The Salto Total Ankle Arthroplasty – Clinical and radiological outcomes at five years

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Abstract

Aims: Modern designs of total ankle arthroplasty (TAA) have the potential to treat symptomatic ankle OA without adversely affecting ankle biomechanics. We present the mid-term results of a modern, mobile-bearing TAA design.

Methods: TAA was performed in 50 consecutive patients (55 ankles) in an independent, prospective, single-centre series. Implant survival, patient-reported outcome measures (PROMs) and radiographic outcomes are presented at a mean of five years (range 2-10.5 years).

Results: A total of three patients (four ankles) died and two (two ankles) were lost to follow-up. Three TAAs were revised for aseptic loosening (in two cases) or infection. Two further patients underwent reoperations, one for arthroscopic debridement of anterolateral synovitis and one for grafting of an asymptomatic tibial cyst. With all-cause revision as an endpoint, implant survival was 93.3% at five to ten years (95% CI 80.5%-97.8%). If reoperations are included this falls to 90.2% (95% CI 75.6%-96.3%) at five years. No other patient demonstrated radiographic evidence of loosening or subsidence. PROMs and satisfaction were excellent at latest follow-up.

Conclusion: At five years, the outcomes for this design of TAA in this series were excellent, and were similar to those of previously published series from the designer centre.

Up to 13% of all cases of osteoarthritis (OA) involve the ankle joint[1], with at least 29,000 cases of symptomatic OA of the ankle presenting annually to specialists in the United Kingdom. This disease burden results in 3000 definitive operations being performed each year to treat end-stage disease[2]. OA of the ankle is severely disabling, and has been estimated to have an adverse effect on quality of life of a similar magnitude to that experienced by patients with end-stage osteoarthritis of the hip, or with congestive cardiac failure[1,3].

The ankle is the most commonly-injured joint in the body, and most cases of symptomatic OA are post-traumatic, as a result either of fractures or instability secondary to ligamentous injury[4-6]. Less common causes are the inflammatory arthropathies, haemochromatosis, and hemophiliac arthropathy[7]. The incidence of ankle fractures has increased over time, especially in young athletes and elderly females, and as a result, surgical treatment of end-stage OA of the ankle is likely to become more common in future years[8-10].

Most cases of end-stage OA of the ankle joint are treated with arthrodesis[11]. However, whilst arthrodesis is highly effective in relieving pain, it results in a reduction in the efficiency of gait, and there is a high risk of adjacent joint arthrosis, particularly of the subtalar joint.[12] Total ankle arthroplasty (TAA) has the potential to address the inherent disadvantages of arthrodesis. Whilst early designs of TAA had high rates of failure through wear and aseptic loosening, there has been substantial evolution in implant design in recent years[13]. Whilst previous designs were highly constrained and employed cemented fixation, current designs are cementless with minimal constraint at the joint surface, reducing the stresses at the bone-implant interface and reducing the risk of

aseptic loosening[14]. Most designs of TAA in use in Europe use an unconstrained mobile bearing in order to address and reduce the degree of polyethylene wear which was problematic in previous generations of TAA.

The Salto prosthesis (Tournier SA, Saint Ismier, France) is one such contemporary TAA prosthesis. It has a cementless, anatomic design with a mobile polyethylene bearing and has been in use since 1997. Early results have been encouraging; a series of cases from the designing centre demonstrated good survival, functional scores and radiological outcomes at a mean of 8.9 years[15], which is comparable to other modern total ankle prostheses[16]. However, the only three independent series to date reported encouraging survival and functional data, but only in the short term[17,18,19].

We report the survival, functional and radiological outcomes of the Salto TAA from an independent centre at a minimum of two years, and a mean of five years' follow-up. To our knowledge, it is the first independent series to date to report outcomes into the medium term following TAA with this implant.

Patients and Methods

1. This is a single-centre, prospective series of 55 Salto TAAs performed in 50 patients between September 2005 and January 2014. Our indications for TAA were end-stage ankle OA or rheumatoid arthritis (RA). TAA was considered contra-indicated in patients with active ankle joint infection and those with poor soft tissues around the ankle. The mean age at the

time of surgery was 70 years (39-87) and 33/55 patients (60%) were male. Patients underwent their final review at a mean of five years (2-10.5 years) following index surgery.

The Salto TAA (Tornier) is a three-component cementless, mobile-bearing anatomic resurfacing prosthesis first implanted in Europe in 1997. The tibial and talar components are both made of cobalt-chromium and are coated with 200-µm plasma-sprayed titanium (T40). Up until 2012, an additional external coating of hydroxyapatite was used to promote osseointegration. The tibial component features a keel for primary fixation and requires a standard bone resection of 7mm. The talar component also features a cylindrical keel for primary fixation and is designed with anatomic articular surfaces. A mobile ultra-high-molecular-weight polyethylene (UHMWPE) bearing articulates freely between the tibial and talar components. [20,21]

All procedures were performed by a single surgeon (PFR) using a standardised technique as described by the designers[15,22,23]. The goal of surgery is to restore the anatomical tibiotalar joint line and tibiocalcaneal axis. The tibial cut is made at 90° to the axis of the tibia with a 7° posterior tibial slope using an extramedullary tibial guide referenced from the anterior tibial crest. The amount of distal tibial resection is measured to match the combined thickness of the metal tibial base plate and the polyethylene insert. Care is taken to ensure proper rotation of the components, which are centred on the line bisecting the space between the medial and lateral facets of the talus. The medial deltoid is released in patients with lateral ligament laxity. Ligamentous balance is achieved by increasing the thickness of the polyethylene insert. The all-cementless

prostheses was used for all patients in this series, rather than the earlier version which had a cemented lateral malleolar component[22].

Post-surgery all patients are immobilised in plaster and are kept non-weight bearing for two weeks, before being permitted to bear weight fully with an off-load walker for the next four weeks, during which range of motion exercises are commenced under the supervision of a physiotherapist.

A total of four patients had had prior surgery to the ipsilateral ankle for previous fractures, seven had undergone previous subtalar fusion, four had undergone a fusion of the midfoot and one had undergone previous forefoot surgery.

All patients were followed up at two weeks, six weeks, three months, six months, at one year and yearly thereafter. At the latest follow-up, modified American Orthopaedic Foot and Ankle Society (AOFAS)[24] , Foot and Ankle Outcome Scores (FAOS)[25] and EuroQol-5 dimension (EQ-5D)[26] scores were collected, along with weight-bearing radiographs of the ankle.

Anteroposterior (AP) and lateral weight-bearing radiographs of the ankle were analysed and measurements were taken as described in the designer series (Fig. 1)[15]. The accuracy of these measurements has previously shown a high level of intraobserver reliability[27], and subsequent series have also used these measurements[28,29]. Component migration was defined as a change of more than 5° in any one of these measurements in relation to the immediate postoperative radiographs. This was based on previous reliability testing[27] and was recommended by Knecht et al[30].

To analyse peri-implant radiolucencies and osteolysis, the tibia and talus were divided into 10 zones on the AP and lateral radiographs, as described by Bonnin (Fig. 2)[15]. A radiolucent line was considered to be pathological if it was greater

than 2mm thick or if present in all zones[31-33]. An osteolytic cyst was defined as a hypodense area greater than 5mm in diameter with no trabeculation within but with peripheral sclerosis, that was not present preoperatively[34]. Radiographs were analysed by two independent surgeons (KK and PFR). The most unfavourable result was recorded in cases of disagreement[34].

Survival was calculated using two different end points: revision[35] (removal or revision of any component, including exchange of polyethylene insert for fracture) and revision/reoperation (including any reoperation on the ankle after implantation). These end points have been frequently used in previous studies[36-43]. Best and worst case survival was calculated to take into account losses to follow-up as described by Murray *et al*[44].

Statistical Analysis

Descriptive statistics were performed for demographic information and postoperative scores. Implant survival was estimated using the Kaplan Meier method[45] and plotted with 95% confidence intervals. Life tables were produced for each end-point. Immediate post-operative radiographic criteria were compared to those at most recent follow-up using Wilcoxon's Signed Rank test for paired data. Statistical analysis was performed using Stata v.12 for Windows (Stata Corp, College Station, TX); $p<0.05$ was considered statistically significant.

Results

Of 50 patients (55 ankles) entered into the study, three (four ankles, 7%) died and two (two ankles, 3.5%) were lost to follow-up. Both patients who were lost to follow-up had moved abroad and did not respond to multiple attempts at

contact. Three patients underwent revisions (three ankles, 5% of the total) meaning that 46 cases (42 patients) were included in the final analysis. Of these 46 cases, three patients (three ankles) were unable to attend for radiographic follow-up either through ill-health (two patients) or because they had moved abroad (one patient). These patients returned completed questionnaires by post.

Revisions and reoperations

Three patients underwent revision surgery, all of which took place in the first four years following surgery. The first case was revised to a fusion at 1.2 years for aseptic loosening of the talar component due to avascular necrosis of the talus. The second patient was revised to a fusion for deep infection at 2.6 years. A cyst had started to form around the tibial component (in zone 3) at five months post-surgery, and the talar component began to subside at 24 months after primary surgery. The patient was offered revision to fusion for aseptic loosening at this stage but declined. She subsequently defaulted follow-up and underwent a staged procedure with removal of prosthesis and subsequent fusion at another centre where a deep periprosthetic infection had been diagnosed. The final patient was revised to a second Salto TAA at 3.7 years for chronic pain. The radiographs before revision did not show osteolysis or implant subsidence. However, intra-operatively, there was poor bony ingrowth on the tibial component.

Two further patients had reoperations following TAA. The first patient underwent an ankle arthroscopy at 2.3 years for anterolateral synovitis.

A second patient was found to have a large medial-sided tibial cyst (Fig. 3) at 4.2 years. Although this was symptomatic, the cyst was grafted with bone from the proximal tibia to mitigate the risk of peri-prosthetic fracture. He recovered well from the procedure and started bearing weight fully after two weeks.

With all-cause revision as the endpoint, implant survival was 93.3% at five to ten years (95% CI 80.5%-97.8%). A Kaplan-Meier plot is given in Figure 4 and a life table is given in Table 1. In the worst-case scenario (taking all losses to follow-up as failures), five year survival falls to 90.0% (95% CI 77.3%-95.7%); in the best-case scenario (taking all losses to follow-up as successes), the five year survival is 93.6% (95% CI 81.4%-98.0%). With revision or reoperation as the endpoint, implant survival is 90.2% (95% CI 75.6%-96.3%) at five years, falling to 86.2% (95% CI 75.6%-96.3%) from six to ten years (Table 2).

Clinical outcomes

Aside from the two patients lost to follow-up, all surviving patients completed the FAOS, AOFAS and EQ5D questionnaires at the latest follow-up point. Clinical outcomes are presented in Table 3. All patients, when questioned, said they would recommend others to have the procedure and 35/46 patients had no or very little pain (VAS 0-2 points).

Radiological outcomes

Of the 43 cases with radiographs available, 30 (70%) had no radiolucent lines. Of the remaining 13, four had radiolucencies in one tibial zone, five had radiolucencies in two tibial zones, two had a radiolucency in a single talar zone and two had radiolucencies in one tibial and one talar zone. Cysts were present

in two ankles; in one case, the cyst was associated with a medial malleolus screw which had been inserted for fracture fixation 47 years prior to TAA. This cyst was treated non-operatively. The second patient had an asymptomatic cyst in the medial tibial plafond; this patient underwent bone grafting as described above. Excluding the cases that underwent revision surgery, there was no radiographic evidence of component migration/subsidence in our series. There were no statistically significant changes in tibial slope, talar or tibiocalcaneal angles from immediate postoperative radiographs to those taken at latest follow-up (p=0.50, p=0.29 and p=0.24 respectively). The tibial angle differed significantly between immediate post-operative and latest radiographs (p=0.008). However, the difference was less than 5 degrees, and so did not fall under Bonnin's definition of subsidence[15].

Discussion

This series has demonstrated excellent implant survival and functional outcomes at a mean of five years following implantation of the Salto TAA. There was a low rate of radiolucent lines suggesting that none of the patients in the series had impending implant failure through aseptic loosening.

Our results compare well to those previously published for this implant. The series of the designer surgeon, which had 87 ankles at a mean follow-up of 8.9 years, reported a 10 year survival rate of 85% with all-cause revision as the end-point, and 65% with reoperation as the end-point[15]. The three independent series repot only shorter-term follow-up. The series of Schenk et al[17], reported five year implant survival of 87% in 401 implants, with a mean of 29 months' follow-up (range 1 to 84). Rodrigues-Pinto et al[18] reported on 119 patients with

implant survival of 98.3% at a mean follow-up of 39 months (this fell to 94.1% if all reoperations were included). Reuver et al[19] reported a 86% survival rate at 36 months in a series of 59 ankles. As the mobile-bearing Salto implant is not licensed for use in the USA, a fixed-bearing version (Salto Talaris) was introduced to the market in 2006[46]. Nodzo *et al* followed 75 implants for a mean of 43 months, reporting implant survival of 98% at that timepoint.

The results reported here are comparable to the results reported overall for TAA. A systemic review and meta-analysis of 58 papers (including 7942 TAAs), showed an overall rate of survival of 89% at 10 years, giving an annual failure rate of 1.2%[16]. The most common implants in this series were the STAR (1283 cases) and Hintegra (1652) prostheses.

In Bonnin's series[15], nineteen patients (19.8%) presented with tibial and/or talar bone cysts that were 5mm or larger. Eight of these patients underwent a second operation with bone grafting, which appeared to be curative, whereas three went on to implant removal and fusion. An additional eight patients had bone cysts appearing on radiologic studies but remained asymptomatic. Several processes are thought to contribute to cyst formation, such as reaction to PE particles mediated by macrophages, joint fluid pressure especially when the prosthesis does not fully cover the surface after bone resection, stress shielding, micro-motion at the bone-implant interface, or even from pre-existing osteoarthritic cysts[48,50]. It has been suggested that cysts are more common when there is delamination of the hydroxyapatite coating in dual-coated prostheses[51]. This would be consistent with the fact that a lower proportion of patients in this

series had cysts (two ankles, 3.6% of the total, one of whom had a deep infection), given that a larger proportion of patients in our series had the non-HA coated implant compared with the earlier series of Bonin.

Of the cases which were revised, two out of three were due to aseptic loosening, with the other being due to deep infection. In the designer series, all three cases of aspetic loosening had their prosthesis left in-situ because the functional results are good. Our results are consistent with worldwide registries[51] which show aseptic loosening as the leading cause for revision in TAA, followed by deep infection.

Aside from the case who underwent grafting of the cyst, the only other reoperation was for anterolateral impingement due to synovitis. She went on to have a good outcome, which is consistent with the study of Kim et al, who found that the median VAS for pain and AOFAS scores after arthroscopic debridement for fibrosis and synovitis was similar to that of uncomplicated TAAs[53].

There are some limitations to our study. First, scores were not collected pre-operatively, so the degree of improvement after surgery cannot be objectively assessed. Secondly, we used the modified AOFAS score, which only consists of the 'subjective' components. However, all our patients have indicated that they would recommend this surgery to someone else with the same condition, which supports the supposition of a good outcome overall. Thirdly, the measurement of implant position and its change on radiographs may be influenced by the position of the patient or the projection of the x-ray beam, and may not be

robustly accurate. Although component migration has been defined as difference of 5 degrees, in order to account for the degree of expected error, studies using radiostereometric analysis (RSA)[54] would be helpful in future studies to detect implant migration at an early stage such that these patients can be monitored more closely and given the appropriate treatment earlier.

Figures

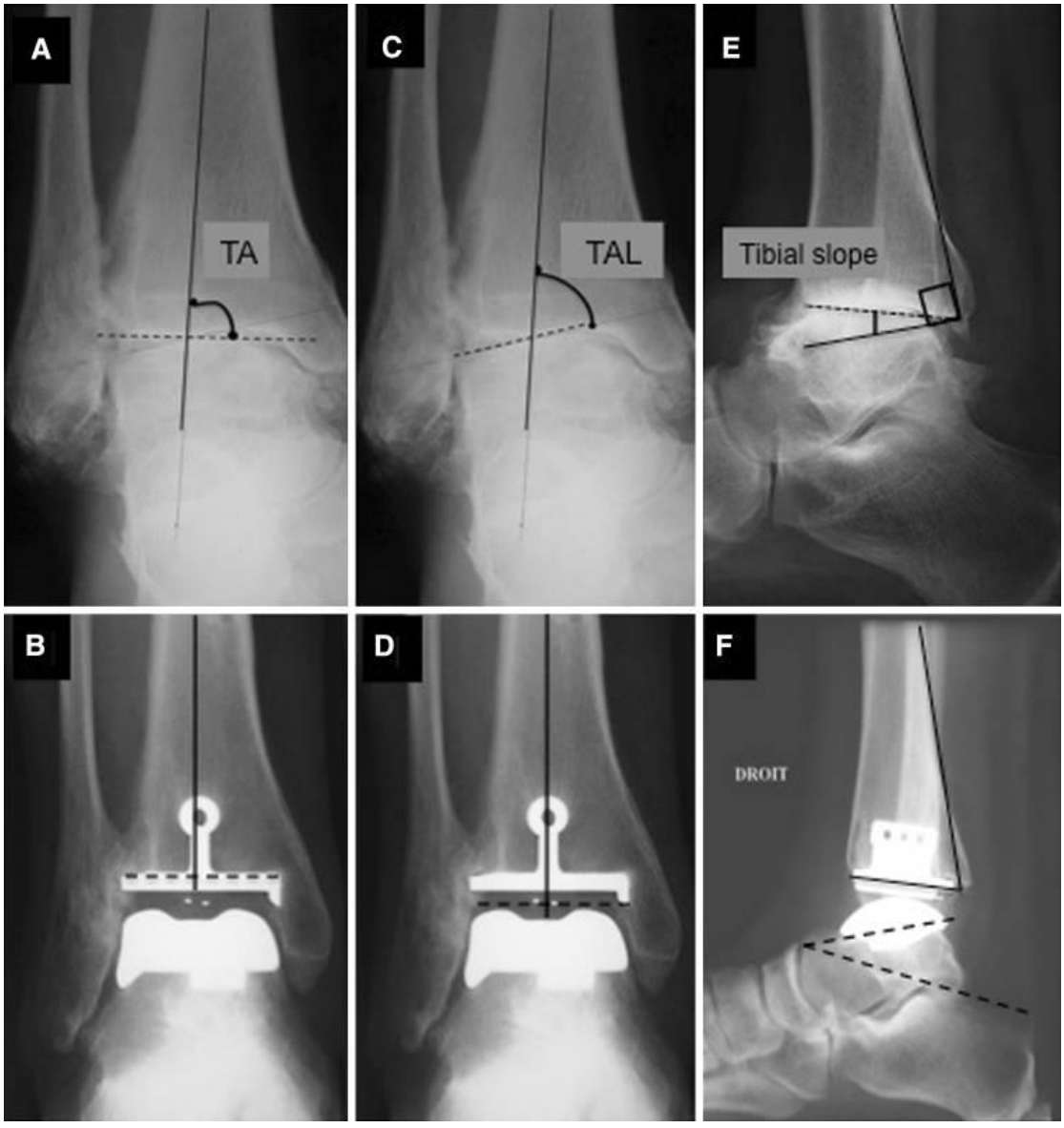

Fig 1. Angle measurements on weightbearing AP and lateral radiographs of the ankle as described by Bonnin[15]. (A&B) Preoperative and postoperative tibial angle, TA, measured between the axis of the tibia and the articular surface of the tibial plafond. (C&D) Preoperative and postoperative talar angle, TAL, measured between the axis of the tibia and the superior articular surface of the talus. (E) Preoperative tibial slope, which is the angle between a line drawn along the posterior tibial cortex and a second line connecting the most anterior and posterior points of the tibial joint surface. (F) Postoperative tibial slope and talocalcaneal angle, which is measured between the undersurface of the talar component and a reference line drawn from the superior border of the talonavicular joint and the most superior aspect of the posterior process of the calcaneus. Any variation greater than 5° in these measurements was considered component migration.

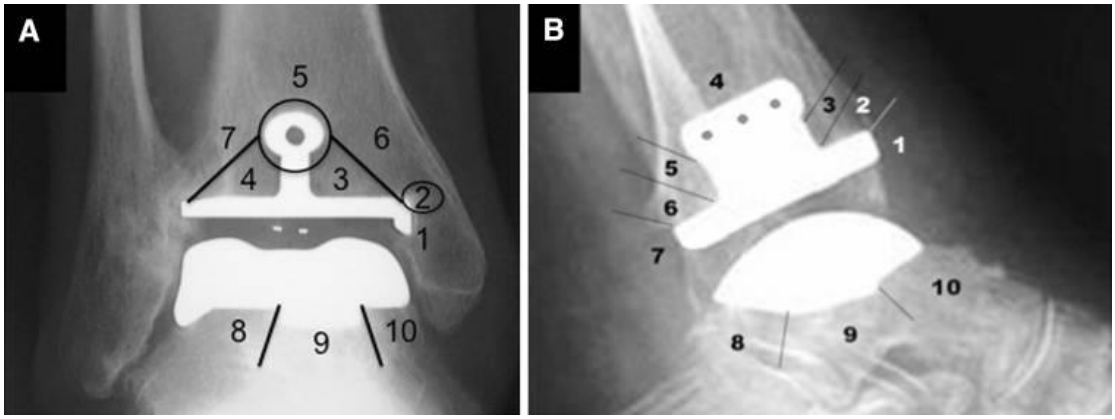

Fig 2. Regions of radiolucency and cyst appearance as described by Bonnin[15] on AP (A) and lateral (B) ankle radiographs.

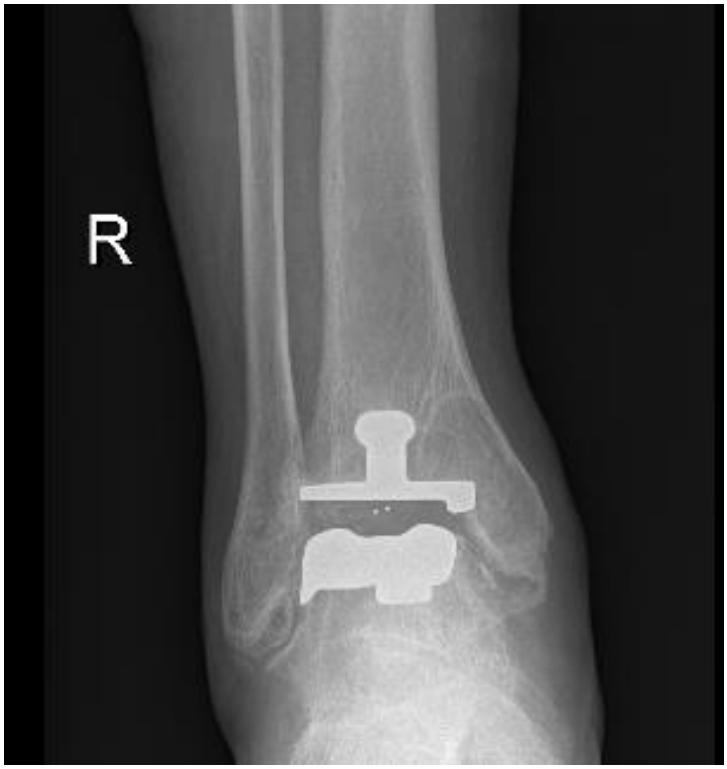

Fig 3. Large medial cyst seen on follow-up x-ray, for which bone grafting was performed.

Fig 4. Kaplan-Meier plot for implant survival

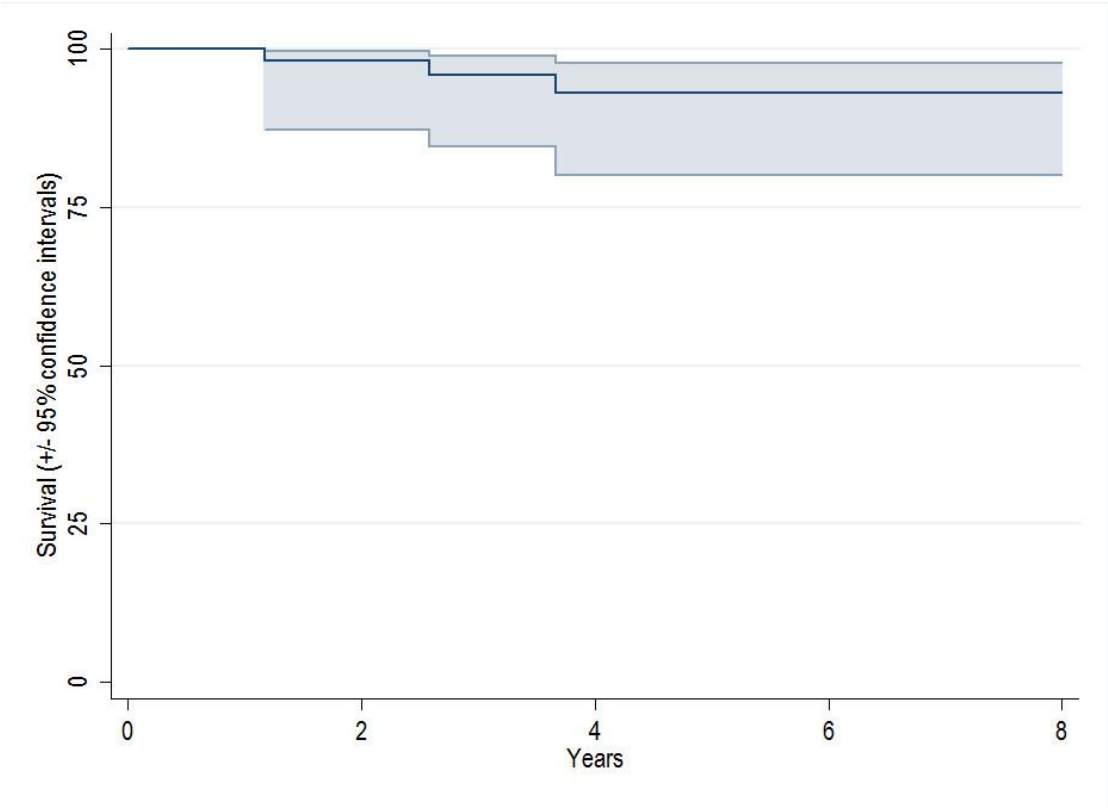

Table 1: Life table with all cause revision as the end-point

Interval	Entering	At risk	Revised	Lost	Survival
1	53	53	0	0	100 (100-100)
2	53	52.5	1	0	98.1 (87.4-99.7)
3	52	45.5	1	12	96.0 (84.8-99.0)
4	39	36	1	5	93.4 (80.5-98.0)
5	33	29.5	0	7	93.4 (80.5-98.0)
6	26	22	0	8	93.4 (80.5-98.0)
7	18	13	0	10	93.4 (80.5-98.0)
8	8	5	0	6	93.4 (80.5-98.0)
9	2	1	0	2	93.4 (80.5-98.0)

Table 2: Life table with revision/reoperation as the end-point

Interval	Total	At risk	Deaths	Lost	Survival
1	53	53	0	0	100 (100-100)
2	53	52.5	1	0	98.1 (87.4-99.7)
3	52	45.5	1	12	96.0 (84.8-99.0)
4	39	36	1	5	93.4 (80.5-98.0)
5	33	29.5	1	6	90.2 (75.6-96.3)
6	26	22	1	7	86.2 (69.0-94.3)
7	18	13	0	10	86.2 (69.0-94.3)
8	8	5	0	6	86.2 (69.0-94.3)
9	2	1	0	2	86.2 (69.0-94.3)

Table 3: Patient-reported outcomes

Score	Subscale	Median	Range
FAOS	Pain	94.4	11.1-100
	Symptoms	85.7	10.7-100
	Activities of Daily Living	97.8	8.8-100
	Quality of Life	84.4	0-100
AOFAS	Pain	30	0-40
	Function	10	0-10
	Distance	5	0-5
	Surface	5	0-5
	Total	50	0-60
EQ5D	Index	0.837	-0.346-1
	VAS	79	10-100

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