

Long-Term Follow up of Correction of Moderate to Severe Coronal Plane Deformity With the Star Ankle Prosthesis

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ABSTRACT

BACKGROUND: Addressing coronal plane deformity when performing a total ankle arthroplasty (TAA) remains a topic of controversy. While surgeons have become bolder in correcting deformity, long-term follow-up is sparse regarding maintenance of correction and viability of the prosthesis. The purpose of this study is to assess the long-term follow up of the correction of moderate to severe coronal plane deformity with the use of a mobile bearing prosthesis.

METHODS: Out of a consecutive series of 130 patients who underwent TAA between 2000 and 2009, 43 patients (44 ankles) had at least 10° of tibiotalar coronal plane deformity, with 25 having between 10° and 20° of deformity and 18 having greater than 20°. Average age at time of the index surgery was 66 yrs (range

41-79). Initial deformity was 17.9° (range 10-29°) in the entire cohort. All patients underwent intraarticular deformity correction with intraoperative soft-tissue balancing as indicated utilizing the STAR prosthesis. Patients requiring realignment osteotomies were performed in a staged fashion prior to undergoing TAA.

RESULTS: Seven patients (16%) were available for long-term follow up (avg 13 yrs; range 9-16 yrs) with retention of the original prosthesis, two of which had greater than 20° of initial deformity. Average final tibiotalar deformity was 4.9°, with a mean correction of 13° ($p = 0.0001$). No additional procedures related to the prosthesis were performed. Eleven patients (12 ankles) were deceased at the time of the study due to unrelated conditions. Of the original cohort, five were deemed failures (2 converted to arthrodesis; 2 underwent component revision; 1 polyethylene fracture) and excluded from long-term follow up. The remaining 20 patients were lost to follow-up, had declined or were unable to participate due to health status.

CONCLUSION: While the low follow-up rate limits the overall generalizability of the results, enduring correction of moderate and severe coronal plane deformity with a mobile bearing prosthesis can be achieved in a cohort of patients traditionally regarded as high-risk. One must be cautious when discussing with patients the utilization of TAA in the setting of moderate and severe coronal plane deformity given the risk of failure. However, provided a well-balanced ankle can be achieved intraoperatively, long-term mobile bearing prosthesis survivorship is achievable.

Key words: Coronal deformity; Ankle arthroplasty; Long-term; Results

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INTRODUCTION

Managing coronal plane deformity at the time of total ankle arthroplasty has been a subject of great debate. Historically it was viewed as a contraindication with suboptimal outcomes being reported,

particularly in ankles with greater than 15° of coronal plane angulation^[1-4]. Concerns regarding the ability to correct the deformity and potential for subsequent malalignment with edge loading of the prosthesis affecting longevity led to reluctance in performing an arthroplasty in these patients^[5-6]. Over the past decade there has been an exponential growth in the utilization of total ankle arthroplasty due to improved designs, encouraging outcomes and greater facility with the surgical technique^[7-12]. As a result, surgeons have become more comfortable in addressing coronal deformity at the time of arthroplasty with recent studies demonstrating favorable results^[13,14].

Management of these deformities has varied with respect to the surgical algorithm utilized depending upon the degree of initial deformity and ability to achieve intraoperative correction^[10,11,15,26]. Both intra-articular and extra-articular methods have been employed as well as fixed and mobile-bearing prostheses^[15,17-19]. However, data is sparse regarding the ability to maintain long-term correction and prosthesis viability. Our group previously reported on the use of a mobile-bearing prosthesis, Scandinavian Total Ankle Replacement (STAR, Stryker, Kalamazoo, MI) to achieve and maintain alignment in those with moderate to severe coronal plane deformity at mid-term follow-up^[19]. The purpose of this study was to assess the radiographic endurance of this correction and clinical outcome at long-term follow-up.

METHODS

Out of a consecutive series of 130 patients who underwent primary TAA between 2000 and 2009 by the senior author (RAM), 43 patients (44 ankles) were identified who had at least 10° of tibiotalar coronal plane deformity, with 25 having between 10° and 20° of deformity and 18 having greater than 20°. For the purpose of this investigation, those within the range of 10° to 20° were considered moderate and those above 20° were considered to have severe deformity. All patients underwent TAA utilizing the STAR prosthesis, which is an unconstrained, uncemented, mobile-bearing implant. The average age at the time of the index surgery was 66 years (range 41-79), with the group being comprised of 29 males and 14 females^[19]. The average follow up time was 13 years (range 9-16).

After obtaining institutional review board approval and consent for data collection, patients were asked to return to the clinic for both radiographic and clinical evaluation. The principal endpoint of the study was to determine if coronal plane alignment could be maintained on a long-term basis utilizing a mobile-bearing prosthesis in those with moderate and severe deformity. Patients were excluded from the study if they were physically unable or declined to participate. Patients were evaluated clinically utilizing the Buechel Pappas scale, which is a 100-point scale consisting of subscales for pain (40 points), function (40 points), range of motion (15 points), and deformity (5 points)^[20]. The function subscale is further divided into five 8-point questions pertaining to limp, standing, walking, stairs, and support. The Buechel-Pappas Scale is an established method for evaluating outcomes following TAA and was determined to be an appropriate instrument for this study because of its low discontinuity error and its balanced coverage of the different components, namely pain, function, deformity and mobility^[20].

Radiographic alignment was determined utilizing previously established methods^[21,22]. Specifically, coronal plane alignment of the components in relation to the long-axis of the tibia was calculated using the highest points of the articular surfaces of the tibial and talar components. The difference in values for the two components was utilized to calculate coronal alignment, as measured on a

digital archived imaging system (Onyx, Jacksonville, FL)^[21,22]. All measurements were performed by the senior author (RAM).

Surgical Technique

A standardized midline anterior surgical approach was utilized and the surgical technique has been well documented^[3,4,21,22]. All patients underwent intraarticular deformity correction with intraoperative soft-tissue balancing as indicated utilizing the STAR prosthesis. Patients requiring realignment osteotomies or arthrodesis were performed in a staged fashion prior to undergoing TAA. Two patients required a calcaneal osteotomy whereas one underwent a triple arthrodesis prior to undergoing TAA. The tibial and talar bone resections were performed perpendicular to the plumb line of the body such that the implanted components would be perpendicular to the mechanical axis of the limb and parallel to the floor^[19,21]. Soft-tissue balancing was performed if the talus was unable to be corrected into a neutral position prior to the talar dome cut being performed. This consisted of a deltoid ligament release and was most commonly encountered in those with varus deformities. After component placement, if congruent polyethylene tracking was unable to be obtained, a deltoid release was performed if not done earlier. If there was continued instability following the release, a lateral ligament reconstruction was performed consisting of an Evans procedure^[19]. No patient required a concomitant deltoid reconstruction nor was a tibial diaphyseal or metaphyseal osteotomy performed concurrently.

Patients were kept nonweightbearing for 2 weeks and allowed to progressively weightbear by 6 weeks. Radiographic evaluation was conducted on a yearly basis with weightbearing radiographs. Recurrence was defined as a greater than 2° in coronal plane angulation relative to the initial correction achieved, as it was felt that this was the minimal amount of deformity that was able to be perceived^[19].

Statistical Analysis

Normality of the data was determined using the Shapiro-Wilk test. For continuous data, the student t-test was used to compare preoperative and final postoperative alignment, with statistical significance set at $\alpha = 0.05$. Preoperative and postoperative data was correlated using Pearson's correlation coefficient. Statistical analysis was conducted using SPSS (IBM SPSS, Chicago, IL) and Microsoft Excel (Redmond, WA).

RESULTS

Seven patients (16%) were available for long-term follow-up (avg 13 yrs, range 9-16) with retention of the original prosthesis with an average initial deformity of 17.3° (range 13°-29°). Two of the patients had greater than 20° of preoperative malalignment. Average final tibiotalar deformity was 4.9°, with a mean correction of 13° ($p = 0.0001$) (Table 1). No additional procedures related to the prosthesis were performed to correct or preserve alignment. Eleven patients (12 ankles) were deceased at the time of the study due to unrelated conditions. Of the original cohort, five were deemed failures (two were converted to arthrodesis; two underwent revision of both components; 1 polyethylene fracture with component retention) and were excluded from long-term follow up. The remaining 20 patients were lost to follow-up, had declined to be formally evaluated or were unable to participate due to health status. Average postoperative Buechel Pappas score was 89.9 (range 80-95). Preoperative alignment was found to be strongly correlated to final postoperative alignment, indicating that those with a greater degree of initial

Table 1 Results of Study Cohort.

Patient	Age at Surgery (yrs)	Length of f/u (yrs)	Preoperative Deformity	Initial Postoperative Deformity	Final Postoperative Deformity	Buechel Pappas score
1	66	15	16 ⁰ Varus	6 ⁰ Varus	6 ⁰ Varus	92
2	69	10	14 ⁰ Varus	6 ⁰ Varus	7 ⁰ Varus	89
3	71	9	13 ⁰ Varus	2 ⁰ Valgus	0 ⁰	95
4	68	13	14 ⁰ Varus	4 ⁰ Varus	3 ⁰ Valgus	93
5	72	14	13 ⁰ Valgus	2 ⁰ Varus	1 ⁰ Varus	86
6	62	14	22 ⁰ Varus	5 ⁰ Varus	7 ⁰ Varus	94
7	69	16	29 ⁰ Varus	7 ⁰ Varus	10 ⁰ Varus	80
Avg	68.1(+/-3.3)	13.0 (+/-2.6)	17.3(+/-6.1)	4.6(+/-2.0)	4.9(+/-3.6)	89.9(+/- 5.3)

coronal malalignment tended to have greater residual malalignment at final follow up. ($R = 0.80, p = 0.03$). Recurrence of deformity was noted in two patients, one of whom (patient 4) was corrected from 14° to 4° of varus at the initial postoperative evaluation and had progressed to a 3° valgus deformity at final follow-up (Table 1). The second patient (patient 7) had a 29° preoperative deformity which was corrected to an initial postoperative deformity of 7° of varus and progressed to 10° at final follow-up.

DISCUSSION

While the low follow-up rate limits the overall generalizability of the results, enduring correction of moderate and severe coronal plane deformity with a mobile bearing prosthesis can be achieved in a cohort of patients traditionally regarded as high-risk. There are several reasons for the suboptimal follow-up. First, long-term studies involve a degree of patient attrition due to their nature and is true of this particular study. An additional long-term study from this institution evaluating the STAR prosthesis demonstrated a similarly low follow-up rate of 29%^[10]. During the study period, TAA was largely viewed as an investigational procedure with FDA approval for the STAR prosthesis being obtained in 2009, following completion of the non-inferiority randomized controlled trial^[23]. Patients had frequently traveled extensively in order to receive a TAA and were either unable to be located, declined to return for evaluation, or were unable to participate due to cognitive or physical disabilities at the time data was being collected for this investigation. Conducting evaluations in person versus by telephone contributed to the loss of follow-up. We had decided to perform in person evaluations to promote uniformity of the radiographs obtained as well as to personally assess the function of the arthroplasty. Second, unfortunately, more than a quarter of the study population was deceased at the time of the investigation (11 of 43) due to unrelated health conditions. This is likely due to the fact that patients were relatively older at the time of the surgery (avg age of 68 yrs). Furthermore, patients with advanced ankle arthritis often have pronounced health-related quality of life impairment that can contribute to reduced longevity^[24,25]. Third, it involved a high-risk population in whom TAA was generally viewed as a contraindication at the time of surgery. While, there are only five known failures in this particular cohort, it is likely that the number of failures is higher and had elected to seek further treatment at an alternate facility.

Recent studies have demonstrated satisfactory outcomes in patients undergoing TAA in the setting of coronal plane deformity. Queen et al demonstrated that those with deformity can achieve similar functional outcomes provided that a balanced ankle can be obtained^[15]. In a cohort of 144 patients comparing those with varus or valgus malalignment versus those with neutral alignment, Lee et al observed that those with coronal deformity can experience similar

functional improvement relative to those without deformity^[14]. The investigation noted that those with varus malalignment had a greater number of concomitant procedures at the time of surgery as well as a lesser degree of correction^[14]. In a subsequent study, Lee and Lee evaluated a group of those with severe deformity (> 20°) relative to those with moderate deformity (5°-20°) and observed similar functional improvements in both cohorts, although there was a greater prevalence of residual malalignment in the severe group^[13]. In the group of patients presented in the current study, while there was residual malalignment noted at the initial postoperative evaluation, it is important to note that it did not increase over time. It appears that if correction can be obtained and maintained, subtle malalignment (approximately 5°) can be tolerated over time.

Critical to achieving a balanced ankle is recognizing the need for concomitant procedures as the degree of deformity increases, utilizing either or a combination of soft-tissue and osseous procedures. In the original cohort of patients of this study, all patients with greater than 18° of varus deformity required a deltoid release^[19]. While osteotomies in this cohort were performed in a staged fashion prior to arthroplasty, it can be performed concurrently, though no patient required a concurrent tibial osteotomy. This is similar to the findings of other investigators when attempting to address deformity through arthroplasty^[13-16].

The use of a mobile versus fixed-bearing prosthesis in this setting remains a subject of debate. While this investigation exclusively employed a mobile bearing ankle, similar outcomes can be expected when a fixed implant is used provided that a well aligned ankle can be achieved^[15,17]. Berlet et al determined that the length of the tibial stem did not influence the ability to maintain coronal deformity correction when using the INBONE II (Wright Medical, Arlington, TN) prosthesis^[17]. This indicates that it is imperative to obtain congruency of the tibiotalar articulation at the time of implantation using soft-tissue and osseous procedures as necessary without relying on the implant itself to maintain correction.

Additional limitations of this study include the fact that sagittal plane alignment was not measured. This was due to the fact that it was not reported in the initial investigation in order to maintain continuity. We did not observe any instances of isolated sagittal malalignment that affected prosthesis survivorship. The radiographic and clinical evaluations were also performed by the operative surgeon, introducing a potential source of bias. Furthermore, limited clinical data was obtained to evaluate the functional outcome of the patients. However, this was a secondary outcome as the primary one was the evaluation of the maintenance of long-term coronal alignment.

CONCLUSION

One must be cautious when discussing with patients the utilization of

TAA in the setting of moderate and severe coronal plane deformity given the risk of failure. While the suboptimal follow-up limits the overall generalizability of the results, an enduring correction can be achieved. Provided that a well-balanced ankle be achieved intraoperatively, long-term mobile bearing prosthesis survivorship is achievable in a group traditionally regarding as being higher risk.

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