

Two to Five-Year Outcomes of Total Ankle Arthroplasty with the Infinity Fixed-Bearing Implant

A Concise Follow-up of a Previous Report*

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Abstract: The fixed-bearing Infinity implant (Wright Medical Group) for total ankle arthroplasty (TAA) was introduced to the U.K. market in 2014 and has rapidly become the most commonly used TAA implant. This is a follow-up report of a multicenter, non-designer, prospective observational study of 503 Infinity fixed-bearing TAA implants. The average follow-up of patients in the current report was 44.9 months (range, 28.3 to 63.9 months). The primary aim was to assess survivorship, complications, and reoperations. Secondary aims were to assess radiographic outcomes and patient-reported outcome measures (PROMs) and the influence of patient factors at 2 years. Four hundred and sixty-nine implants were evaluated at 2-year follow-up. Fifteen patients died, 8 withdrew, and 3 were lost to follow-up. The 2-year survivorship was 98.8%, and the non-revision reoperation rate was 2.8%. There was a significant improvement across all functional outcome scores from baseline to 2 years. The early experience and small rate of adverse events reported in this study continue to support the use of the Infinity TAA implant for the treatment of end-stage ankle arthritis.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

Background

The fixed-bearing Infinity implant (Wright Medical Group) for total ankle arthroplasty (TAA) was introduced to the U.K. market in 2014 and is now the most used TAA implant in the most recent registry report¹. Its use represents a notable shift in practice away from a mobile-bearing design. Initial concerns regarding fixed-bearing designs were based on poor outcomes from early-generation implants² and laboratory studies³. Recent studies have reported better outcomes of fixed-bearing compared with mobile-bearing implants⁴⁻⁷. Our group previously reported early experience with, and complications of, the fixed-bearing Infinity TAA implant with a minimum 6-month follow-up, with low levels of pain, high levels of function as measured by patient-reported outcome measures

(PROMs), and a low complication rate reported⁸. We now present the 2 to 5-year follow-up.

This was a prospective, multicenter, observational study of the Infinity TAA implant; procedures were performed at 11 hospitals across the U.K. by specialist foot and ankle orthopaedic surgeons. Included were patients ≥ 21 years of age with end-stage ankle arthritis who were deemed suitable candidates for the Infinity TAA implant by the treating surgeon. Excluded were patients whom the surgeon thought were not appropriate for an Infinity TAA (e.g., those with severe comorbidity, inadequate bone stock, or severe deformity). Cases of revision of an arthrodesis or revision of a previous TAA were excluded.

TAA has a higher rate of failure than hip and knee arthroplasty⁹ and outcome data to support the use of TAA are

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Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (<http://links.lww.com/JBJS/H729>).

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required. There has been a notable increase in the number of novel TAA implants now available on the market, many with limited non-designer outcome data. Our hypothesis was that the Infinity fixed-bearing TAA implant is a safe and effective implant for the treatment of end-stage ankle arthritis when implanted by a cohort of non-designer surgeons.

Methods

The primary aim of this study was to assess survivorship and safety, as measured by complications and reoperations, of the fixed-bearing Infinity TAA implant. Secondary aims were to assess radiographic outcomes and PROMs and the influence of patient factors on the improvement in PROMs from baseline to 2 years.

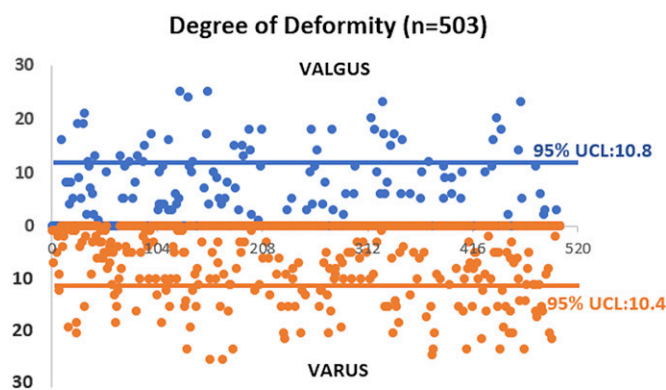
This study was registered at ClinicalTrials.gov (NCT03063593).

Surgical Technique

All procedures were performed through an anterior approach using a standardized technique with intraoperative fluoroscopy¹⁰ and either patient-specific instrumentation (PSI) or standard instrumentation. The study was pragmatic and allowed surgeons to employ their own practice with respect to surgical technique, use of PSI, thromboprophylaxis, and postoperative immobilization.

Data Collection

Patient demographics and arthritis type were recorded. Coronal plane deformity and the Canadian Orthopaedic Foot and Ankle Society (COFAS) preoperative arthritis type¹¹ were assessed on preoperative standing radiographs (Fig. 1, Table I). Adverse events, including all complications and any additional unplanned reoperations, were recorded. Revision was defined as removal or exchange of ≥ 1 of the components, not including incidental polyethylene exchange¹². All other operations constituted a reoperation other than revision. The study received ethical and local approvals in all participating centers (REC reference 15/NI/0236).



Bland-Altman plot of preoperative coronal plane deformity. UCL = upper confidence limit. (Figure reproduced with permission from: Townshend DN, Bing AJF, Clough TM, Sharpe IT, Goldberg A; UK INFINITY study group. Early experience and patient-reported outcomes of 503 INFINITY total ankle arthroplasties. *Bone Joint J.* 2021 Jul;103-B(7):1270-6. © 2021 Author(s) et al. <https://creativecommons.org/licenses/by-nc-nd/4.0/>)

TABLE I Demographics (N = 503 Ankles)*

Sex	
Male	301 (59.8%)
Female	202 (40.2%)
Age at TAA† (yr)	67.8 (23.9-88.5)
BMI† (kg/m ²)	29.3 (18.9-48.0)
Smoking status	
Current, >1 pack/day	2 (0.4%)
Current, ≤ 1 pack/day	29 (5.8%)
Never	283 (56.3%)
Previous	189 (37.6%)
COFAS type	
1 (no deformity)	261 (51.9%)
2 (intra-articular deformity)	122 (24.3%)
3 (extra-articular deformity)	31 (6.2%)
4 (preexisting hindfoot arthritis or fusion)	89 (17.7%)
Primary diagnosis	
Degenerative	327 (65.0%)
Posttraumatic	138 (27.4%)
Inflammatory arthritis	38 (7.6%)
Coronal plane deformity	
Varus $\geq 15^\circ$	58 (11.5%)
Valgus $\geq 5^\circ$	28 (5.6%)
Previous surgery on index joint	131 (26.0%)
Joints affecting ambulation	243 (48.3%)
Any concomitant health conditions	406 (80.7%)
Concomitant musculoskeletal health conditions	206 (41.0%)

*The values are given as the number, with the percentage in parentheses, except where otherwise noted. †The values are given as the mean, with the range in parentheses.

Data were collected preoperatively and then at 6 months and 1, 2, and 5 years. Adverse events at any routine or additional “out of window” visit were reported by the research staff at each individual site. Site monitoring was conducted by the sponsor.

PROMs included the Manchester-Oxford Foot Questionnaire (MOXFQ)^{13,14}, the Ankle Osteoarthritis Scale (AOS)⁸, and the 5-level EuroQol 5-Dimension (EQ-5D-5L) index¹⁵. The MOXFQ comprises 16 questions for assessing 3 domains (pain, walking/standing, and social interaction). The AOS includes a pain and a disability subscale with 9 items each. A higher score on both the MOXFQ and AOS indicates worse symptoms experienced by the patient. The minimum clinically important difference (MCID) is the smallest change in a treatment outcome that a patient would indicate as important. The MCID for the walking/standing domain of the MOXFQ, as described by Dawson et al., is 16 points^{16,17}. The MCID for the AOS, as described by Waly et al., is 12.35 points¹⁸. The EQ-5D-5L is a general health score and contains 5 items assessing mobility, self-care, usual activities, pain and

discomfort, and anxiety and depression. A higher score on the EQ-5D-5L indicates a better quality of life.

Postoperative radiographs were evaluated by the co-investigator surgeons according to an agreed-upon protocol. Radiolucencies were defined as linear or cystic, and progressive or nonprogressive. Subsidence was defined as >5 mm of sinkage or 5° angulation of either metal component. All radiolucencies were reported, with linear radiolucencies of >2 mm in width (distance from implant to bone) and cystic radiolucencies of >5 mm considered clinically notable. Those performing radiographic evaluations were not blinded to clinical and PROMs data.

Study assessments were in-person until March 2020. The COVID-19 pandemic¹⁹ led to reviews and completion of questionnaires by telephone to the extent possible. During the recovery phase from the pandemic (beginning around November 2021, and dependent on regional variation), a hybrid model of face-to-face and telephone follow-up was employed. Radiographs were obtained during the COVID pandemic only if there was a clinical indication.

Statistical Analysis

Separate statistical analyses for factors at baseline and 2 years were performed (SAS, version 9.4; SAS Institute). Compar-

isons of PROM scores among the categories of a factor were performed using a t test for 2 independent samples if the factor had 2 possible categories, or using 1-way analysis of variance (ANOVA) plus pairwise comparisons if the factor had ≥3 categories. Ninety-five percent confidence interval (CI) estimates are provided. The impact of patient factors on outcome after TAA was analyzed using 2-year improvement in the PROMs (total MOXFQ, total AOS, and EQ-5D-5L index) as dependent variables. Multivariable linear regression was performed to examine the independent effects of demographic, clinical, and surgical factors on the dependent variables. The following variables were entered into the regression analysis: age (<65 versus ≥65 years), sex, body mass index (BMI), smoking status, arthritis type, coronal deformity (<15° versus ≥15°), COFAS type, previous surgery, instrumentation type, provider/surgeon, and baseline score. The outcome variable of interest was the PROM improvement score from baseline. A stepwise linear regression analysis was used to determine the significant predictors. For the regression analysis, a p value of <0.05 was considered significant. Preliminary analysis showed that the surgeon or provider was not a significant predictor of any of the dependent variables, and this variable was therefore not

Additional Procedures at Index Surgery

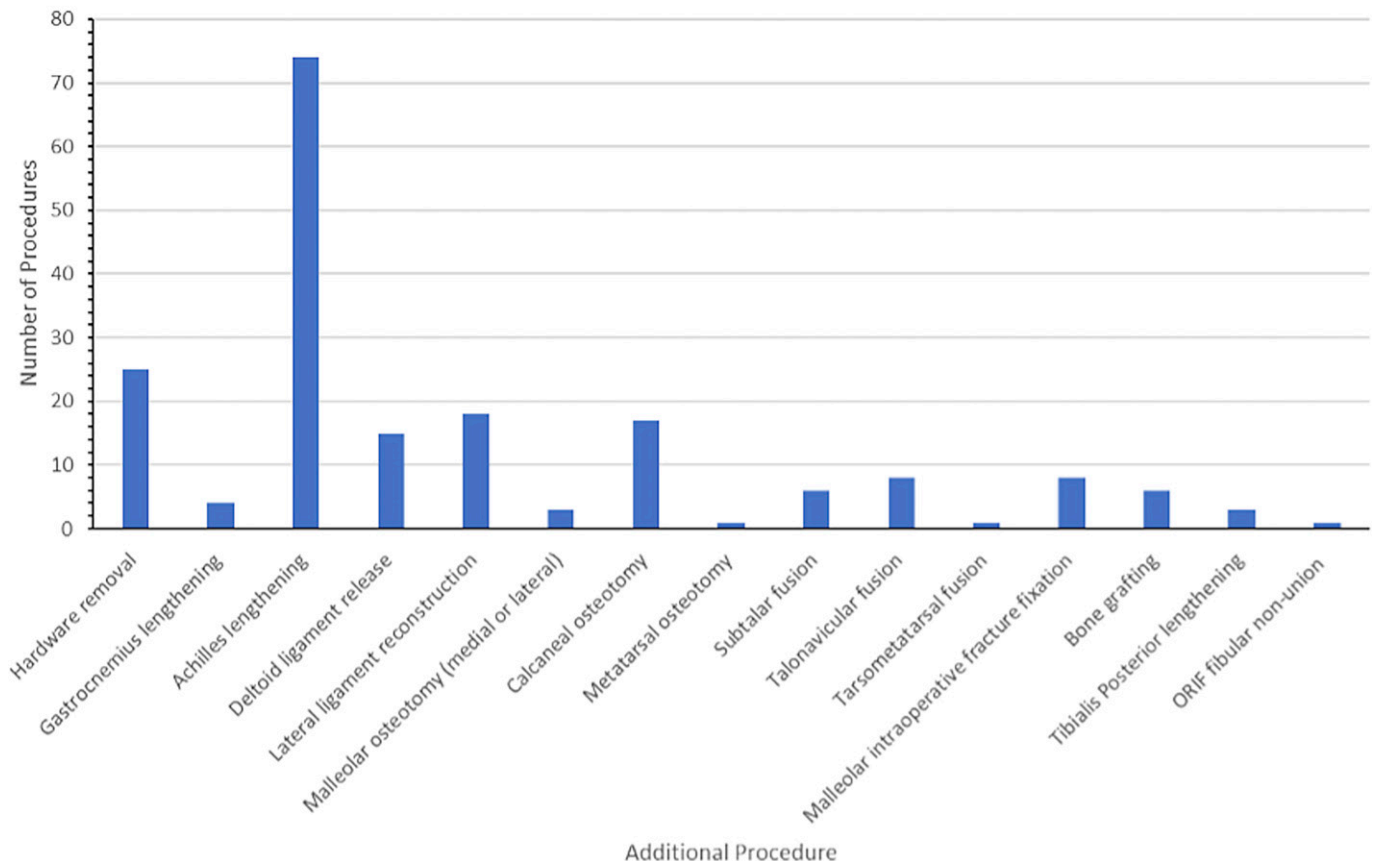


Fig. 2
Additional procedures at the time of the index surgery. ORIF = open reduction and internal fixation.

TABLE II Postoperative Complications According to Glazebrook Classification⁴⁸ (N = 503 Ankles)

Low-grade	
Intraoperative bone fracture	8 (1.6%)
Wound-healing problems	25 (5.0%)
Medium-grade	
Technical error	2 (0.4%)*
Subsidence	0
Postoperative bone fracture	5 (1.0%)
High-grade	
Deep infection	2 (0.4%)*
Aseptic loosening	6 (1.2%)*
Implant failure	0
Not related to implant	
Deep vein thrombosis	0
Pulmonary embolism	4 (0.8%)
Death	15 (3.0%)
Other	
Tibial nerve injury, Achilles tendon rupture, nonunion medial malleolar osteotomy	3 (0.6%)
*Led to revision.	

included in the final models for PROMs. Model diagnostics were calculated to validate the assumptions of the regression and to assess goodness of fit. In the final model, the effect estimates represent the predicted changes in the score improvement. For continuous variables (BMI and baseline score), these estimates relate to the expected changes in the response outcome for a 1-unit change in the predictor variable. For the categorical variables, the estimates are given relative to the reference category.

Kaplan-Meier analysis, namely the Kaplan-Meier estimator, was utilized to show the estimates of the cumulative percentage probability of implant survival. Patient deaths were censored at the date of death. Patients withdrawn from the study (including those lost to follow-up) were censored at the date of withdrawal or date of last contact. The 95% CI was calculated for each estimator. A Kaplan-Meier survivorship curve was utilized to graphically show the Kaplan-Meier estimator, with the accompanying 95% CI, over time. An analysis of covariance (ANCOVA) model was utilized to assess whether the increase in PROMs (AOS, MOXFQ, and EQ-5D-5L separately) from baseline differed statistically according to whether the patient developed a >2-mm linear radiolucency. The 2-year improvements from baseline for the PROMs were compared with the established MCIDs. The percentage of patients achieving, or exceeding, the MCID in scores was calculated for each visit.

Because of the interim nature of the present study, a post-hoc power calculation was conducted to ensure that sufficient statistical power was available for the ANOVA analyses for the MOXFQ, AOS, and EQ-5D-5L. The power analysis was implemented in SAS 9.4 (SAS Institute). The sample sizes avail-

able for use in the multiple linear regression analyses, after missing data were removed, were 470, 466, and 488, respectively, for the MOXFQ, AOS, and EQ-5D-5L improvements. The final models resulted in R² values of 0.1368 for the MOXFQ, 0.2347 for the AOS, and 0.4085 for the EQ-5D-5L. The power to detect significant effects utilizing those available sample sizes and the corresponding R² values was >90% for each of separately modeled patient-reported outcome measures (MOXFQ, AOS, and EQ-5D-5L). The 95% CI estimates are provided for all statistical estimates.

Source of Funding

This study was funded by Wright Medical, now part of Stryker, and adopted into the U.K. National Institute for Health and Care Research (NIHR) portfolio.

Results

Five hundred and nineteen ankles in 512 patients were enrolled between April 2016 and November 2019 from 11 centers. Sixteen ankles were withdrawn from the study prior to implantation: 2 were excluded as they received different implants, 4 were excluded as they proceeded to arthrodesis, 1 was excluded for arthrodesis takedown and conversion to TAA, and the remainder were withdrawn because of delays to surgery. A total of 503 Infinity TAA implants in 496 patients were therefore studied.

The mean follow-up of patients in the current report was 44.9 months (range, 28.3 to 63.9 months). Of the 503

TABLE III COFAS Reoperation and Revision Coding⁴⁹

Total no. of cases	503
Cases with revision (no. [%])	8 (1.6%)*
Reoperations/revisions by type (no. [%])	
Type 1 – no reoperation within or surrounding the ankle	481 (95.6%)
Type 2 – hardware removal	0
Type 3 – unplanned procedures related to the TAA	12 (2.4%)
Type 4 – debridement of gutters or heterotopic ossification	3 (0.6%)
Type 5 – exchange of polyethylene bearing	1
Type 6 – debridement of osteolytic cysts	0
Type 7 – deep infection requiring debridement, no metal component removal	0
Type 8 – revision of arthrodesis	Not applicable
Type 9 – revision of metal components for aseptic loosening, fracture, or malposition	6 (1.2%)
Type 10 – revision of metal components secondary to infection	2 (0.4%)
Type 11 – amputation above the level of the ankle	0
*See Table IV for details of revision procedures.	

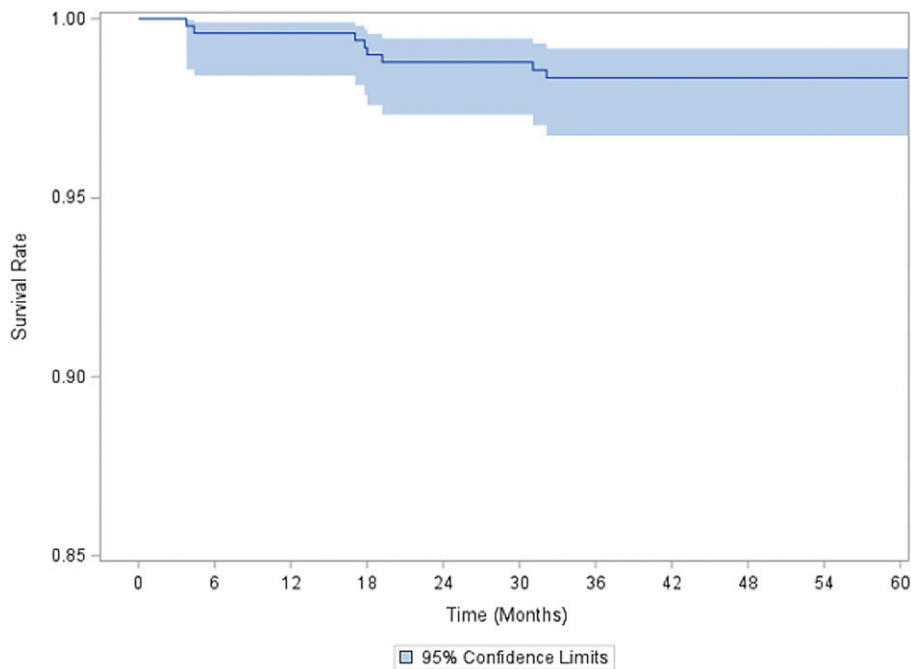


Fig. 3
Kaplan-Meier survivorship curve.

implants studied, 469 remained active in the study at the 2-year follow-up. Three patients were lost to follow-up, 8 withdrew, and 15 died of unrelated causes.

There were 190 additional procedures in 167 ankles at the index surgery (Fig. 2). Thirty-one ankles received an Inbone talar implant (flat cut talar component and part of the Infinity

TABLE IV Causes of Revision

Etiology of Arthritis	COFAS Type	Preop. Coronal Plane Deformity (Tibiotalar Angle)	Postop. Coronal Alignment	Initial Radiolucency	Time to Revision (mo)	Reason for Revision	Action
Degenerative	4	8° valgus	10° varus	No	5	Poor bone stock, intraoperative fracture, lost anterior cortical contact, and continued to dorsiflex	Revised to Inbone
Posttraumatic	4	5° varus	0°	No (tibial radiolucency of <2 mm at 6 and 12 mo)	13	Aseptic loosening, tibia	2-stage revision to Inbone
Degenerative	2	15° varus	2° varus	No	4	Deep infection	2-stage revision to Inbone
Degenerative	2	12° varus	4° varus	No (tibial radiolucency of <2 mm at 9 mo)	18	Aseptic loosening, tibia	2-stage revision to Inbone
Degenerative	1	0°	0°	Yes	19	Aseptic loosening, tibia	2-stage revision to Inbone
Degenerative	1	7° varus	1° varus	No	17	Aseptic loosening, tibia	2-stage revision to Inbone
Degenerative	1	0°	0°	No	32	Aseptic loosening, tibia	Revision to Infinity (tibia only, with polyethylene exchange)
Degenerative	2	13° valgus	0°	No	31	Deep infection	Revision to arthrodesis

TABLE V Modeling of 2-Year MOXFQ Total Score Improvement*

	Preoperative				2-Yr Improvement		2-Yr Model		
	No. Available	Mean	95% CI	P Value	Mean	95% CI	Effect Estimate	P Value	R ²
Overall model R ²									0.1368
Preoperative score							0.5437	<0.001	0.076
BMI							—	NS	—
Male†	299	72.30	70.62, 73.98	<0.0001	53.34	50.50, 56.17	—	NS	—
Female	202	79.29	77.43, 81.16		52.26	48.59, 55.94			
Age ≥65 yr†	324	73.70	72.05, 75.36	0.0029	54.81	52.11, 57.50	6.97	0.0029	0.0146
Age <65 yr	176	77.77	75.79, 79.74		49.29	45.31, 53.27			
Patient-specific instrumentation§	99	73.48	70.44, 76.52	0.2134	52.59	47.70, 57.48	—	NS	—
Standard instrumentation	402	75.52	74.11, 76.94		52.99	50.46, 55.52			
Diagnosis: posttraumatic#	138	76.12	73.61, 78.64	0.2067	55.65	51.64, 59.66	8.06	0.0019	0.016
Diagnosis: inflammatory arthritis#	38	78.94	74.68, 83.20	0.2932	49.77	40.08, 59.46	—	NS	—
Diagnosis: degenerative	325	74.25	72.65, 75.85		52.10	49.29, 54.91			
Previous smoker**	187	75.00	72.80, 77.19	0.3671	51.15	47.34, 54.97	-4.65	0.0368	0.0068
Current smoker**	31	81.33	76.62, 86.03	0.0028	48.93	36.43, 61.42	—	NS	—
Never smoker	283	74.52	72.85, 76.20		54.52	51.73, 57.30			
Had previous surgery††	131	77.63	75.02, 80.25	0.2218	47.43	42.59, 52.27	-9.96	0.0003	0.0234
No previous surgery	370	74.23	72.76, 75.70		54.77	52.27, 57.26			
Varus deformity ≥15°‡‡	58	72.91	68.41, 77.42	0.5013	54.60	47.40, 61.79	—	NS	—
Varus deformity <15°	443	75.41	74.08, 76.74		52.68	50.32, 55.04			
Valgus deformity ≥15°§§	28	73.31	68.18, 78.44	0.1971	54.66	46.47, 62.85	—	NS	—
Valgus deformity <15°	473	75.23	73.90, 76.56		52.81	50.48, 55.14			
COFAS type 1	258	75.52	73.82, 77.22		51.78	48.57, 54.99			
COFAS type 2##	123	73.12	70.44, 75.80	0.1339	54.78	50.55, 59.00	—	NS	—
COFAS type 3##	31	73.64	67.19, 80.09	0.4979	50.31	40.60, 60.02	—	NS	—
COFAS type 4##	89	77.24	74.08, 80.39	0.3396	54.61	49.14, 60.07	—	NS	—

*NS = not significant in the final model. Baseline p values based on 1-way ANOVA; comparisons including the reference category. For factors with >2 categories, the p value is based on the least-squares mean difference between the category and the reference. For the modeling of the 2-year score improvement, a stepwise regression analysis was employed with all of the factors in the first column as predictors. For continuous variables (i.e., baseline score), the effect estimate describes the change in the improvement score if the predictor variable was increased by 1 point. For categorical variables, the effect estimate is the difference relative to the reference category. †Reference = female. ‡Reference = age of <65 years. §Reference = standard instrumentation. #Reference = degenerative disease. **Reference = never smoker. ††Reference = no previous surgery. ‡‡Reference = varus deformity of <15°. §§Reference = valgus deformity of <15°. ##Reference = COFAS type 1.

Total Ankle System). Surgery was performed at 11 centers (19 surgeons), with an average of 42 implants per center (range, 14 to 97 implants). PSI was used in 101 (20.1%) of the ankles. Complications are listed in Table II. The rates of intraoperative bone fracture (malleolar) and overall deep infection were 1.6% and 0.4%, respectively. There was 1 transection of the tibial nerve, which was managed with an interposition graft. There were 4 cases of pulmonary embolism (0.8%) and no reported cases of deep vein thrombosis.

Reoperations and Revisions

Fourteen (2.8%) of the ankles required a further 16 unplanned reoperations other than revision (Table III), including 1 simultaneous subtalar arthrodesis and lateral gutter debridement. One

patient underwent an Achilles lengthening and posterior capsular debridement for heterotopic ossification, which required an incidental polyethylene exchange for surgical access. Of the other procedures related to TAA, there was 1 metatarsal osteotomy and lateral ligament repair, 1 skin graft, 1 skin flap, and 1 subtalar arthrodesis (with lateral ligament repair). All reoperations were after 12 months, except those for wound complications.

Eight cases (1.6%) were revised, and Kaplan-Meier survival analysis demonstrated a cumulative survival rate of 98.8% (95% CI, 97.3% to 99.4%) at 2 years (Fig. 3, Table IV).

Radiographic Outcomes

Radiographs were available for 451 (96.2%) of 469 ankles at 2 years. Radiolucencies were reported in 14.9%; linear radiolucencies of

TABLE VI Modeling of 2-Year AOS Total Score Improvement*

	Preoperative				2-Yr Improvement		2-Yr Model		
	No. Available	Mean	95% CI	P Value	Mean	95% CI	Effect Estimate	P Value	R ²
Overall model R ²									0.2347
Preoperative score							0.63	<0.001	0.1752
BMI							—	NS	—
Male†	300	63.23	61.19, 65.26	0.0008	45.39	42.55, 48.24	—	NS	—
Female	201	68.54	66.29, 70.80		44.56	40.84, 48.29			
Age ≥65 yr‡	325	64.68	62.73, 66.63	0.2500	47.01	44.29, 49.73	5.88	0.008	0.0126
Age <65 yr	175	66.56	64.08, 69.04		41.25	37.25, 45.25			
Patient-specific instrumentation§	99	62.09	58.41, 65.77	0.0368	44.83	39.69, 49.96	—	NS	—
Standard instrumentation	402	66.17	64.49, 67.84		45.12	42.60, 47.65			
Diagnosis: posttraumatic#	138	66.25	63.25, 69.24	0.2569	47.64	43.52, 51.77	8.26	0.0009	0.0132
Diagnosis: inflammatory arthritis#	38	71.68	67.09, 76.27	0.0127	43.99	34.71, 53.27	—	NS	—
Diagnosis: degenerative	325	64.25	62.34, 66.15		44.08	41.25, 46.91			
Previous smoker**	188	65.36	62.92, 67.80	0.2393	44.34	40.73, 47.96	—	NS	—
Current smoker**	30	70.06	64.33, 75.79	0.7418	42.56	29.69, 55.43	—	NS	—
Never smoker	283	64.86	62.77, 66.96		45.82	42.87, 48.77			
Had previous surgery††	131	67.08	64.03, 70.12	0.1890	39.74	34.75, 44.73	-9.48	0.0003	0.0209
No previous surgery	370	64.75	62.98, 66.52		46.89	44.40, 49.37			
Varus deformity ≥15°‡‡	58	62.83	57.87, 67.79	0.2393	46.82	40.13, 53.51	—	NS	—
Varus deformity <15°	443	65.69	64.08, 67.30		44.83	42.42, 47.23			
Valgus deformity ≥15°§§	28	64.31	57.80, 70.81	0.7418	45.48	36.26, 54.70	—	NS	—
Valgus deformity <15°	473	65.42	63.84, 67.00		45.04	42.71, 47.37			
COFAS type 1	258	65.48	63.43, 67.53		44.71	41.57, 47.85			
COFAS type 2##	123	63.91	60.77, 67.05	0.4109	48.53	43.94, 53.11	—	NS	—
COFAS type 3###	31	66.24	58.38, 74.10	0.8192	38.81	28.59, 49.03	-9.24	0.0292	0.008
COFAS type 4###	89	66.71	62.98, 70.45	0.5663	43.49	38.22, 48.76	—	NS	—

*NS = not significant in the final model. Baseline p values based on 1-way ANOVA; comparisons including the reference category. For factors with >2 categories, the p value is based on the least-squares mean difference between the category and the reference. For the modeling of the 2-year score improvement, a stepwise regression analysis was employed with all of the factors in the first column as predictors. For continuous variables (i.e., baseline score), the effect estimate describes the change in the improvement score if the predictor variable was increased by 1 point. For categorical variables, the effect estimate is the difference relative to the reference category. †Reference = female. ‡Reference = age of <65 years. §Reference = standard instrumentation. #Reference = degenerative disease. **Reference = never smoker. ††Reference = no previous surgery. ‡‡Reference = varus deformity of <15°. §§Reference = valgus deformity of <15°. ##Reference = COFAS type 1.

>2 mm, in 6.7%; and cystic radiolucencies of >5 mm, in 7.5%. The patients with radiolucencies did not have significantly poorer values in any domain of the PROMs compared with the patients without radiolucencies.

PROMs

Improvements in PROMs were recorded in all domains of the MOXFQ, AOS, and EQ-5D-5L from baseline to 2 years. We found that 87.9% of the patients reached the MOXFQ walking/standing MCID and 87.4% reached the AOS MCID at 2 years. The summary statistics are shown in Tables V, VI, and VII. Positive effects on improvement for both the MOXFQ and AOS were seen for the variables of an age of ≥65 years, posttraumatic

arthritis (previous fracture), and no prior surgery. Female patients reported worse baseline scores and worse postoperative scores, but similar improvement overall was seen for male and female patients. Coronal plane deformity did not significantly affect PROMs. Patients classified as COFAS type 3 showed less improvement in AOS scores. Patients with inflammatory arthritis, previous smokers, prior surgery, and patients with high BMI demonstrated less improvement in the EQ-5D-5L.

Conclusions

To our knowledge, this study is the largest report to date on the prospective collection of outcome data on fixed-bearing TAA. We report 2-year survivorship of 98.8%, with a

TABLE VII Modeling of 2-Year EQ-5D-5L Total Score Improvement*

	Preoperative				2-Yr Improvement		2-Yr Model		
	No. Available	Mean	95% CI	P Value	Mean	95% CI	Effect Estimate	P Value	R ²
Overall model R ²									0.4085
Preoperative score							-0.743	<0.001	0.3697
BMI							-0.006	0.0074	0.0096
Male†	300	0.43	0.40, 0.46	0.0215	0.35	0.32, 0.38	—	NS	—
Female	202	0.38	0.34, 0.41		0.34	0.29, 0.38			
Age ≥65 yr‡	325	0.42	0.39, 0.45	0.2377	0.35	0.32, 0.39	—	NS	—
Age <65 yr	176	0.39	0.35, 0.43		0.32	0.28, 0.37			
Patient-specific instrumentation§	99	0.43	0.39, 0.48	0.2507	0.35	0.29, 0.41	—	NS	—
Standard instrumentation	403	0.40	0.38, 0.43		0.34	0.31, 0.37			
Diagnosis: posttraumatic#	138	0.39	0.34, 0.43	0.1198	0.39	0.34, 0.43	0.063	0.0133	0.0073
Diagnosis: inflammatory arthritis#	38	0.32	0.24, 0.40	0.0137	0.31	0.22, 0.40	-0.099	0.0128	0.0095
Diagnosis: degenerative	326	0.43	0.40, 0.45		0.33	0.30, 0.36			
Previous smoker**	188	0.42	0.38, 0.45	0.8919	0.32	0.27, 0.36	-0.044	0.0379	0.0055
Current smoker**	31	0.30	0.18, 0.43	0.0187	0.36	0.21, 0.52	—	NS	—
Never smoker	283	0.41	0.39, 0.44		0.36	0.33, 0.39			
Had previous surgery††	131	0.37	0.33, 0.42	0.0519	0.33	0.27, 0.38	-0.083	0.0014	0.0069
No previous surgery	371	0.42	0.40, 0.45		0.35	0.32, 0.38			
Varus deformity ≥15°‡‡	58	0.45	0.38, 0.51	0.2199	0.35	0.27, 0.43	—	NS	—
Varus deformity <15°	444	0.40	0.38, 0.43		0.34	0.32, 0.37			
Valgus deformity ≥15°§§	28	0.43	0.34, 0.53	0.6247	0.35	0.26, 0.43	—	NS	—
Valgus deformity <15°	474	0.41	0.39, 0.43		0.34	0.32, 0.37			
COFAS type 1	259	0.41	0.38, 0.44		0.33	0.30, 0.37			
COFAS type 2###	123	0.43	0.38, 0.47	0.5742	0.36	0.30, 0.41	—	NS	—
COFAS type 3###	31	0.41	0.32, 0.49	0.9208	0.33	0.22, 0.43	—	NS	—
COFAS type 4###	89	0.38	0.33, 0.44	0.3390	0.37	0.30, 0.44	—	NS	—

*NS = not significant in the final model. Baseline p value based on 1-way ANOVA; comparison including the reference category. For factors with >2 categories, the p value is based on the least-squares mean difference between the category and the reference. For the modeling of the 2-year score improvement, the stepwise regression analysis was employed with all of the factors in the first column as predictors. For continuous variables (i.e., baseline score, body mass index [BMI]), the effect estimate describes the change in the improvement score if the predictor variable was increased by 1 point. For categorical variables, the effect estimate is the difference relative to the reference category. †Reference = female. ‡Reference = age of <65 years. §Reference = standard instrumentation. #Reference = degenerative disease. **Reference = never smoker. ††Reference = no previous surgery. ‡‡Reference = varus deformity of <15°. §§Reference = valgus deformity of <15°. ###Reference = COFAS type 1.

revision rate of 1.6% at a mean of 44.9 months (range, 28.3 to 63.9 months); 1.0% of the cases were revised due to tibial-side failure, and we found a deep infection rate of 0.4%. Cody et al.²⁰ reported a 10% revision rate among 159 ankles (mean follow-up, 20 months; range, 12 to 37 months), with 3.8% of the ankles undergoing revision due to tibial loosening, but 3.8% due to deep infection. Penner et al.²¹ reported a 3.0% revision rate among 67 Infinity TAA implants (mean follow-up, 35.4 months; range, 27 to 47 months) with tibial (and talar)-side failure in 1 case (1.5%). King et al.²² reported no revisions among 19 patients (mean follow-up, 32 months; range, 24 to 41 months). Saito et al.²³ reported a 4.7% revision

rate among 54 ankles (mean follow-up, 24.5 months; range, 18 to 39 months), all due to tibial subsidence. More recently, Baumfeld et al.³ reported no revisions among 48 ankles at an average follow-up of 4 years, and Rushing et al.⁵⁰ reported a 1.8% revision rate among 55 ankles at 22 months (range, 12 to 43 months). Other fixed-bearing, fourth-generation implants include the Zimmer Trabecular Metal, Cadence (Smith & Nephew), and Vantage (Exactech) systems. TAA with the Zimmer Trabecular Metal implant is characterized by a lateral surgical approach. Maccario et al.²⁴ reported a 2.3% revision rate among 86 patients at 60 to 90 months, and Barg et al.²⁵ reported a 7% revision rate among 55 patients at a mean of

24 months. Early studies reported potential problems involving lateral wound complications^{24,26}. Three studies of the Cadence TAA reported revision rates of 12.5% at 12 to 33 months²⁷, 5.2% at a minimum of 2 years²⁸, and 0% at a minimum of 2 years²⁹. The Vantage TAA offers both fixed and mobile-bearing options; King et al. reported satisfactory results with no revisions in a fixed-bearing cohort of 22 implants at 24 to 30 months³⁰.

In our study, patients ≥ 65 years of age had significantly better improvement in patient-reported outcomes. Kofoed and Lundberg-Jensen³¹ first reported on the impact of age on the clinical outcome and survival rate of TAA in a cohort of 100 ankles, finding no significant impact on outcome or survival rate. Other studies in smaller cohorts have similarly found no effect of age on clinical outcome^{32,33}. A study investigating the effect of sex on both ankle replacement and ankle arthrodesis found higher preoperative AOS scores for females but similar overall improvements in males and females³⁴. Systematic reviews within knee and hip arthroplasty have shown significantly worse preoperative and postoperative pain and disability outcomes for female patients³⁵. Theories regarding these differences include sex-specific biological differences, gender differences in pain perception and behavior, sex-specific thresholds for undergoing surgery, and subconscious bias of the physicians^{36,37}. Sex has not been shown to influence revision rate³⁸.

We found no significant difference in improvement in PROM scores between patients with varus or valgus deformity of $\geq 15^\circ$ compared with $< 15^\circ$. Early studies reported increased failure rates in TAA with preoperative deformity. Wood and Deakin³⁹ suggested a threshold of 15° , and Haskell and Mann reported a 10-fold greater failure rate with the presence of coronal plane deformity⁴⁰. However, more recently, authors have reported similar results to those of this series, with comparable results achieved with notable deformity, provided that appropriate additional procedures are performed to balance the foot and ankle⁴¹⁻⁴³. In the COFAS-type analysis, patients classified as type 3 (extra-articular hindfoot deformity) reported less improvement at 2 years for the AOS outcome but not for the MOXFQ. Shlykov et al. similarly reported less improvement among patients with higher COFAS types⁵¹ and this information may be useful in counseling patients around expectations and the shared decision-making process.

We did not find a difference in outcomes between the use of standard instrumentation and PSI. Other studies have shown benefits of PSI in terms of operative time and reduced fluoroscopy radiation exposure⁴⁴. Longer-term studies of PSI versus standard instrumentation are required.

The strengths of this study were the large number of patients and the inclusion of multiple non-designer sites, including specialist and district general hospitals. Furthermore, the pragmatic design ensures that the results are generalizable and allows surgeons to translate these findings to their own practice. Our analysis of the influence of patient factors on patient-reported outcome at 2 years will help inform the shared decision-making process when counseling patients.

The weaknesses of this study include potential reporting bias, although regular investigator meetings and annual note review by each principal investigator (PI) helped to mitigate any missing data. The exception was during the COVID pandemic, but all PIs carried out a note review after the lockdowns ended and prior to collection of the data for this paper. Telephone questionnaires may be positively biased⁴⁵ but were administered by independent research staff. Kaplan-Meier analysis treats death as a censoring event, and the competing risk of death may also be considered a limitation to survivorship analysis. An independent radiographic assessment was not undertaken. Post-implantation alignment has been shown to be reliable compared with alternative TAA systems^{22,46,47} and was therefore not specifically addressed in this large cohort.

The 2 to 5-year outcomes reported in this study support the continued use of the Infinity TAA implant as a safe and effective implant for use in the treatment of end-stage ankle arthritis. While older, male patients without prior surgery showed the greatest improvements, patients across all groups demonstrated significant reported functional gains. ■

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