■ FOOT & ANKLE

Early experience and patient-reported outcomes of 503 INFINITY total ankle arthroplasties

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Aims

This is a multicentre, non-inventor, prospective observational study of 503 INFINITY fixed bearing total ankle arthroplasties (TAAs). We report our early experience, complications, and radiological and functional outcomes.

Methods

Patients were recruited from 11 specialist centres between June 2016 and November 2019. Demographic, radiological, and functional outcome data (Ankle Osteoarthritis Scale, Manchester Oxford Questionnaire, and EuroQol five-dimension five-level score) were collected preoperatively, at six months, one year, and two years. The Canadian Orthopaedic Foot and Ankle Society (COFAS) grading system was used to stratify deformity. Early and late complications and reoperations were recorded as adverse events. Radiographs were assessed for lucencies, cysts, and/or subsidence.

Results

In all, 500 patients reached six-month follow-up, 420 reached one-year follow-up, and 188 reached two-year follow-up. The mean age was 67.8 years (23.9 to 88.5). A total of 38 patients (7.5%) presented with inflammatory arthritis. A total of 101 (20.0%) of implantations used patient-specific instrumentation; 167 patients (33.1%) underwent an additional procedure at the time of surgery. A total of seven patients died of unrelated causes, two withdrew, and one was lost to follow-up. The mean follow-up was 16.2 months (6 to 36). There was a significant improvement from baseline across all functional outcome scores at six months, one, and two years. There was no significant difference in outcomes with the use of patient-specific instrumentation, type of arthritis, or COFAS type. Five (1.0%) implants were revised. The overall complication rate was 8.8%. The non-revision reoperation rate was 1.4%. The 30-day readmission rate was 1.2% and the one-year mortality 0.74%.

Conclusion

The early experience and complications reported in this study support the current use of the INFINITY TAA as a safe and effective implant in the treatment of end-stage ankle arthritis.

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Introduction

Total ankle arthroplasty (TAA) has become increasingly popular as an alternative to ankle arthrodesis.[1,2] The National Joint Registry for England and Wales has captured ankle arthroplasties from 1 January 2010. Up until the 31 December 2019, there were 7,837 procedures recorded including data on 12 different implants.[3] The INFINITY TAA (Wright Medical, USA) is a highly instrumented, fourth generation, fixed bearing, three component TAA. It was released to the European market in 2014, where it is CE marked for uncemented use. In 2019, it was the most commonly used (67.4%) TAA in the UK.[3] Prior to the release of the INFINITY TAA, almost all implants in the UK registry were of a mobile bearing design.

With the introduction of Medical Device Regulation 2017/745 (MDR), it is now essential for companies to develop improved clinical documentation and follow-up of all implants, and is especially important in the responsible

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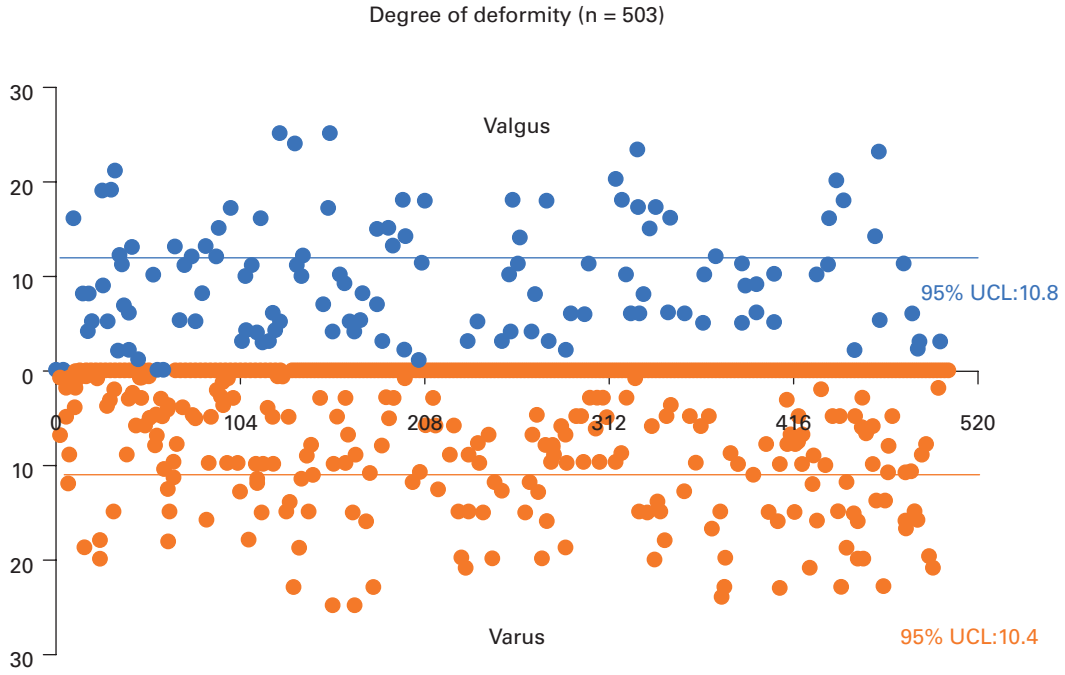

Fig. 1

Bland-Altman plot showing range of coronal plane deformity.

Table I. Demographic data.

Variable	Data
Sex, M:F, n (%)	301:202 (59.8:40.2)
Mean age , yrs (range)	67.8 (23.9 to 88.5)
Mean BMI, kg/m^2 (range)	29.3 (18.9 to 48.0)
Smoking status, n (%)	
Current > one pack/day	2 (0.40)
Current ≤ one pack/day	29 (5.77)
Never	283 (56.26)
Previous	189 (37.57)
COFAS type, n (%)	
Type 1 (no deformity)	261 (51.9)
Type 2 (intra-articular deformity)	122 (24.2)
Type 3 (extra-articular deformity)	31 (6.2)
Type 4 (pre-existing hindfoot arthritis or fusion)	89 (17.7)
Primary diagnosis, n (%)	
Degenerative	327 (65.0)
Post-traumatic	138 (27.4)
Inflammatory arthritis	38 (7.6)

COFAS, Canadian Orthopaedic Foot and Ankle Society.

Table II. Additional procedures (at index arthroplasty).

Procedure	n
Ankles with additional procedure	167
Hardware removal	25
Gastrocnemius lengthening	4
Achilles lengthening	74
Deltoid ligament release	15
Lateral ligament reconstruction	18
Malleolar osteotomy (medial or lateral)	3
Calcaneal osteotomy	17
Metatarsal osteotomy	1
Subtalar fusion	6
Talonavicular fusion	8
Tarsometatarsal fusion	1
Malleolar intraoperative fracture fixation	8
Bone grafting	6
Tibialis posterior lengthening	3
ORIF fibular nonunion	1
Total number of additional procedures	190

ORIF, open reduction and internal fixation.

introduction of technology.[4] Substantial clinical data with extensive follow-up is required to demonstrate that any new implant is safe and clinically effective.[5]

The aim of this study is to describe the early complications, reoperations, patient-reported outcomes, and radiological analysis of 503 INFINITY TAA.

Methods

Study design. A prospective, multicentre, observational study was designed to collect data on a minimum of 500 patients implanted with the INFINITY TAA. Inclusion criteria were patients aged over 21 years with end-stage ankle arthritis, and those deemed suitable for implantation with an INFINITY TAA by the treating surgeon. Exclusion criteria included patients not deemed suitable for implantation of an INFINITY TAA, such as those with poor bone stock, severe deformity, or severe comorbidity. Conversions of arthrodesis to arthroplasty or revision from previous TAA were excluded. All surgery was performed by surgeons experienced in performing ankle joint arthroplasty (> ten TAA/year) and who had received training on using the INFINITY TAA.

Table III. Complications (Glazebrook classification).[13]

Grade	n (%)
Low grade	
Intraoperative bone fracture	8 (1.6)
Wound healing problems	19 (3.8)
Medium grade	
Technical error	1 (0.2)*
Subsidence	0 (0.0)
Postoperative bone fracture	1 (0.2)
High grade	
Deep infection	1 (0.2)*
Aseptic loosening	3 (0.6)*
Implant failure	0 (0.0)
Not related to implant	
Deep vein thrombosis	0 (0.0)
Pulmonary embolism	3 (0.6)†
Death	7 (1.4)
Other	
Tibial nerve injury	1 (0.2)

*Led to revision.
†Deep vein thrombosis not reported.

Table IV. Canadian Orthopaedic Foot and Ankle Society reoperation and revision coding.[14]

Variable	n (%)
Total cohort	503
Cases with no reoperations	491 (97.6)
Cases with reoperation	7 (1.4)*
Cases with revision	5 (1.0)
Reoperations by type	
2: Hardware removal	N/A
3: Repeat operation outside the ankle arthroplasty	6 (1.2)
4: Debridement of gutters or heterotopic ossification	2 (0.4)
5: Exchange of polyethylene bearing	N/A
6: Debridement of osteolytic cysts	N/A
7: Deep infection requiring debridement, no metal component removal	N/A
9: Revision of metal components for aseptic loosening, fracture or malposition	4 (0.8)
10: Revision of metal components secondary to infection	1 (0.2)
11: Amputation above the level of the ankle	N/A

*One ankle underwent two reoperations (subtalar fusion and lateral gutter debridement).
N/A, not applicable.

In all, 519 ankles in 512 patients were recruited between April 2016 and November 2019 from 11 centres. A total of 16 ankles withdrew from the study prior to implantation, of which two were excluded as they received different implants (Salto (Integra Lifesciences) and INBONE (Wright Medical)), four were excluded as they proceeded to fusion, one revision from fusion to TAA was excluded, and the remainder were withdrawn for delays to surgery. A total of 503 INFINITY TAA in 496 patients were studied.

Technique. All procedures were performed through an anterior approach using either patient-specific instrumentation (PSI, Prophecy; Wright Medical, USA) or standard instrumentation using a standardized technique with intraoperative fluoroscopy documented previously.[6] Thromboprophylaxis and postoperative management was according to local protocol.

Preoperatively, patient demographics, comorbidities, and aetiology of arthritis were recorded. Standing radiographs were assessed for coronal plane deformity and the Canadian Orthopaedic Foot and Ankle Society (COFAS)[7] preoperative arthritis type (see Table I and Figure 1). All complications and any additional unplanned reoperations were reported as adverse events. Revisions were defined as per Henricson et al[8] as removal or exchange of one or more of the components. All other operations constituted a reoperation.

The study protocol required data collection preoperatively and then at six months, one year, two years, five years, seven years, and ten years. Patient-reported outcome questionnaires included the disease-specific Manchester-Oxford Foot and Ankle Questionnaire (MOXFQ)[9] and Ankle Osteoarthritis Score (AOS),[10] and the general health measure EuroQol five-dimension five-level (EQ-5D-5L).[11]

Postoperative radiographs were assessed by the treating surgeon (a member of the Infinity Study group) and reported according to an agreed protocol. Radiolucencies were defined as linear or cystic, progressive or non-progressive. All radiolucencies were reported. Linear radiolucencies > 2 mm in width (distance from implant to bone) and cystic radiolucencies > 5 mm were considered significant.

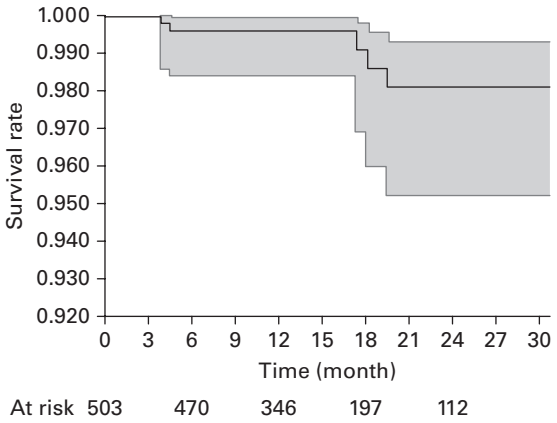

Fig. 2

Kaplan Meier curve with 95% confidence intervals and at risk patients.

Study reviews were conducted in-person for all visits until March 2020. The COVID-19 pandemic[12] led to telephone reviews and completion of questionnaires where possible. Radiographs were only obtained at this time only if there was a clinical need. Adverse events, however, were still recorded.

Statistical analysis. Statistical analyses were performed using statistical software (SAS version 9.4; SAS, USA). Tests for significant improvement from baseline and at each postoperative follow-up were performed via a paired *t*-test for two related samples or a Wilcoxon signed (WS) rank test when normality assumption was not met. A type 1 error rate of 5% ($p < 0.05$) was accepted to detect a statistically significant difference. Preliminary comparisons of patient-reported outcome measure improvement at six-month and at one-year follow-up were carried out for instrumentation (standard vs specific), arthritic, or COFAS type (types 1 to 4), and degree of deformity ($< 10°$ vs $\geq 10°$ deformity in varus/valgus). The comparisons

Table V. Causes of revision.

Aetiology of arthritis	COFAS type	Preoperative coronal plane deformity (tibio-talar angle)	Postoperative coronal alignment	Initial lucency?	Time to revision, mths	Reason for revision	Action
Osteoarthritis	4	8° valgus	10° varus	No	5	Poor bone stock, Intraoperative fracture, lost anterior cortical contact and continued to dorsiflex	Revised to INBONE
Post-traumatic	4	5° varus	0°	Nil initially Hazy tibial lucency < 2 mm at 6/12 months	13	Aseptic loosening tibia	Two stage revision to INBONE
Osteoarthritis	2	15° varus	2° varus	No	4	Deep infection	Two stage revision, awaiting IMBONE
Post-traumatic	2	12° varus	4° varus	No, tibial radiolucency at 9 months	18	Aseptic loosening tibia	Two stage revision, awaiting INBONE
Osteoarthritis	1	0°	0°	Yes	19	Aseptic loosening tibia	Two stage revision, awaiting INBONE

COFAS, Canadian Orthopaedic Foot and Ankle Society.

Table VI. Patient-reported outcome measures.

Outcome measure	Baseline (n = 503)	Six months (n = 476)		One year (n = 420)		Two years (n = 188)	
	Total, mean (SD)	Total, mean (SD)	Change from baseline, mean (SD)*	Total, mean (SD)	Change from baseline, mean (SD)*	Total, mean (SD)	Change from baseline, mean (SD)*
Total MOXFQ	75.1 (14.6)	30.3 (25.3)	-45.0 (25.1)	25.7 (25.0)	-49.0 (25.0)	22.7 (25.2)	-51.0 (24.4)
Pain	71.5 (17.4)	31.5 (25.7)	-40.0 (26.4)	28.0 (25.8)	-43.0 (26.2)	24.7 (25.9)	-47.0 (24.4)
Walking/standing	85.0 (15.1)	34.9 (29.4)	-50.0 (30.2)	28.7 (29.0)	-56.0 (30.1)	26.0 (29.2)	-58.0 (29.7)
Social interaction	62.3 (22.0)	23.0 (24.7)	-39.0 (26.5)	19.5 (24.3)	-39.0 (26.5)	16.8 (23.9)	-42.0 (25.3)
Total AOS	65.4 (17.4)	24.2 (22.3)	-41.0 (24.1)	21.4 (22.5)	-43.0 (24.3)	20.1 (23.3)	-43.0 (24.7)
Disability	70.6 (17.3)	27.0 (25.2)	-46.0 (26.0)	23.9 (25.1)	-46.0 (26.0)	22.8 (26.0)	-45.0 (26.6)
Pain	60.4 (19.6)	21.5 (21.8)	-41.0 (25.7)	18.8 (21.9)	-41.0 (25.7)	17.5 (23.1)	-41.0 (26.7)
EQ-5D index	0.41 (0.25)	0.73 (0.22)	-0.3 (0.3)	0.74 (0.24)	-0.3 (0.3)	0.75 (0.24)	-0.3 (0.3)

*All $p < 0.001$ for change from baseline based on *t*-test and Wilcoxon signed rank test.
AOS, Ankle Osteoarthritis Score; EQ-5D, EuroQol five-dimension; MOXFQ, Manchester-Oxford Foot and Ankle Questionnaire; SD, standard deviation.

were implemented via analysis of covariance (ANCOVA) with groups as a fixed effect, and the baseline as covariate.

Results

Of the 503 implants studied, one patient was lost to follow-up and two withdrew consent to follow-up. Therefore, 500 reached the six-month follow-up window, of which 420 (83.5%) reached one-year follow-up, and 188 (37.4%) reached two-year follow-up.

Surgeons used patient specific instrumentation in 99 patients (19.7%). A total of 190 additional procedures were performed in 167 ankles, the majority of which were procedures to lengthen the gastrocnemius or achilles (Table II). In all, 31 patients were implanted with an INBONE talus. Surgery was performed by 19 surgeons in 11 centres. Centres contributed an average of 42 (20 to 97) implants.

Overall, seven patients died (unrelated to TAA surgery). The 30-day mortality was 0% and the one year mortality was 0.74%. The 30-day readmission rate was 1.2%.

Postoperative complications related to the surgery are listed in Table III. The rate of intraoperative malleolar fracture was 1.6% and deep infection rate 0.2%. There was a single case of transection of tibial nerve which was managed with an interposition graft. There were three pulmonary emboli (0.6%) and no reported deep vein thrombosis (DVT).

Reoperations and revisions. A total of seven patients (1.4%) required further unplanned reoperation other than revisions. Table IV lists reoperations according to the COFAS reporting classification.[14] One patient underwent a subtalar fusion and lateral gutter debridement at the same operation.

Of the procedures related to TAA, there was one first ray dorsiflexion osteotomy and lateral ligament reconstruction, one split thickness skin graft, one rotational skin flap, and one subtalar fusion (with concomitant lateral ligament reconstruction). All reoperations, with the exception of those related to wound complications, were at 12 months or longer.

Five patients were revised, giving cumulative survival rates of 99.6% at six months, 99.5% at one year, and 97.3% at two years (Figure 2). Details of the revision procedures are in Table V.

Patient-reported outcomes. There were improvements in patient-reported outcome scores recorded in all domains of the MOXFQ, AOS, and EQ-5D from baseline to six months, which were maintained at one year and two years ($p < 0.001$)

(see Table VI). The minimum clinically important difference (MCID) is defined as the smallest change in a treatment outcome that a patient would indicate as important. The MCID in the walking standing domain of the MOXFQ, described by Dawson et al,[15,16] was 16 points. Using this value, 83.6% reached MOXFQ walking/standing MCID at six months, 89.4% at one year, and 88.2% at two years. The MCID in the total AOS, described by Coe et al,[17] is 28 points. Using this value, 86.7% reached AOS MCID at six months, 89.0% at one year, and 87.2% at two years.

There was no significant difference in change from baseline to six months between standard and patient specific instrumentation (MOXFQ p = 0.33, AOS 0.21, EQ-5D 0.23) arthritis type (MOXFQ 0.90, AOS 0.49, EQ-5D 0.63) or COFAS type (MOXFQ 0.37, AOS 0.09, EQ-5D 0.47) and baseline to one year between standard and patient specific instrumentation (MOXFQ 0.08, AOS 0.21, EQ-5D 0.09), arthritis type (MOXFQ 0.44, AOS 0.18, EQ-5D 0.19) or COFAS type (MOXFQ 0.56, AOS 0.11, EQ-5D 0.15). Patients with coronal plane deformity > 10° showed greater improvement compared to those < or equal to 10° at six months in all domains of MOXFQ only at six months (p = 0.030), but this was not evident at one year.

Radiological outcomes. Radiographs were available for review in 472/500 patients (93.8%) at six months, 374/420 (89.0%) at one year, and 149/188 (79.2%) at two years. Visible radiolucencies were reported in 10.4% at six months, 14.2% at one year, and 16.1% at two years. Of these, linear radiolucencies > 2 mm in width were reported in 27 patients (5.8%) at six months, 29 (7.7%) at one year, and ten (6.7%) at two years. Cystic radiolucencies > 5 mm were reported in three patients (0.6%) at six months, six (1.7%) at one year, and eight (5.4%) at two years. Of the 49 linear radiolucencies reported at six months, 17 (34.7%) were reported to still be visible at one year and four at two years.

There was no negative significant correlation in any domain of the patient reported outcomes between the presence or absence of any radiolucency, any linear radiolucency > 2 mm, or any cystic radiolucency > 5 mm.

Discussion

This study is one of the largest, non-inventor, multicentre post-market surveillance studies of TAA. It has shown improvement in disease specific and general health patient-reported outcomes with low rate of early complications, reoperations and revision rates.

In this series, the early overall complication rate was 6.4% and the reoperation rate was 1.4%. This is lower than many series reporting early outcomes of TAA.[18–21] Patients were operated by experienced foot and ankle surgeons,[18] and the average number of ankles implanted per year by contributing surgeons was 15 (10 to 33) and by centres was 27 (11 to 65). The revision rate in this series was 1.0% (mean follow-up 16.2 months; 6 to 36). Penner et al[22] reported a 3.0% revision rate in 67 INFINITY TAA (mean follow-up 35.4 months; 27 to 47) with tibial (and talar) side failure in one patient (1.5%). King et al[23] reported no revisions in 19 patients (mean follow-up 32 months; 24 to 41). Saito et al[24] reported 4.7% revision rate in 54 ankles (mean follow-up 24.5 months; 18 to 39) noting that all were due to tibial subsidence. Cody et al[25] reported a 10% revision rate in 159 ankles (mean follow-up 20 months; 12 to 37), of which 3.8% were attributed to tibial loosening but 3.8% were due to deep infection. In this study, we report an overall revision rate of 1.0% (mean 16.2; 6 to 36), of which 0.6% were due to tibial side failure. Our deep infection rate was 0.2%.

This series included all ankles in which the surgeon considered the patient suitable for INFINITY TAA implant. A small number (6.2%) of ankles used a hybrid INBONE talus. This option is available to maintain joint height in the setting of a flattened talar dome due to wear. In patients with poor bone stock or significant deformity, either an arthrodesis or stemmed implant should be considered. We note that almost half of the patients in this series were COFAS types 2 to 4. (Table I). The reporting of deformity has not been standardized, and we would advocate using a grading of complexity such as the COFAS grade to allow surgeons to compare this reported study population to their own.

The reporting and significance of radiolucencies around TAA remains controversial, and the terminology is heterogenous.[26–29] Radiological radiolucency may be suggestive of, but is not specific for, clinical loosening. We have avoided use of the word osteolysis, which implies a biological response leading to radiolucency and is unlikely to be responsible for early linear radiolucencies. Early linear radiolucencies < 2 mm were a common finding and may be reflective simply of areas of imperfect seating of the implant. The clinical significance of these is unknown, but the presence of asymptomatic radiolucencies in our study had no adverse effect on patient outcomes at one year. Of three patients revised for aseptic loosening, only one had evidence of visible early linear radiolucency but all had a broad visible radiolucency prior to revision. Due to the nature of plain radiographs, small radiolucencies may not be consistently apparent. A visible gap of 2 mm (and hence a linear radiolucency of > 2 mm between the bone and the implant) was considered clinically significant for the purpose of ongoing analysis.[26,30–32] The reporting and aetiology of periprosthetic cysts around TAA is also heterogenous and controversial. It has been suggested that early cysts may be common and non-progressive, and some cysts may even be present prior to surgery.[26,33] The study protocol intends to follow and report on these radiolucencies at ten years.

Weaknesses of this study include the fact that postoperative alignment was not routinely recorded (unless a revision procedure was required). However, alignment to the mechanical axis can only be truly measured on a long leg film and it may be misrecorded on standard ankle radiographs.[34] This study was observational in design, and the clinical investigators did not recommend deviation from each individuals standard of care protocol, which did not always routinely capture long leg films. Post-implantation alignment with the INFINITY TAA has already been shown to be reliable and improved compared to alternative TAA systems.[23,35,36] It is noted that the proportion of patients reported as post-traumatic arthritis is lower than that reported in other registries.[37,38] The reporting of aetiology of ankle arthritis is inconsistent in the literature, with some surgeons recording only prior fractures as a cause of

post-traumatic arthritis, and others reporting severe sprains as a cause of post-instability arthritis. In this series, 17 patients (3.4%) required ligamentous reconstruction at the time of TAA.

The early experience and complications reported in this study support the INFINITY TAA as a safe and effective implant for use in the treatment of end stage ankle arthritis.

Take home message

- This is one of the largest non-inventor series of early outcomes after total ankle arthroplasty. It has shown low complications and good patient-reported outcomes in a fourth generation fixed bearing total ankle arthroplasty.

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