8.0)	.32
P value	.09	.10	

Note: Values indicate mean (SD).
[a]Significant difference.

Table 5. Results of the Radiographic Parameters

Parameter	Neutral Group	Varus Group	*P* Value
Tibial anterior surface angle (°)			
Preoperative			.50
Mean ± SD	84.4 ± 3.7	85.1 ± 4.0	
Range	75–93	77–94	
Last follow-up			.93
Mean ± SD	88.8 ± 2.7	88.4 ± 2.7	
Range	82–96	85–93	
P value	<.001[a]	.022[a]	
Tibial axis-medial malleolus angle (°)			
Preoperative			.036[a]
Mean ± SD	37.8 ± 10.2	45.2 ± 12.2	
Range	18–65	19–73	
Last follow-up			.53
Mean ± SD	16.0 ± 4.6	17.0 ± 5.3	
Range	4–25	5–26	
P value	<.001[a]	<.001	
Talar tilt angle (°)			
Preoperative			<.001[a]
Mean ± SD	2.6 ± 3.6	13.9 ± 8.7	
Range	0–9	10–30	
Last follow-up			.28
Mean ± SD	0.5 ± 0.7	0.4 ± 0.7	
Range	0–1	0–3	
P value	.0019[a]	<.001[a]	
Tibial lateral surface angle (°)			
Preoperative			.85
Mean ± SD	79.0 ± 6.1	78.9 ± 4.7	
Range	60–93	70–86	
Last follow-up			.68
Mean ± SD	80.6 ± 6.8	81.2 ± 6.5	
Range	60–90	64–90	
P value	.13	.27	

Note: Values indicate mean ± SD and range.
[a]Significant difference.

Table 6. Number of Concomitant Procedures During the Total Ankle Arthroplasty

Procedure	Neutral Group (No. [%])	Varus Group (No. [%])	*P* Value
Tendon transfer of flexor digitorum longus	2 (5.4)	0 (0)	.34
Gastrocnemius fascia resection	3 (8.1)	3 (18.8)	.26
Deltoid ligament release	3 (8.1)	7 (43.8)	.023[a]

[a]Significant difference.

Table 7. Summary of Complications Following Surgery

Complication	Neutral Group (No. [%])	Varus Group (No. [%])	*P* Value
Deep infection	1 (2.7)	0 (0)	.51
Medial malleolus fracture	2 (5.4)	2 (12.5)	.37
Lateral malleolus fracture	0 (0)	1 (6.3)	.12
Talus fracture	1 (2.7)	0 (0)	.51
Talar component subsidence	2 (5.4)	2 (12.5)	.37
Delayed wound healing	5 (13.5)	2 (12.5)	.92
Total	11 (30.0)	7 (43.8)	.32

concomitant medial malleolar osteotomy was performed to achieve neutral alignment at the time of TAA using different prostheses from the TNK ankle.[9,10,22] Some studies[12,21,23] reported that only a few concomitant medial malleolus osteotomies (0.3%–4.1%) were performed, whereas other studies[9,10] performed osteotomy more often (13.6%–36.3%). Lee et al[12] reported that only one of 41 patients (2.4%) underwent concomitant medial malleolar osteotomy in the varus group. In contrast, Usuelli et al[10] reported that four of 11 patients (36.3%) in the varus group and seven of 70 patients (10%) in the neutral group underwent medial malleolar osteotomy. Doets et al[22] reported that medial malleolar osteotomy is an easy technique for the realignment of the varus ankle at the time of TAA, and can serve as an alternative to medial ligament release or lateral ligament reconstruction. Thus far, no consensus seems to exist regarding the indication for concomitant medial malleolar osteotomy; however, the advantages of not performing concomitant osteotomy include less invasive surgery for patients and weightbearing can be allowed soon after surgery.

Coronal deformity of the ankle was evaluated using the TT angle in the present study, which describes the congruence of the ankle, as the previous studies used.[3,9,10,24,25] Several other studies used the tibiotalar angle to assess coronal alignment.[4,11,12] Similar to the present study, Trajkovski et al[3] showed that preoperative TT angle in the varus group was significantly greater than in the neutral group (19.9° versus 1.3°), whereas preoperative TAS angle in the varus group was slightly greater than in the neutral group (87.2° versus 88.2°).

With regard to SAFE-Q, the varus group had slightly better postoperative outcomes in the social, function, and health subscales than the neutral group, contrary to the hypothesis (Table 3). However, the level of improvement was not significantly different between the groups, indicating that the change attributable to the operation was not significantly different; in addition, postoperative higher scores in the varus group correspond to preoperative higher scores. Other possible reasons may be that the number of patients was lower in the varus group than in the neutral group and that the follow-up period was slightly shorter in the varus group.

Outcomes of TAA using the TNK ankle prosthesis have been shown to be satisfactory in several reports[13-15]; however, these reports did not investigate the relationship between preoperative coronal deformity and postoperative outcomes. In 1990, Takakura et al[13] reported that postoperative outcomes were satisfactory in 67% of ceramic prostheses without cement. In 2004, they reported satisfactory outcomes with 70 ankles (39 osteoarthritis ankles and 31 RA ankles) using the current third-generation TNK ankle prosthesis.[14] The outcomes are in agreement with the report by Nagashima et al[15] in which favorable outcomes were noted in 21 RA ankles using the same prosthesis. These previous studies support the present findings that outcomes following TAA using the TNK ankle prosthesis were satisfactory independent of preoperative coronal deformity.

No significant differences were observed between the neutral and varus groups in the rate of the postoperative complications in the present study, which concur with the previous studies.[4,10-12] The rate of medial malleolus fracture was 12.5% in the varus group in the present study, which was relatively high; however, this rate seems similar to the rates in several previous reports, which range from 0% to 11.8%.[11,26-28]

Several limitations of the present study should be noted. First, the number of patients was relatively small; however, a priori power analysis showed that the number of patients in the present study could be powered to detect significant differences. Second, the TNK ankle prosthesis was used in the present study so that the results would not be translated to the other prostheses. Third, statistically significant outcomes in the present study may not be clinically significant because minimum clinically important differences in the JSSF and SAFE-Q have not been determined previously. Fourth, the follow-up period in the current study was an average of 3 years after surgery, which is relatively short. In addition, the slightly shorter follow-up period in the varus group may have affected the postoperative outcomes. Thus, long-term outcomes of the present cases should be investigated in the future.

Conclusions

Outcomes of TAA using the TNK ankle prosthesis were favorable in patients with severe varus ankle alignment and in those with neutral ankle alignment without concomitant osteotomy. Satisfactory outcomes could be achieved in patients with severe varus ankle alignment after TAA using the TNK ankle prosthesis without concomitant osteotomy.

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