

Early outcomes and radiographic alignment of the Infinity total ankle replacement with a minimum of two year follow-up data



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ARTICLE INFO

Article history:

Received 13 March 2018

Received in revised form 24 September 2018

Accepted 3 November 2018

Keywords:

Ankle replacement

Ankle arthroplasty

Alignment

Patient reported outcomes

ABSTRACT

Background: The Infinity total ankle replacement (Wright Medical Technology, Memphis, TN) is a low profile, fluoroscopically navigated, fixed-bearing device. We hypothesised that the fluoroscopic navigation would allow more accurate alignment of the prosthesis than conventional techniques. We present our minimum two year follow up data of Infinity ankle replacements.

Methods: All total ankle replacements (TARs) performed at our institution were prospectively followed-up with EQ5-D and MOx-FQ scores as well as intra-operative radiation exposure and radiographic alignment data. Post-operative radiographs were used to measure the alignment of the prostheses. We identified 20 implants with minimum of two year follow up which were compared to a control group of 20 Zenith TAR's (Corin, Cirencester, UK).

Results: Intra-operative fluoroscopic navigation has allowed excellent alignment of all prostheses. Median deviations from 90° alignment to the anatomical axis of the tibia were 1.5° and 1.2° in the anterior-posterior (AP) and lateral planes respectively, compared to 2.8° and 3.1° in the Zenith group. This difference reached significance ($p < 0.05$) using the Mann–Whitney U test. At 2 years, MOx-FQ scores had fallen from pre-operative mean of 63.9 ± 17.1 to 15 ± 12.7 . EQ-5D VAS scores had improved from 71.3 ± 17.3 to 81.4 ± 9.7 points. Radiation exposure had a mean screening time of 82 ± 29.4 s and a decrease in exposure per patient was observed over time. No patients have undergone, or are awaiting, revision surgery. Complications include one intraoperative medial malleolar tip avulsion fracture, one medial malleolar stress fracture, and one patient who developed CRPS.

Conclusions: We present evidence that this system achieves better anatomical alignment of the components when compared to techniques without fluoroscopic navigation. The implant survival and complication profile at a minimum of two years is satisfactory.

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1. Introduction

Ankle arthritis has been demonstrated to have as much impact on quality of life as hip and knee arthritis [1]. The options available for operative treatment include ankle fusion or ankle joint replacement. Debate continues over the most reliable surgical option and this has been the subject of numerous clinical trials and ongoing studies [2–4]. Total ankle arthroplasty has been performed at our institution since 2003 with all operating surgeons going through their learning curve in both operative technique and patient selection.

The Infinity total ankle replacement was developed as a low profile, resurfacing, fixed bearing implant (Fig. 1). Design features also include bone implant interface visibility and image intensifier

guided alignment jigs for use during implantation. The alignment jigs require intraoperative radiographs to eliminate parallax initially before determining the anatomic axis comparable to preoperative long leg alignment planning views (Fig. 2). Images are used perioperatively to confirm resection height, sizing, bone cuts and eventual implant placement. The system was released in the UK in July 2014 after initial use by the originator in North America and following FDA approval. The tibial resurfacing component is titanium with three angled pegs whilst the talar component is cobalt chrome and is a pegged insertion prosthesis. Initial post-operative radiographs showing the implanted components can be seen in Fig. 3.

Our unit decided to use the implant due to the potential benefits of reduced bone resection and improved alignment with intra-operative fluoroscopic navigation. We hypothesised that the fluoroscopic navigation would allow more accurate alignment of the prosthesis than conventional techniques. Our unit has implanted over 60 Infinity total ankle replacements and this article presents those with a minimum two year follow up data.

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Fig. 1. Anterior and lateral photographs of the Infinity ankle replacement (Wright Medical Technology, Memphis, TN).

2. Method

The first 20 Infinity TARs implanted at our institution between July 2014 and December 2015 were prospectively followed up. The surgery was performed by one of three fellowship trained foot and ankle orthopaedic surgeons who had previously used a variety of ankle replacement systems. As a comparative group the prior 20 Zenith TARs performed at the institution between 2011 and 2014 were used to compare alignment data.

The surgical approach is a midline anterior incision using the interval between tibialis anterior and extensor hallucis longus, under thigh tourniquet and antibiotic cover. Implantation was performed according to the operative instructions given by the manufacturer and with image guidance throughout, with components being implanted uncemented. The wounds were closed using interrupted nylon sutures and the patient is placed into a below knee back slab cast and observed overnight. The patient is discharged at 36–48 h post-operatively and allowed to mobilise non-weight bearing, and encouraged to elevate the leg. At 2 weeks the plaster and sutures are removed and patients are placed into a postoperative walking boot and allowed to progress from partial to full weight bearing over the following 4 weeks as their symptoms

allow. They are encouraged to begin range of movement exercises as early as possible. If there is any concern that the wound has not fully healed at the 2 week stage the patient is placed back in to a below knee plaster and monitored weekly. Patients are then seen at 6 weeks, 3, 6, 12, and 24 months, with continued annual clinical and radiographic review. All implants are entered into the National Joint Registry, and patient reported outcome measures are taken preoperatively and at annual intervals using the MOX-FQ and EQ5-D scorings [5]. The EQ-5D scores include responses across 5 dimensions of quality of life, specifically mobility, self-care, usual activities, pain and anxiety/depression scored on a 3 level basis. It also includes a visual analogue scale (VAS) indicating the patient's overall quality of life from 0 to 100.

Standing antero-posterior (AP) and lateral ankle radiographs along with long leg alignment radiographs were obtained preoperatively. The severity of the degenerative changes were graded according to the COFAS grading system [6]. Postoperative radiographs of the ankle were taken for the Infinity group at 6 weeks, 12 and 24 months. For the comparative alignment data using the Zenith ankle replacement, the first post-operative radiograph available was used. All radiographs were taken with the patient weight-bearing on the operative side and were reviewed by the senior author.

Ankle alignment was measured using the technique outlined by Lee et al. [7]. The medial distal tibial angle (MDTA – Fig. 4) was calculated from the inclination of the ankle joint and a line parallel to the anatomical axis of the tibia on the AP radiograph. Values greater than 90° indicate a valgus ankle joint with values less than 90° indicating varus. Likewise, the anterior distal tibial angle (ADTA – Fig. 5) was calculated from the inclination of the ankle joint and the anatomical axis of the tibia on the lateral radiograph. Values greater than 90° indicate an ankle joint in extension with values less than 90° indicating an ankle joint in flexion relative to the anatomical axis. Measurements were taken by two independent reviewers and a mean was taken of these measurements. Blinding was not possible due to different appearances of the two prostheses on radiographs. Pearson's coefficient for the two sets of data was 0.78 indicating good linear correlation of the two data sets. A Bland – Altman plot for this data can be in Fig. 6. This demonstrates disagreement between the two reviewers of 0.53° with a standard deviation of 1.96° .

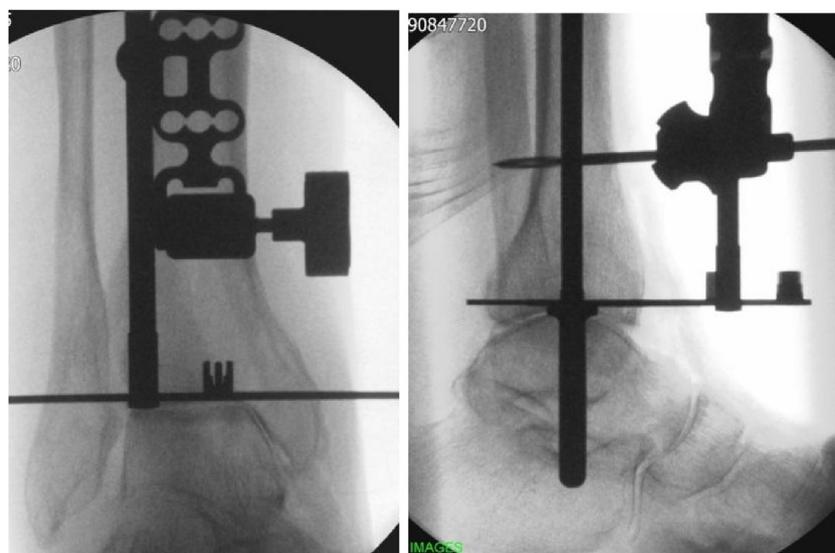


Fig. 2. Images of intraoperative fluoroscopic navigation setting the anatomical axis.

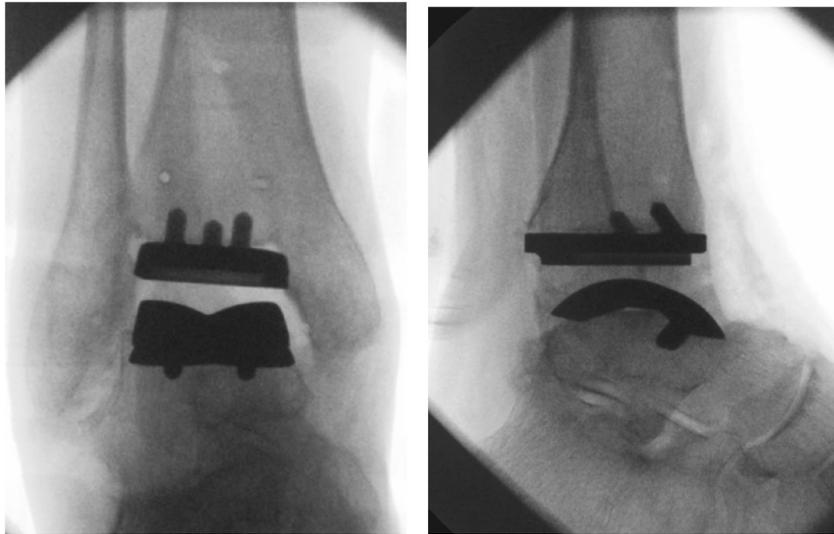


Fig. 3. Radiographs of implanted components.

The ideal alignment of the replacement was taken to be 90° to the anatomical axis in both the AP and the lateral plane which should allow optimal load distribution through the polyethylene on a balanced plantigrade foot. For the post-operative data, values for deviation away from the ideal positioning of the implants orthogonal to the anatomical axis were calculated to allow direct comparison of the two different prostheses.

The data for the two groups were analysed for differences in radiographic alignment of the ankle joint pre- and postoperatively using the Mann–Whitney U test. The null hypothesis stated that there was no difference in the postoperative alignment of the Infinity and Zenith ankle replacements. For the Infinity group pre- and postoperative patient reported outcome measures were compared using a paired t-test. A significance level of 95% was used for all comparisons.

3. Results

The Infinity group included 10 females and 9 males, and one patient had bilateral ankle replacements. 17 were performed for osteoarthritis (OA) and 3 for rheumatoid arthritis (RA). The COFAS scores were 11 grade 1, 3 grade 2, 2 grade 3 and 4 grade 4. The average age in this group was 72 (range 56–88). Mean follow up for the Infinity group at the time of writing was 32 months (range 24–41). The Zenith group included 9 males and 11 females. 16 were performed for OA and 4 were performed for RA, and the average age for this group was 68 years (range 43–83).

Preoperatively, the Infinity group showed a median MDTA of 86.7° (range 81.3° – 100.3°) and a median ADTA of 84.4° (range 77.2° – 92.0°). This equates to a median deviation from 90° of 4.7° in the AP plane (range 0.2° – 8.3°) and 5.7° (range 0.6° – 12.8°) in the

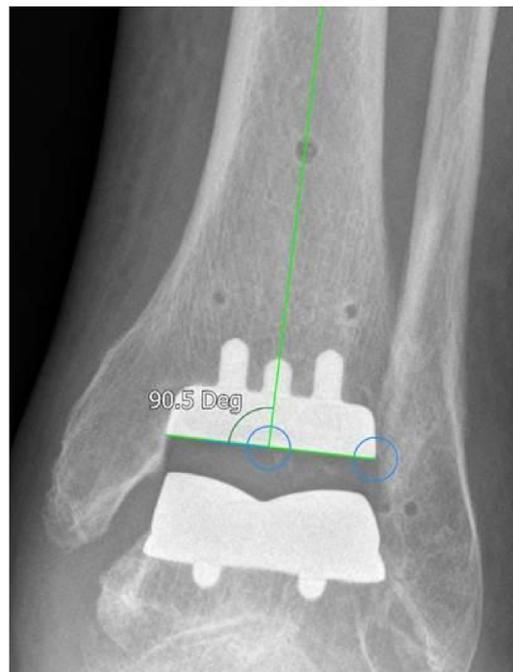


Fig. 4. MDTA.

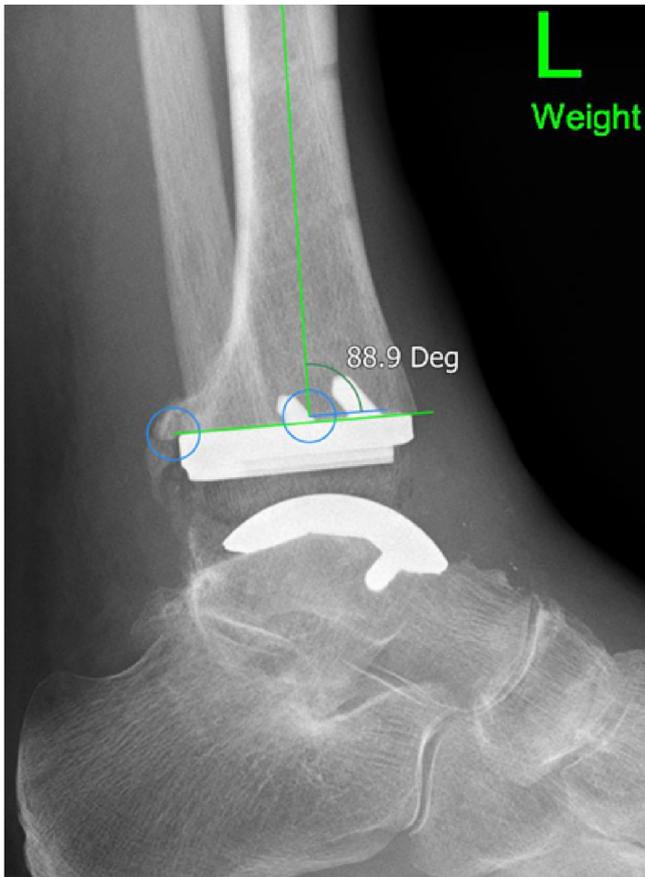


Fig. 5. ADTA.

lateral plane. The largest deformities, therefore, were 10.3° of valgus, 8.7° of varus, 12.8° of flexion and 2.0° of extension. Preoperatively for the Zenith group, the median MDTA was 88.8° (range, 78.7°–93.3°) and the median ADTA was 83.4° (range, 73.3°–100.7°). The largest deformities, therefore, were 3.3° of valgus, 11.3° of varus, 16.7° of flexion and 10.7° of extension. The median deviation from 90° in this group was 2.9° on the AP view (range 0.1°–11.3°) and 7.7° on the

lateral view (range, 2.2°–16.7°). Comparing the median deviations from 90° in each plane for each group the Mann–Whitey U test reveals no statistically significant difference in the degree of preoperative deformity ($p < 0.05$).

Postoperatively, the Infinity group demonstrated a median MDTA of 88.9° (range 84.6°–92.1°), this converts to a median deviation from 90° of 1.2° on the AP view (range 0.1°–5.4°). The median ADTA was 89.3° (range 86.7°–91.8°). Median deviation from 90° was 1.0° in this plane (range 0°–3.3°). For the Zenith group, the median postoperative MDTA was 87.2° (range 82.7°–92.6°) with a median deviation from 90° of 2.8° on the AP view (range 0.2°–7.3°). The median postoperative ADTA was 87.4° (range 80.6°–94.2°) with a median deviation from 90° degrees of 3.1° in this plane (range 0.2°–9.4°). The difference in the deviations from 90° in both the AP and lateral planes between the two groups was statistically significant using the Mann–Whitney U test ($p < 0.05$). Comparisons of the postoperative alignment data for both the Infinity and Zenith groups can be found in Figs. 7 and 8.

Preoperative MOx-FQs demonstrate a mean score of 63.9 ± 17.1 . At 12 months post-operatively, the mean MOx-FQ score had fallen to 20 ± 16.0 and at 24 months the mean MOx-FQ score had fallen further to 15 ± 12.7 . The improvement reached statistical significance using a paired student's t-test at both 12 and 24 months ($p < 0.05$). All patients demonstrated an improvement in MOx-FQ scores with a mean improvement at 24 months of 50 ± 22.1 points.

EQ-5D data shows an improvement in overall quality of life which continues out to 2 year follow up. Table 1 shows the breakdown of the data across the five domains of the EQ-5D. It can be seen that only an average of 38% of patients scored themselves as level 1 (no symptoms or problems) pre-operatively but 62% and 78% of patients scored themselves as level 1 at the 1 and 2 year points respectively. No patients scored themselves at level 3 (severe symptoms or problems) at the 2 year time point. Quality of life, as measured using visual analogue (VAS) scores, improved at both the 1 and 2 year time point and EQ-5D index values also improved after both 1 and 2 years. In the patients that we have 3 year data for this improvement is maintained. VAS and EQ-5D index values can be seen plotted in Figs. 9 and Fig. 1010 .

Image intensifier exposure data was available for 16 of the 20 cases with a mean screening time of 82 ± 29.4 s and median overall exposure of 23.9 cGycm^2 (range 11.1–140.1). This data demonstrated a downward trend over time suggesting a learning curve

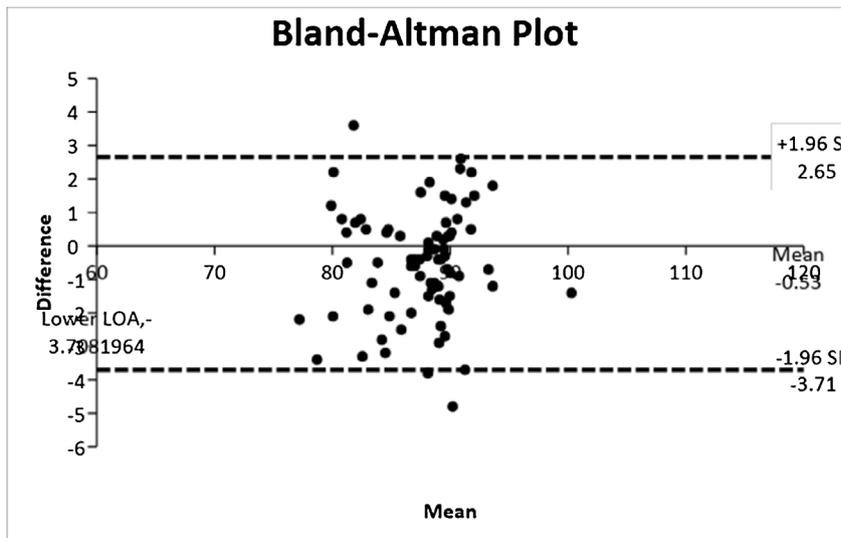


Fig. 6. Bland–Altman plot of all alignment measurements.

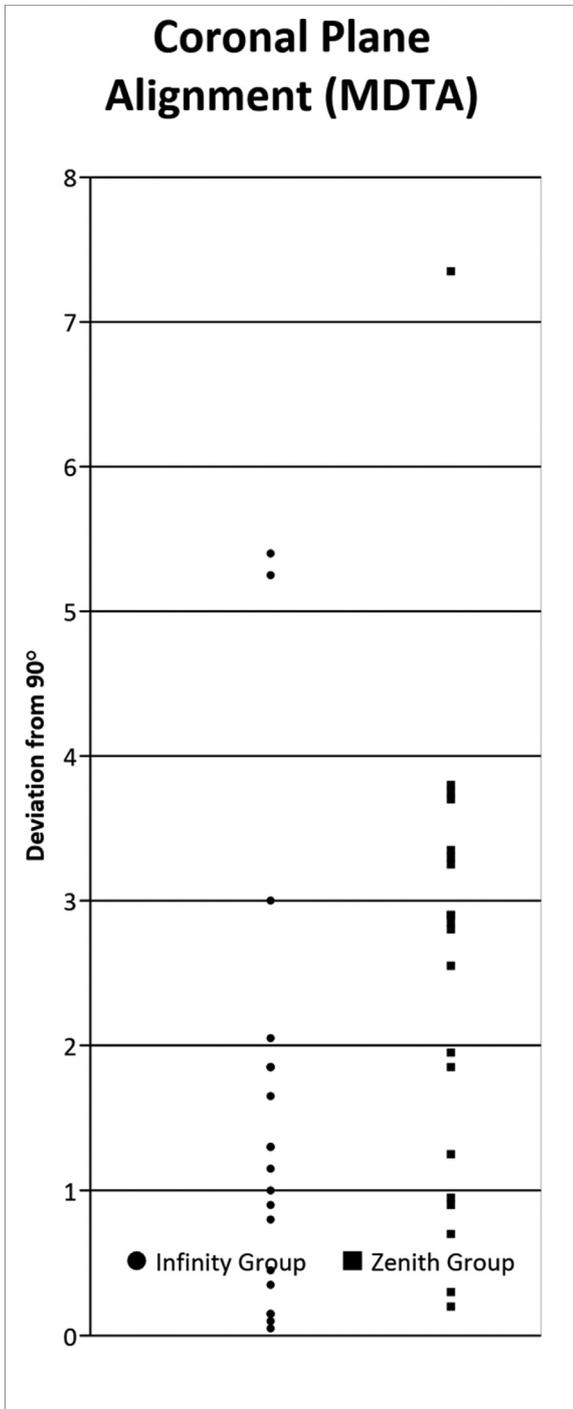


Fig. 7. Comparison of the post-operative MDTAs and ADTAs of the Infinity and Zenith groups.

being present in the use of the image-intensifier. However, the coefficient of determination (R^2) for the trend line did not reach statistical significance. This data can be seen plotted in Fig. 11.

There was one recorded intra-operative complication with a medial malleolar tip avulsion fracture occurring as the joint was distracted with a laminar spreader, which was stabilised at the time of initial surgery with a cannulated screw. This fracture healed with no complications. Another patient sustained a stress fracture of a medial malleolus, which was noted at six weeks. The patient remained in a postoperative boot for a further 6 weeks and the fracture healed uneventfully. One patient developed complex

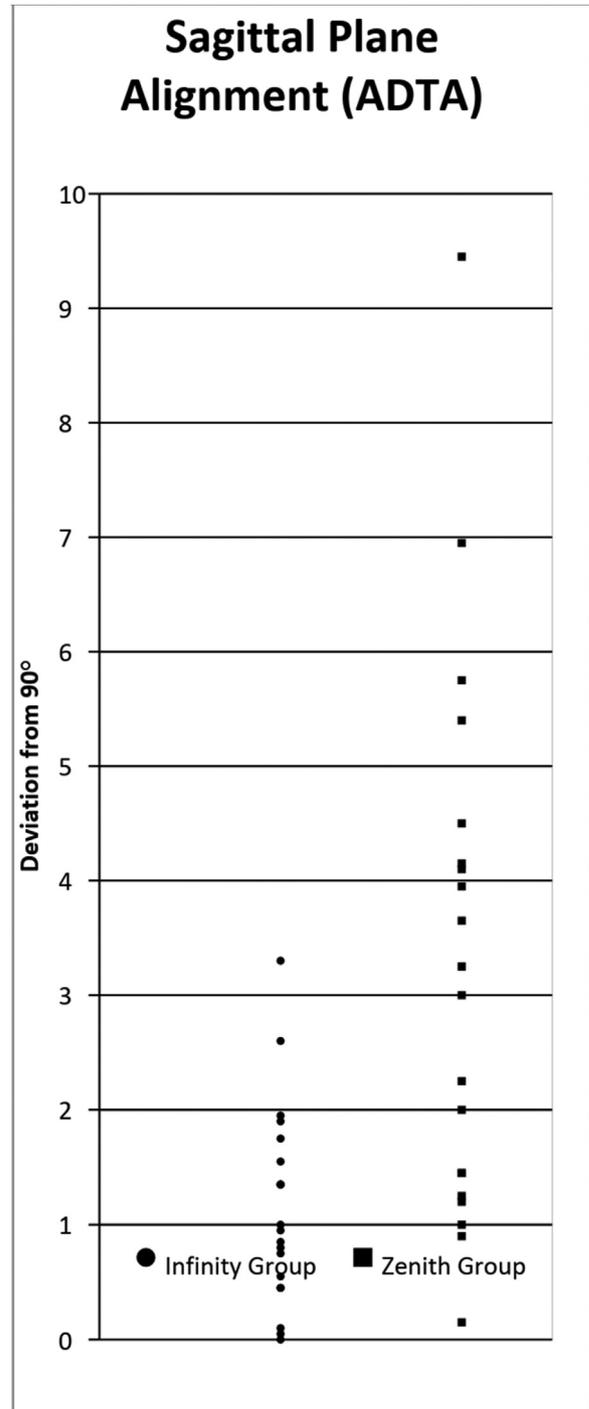


Fig. 8. Comparison of the post-operative MDTAs and ADTAs of the Infinity and Zenith groups.

regional pain syndrome (CRPS). This was treated with input from the pain service and improved with neuromodulatory medication. This indicates an overall complication rate of 15% (3/20 ankles) with a 0% reoperation rate to date although one further intraoperative procedure was required due to intraoperative fracture,

Postoperative radiographic surveillance of the 20 Infinity TARs in this series has revealed no evidence of loosening or osteolysis around the implants. An example of 2 year follow up radiographs can be seen in Fig. 12. There have been no wound breakdowns, deep infections or revisions for this group at the time of writing.

Table 1
EQ-5D data breakdown.

| EQ-5D Dimension | | Pre-op | 12 months | 24 months |
|--------------------|---------|--------|-----------|-----------|
| Mobility | Level 1 | 12.5 | 25 | 72.22 |
| | Level 2 | 87.5 | 75 | 27.78 |
| | Level 3 | 0 | 0 | 0 |
| Self-care | Level 1 | 81.25 | 91.67 | 88.89 |
| | Level 2 | 18.75 | 8.33 | 27.78 |
| | Level 3 | 0 | 0 | 0 |
| Usual activities | Level 1 | 18.75 | 66.67 | 77.78 |
| | Level 2 | 68.75 | 25 | 22.22 |
| | Level 3 | 12.5 | 8.33 | 0 |
| Pain/discomfort | Level 1 | 0 | 41.67 | 61.11 |
| | Level 2 | 68.75 | 41.67 | 38.9 |
| | Level 3 | 31.25 | 8.33 | 0 |
| Anxiety/depression | Level 1 | 75 | 83.33 | 88.89 |
| | Level 2 | 25 | 16.67 | 27.78 |
| | Level 3 | 0 | 0 | 0 |

Mean EQ VAS Scores

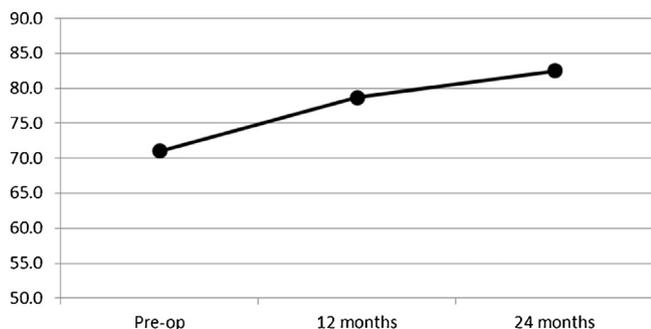


Fig. 9. EQ-5D VAS scores.

Mean EQ Index Values

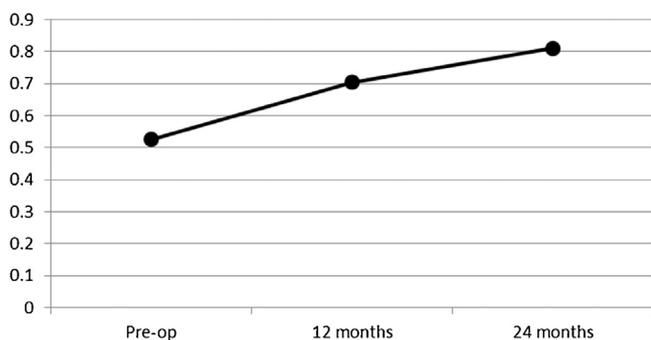


Fig. 10. EQ-5D index scores.

4. Discussion

Debate continues regarding the optimum form of intervention for ankle arthritis. The choice between arthroplasty and arthrodesis can often be difficult, and is affected by surgical training, experience and preference. The meta-analysis of the literature by Haddad et al. [2] showed that TAR and fusion have similar intermediate term outcomes in terms of clinical scores, patient satisfaction and revision rate. Both have been shown to improve

Image Intensifier Exposure

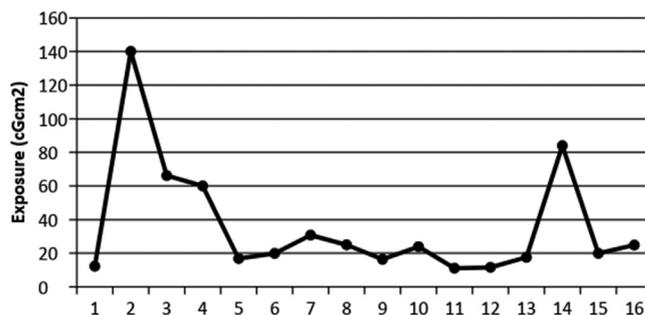


Fig. 11. Image intensifier exposure.

quality of life at 1 year but with no difference between the two operations. The result of studies, such as the UK based TARVA trial [8] are awaited to compare the interventions in a comparative and a randomized controlled trial.

We have used ankle arthroplasty in our institution since 2003 as an option for the management of ankle arthritis. From 2004–2011 we used the Mobility (DePuy) ankle replacement system, with reasonable outcomes. We had concerns over the reproducibility of implantation and alignment, and noted problems with medial pain and later loosening and cyst formation, similar to other series [9]. In 2011 we moved to the Zenith (Corin) system which was seen as a progression of the Mobility design. Whilst the design had improved we noted variation in alignment and continued concerns over medial pain.

The Infinity ankle replacement system was released for use in the UK in July 2014. The system was designed to minimise bone resection and allow visualisation of the bone-implant interface. The surgical technique used image guided alignment via a standard anterior approach in a reproducible manner. The implant was a fixed bearing design, which has been shown in mid-term clinical review papers to have no detrimental effect on survival or outcomes, despite the potential biomechanical and kinematic benefits of a three component system [10,11]. As a team we elected to use the new implant for its potential benefits, but with prospective data collection and careful monitoring to ensure the results were at least comparable to previous implant designs.

In our review of the first 20 Infinity ankle replacements performed in our unit we have found encouraging early results. These include excellent anatomical alignment of the tibiotalar component, positive early clinical outcome data and low rates of complications. We discuss each of these points further below.

The analysis of our postoperative alignment suggests that intraoperative fluoroscopic navigation allows for accurate placement of the tibiotalar component, and this alignment is improved when compared to the non-radiologically assisted implantation of the Zenith. This was a statistically significant result even in our small study group. There was also a narrower range of values in the Infinity group and this reduced spread from the anatomical axis is reassuring. This result reflects recent work by Saito et al. [12] who found a mean MDTA of $1.8^\circ \pm 1.3^\circ$ and a mean ADTA $1.8^\circ \pm 1.6^\circ$. It is important to note that these results reflect radiographic findings only and there is, as yet, no data to suggest that improving the radiographic alignment by a few degrees correlates with a significant clinical benefit. It does, however, demonstrate that the radiologically guided system achieves its aim of more accurate alignment. The absence of any radiographic loosening or osteolysis out to 2 years is again reassuring but needs careful further monitoring.

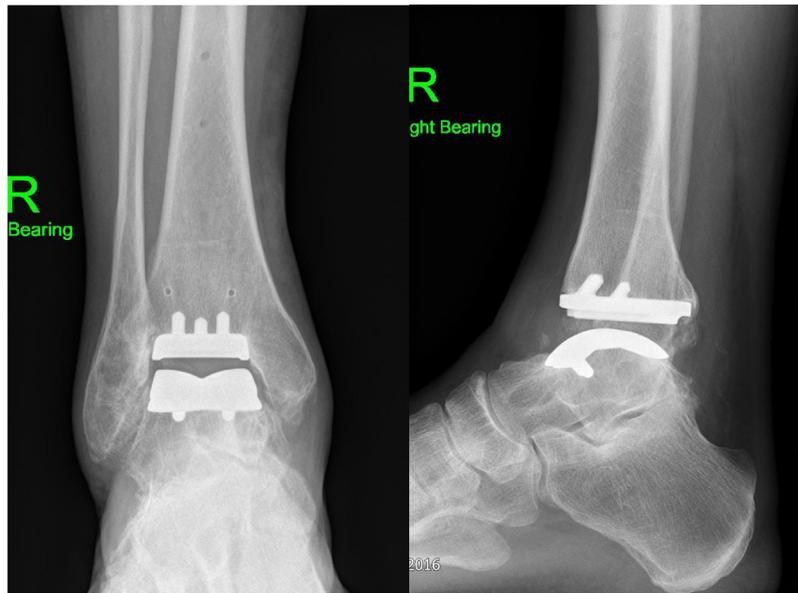


Fig. 12. Implants at 2 years post operatively.

The PROMs data indicates all patients have benefitted from the procedure. MOx-FQ scores all improved at 1 year. This improvement was maintained out to 2 years although some scores did rise from a very successful 1 year score and overall mean score was lower at 2 years. EQ-5D data shows a significant improvement in quality of life for the patients in this series. Mean VAS scores improved at both the 1 and 2 year time points and overall index scores also improved. If we assume that EQ-5D index scores would have remained constant over the course of the study we can calculate quality adjusted life years (QALYs) gained as a result of our intervention. A pre-operative mean index score of 0.526 over 2 years gives a reference measurement of 1.05 QALYs. The mean postoperative EQ-5D index score at 1 year was 0.704 and at 2 years 0.811. This gives us a comparative measurement of from our reference value and indicates that an average of 0.465 QALYs have been gained per patient as a result of their surgery.

There was one intra-operative complication, which represented a tip avulsion of the medial malleolus when the joint was distracted using the laminar spreader (in the first case of the series). There were no instances of injury to the medial or lateral malleoli from the saw or other instruments. Recent literature has suggested that the learning curve for implantation of an ankle replacement stabilizes at 28 implants [13]. In this paper Usulli noted that 6 malleolar fractures occurred (4 medial and 2 lateral) and one deep infection in their series. Saito [12] noted 5 cases of gutter impingement, 3 peri-operative fractures, subsidence of a component in 5 cases, persistent hindfoot malalignment in 1 case, an overall complication rate of 21.8% in their larger series of Infinity ankle replacements. Our experience in using the Infinity system has demonstrated a much shorter learning curve with a lower complication rate of 15%. This may in part be due to the accurate fluoroscopic sizing and placement of the alignment jigs and cutting blocks.

The use of intra-operative fluoroscopy has been raised as a concern in terms of increased radiation exposure. Due to differences in patient habitus, c-arm operator and minor changes in theatre set up etc. variability is to be expected. The overall mean radiation exposure across the 16 cases with available data was low, averaging 82 ± 29.4 s. This is comparable to other ankle systems using fluoroscopic guidance. One reviewer found the average screening time to be 77 ± 34 s across three prostheses using intra-operative fluoroscopic navigation for primary TAR [14]. When

looking at revision ankle replacements, Roukis et al. found an average screening time of 64.9 ± 11.8 s in case series of 41 revision procedures [15]. This did include many cases of single component revisions and there was significant variety in terms of explanted prostheses and additional procedures performed.

5. Conclusion

In this study we have demonstrated that the Infinity ankle replacement system allows for reproducible, safe implantation of a fixed bearing ankle joint arthroplasty in a non-designer series. The early patients outcomes are satisfactory, and early radiographic data suggests no implant loosening with significantly improved alignment when compared to an implant that is not fluoroscopically navigated. Longer follow up is required to confirm whether the prosthesis design and improved alignment confers an implant survival benefit and further work is required to determine if this improved radiological alignment leads to improved clinical outcomes.

Conflict of interest

The authors declared that there is no conflict of interest.

Funding

We wish to confirm that has been no significant financial support for this work that could have influenced its outcome. The senior author, Mr Ian Sharpe, has received financial compensation for teaching services delivered on behalf of the proprietor of this prosthesis Wright Medical. He receives no financial gain from sales or usage of the implant.

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