Article

AMERICAN ORTHOPAEDIC FOOT & ANKLE SOCIETY

Foot & Ankle International®
2019, Vol. 40(9) 997–1006

DOI: 10.1177/1071100719849084
journals.sagepub.com/home/fai

Total Ankle Arthroplasty Survival and Risk Factors for Failure

Mario I. Escudero, MD[1,2], Vu Le, MD, FRCSC[1], Maximiliano Barahona, MD[2], Michael Symes, MBBS, MPH, FRACS[1], Kevin Wing, MD, FRCSC[1], Alastair Younger, MB, ChB, MSc, ChM, FRCSC[1], Andrea Veljkovic, MD, FRCSC[1], and Murray Penner, MD, FRCSC[1]

Abstract

Background: Total ankle arthroplasty (TAA) is an increasingly selected treatment for end-stage ankle arthritis; however, failure and revision of the tibial and talar components remains an issue. Although multiple risk factors have been shown to contribute to early component revision, no study has looked at combining such risk factors into a predictive model that could potentially decrease revision rates and improve implant survival. This study aimed to develop a predictive model for TAA failure based on patient characteristics, patient-reported outcomes (PROs), and immediate postoperative radiographs.

Methods: A retrospective review of a single-site ankle arthritis database was conducted. All patients with current-generation ankle replacements including the Hintegra and Infinity prostheses implanted between 2004 and 2015 and with complete postoperative radiographs taken between 6 and 12 weeks postoperatively were included. Eight coronal and sagittal radiographic parameters were assessed and performed twice by 2 independent orthopedic surgeons on included TAAs. These radiographic parameters were then analyzed in association with patient demographics and PRO. Advanced statistical methods including survival analysis were used to construct a predictive model for TAA survival. A total of 107 patients were included and analyzed with a median clinical follow-up of 49 months (minimum 24 months).

Results: A predictive model was created, with 4 parameters identified as being statistically associated with TAA metal-component revision: diabetes mellitus, poor baseline Ankle Osteoarthritis Scale (AOS) score, excessively dorsiflexed talar component, and an anteriorly/posteriorly translated talus relative to the tibial axis. The presence of 3 parameters predicted TAA survival of 0.60 whereas presence of all 4 parameters predicted survival of only 0.13 in the period studied.

Conclusion: Our predictive model is based on a combination of patient factors, PROs, and radiographic TAA alignment. We believe it can be used by surgeons to predict failure in their TAA patients, thereby optimizing postoperative outcomes by improving patient selection and modifiable outcome-specific parameters.

Level of Evidence: Level III, retrospective cohort study using prospectively collected data.

Keywords: ankle arthroplasty, ankle replacement, revision ankle arthroplasty, ankle arthroplasty failure, ankle arthritis, predictive model

Introduction

Ankle arthritis is a common condition that is a major cause of chronic disability, lost income, and decreased quality of life.[15] For end-stage disease failing conservative management, the 2 commonly accepted operative treatments include ankle arthrodesis and total ankle arthroplasty (TAA).[8] Although they have comparable clinical results,[8] TAA continues to grow in popularity with patients and surgeons,[44] with modern third- and fourth-generation TAAs providing better outcomes than earlier implant designs.[27] Despite this, rates of reoperation, revision, and other TAA-specific complications not only represent areas of concern but also areas of potential optimization.[8,27]

Recently, the focus of outcomes assessment has shifted away from physician-specific parameters to include more patient-specific factors. Patient-reported outcome measures

[1]University of British Columbia, Vancouver, Canada
[2]Hospital Clinico, University of Chile, Santiago, Chile

Corresponding Author:
Mario I. Escudero, MD, Clinical Hospital University of Chile, Santos Dumont 999, 3er piso, Oficina Traumatología, Santiago, 8380456, Chile.
Email: marioescudero@uchile.cl

(PROMs) are used to evaluate pain, function, and quality of life to better assess outcomes subsequent to the treatment of foot and ankle conditions, including joint replacements.[3,4,7] Thus, operative criteria and decision-making tools should account for patient-specific characteristics and demographics such as gender, age, preoperative deformity, smoking status, preoperative function, and baseline comorbidities among patients undergoing TAA. Further, TAA positioning needs to be optimized, as TAA alignment has been shown to affect outcomes and survival,[3,8,9,21,52] with the primary imaging modality being plain radiography. With TAA's growth in popularity and increasing numbers of patients being offered TAA surgery, it is important to identify patient-specific and prosthesis positioning–specific risk factors that may predispose patients to suboptimal results and TAA failure.

This study had 2 main purposes. One was to analyze TAA survival and identify risk factors for TAA failure based on baseline patient characteristics and demographics, PROMs, and TAA radiographic alignment parameters. The second was to develop a predictive model that could predict TAA failure based on the risk factors identified.

Methods

Patient Enrollment

The ankle arthritis database from a single center, based on prospectively collected data, was retrospectively reviewed. All skeletally mature patients enrolled between 2004 and 2015, and undergoing treatment of end-stage ankle arthritis (ESAA) with the Hintegra Total Ankle System (Integra LifeSciences, Plainsboro, NJ) or Infinity Total Ankle System (Wright Medical Technology, Arlington, TN) were included. All surgeries were performed by one of 3 fellowship-trained orthopedic foot and ankle surgeons with extensive TAA experience. The recommendation for total ankle replacement was based on a combination of the surgeon's preoperative clinical examination, radiographic findings, and patient preference. Institutional research ethics board approval was granted and informed consent was obtained from all study participants. All included patients had a minimum of 2 years' clinical follow-up.

Patients were excluded for receiving a TAA if they had any of the following: osteonecrosis of the talus or tibia, active infection in the ankle within 12 months prior to surgery, medical conditions precluding safe surgery, or severe osteoporosis. Also excluded were patients who received a second-generation TAA given the higher rate of revisions reported by Lefrancois previously[27] and patients without a complete series of postoperative radiographs (weightbearing anteroposterior and lateral) taken at 6 to 12 weeks.

Data Collection

Patient assessments were completed preoperatively at 6 months, 1 year postsurgery, and annually thereafter. Baseline demographics, comorbidities, smoking status, the Canadian Orthopaedic Foot and Ankle Society (COFAS) preoperative classification,[24] end-stage ankle arthritis etiology, and PROMs were collected as part of part of the Musculoskeletal Outcomes Data Evaluation and Management System questionnaire. This is currently the only standardized, validated scoring instrument applicable to foot and ankle surgery published by the American Academy of Orthopaedic Surgeons.[9]

TAA Failure Definition

TAA failure was defined as either reoperation requiring removal of one or both metal components of the prosthesis or amputation above the level of the ankle.[34]

Patient-Reported Outcome Measures

The PROMs analyzed were the Ankle Arthritis Score (AAS), the Ankle Osteoarthritis Scale (AOS) score, and the the Short Form-36 physical component summary (SF-36 PCS) scores at baseline and at 6 months postoperatively. These scores are validated, self-reported, ankle arthritis–specific PROMs.[11,30,55]

Radiographic Outcomes

Seven sagittal and coronal radiographic outcomes (medial distal tibia angle, talar tilt angle, talar center migration, sagittal distal tibial angle, lateral talar station, tibia-talus ratio, and gamma angle) were measured according to previously described methods,[2,20,45,51-54] and 1 additional measurement was devised for this study: posterior tibial component over- or underhang. Postoperative measurements (3 coronal and 5 sagittal) were performed by 2 independent orthopedic surgeons, twice each (Figures 1-3). Normal ranges for each radiographic parameter were defined based on previously published literature when available, and expert opinion when not available (Table 1). Inter- and intraobserver reliability of radiographic measurements were calculated with the type 1 intraclass correlation coefficient (Table 2).[42]

Statistical Analysis

Standard summary statistics were generated followed by a survival analysis. A univariate analysis was performed using baseline demographics, radiographic parameters previously described, and PROMs collected preoperatively and at 6 months postsurgery using a log-rank test. A multivariate Cox proportional hazards model was estimated to

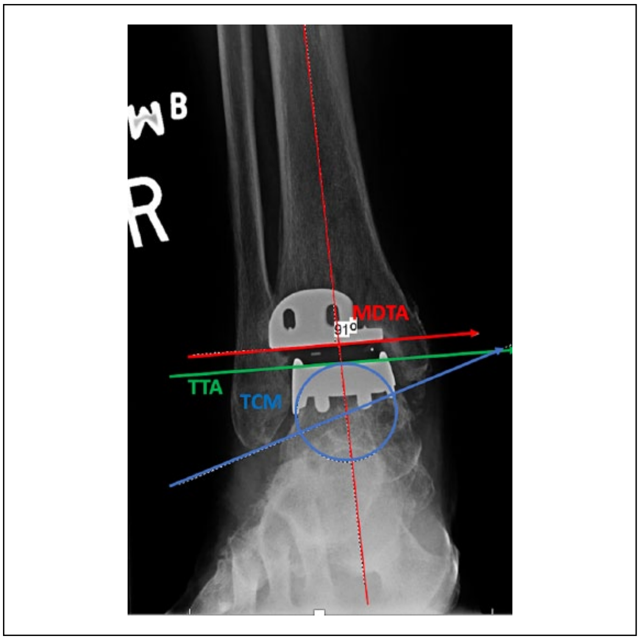


Figure 1. The coronal alignment measurements used. MDTA, medial distal tibia angle; TTA, talar tilt angle; TCM, talar center migration.

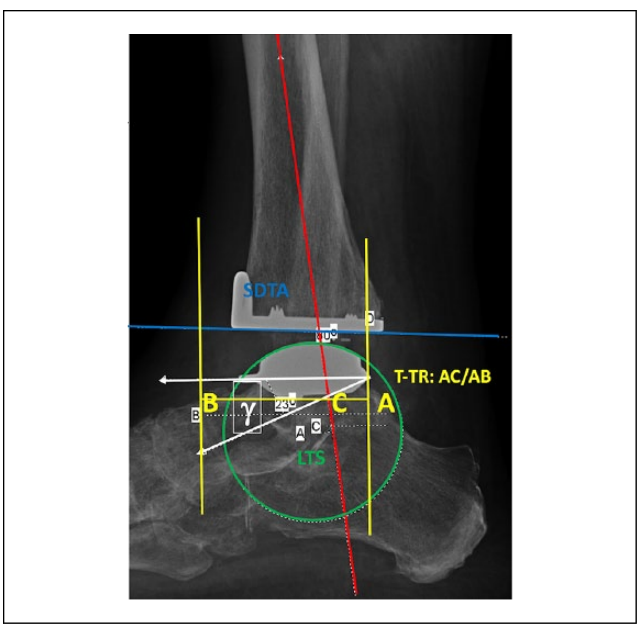


Figure 2. The sagittal alignment measurements used. γ, gamma angle; LTS, lateral talar station; SDTA, sagittal distal tibia angle; T-TR, tibia-talar ratio.

predict risk factors for failure. Then, a stepwise regression analysis was performed; the variables that had a probability lower than .10 were kept in the model. Using Harrell *C* concordance and Somers *D* statistics, we compared the predictive power of the different survivals models constructed with the variables kept in the stepwise regression.

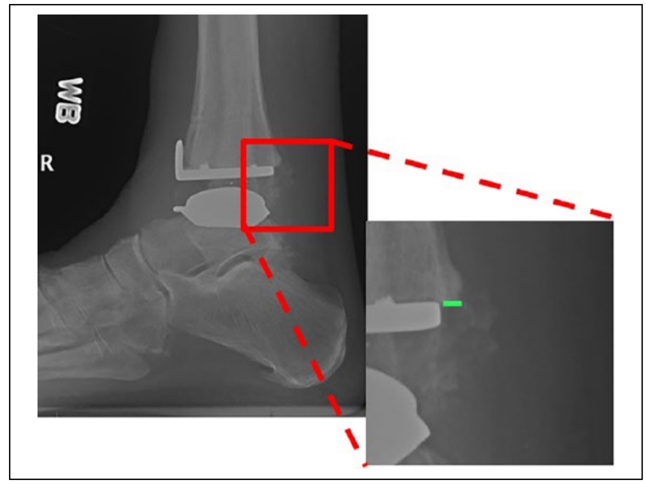


Figure 3. Posterior tibial component over-/underhang measurement.

Table 1. Defined Normal Ranges for Each Radiographic Parameter Measured.

Measurement	Range Defined as Normal[a]
Medial distal tibia angle, degrees, mean ± SD	90 ± 3[45,57,b]
Talar center migration, mm, range	−1.4 to 2.1[57,b]
Talar tilt angle, degrees	0[c]
Sagittal distal tibia angle, degrees, mean ± SD	
Hintegra	86 ± 3
Infinity	90 ± 3[17,38,b]
Tibia-talus ratio, %, mean ± SD	34.8 ± 3.8[47,48,b]
Lateral talar station, mm	−0.8 to 3.2[53,54,b]
Gamma angle, degrees, mean ± SD	17 ± 3[51,b]
Posterior tibial component overhang, mm, mean ± SD	0 ± 3[c]

Abbreviation: SD, standard deviation.
[a]Previously published data were used when available and expert opinion when not.
[b]Mean value as previously published.
[c]Based on expert opinion of senior authors.

Table 2. The Intraclass Correlation Coefficient for Intra-/Interobserver Reliability for Each of the Radiographic Measurements.[a]

	Intraobserver ICC	Interobserver ICC
MDTA	0.83 (0.80-0.86)	0.68 (0.60-0.76)
T-T ratio	0.71 (0.62-0.80)	0.55 (0.47-0.63)
SDTA	0.87 (0.85-0.89)	0.74 (0.68-0.80)
LTS	0.86 (0.84-0.88)	0.73 (0.67-0.79)
Gamma angle	0.79 (0.74-0.84)	0.67 (0.58-0.76)
TCM	0.83 (0.80-0.86)	0.60 (0.48-0.72)
TTA	0.98 (0.97-0.98)	0.93 (0.93-0.94)
Posterior overhang	0.67 (0.57-0.77)	0.61 (0.49-0.73)

Abbreviations: ICC, intraclass correlation; LTS, lateral talar station; MDTA, medial distal tibia angle; SDTA, sagittal distal tibia angle; TCM, talar center migration; T-T, tibia-talar; TTA, talar tilt angle.
[a]<0.4 indicates poor reliability, 0.4-0.599 indicates fair reliability, 0.60-0.749 indicates good reliability, 0.75-0.99 indicates excellent reliability, and 1.0 indicates perfect reliability.[42]

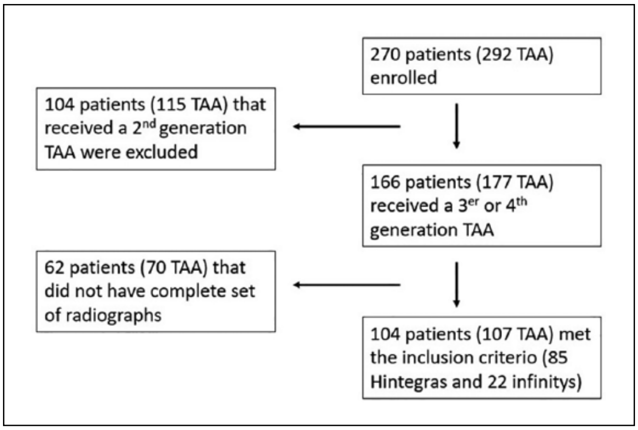


Figure 4. Flowchart showing the patient exclusion criteria and the number of patients available for analysis. TTA, talar tilt angle.

In addition, the likelihood ratio and Wald chi-square were used to select the final model. Hazard ratios and the *P* values are reported. After the model was created, a test of proportional hazards assumption (ph-test) was performed and considered acceptable if the probability was greater than .15 ($P > .15$).

All significant variables included in the multivariate survival model were used to construct a score. The value of 1 was assigned if the risk variable was present; otherwise, it was assigned a value of 0. A binomial regression analysis was used to determine if the score should be weighted. Given that the odds ratio of the independent variables was similar with respect to the score, a non-weighted score was constructed. Then a univariate Cox proportional hazards model was estimated, using the score as the independent variable. Additionally, the ph-test was performed after this model, and considered acceptable if probability was greater than 0.15 ($P > .15$). The power ($1 - \beta$) was calculated by a Wald test for a Cox proportional hazards model.

Finally, a univariate logistic regression model was estimated using failure as the dependent variable and the score as the independent variable. Then, a receiver operating characteristic (ROC) curve was calculated and interpreted according to Hosmer and Lemeshow's recommendations.[19] For internal validation of our predictive score, bootstrap (200 replicates) and jackknife estimations were utilized. The probability of failure by each outcome of the score is reported with confidence intervals of 95%.

No missing data were found in the failure group for the variables included in the score (n=12/107), but 16 missing were found in the control group. Using missing imputation, values were estimated by linear regression and multivariate normal regression. Both results, with missing data treatment (n=107) and no missing data treatment, are reported for the logistic regression of the score (n=91). The data were processed using Stata, version 11.2 (StataCorp LP, College Station, TX).

Results

A total of 107 TAA (104 patients) met the inclusion criteria; 85 Hintegra and 22 Infinity TAA (Figure 4). Twelve patients (11%) had a TAA failure: 11 patients were revised for aseptic loosening and 1 for periprosthetic infection. The median follow-up was 49 months (18-131 months), the total time at risk was 503 years, and the median time to failure was 40 months (24-114 months) (Figure 5). All radiographic measurements demonstrated at least fair reliability (T-T ratio), but most of them showed good to excellent, inter- and intraobserver reliability (see Table 2).

The results of the univariate analyses are summarized in Table 3. The preoperative AOS score greater than 63, "normal" gamma angle, and previous SF-36 were the significant variables.

After the multivariate analysis, 4 variables were found to have a probability less than .10 to predict failure: the presence of diabetes mellitus (DM), a baseline AOS score >63, a gamma angle >19 degrees, and a T-T ratio <0.32 or >0.39 (see Table 4). This model with 4 variables has an acceptable prediction power with a Harrell *C* of 88% or Somers *D* of 75%.[36] Compared with a model that included only DM and baseline AOS scores, the model with the 4 variables in it was significantly better by log-likelihood ratio test ($P = .01$) and Wald χ^2 test ($P = .05$). Because of these results, the model with 4 variables was kept. As such, a predictive score was developed using these 4 variables and the above values that were associated with failure. The value of 1 was assigned if the risk variable was present; otherwise, it was assigned a value of 0. For example, a patient with DM who had an AOS score before surgery of 30 and a gamma angle of 15 degrees and a T-T ratio of 0.30 scores 2 points (1+0+0+1). The binomial regression showed equivalent odds ratio for each variable of the score, so no factor was added to the sum of each variable (Table 5). The predictive score has a hazard ratio of 10.51 (2.57-42.94), a ph-test of 0.21, and a power ($1 - \beta$) of 0.93.

The probability of TAA failure in the time studied, for each possible value of the score in this predictive model was obtained by a logistic regression with 200 replicates bootstrap estimation and 89 Jackknife replicates (Figure 6). The ROC curve is shown in Figure 7, the area under the ROC curve was 0.83 (0.71-0.94), which is considered "very good" discrimination according to Hosmer and Lemeshow.[19] Also, the probabilities with missing data imputation are shown in Figure 6.

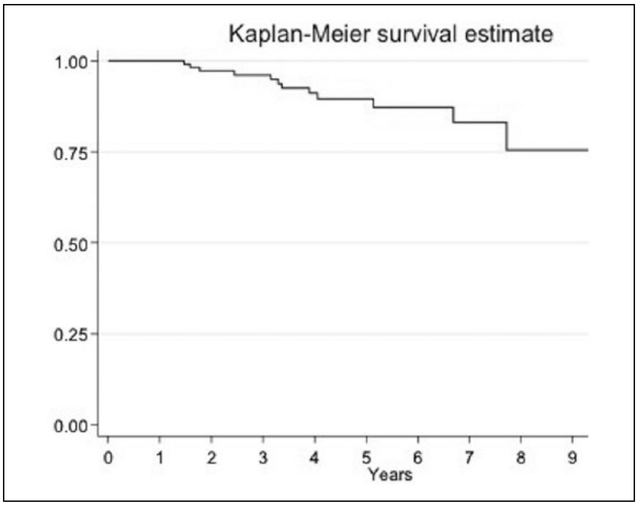


Figure 5. The Kaplan-Meier estimated survival curve for the entire TAA cohort with revision of tibial and/or talar component as the end point.

Table 3. The Results of the Univariate Analysis of Kaplan-Meier Curve Using Log Rank Test.

	P (Log Rank)
DTCA angle	.34
TTA	.28
DTSA sagittal angle	.95
Overhang	.54
Gamma angle >19 degrees	.05
TCM angle	.82
T-T ratio	.84
LTS angle	.89
Inflammatory arthritis	.78
Age	
>65	.38
>70	.52
Diabetes	.26
BMI	
>30	.93
>35	.74
>25	.62
Gender	.85
Side	.90
AOS score presurgery	.06
AOS score presurgery >63	<.00
SF-36 score presurgery	.02
AAS score presurgery	.33
Smoking	.27

Abbreviations: AAS, Ankle Arthritis Score; AOS, Ankle Osteoarthritis Scale; BMI, body mass index; DTCA, distal tibial coronal angle; DTSA, distal tibial sagital angle; LTS, lateral talar station; SF-36, Short Form–36; TCM, talar center migration; T-T, tibia-talar; TTA, talar tilt angle.

Table 4. Hazard Ratios (HRs) for the 4 Variables That Showed Strong Correlation With TAA Survival.

Variable	Hazard Ratio	*P* Value
Diabetes mellitus	24.83	.010
Baseline AOS score >63	29.54	.003
Gamma angle >19 degrees	05.25	.063
T-T ratio 0.32 > X > 0.39	08.53	.072

Abbreviations: AOS, Ankle Osteoarthritis Scale; TAA, total ankle arthroplasty; T-T, tibia-talar.

Table 5. Results of the Binomial Regression Using the Sum as the Dependent Variable.

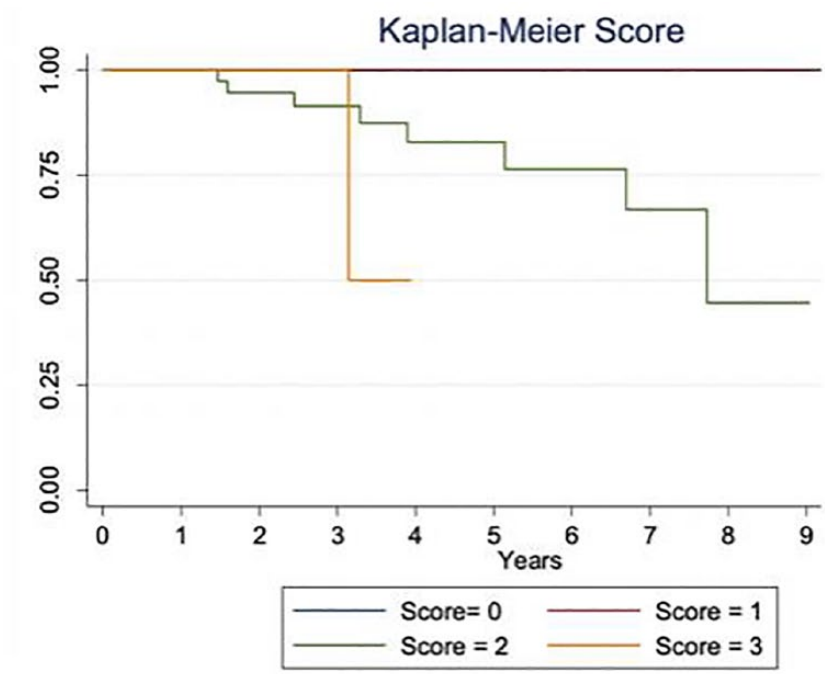
Variable	Odds Ratio[a]
Diabetes mellitus	3.18 (1.28-7.92)
Baseline AOS score >63	3.24 (1.99-5.25)
Gamma angle >19 degrees	3.29 (2.01-5.36)
T-T ratio 0.32 > X > 0.39	3.49 (1.89-6.44)

Abbreviations: AOS, Ankle Osteoarthritis Scale; T-T, tibia-talar.
[a]All odds ratios are similar, so no weighted score was constructed.

Discussion

Despite the growing popularity and improved patient outcomes associated with TAA, it is still associated with higher revision rates when compared with arthrodesis.[8] With revision TAA being associated with increased health care costs, low patient satisfaction, worse functional outcomes, and poor longevity, the ability to predict the chance of revision after primary TAA could be very useful.[23,43] The present study showed that patients presenting with DM, poor baseline function represented by an AOS score >63, a dorsiflexed talar component represented by a gamma angle >19 degrees, and an anteriorly or posteriorly displaced talus postoperatively in relation to the long axis of the tibia were at substantial risk of TAA failure at an intermediate-term follow-up. These factors individually have been shown to be associated with poor outcomes, but this study is the first to combine them into a score that directly correlated with implant survival.

The adverse impact of diabetes on TAA clinical outcomes has been previously documented by Choi et al,[6] who studied the impact of DM on TAA outcomes in 173 patients. They found that the mean AOS and AOFAS scores were significantly worse in patients with DM, and that the DM group presented with a higher rate of delayed wound healing. DM was also associated with TAA failure and an increased incidence of early-onset osteolysis compared with the non-DM group. A similar effect from DM has also been demonstrated in a number of other orthopedic conditions, including hip



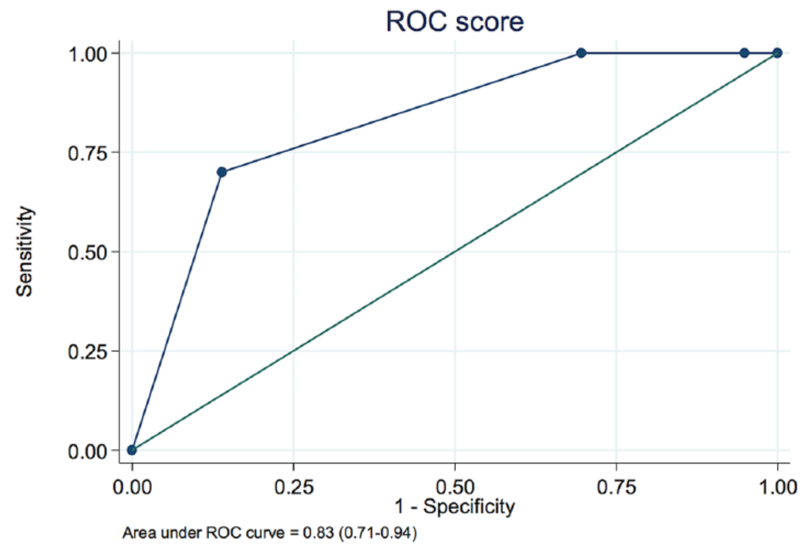
SCORE	FAILURE RATE	SURVIVAL	FAILURE RATE WITH MI LR
0	0 (0-0.003)	0.9994 (0.9976 - 1)	0 (0-0.02)
1	0 (0-0.02)	0.994 (0.98-1)	0.04 (0-0.09)
2	0.06 (0-0.112)	0.94 (0.898-1)	0.2 (0.09-0.32)
3	0.40 (0.16-0.63)	0.60 (0.378-0.84)	0.64 (0.32-0.96)
4	0.87 (0.65-1)	0.13 (0-0.36)	0.93 (0.75-1)

Figure 6. The Kaplan-Meier estimated survival curve (top panel) and the survival/failure probability for each outcome of the score (90% confidence interval) with and without missing data (bottom panel). LR, linear regression; MI, missing imputation.

and knee arthroplasty, spinal surgery, and ankle fracture surgery, with not only higher complication rates but also lower implant survival rates.[32,33,49,56] In the present study, even when adjusting for BMI and other comorbidities associated with diabetes, DM still showed an independent strong correlation with a lower TAA survival.

PROMs are becoming an increasingly common tool in the evaluation and treatment of foot and ankle conditions.[7,55] The Ankle Osteoarthritis Scale (AOS) is one such instrument, and is a validated, self-reported, ankle-specific PROM.[39] The present study demonstrated that a threshold of an AOS score >63 points was found to be a significant risk factor for TAA failure (Table 3). Currently only one other study has looked at ankle arthritis–specific PROMs and found a similar association with TAA survivorship. Croft et al[7] examined the Ankle Arthritis Score[55] and found that with each 1-point increase in the AAS, there was a 1% increase in the likelihood that a patient would require a revision procedure.

TAA component positioning has been demonstrated to be critical for TAA survival by numerous authors.[2,12,21] Espinosa et al[12] compared the effect of talar component



AREA UNDER ROC CURVE	DISCRIMINATION
0.50-0.60	Luck
0.61-0.70	Low
0.71-0.80	Acceptable
0.81-0.90	Very good
0.91- 1	Excellent

Figure 7. The area under the ROC curve was 0.83 (0.71-0.94), showing a very good discrimination according to Hosmer and Lemeshow.[19] ROC, receiver operating characteristic.

malalignment and found that with as little as 2 degrees of coronal plane malalignment, contact pressures became substantially higher and more narrowly distributed, exceeding the threshold for potential polyethylene damage via edge loading. Similarly, Kakkar et al[22] reported that improper alignment of the prosthesis may result in excessive eccentric loads, potentially contributing to bone overload, leading to the conclusion that proper implant positioning was likely important for long-term implant durability. Fukuda et al[13] also noted that malrotation of the talar component resulted in increased peak pressures, decreased contact area, and increased rotational torque and felt that this may contribute to premature polyethylene wear and potential talar component loosening. In this study, the talus component sagittal alignment correlated with TAA survival, with a dorsiflexed talus component, represented by a gamma angle >19 degrees, being associated with implant failure. This finding highlights the importance of avoiding ankle plantarflexion when performing talar cuts during TAA. Another radiologic parameter we found to be associated with TAA survival was the T-T ratio, which was originally described by Tochigi et al.[47,48] Although it has previously been associated with TAA functional outcomes by other authors,[2,50] this is the first study to find an association with implant survival. Our findings demonstrated that a T-T ratio less than 0.32 (talus anterior to the tibia) or greater than 0.39 (talus posterior to the tibia) represents a risk factor for TAA failure. Additionally, a talar component centered under the tibia (represented by a T-T ratio between 0.32 and 0.39) was important for implant survival. Also, there was a correlation between tibial component overhang and TAA survival in our cohort (Figure 4). Compared with those that did not fail, the failed TAAs had a significantly lower median posterior underhang (–1.45 mm vs +0.4 mm, $P = .02$). However, when time is accounted for with a survival analysis, there was no association. An overhang of the tibial component may protect the TAA from an early tibial component failure due to aseptic loosening, as has been demonstrated in total knee arthroplasty,[1,37] but more research is warranted.

In the present study, the revision rate observed (11%) is in accordance with other studies reporting intermediate-term outcomes.[8,10,18,35] A systematic review of the literature revealed revision rates ranging from 0% to 32% at 5 years after an ankle replacement, with an overall failure rate of 10%.[8,40] A review of national registry data from Norway, Sweden, and New Zealand revealed mean revision rates of 21.8% and 43.5% at 5 and 10 years, respectively, after ankle replacement with the STAR, Agility, Buechel-Pappas, Hintegra, Mobility, and Ramses prostheses.[25]

Limitations

In this analysis, the mere presence of DM was assessed rather than actual hemoglobin A1c (HbA1c) levels. Some studies have suggested the positive association between tight preoperative glycemic control and clinical outcomes[5,28,31] as opposed to simply the presence of DM. However, a recent review[29] demonstrated that many of the studies analyzed HbA1c as a dichotomous variable when regression analysis should be used. Furthermore, the authors concluded that there is no clear evidence indicating a critical level of HbA1c beyond which the risk of postoperative complications becomes significant or the risk-to-benefit ratio becomes prohibitive. Further investigation regarding the HbA1c cut-off levels and its relation to TAA survival are needed. Another limitation is the inclusion of 2 different implants in the present study. A third-generation mobile bearing system and a fourth-generation fixed bearing system were analyzed as a single cohort. Also, the numbers in each group were different (Hintegra = 85, Infinity = 22) which could be a potential confounding factor in the analysis. Nevertheless, numerous studies that have compared fixed vs mobile bearing TAA have not found significant differences in terms of clinical outcomes, survival rate, gait biomechanics, or tibial bone strain.[8,14,52,41,46] Another possible concern is that a mobile bearing TAA could shift the T-T ratio over time and differ with a fixed bearing TAA; given that we utilized the first WB radiographs at 6 to 12 weeks postsurgery for both implant designs, there should be minimal difference between a fixed and a mobile bearing TAA. This belief is supported by a recent publication by Usuelli et al.[50] In the authors' opinion, this model is valid for mobile and fixed bearing TAA systems, but further research is needed, perhaps with a larger sample of a single TAA design. The imaging modality of choice in the assessment of TAA alignment is controversial. Radiographic measurements, although inexpensive and fast to obtain, are not as reliable as other imaging modalities given that they are user dependent and sensitive to patient positional differences.[16,26] Weightbearing CT scan could be a more accurate method to quantify TAA component alignment and rotation with potentially decreased image quality and increased monetary cost. Also, this predictive model was constructed based on 107 TAA and 12 failures. Although these are relatively small numbers, the data were prospectively collected and the internal validity of our predictive model was confirmed via statistical analysis. We acknowledge that further multicenter studies with larger numbers are needed to confirm our findings. Finally, this study only included patients with TAAs performed by experienced foot and ankle orthopedic surgeons, and thus the predictive model may not be generalizable to cases performed by less experienced hands. Further research inclusive of surgeons of variable experience is warranted.

Conclusion

In conclusion, this is the first reported predictive model that incorporated patient baseline demographics, PROMs, and postoperative TAA alignment with TAA survival. The number of TAAs analyzed achieved adequate statistical power and there was an acceptable intermediate follow-up median of 49 months. This model could help foot and ankle surgeons counsel patients regarding implant survival and expectations post-TAA surgery. In addition, it may allow surgeons to identify modifiable risk factors for TAA failure based on baseline patient characteristics and demographics, PROMs, and TAA radiographic alignment parameters.

Acknowledgments

We would like to acknowledge Manuel J. Pellegrini for his contribution to this study.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Kevin Wing, MD, FRCSC, Alastair Younger, MD, ChB, MSc, ChM, FRCSC, Andrea Veljkovic, MD, FRCSC, and Murray Penner MD, FRCSC, report personal fees from Wright Medical Company, other from Zimmer, outside the submitted work. ICMJE forms for all authors are available online.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

ORCID iDs

Mario I. Escudero, MD, https://orcid.org/0000-0002-8076-3360
Vu Le, MD, FRCSC, https://orcid.org/0000-0003-1625-4200
Michael Symes, MBBS, MPH, FRACS, https://orcid.org/0000-0002-4613-2653

References

1. Abram SGF, Marsh AG, Brydone AS, Nicol F, Mohammed A, Spencer SJ. The effect of tibial component sizing on patient reported outcome measures following uncemented total knee replacement. *Knee*. 2014;21(5):955-959.
2. Barg A, Elsner A, Anderson AE, Hintermann B. The effect of three-component total ankle replacement malalignment on clinical outcome: pain relief and functional outcome in 317 consecutive patients. *J Bone Joint Surg*. 2011;93(21):1969-1978.
3. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ. Can preoperative patient-reported outcome measures be used to predict meaningful improvement in function after TKA? *Clin Orthop Relat Res*. 2017;475(1):149-157.
4. Berliner JL, Brodke DJ, Chan V, SooHoo NF, Bozic KJ. John Charnley Award: preoperative patient-reported outcome measures predict clinically meaningful improvement in function after THA. *Clin Orthop Relat Res*. 2016;474(2):321-329.

5. Cancienne JM, Cooper MT, Laroche KA, Verheul DW, Werner BC. Hemoglobin A1c as a predictor of postoperative infection following elective forefoot surgery. *Foot Ankle Int*. 2017;38(8):832-837.
6. Choi WJ, Lee JS, Lee M, Park JH, Lee JW. The impact of diabetes on the short- to mid-term outcome of total ankle replacement. *Bone Joint J*. 2014;96(12):1674-1680.
7. Croft S, Wing KJ, Daniels TR, et al. Association of Ankle Arthritis Score with need for revision surgery. *Foot Ankle Int*. 2017;38(9):939-943.
8. Daniels TR, Younger AS, Penner M, et al. Intermediate-term results of total ankle replacement and ankle arthrodesis. *J Bone Joint Surg*. 2014;96(2):135-142.
9. Daum WJ, Brinker MR, Nash DB. Quality and outcome determination in health care and orthopaedics: evolution and current structure. *J Am Acad Orthop Surg*. 2000;8(2): 133-139.
10. Deleu P-A, Devos Bevernage B, Gombault V, Maldague P, Leemrijse T. Intermediate-term results of mobile-bearing total ankle replacement. *Foot Ankle Int*. 2015;36(5):518-530.
11. Domsic RT, Saltzman CL. Ankle osteoarthritis scale. *Foot Ankle Int*. 1998;19(7):466-471.
12. Espinosa N, Walti M, Favre P, Snedeker JG. Misalignment of total ankle components can induce high joint contact pressures. *J Bone Joint Surg*. 2010;92(5):1179-1187.
13. Fukuda T, Haddad SL, Ren Y, Zhang L-Q. Impact of talar component rotation on contact pressure after total ankle arthroplasty: a cadaveric study. *Foot Ankle Int*. 2010;31(5):404-411.
14. Gaudot F, Colombier J-A, Bonnin M, Judet T. A controlled, comparative study of a fixed-bearing versus mobile-bearing ankle arthroplasty. *Foot Ankle Int*. 2014;35(2):131-140.
15. Glazebrook M, Daniels T, Younger A, et al. Comparison of health-related quality of life between patients with end-stage ankle and hip arthrosis. *J Bone Joint Surg*. 2008;90(3): 499-505.
16. Hanna RS, Haddad SL, Lazarus ML. Evaluation of periprosthetic lucency after total ankle arthroplasty: helical CT versus conventional radiography. *Foot Ankle Int*. 2007;28(8):921-926.
17. Hintermann B, Valderrabano V, Dereymaeker G, Dick W. The Hintegra ankle: rationale and short-term results of 122 consecutive ankles. *Clin Orthop Relat Res*. 2004;424:57-68.
18. Hofmann KJ, Shabin ZM, Ferkel E, Jockel J, Slovenkai MP. Salto Talaris total ankle arthroplasty. *J Bone Joint Surg*. 2016;98(24):2036-2046.
19. Hosmer DW, Lemeshow S, Sturdivant RX. *Applied Logistic Regression*. New York, NY: John Wiley; 2013.
20. Hsu AR, Jones CP, Cohen BE, Davis WH, Ellington JK, Anderson RB. Clinical outcomes and complications of percutaneous Achilles repair system versus open technique for acute Achilles tendon ruptures. *Foot Ankle Int*. 2015;36(11): 1279-1286.
21. Huang NFR, Dowsey MM, Ee E, Stoney JD, Babazadeh S, Choong PF. Coronal alignment correlates with outcome after total knee arthroplasty: five-year follow-up of a randomized controlled trial. *J Arthroplasty*. 2012;27(9):1737-1741.
22. Kakkar R, Siddique MS. Stresses in the ankle joint and total ankle replacement design. *Foot Ankle Surg*. 2011;17(2): 58-63.
23. Kamrad I, Henricsson A, Karlsson MK, et al. Poor prosthesis survival and function after component exchange of total ankle prostheses. *Acta Orthop*. 2015;86(4):407-411.
24. Krause FG, Silvestro MD, Penner MJ, et al. Inter- and intraobserver reliability of the COFAS end-stage ankle arthritis classification system. *Foot Ankle Int*. 2010;31(2):103-108.
25. Labek G, Klaus H, Schlichtherle R, Williams A, Agreiter M. Revision rates after total ankle arthroplasty in sample-based clinical studies and national registries. *Foot Ankle Int*. 2011;32(8):740-745.
26. Lawlor MC, Kluczynski MA, Marzo JM. Weight-bearing cone-beam CT scan assessment of stability of supination external rotation ankle fractures in a cadaver model. *Foot Ankle Int*. 2018;39(7):850-857.
27. Lefrancois T, Younger A, Wing K, et al. A prospective study of four total ankle arthroplasty implants by non-designer investigators. *J Bone Joint Surg*. 2017;99(4):342-348.
28. Liu J, Ludwig T, Ebraheim NA. Effect of the blood HbA1c level on surgical treatment outcomes of diabetics with ankle fractures. *Orthop Surg*. 2013;5(3):203-208.
29. Lopez LF, Reaven PD, Harman SM. Review: the relationship of hemoglobin A1c to postoperative surgical risk with an emphasis on joint replacement surgery. *J Diabetes Complicat*. 2017;31(12):1710-1718.
30. Madeley NJ, Wing KJ, Topliss C, Penner MJ, Glazebrook MA, Younger AS. Responsiveness and validity of the SF-36, Ankle Osteoarthritis Scale, AOFAS Ankle Hindfoot Score, and Foot Function Index in end stage ankle arthritis. *Foot Ankle Int*. 2012;33(1):57-63.
31. Maradit Kremers H, Schleck CD, Lewallen EA, Larson DR, Van Wijnen AJ, Lewallen DG. Diabetes mellitus and hyperglycemia and the risk of aseptic loosening in total joint arthroplasty. *J Arthroplasty*. 2017;32(9)(suppl):S251-S253.
32. Marchant MH, Viens NA, Cook C, Vail TP, Bolognesi MP. The impact of glycemic control and diabetes mellitus on perioperative outcomes after total joint arthroplasty. *J Bone Joint Surg Am*. 2009;91(7):1621-1629.
33. Meding JB, Reddleman K, Keating ME, et al. Total knee replacement in patients with diabetes mellitus. *Clin Orthop Relat Res*. 2003;416(416):208-216.
34. Mercer J, Penner M, Wing K, Younger ASE. Inconsistency in the reporting of adverse events in total ankle arthroplasty: a systematic review of the literature. *Foot Ankle Int*. 2016;37(2):127-136.
35. Muir D, Aoina J, Hong T, Mason R. The outcome of the mobility total ankle replacement at a mean of four years: can poor outcomes be predicted from pre- and post-operative analysis? *Bone Joint J*. 2013;95(10):1366-1371.
36. Newson RB. Comparing the predictive powers of survival models using Harrell's C or Somers' D. *Stata J*. 2018;10(3): 339-358.
37. Nielsen CS, Nebergall A, Huddleston J, Kallemose T, Malchau H, Troelsen A. Medial overhang of the tibial component is associated with higher risk of inferior knee injury and osteoarthritis outcome score pain after knee replacement. *J Arthroplasty*. 2018;33(5):1394-1398.
38. Penner M, Davis WH, Wing K, Bemenderfer T, Waly F, Anderson RB. The infinity total ankle system: early clinical

results with 2- to 4-year follow-up [published online ahead of print June 1, 2018]. *Foot Ankle Spec*. doi:10.1177/1938640018777601.
39. Pinsker E, Inrig T, Daniels TR, Warmington K, Beaton DE. Reliability and validity of 6 measures of pain, function, and disability for ankle arthroplasty and arthrodesis. *Foot Ankle Int*. 2015;36(6):617-625.
40. Pyevich MT, Saltzman CL, Callaghan JJ, Alvine FG. Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. *J Bone Joint Surg*. 1998;80(10):1410-1420.
41. Queen RM, Franck CT, Schmitt D, Adams SB. Are there differences in gait mechanics in patients with a fixed versus mobile bearing total ankle arthroplasty? A randomized trial. *Clin Orthop Relat Res*. 2017;8:1-8.
42. Shrout PE, Fleiss JL. Intraclass correlations: uses in assessing rater reliability. *Psychol Bull*. 1979;86(2):420-428.
43. Sodhi N, Yao B, Newman JM, et al. A comparison of relative value units in primary versus revision total ankle arthroplasty. *Surg Technol Int*. 2017;31:322-326.
44. Stavrakis AI, SooHoo NF. Trends in complication rates following ankle arthrodesis and total ankle replacement. *J Bone Joint Surg*. 2016;98(17):1453-1458.
45. Stufkens SA, Barg A, Bolliger L, Stucinskas J, Knupp M, Hintermann B. Measurement of the medial distal tibial angle. *Foot Ankle Int*. 2011;32(3):288-293.
46. Terrier A, Fernandes CS, Guillemin M, Crevoisier X. Fixed and mobile-bearing total ankle prostheses: effect on tibial bone strain. *Clin Biomech (Bristol, Avon)*. 2017;48:57-62.
47. Tochigi Y, Suh J-S, Amendola A, Pedersen DR, Saltzman CL. Ankle alignment on lateral radiographs. Part 1: sensitivity of measures to perturbations of ankle positioning. *Foot Ankle Int*. 2006;27(2):82-87.
48. Tochigi Y, Suh J-S, Amendola A, Saltzman CL. Ankle alignment on lateral radiographs. Part 2: reliability and validity of measures. *Foot Ankle Int*. 2006;27(2):88-92.
49. Tsang S-TJ, Gaston P. Adverse peri-operative outcomes following elective total hip replacement in diabetes mellitus: a systematic review and meta-analysis of cohort studies. *Bone Joint J*. 2013;95(11):1474-1479.
50. Usuelli FG, Maccario C, Manzi L, Tan EW. Posterior talar shifting in mobile-bearing total ankle replacement. *Foot Ankle Int*. 2015;37(3):281-287.
51. Valderrabano V, Hintermann B, Dick W. Scandinavian Total Ankle Replacement. *Clin Orthop Relat Res*. 2004;424:47-56.
52. Valderrabano V, Pagenstert GI, Müller AM, Paul J, Henninger HB, Barg A. Mobile- and fixed-bearing total ankle prostheses: is there really a difference? *Foot Ankle Clin*. 2012;17(4):565-585.
53. Veljkovic A, Norton A, Salat P, et al. Lateral talar station. *Foot Ankle Int*. 2013;34(12):1669-1676.
54. Veljkovic A, Norton A, Salat P, et al. Sagittal distal tibial articular angle and the relationship to talar subluxation in total ankle arthroplasty. *Foot Ankle Int*. 2016;37(9):929-937.
55. Wing KJ, Chapinal N, Coe MP, et al. Measuring the operative treatment effect in end-stage ankle arthritis: are we asking the right questions? A COFAS multicenter study. *Foot Ankle Int*. 2017;38(10):1064-1069.
56. Yang K, Yeo SJ, Lee BP, Lo NN. Total knee arthroplasty in diabetic patients: a study of 109 consecutive cases. *J Arthroplasty*. 2001;16(1):102-106.
57. Yi Y, Cho J-H, Kim J-B, Kim J-Y, Park S-Y, Lee W-C. Change in talar translation in the coronal plane after mobile-bearing total ankle replacement and its association with lower-limb and hindfoot alignment. *J Bone Joint Surg*. 2017;99(4):e13-e10.