Successful Re-replacement With Third-Generation Ceramic Talar Whole Prosthesis

Written by Toni Rizzo

Re-replacement or arthrodesis for a painful, loosening total ankle arthroplasty (TAA) is difficult because of the large cavity left after prosthesis removal. Prostheses for TAA have evolved since the first-generation metal prostheses used by the presenter, Yoshinori Takakura, MD, Nara Medical University, Nara, Japan, from 1975 to 1980. Prof Takakura used the second-generation prosthesis, made of ceramic and fixed with cement, from 1980 to 1991. Subsequently, he developed the third-generation ceramic Takakura Nara Kyocera (TNK) ankle prosthesis, which is fixed with a screw. This prosthesis is custom made from a computed tomographic image of the patient's normal opposite talus.

From 1992 to 2012, total replacements were performed in 213 patients (229 ankles) with osteoarthritis (OA), using the third-generation TNK prosthesis [Takakura Y et al. IFFAS 2014]. The patients included 22 men and 191 women, with a mean age of 68 years (range, 52 to 85 years). After a mean follow-up period of 8.2 years (range, 1.8 to 20 years), the outcomes were good (n = 63) to excellent (n = 97) in 83.3% of the patients, fair in 14 patients, and poor in 18 patients. The survival rate of the TNK prosthesis in this group of patients was 92% at 19 years. Among the 213 patients, there were 13 deaths and 5 patients lost to follow-up at 19 years.

From 1993 to 2012, 16 of the patients (6.9%; 3 men and 13 women), with a mean age of 73.7 years (range, 59 to 83 years), required revision surgery because of infection. Two of these patients underwent arthrodesis and 14 underwent re-replacement surgery with the third-generation ceramic talar prosthesis. Four of the re-replacement patients received a talar dome prosthesis and 10 received a talar whole prosthesis. The time from first arthroplasty to revision was an average of 4.2 years (range, 1.8 to 12.1 years). Seven of the patients also received a tibial prosthesis fixed with cement. All patients wore a below-the-knee non–weight-bearing cast for the first 2 weeks, followed by a weight-bearing cast for 3 weeks. The patients were assessed with the American Orthopaedic Foot & Ankle Society ankle-hindfoot scoring system.

At an average follow-up of 5.3 years (range, 2 to 12 years), 78.6% of the patients had good (n = 4) to excellent (n = 7) results, 2 patients had fair results, and 1 patient had poor results. One patient underwent re-revision. Two patients who received a talar dome prosthesis underwent re-replacement with a talar whole prosthesis at 2.3 and 3.7 years after revision because the remaining talar head and neck developed loosening and fracture.

In summary, revision surgery for 14 patients with OA who had a failed TAA was performed with a ceramic talar dome or talar whole prostheses. Prof Takakura did not recommend use of a talar dome prosthesis for revision surgery of TAA. However, he did recommend re-replacement with a talar whole prosthesis after a failed TAA.

No Significant Difference in TAA Outcomes in Varus vs Neutral Ankles

Written by Toni Rizzo

Total ankle arthroplasty (TAA) has gained greater acceptance as an alternative surgical treatment to ankle arthrodesis for end-stage ankle arthritis. Implant design and techniques have improved over the last few decades, with increased implant survival and equivalent pain relief and functional outcomes compared with ankle arthrodesis. Coronal malalignment remains a challenge for successful TAA. Previous study results suggest that a 10° to 15° varus alignment is a relative contraindication and a 20° varus alignment is an absolute contraindication for TAA [Valderrabano V et al. *J Bone Joint Surg Br.* 2005; Wood PL, Deakin S. *J Bone Joint Surg Br.* 2003]. More recent studies reported good TAA outcomes in patients with varus, including those with >20° varus alignment [Sung KS et al. *Foot Ankle Int.* 2014; Trajkovski T et al. *J Bone Joint Surg Am.* 2013].

The objective of this study, presented by Alan Y. Yan, MD, Duke University Medical Center, Durham, North Carolina, USA, was to compare outcomes of TAA in patients with varus vs neutral (<5° [valgus]) alignment. A total of 230 TAAs were prospectively followed from October 2007 to October 2011. The varus alignment group included 100 ankles (96 patients) and the neutral alignment group included 130 ankles (129 patients). The patients received the STAR ankle, the Salto Talaris, or the INBONE I or II. The preoperative and postoperative outcome measures included the Short Form-36 (SF-36), the Short Musculoskeletal Function Assessment Questionnaire (SMFA), Visual Analog Scale (VAS), Foot and Ankle Disability Index (FADI), and American Orthopaedic Foot & Ankle Society (AOFAS) hind foot-ankle scores. The mean follow-up was 43.2 months for the varus group and 45.0 months for the neutral group.

Analysis of the outcome measures showed no significant difference in preoperative, postoperative, or mean

Table 1. Clinical Outcomes

Measure	Cohort	Patients, n	Mean (SD)	*P* Value
Months				
Postoperative	Varus	97	43.2646 (16.2065)	< .001
	Neutral	126	45.0121 (15.1122)	< .001
FADI				
Preoperative	Varus	61	0.5552 (0.1337)	< .001
	Neutral	83	0.5511 (0.1100)	< .001
Postoperative	Varus	21	0.1269 (0.1012)	< .001
	Neutral	23	0.1336 (0.1099)	< .001
Change	Varus	21	−0.4077 (0.1415)	< .001
	Neutral	23	−0.3746 (0.1863)	< .001
VAS				
Preoperative	Varus	87	72.6207 (19.5021)	< .001
	Neutral	113	69.6903 (20.3475)	< .001
Postoperative	Varus	98	11.8061 (19.1557)	< .001
	Neutral	125	12.5680 (20.1155)	< .001
Change	Varus	85	−62.4000 (23.3698)	< .001
	Neutral	108	−56.8056 (28.2864)	< .001
SMFA				
Preoperative	Varus	87	36.2576 (12.6809)	< .001
	Neutral	116	37.5824 (11.8220)	< .001
Postoperative	Varus	96	15.0812 (13.9014)	< .001
	Neutral	126	16.0714 (13.3254)	< .001
Change	Varus	83	−20.7920 (13.8284)	< .001
	Neutral	112	−21.6255 (12.5789)	< .001
AOFAS				
Preoperative	Varus	84	39.5238 (14.9316)	< .001
	Neutral	111	41.0090 (15.9650)	< .001
Postoperative	Varus	71	79.2394 (16.1798)	< .001
	Neutral	90	79.6222 (14.5468)	< .001
Change	Varus	60	41.1333 (21.3545)	< .001
	Neutral	82	37.2683 (20.8747)	< .001
SF-36				
Preoperative	Varus	82	48.7840 (18.4881)	< .001
	Neutral	111	46.7932 (16.9667)	< .001
Postoperative	Varus	85	72.4127 (21.5670)	< .001
	Neutral	119	72.3058 (18.7050)	< .001
Change	Varus	70	23.5920 (20.7324)	< .001
	Neutral	101	24.7120 (16.9819)	< .001

AOFAS, American Orthopaedic Foot & Ankle Society hind foot-ankle score; FADI, Foot and Ankle Disability Index; SF-36, Short Form-36; SMFA, Short Musculoskeletal Function Assessment Questionnaire; VAS, Visual Analog Scale.

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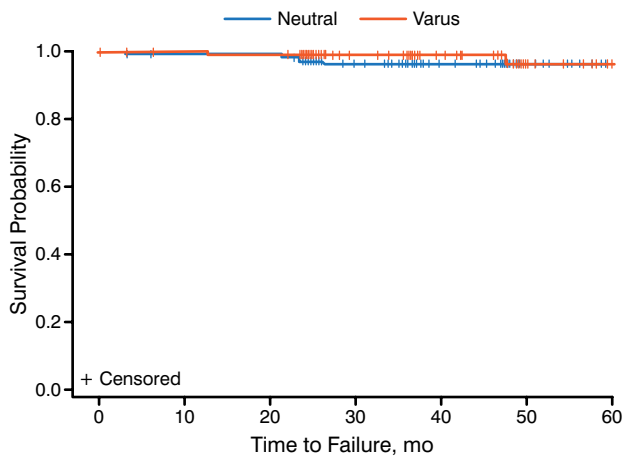
improvement in the SF-36, SMFA, VAS, FADI, or AOFAS scores (Table 1). The mean changes from baseline for the varus vs neutral group were as follows: SF-36, 23.6 vs 24.7; SMFA, 20.8 vs 21.6; VAS, 62.4 vs 56.8; FADI, 0.41 vs 0.37; and AOFAS score, 41.1 vs 37.3.

Most varus ankles (97%) were corrected to neutral (mean 0.5°; −3.9° to 4.1°), all of which maintained neutral at the last follow-up (mean 0.7°; −4.3° to 4.3°).

The varus group required significantly more procedures than the neutral group for soft tissue balancing and osteotomy at index procedures, the most common of which was medial deltoid ligament release (75% vs 4%). Kaplan–Meier estimates (revision end point) projected implant survival of 96.6% (95% CI, 85.8 to 99.2) in the varus group and 96.5% (95% CI, 91.1 to 98.7) in the neutral group over 60 months (Figure 1).

This study demonstrated no significant difference in outcomes after TAA was performed for end-stage

Figure 1. Kaplan–Meier Curve With Revision End Point



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arthritis in patients with moderate to severe varus alignment vs neutral alignment. The outcomes of TAA for end-stage ankle arthritis were similar in patients with preoperative varus deformity >20°. The contraindicated limits of varus deformity may need to be redefined based on current evidence.

PROMIS PF CAT Provides Consistent Outcomes Assessment With Excellent Precision and Efficiency

Written by Toni Rizzo

There is a tangible need for improved tools to measure patient outcomes after treatment of foot and ankle disorders. Numerous clinical outcome measures are used to evaluate foot and ankle disorders and procedures, but consensus on these measures has not been reached. Evidence of validity, reliability, and responsiveness for foot and ankle disorders has been published only for a few scores designed for foot and ankle patient-reported outcome (PRO) measures. Of these few scores, only the Foot Function Index (FFI) and Foot and Ankle Ability Measure (FAAM) have been used in published studies ≥5 times in the last decade [Hunt KJ, Hurwit D. *J Bone Joint Surg Am.* 2013; Martin et al. *J Orthop Sports Phys Ther.* 2007].

The Patient-Reported Outcomes Measurement Information (PROMIS) physical function computerized adaptive testing (PF CAT) has been validated for orthopaedic patients, as well as for lower extremity patients specifically [Hung M et al. *Foot Ankle Int.* 2013]. However, the responsiveness of the PF CAT has not been determined in foot and ankle patients. This study, presented by Kenneth J. Hunt, MD, Stanford University, Stanford, California, USA, compared the psychometric properties and efficiency of the PF CAT with the FAAM and FFI.

Table 1. Person and Item Reliability

Instrument	Person Reliability	Item Reliability
PF CAT	0.96	0.99
FAAM	0.95	0.99
FFI	0.93	0.99

FAAM, Foot and Ankle Ability Measure; FFI, Foot Function Index; PF CAT, physical function computerized adaptive testing.

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Ten participating US sites enrolled 328 patients undergoing ankle, hindfoot, or forefoot surgery. Preoperative and 6-month PROs were collected through the National Orthopaedic Foot and Ankle Outcomes Research Network using the FAAM, FFI, and PF CAT.

The patients underwent surgery for ankle instability, ankle arthritis, hallux valgus, hammertoe, hallux rigidus, and flatfoot; 56% completed the 6-month surveys. Construct validity, determined using the Rasch model, was high for all 3 instruments. Pearson correlations showed that the PF CAT was highly correlated with the FFI 5-point verbal rating scale (FFI-5pt) ($r=0.685$) and the FAAM Activity of Daily Living subscale (FAAM_ADL) ($r=0.792$). All 3 measures demonstrated excellent item reliability, suggesting that the order of item difficulty would be comparable across various patient samples. Person reliability was also high, suggesting similar ordering of individuals' function levels with repeated measures (Table 1).

Paired *t* tests showed that the PF CAT had a preoperative responsiveness measure of −1.6965 and a postoperative responsiveness measure of −0.2476, resulting in a change score of 1.44888 (95% CI, 0.47119 to 2.42657; $t=2.930$; $P=.004$; Figure 1).

For the FAAM_ADL, the preoperative (1.2693) and postoperative (3.9964) measures resulted in a change score of 2.72717 (95% CI, 2.19813 to 3.25620; $t=10.207$; $P=.000$). Both the PF CAT and FAAM_ADL change scores indicated that patients had significantly improved physical function at 6 months.

The FFI-5pt had a preoperative measure of 0.4866 and a postoperative measure of 0.1828, resulting in a change score of −0.30381 (95% CI, −0.58721 to −0.02040; $t=-2.120$; $P=.036$), indicating that patients had significantly deteriorated function at 6 months. All 3 instruments were responsive to change, but the FFI-5pt change was in the opposite direction.