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Original article

Poor outcomes of fusion with Trabecular Metal implants after failed total ankle replacement: Early results in 11 patients

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ABSTRACT

Introduction: One of the reasons for revision of total ankle replacement (TAR) implants is loosening due to subchondral cysts. Reconstruction and fusion of the ankle is often the first choice for revision procedures due to the large bone defects, which are typically filled with autograft and/or allograft. Filling the defect with a trabecular metal tantalum implant is a potential alternative given the biomechanical properties of this component.
Hypothesis: Using tantalum as a spacer provides primary stability and contributes to fusion of the ankle joint after removal of failed TAR implants.
Methods: Eleven patients underwent arthrodesis an average of 6.9 years after TAR. The mean height of the bone defect was 32 mm. It was filled with a specially designed quadrangular implant (Trabecular Metal™, Zimmer/Biomet) combined with an iliac crest graft. Ten patients underwent tibio-talo-calcaneal (TTC) arthrodesis fixed with an angled retrograde nail and one patient underwent talocrural arthrodesis fixed with two plates (anterolateral and anteromedial). The clinical, functional (AOFAS and SF36 scores) and radiological (plain X-rays and CT scan) outcomes were determined.
Results: At a mean follow-up of 19.3 months, the mean total AOFAS score was 56 (21–78) and the mean SF36 score was 60.5 (19–84). One patient was lost to follow-up and four patients still had pain. The tantalum implant was integrated in six patients. Five patients achieved fusion of the subtalar joint and 8 achieved fusion of the talocrural joint. Three patients required surgical revision.
Discussion: Our hypothesis was not confirmed. The clinical outcomes after more than 1 year of follow-up are disappointing, as was the large number of nonunion cases and the lack of tantalum integration. These technical failures can be explained by insufficient construct stability and/or insufficient implant porosity.
Level of Evidence: IV (retrospective cohort study).

1. Introduction

The 10-year survivorship of 3rd generation total ankle replacement (TAR) implants is only 69% to 78% in Scandinavian registers [1,2]. One of the main reasons for TAR revision is implant loosening due to subchondral cysts [3]. The size of the bone defects makes TAR revision challenging. In many cases, tibio-talo-calcaneal (TTC) arthrodesis must be performed instead of talocrural fusion. The ankle fusion rate after TAR removal is 84% [4]. If significant defects are seen on radiographs, a CT scan should be performed to assess the size of these defects [5]. When large subchondral cysts are present, reconstruction-arthrodesis of ankle is a surgical challenge. It requires a massive graft to fill the defects or to correct alignment problems and create an osteoinductive environment. The drawbacks of autografts are the limited amount of bone available, the comorbidity at the donor site and the compaction with potential loss of height during union [6,7]. Allografts can also be used. However, the nonunion rate is high at 24% [8] and there is gradual loss of height [9,10]. Using bone cement as a spacer brings an inert foreign body into the joint. Since it does not contribute to osteointegration, it is not suitable for this surgery. Tantalum (Ta) is an inert trabecular metal used as a spacer in hip, knee and spine surgery. The revision rate for tantalum implants used in acetabular defects is 12% [11].

Tantalum, the 73rd element in Mendeleev's periodic table, is a very dense metal, with minerals that have not direct impact on the

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Table 1
Preoperative and intraoperative data.

Patient	Gender	TAR type	Age at revision (years)	Arthrodesis technique	Bone graft harvesting technique
1	M	AES	73	TTC with retrograde nail	Posterior iliac crest autograft combined with bone substitute
2	M	AES	92	TTC with retrograde nail	Posterior iliac crest autograft combined with bone substitute
3	F	AES	56	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
4	F	Salto	43	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
5	M	Hintegra	58	TT with plate	Reamed anterior iliac crest autograft combined with bone substitute
6	F	AES	74	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
7	F	Ramsès	86	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
8	F	AES	82	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
9	M	AES	53	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
10	M	Hintegra	64	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute
11	M	AES	73	TTC with retrograde nail	Reamed anterior iliac crest autograft combined with bone substitute

F: female; M: male; TAR: total ankle replacement; TT: tibio-talar; TTC: tibio-talo-calcaneal.

natural environment and the biological cycle. Made of 98% tantalum, Trabecular Metal™ (TM) (Zimmer/Biomet, Warsaw, USA) is a structure with 550 μm diameter pores on average and a hexagonal network like cancellous bone. This provides it with a very good potential to integrate into bone tissue (80% of its volume) [12]. TM has excellent fatigue resistance [13], a fairly low modulus of elasticity (3 GPa) [14] that is similar to that of subchondral bone (1.5 GPa) and very good biocompatibility [15]. The material's low stiffness minimizes stress-shielding [12]. Tantalum contributes to osteoblast adhesion and proliferation, along with mineralization [14]. Despite these good properties, there is very little published data on its use in ankle surgery. Although a few studies have been done with a tantalum spacer, its design was not intended for this indication. In 2013, ankle spacer implants (Zimmer/Biomet, Warsaw, USA) were introduced specifically for ankle and TTC fusion procedures using a retrograde nail.

Our aim was to assess the outcomes after at least 1 year of follow-up of TAR revision by reconstruction-arthrodesis when using this spacer. We hypothesized that using tantalum as a spacer leads to successful fusion after removal of failed TAR implants.

2. Materials and methods

Between September 2013 and September 2015, a single experienced surgeon (JLB) operated on a continuous cohort of 11 patients for TAR revision with reconstruction-arthrodesis using the specially designed TM spacer. The 6 men and 5 women had a mean age of 69 years (43–92).

2.1. Patients

Five of the patients were employed at the time of revision (one had a work-related injury), four were retired, one was unemployed and one was on disability. The indications for the initial TAR were chronic ankle laxity in 4 cases, post-traumatic osteoarthritis in 3 cases, primary osteoarthritis in 3 cases and rheumatoid arthritis in 1 case. There were 7 AES™ implants (Biomet, Warsaw, USA), 2 Integra™ implants (Newdeal SAS, St Priest, France), 1 Ramses™ implant (Talus Group) and 1 Salto™ implant (Integra, Plainsboro, USA). The mean AOFAS ankle score [16] was 38/100 (19–40) before the TAR procedure.

TAR revision by reconstruction-arthrodesis was performed an average of 6.9 years (1.8–13.4) after the primary TAR procedure. The indication for revision was collapse of the implants due to subchondral cysts in 7 patients and severe misalignment with subchondral cysts in 4 patients. The preoperative AOFAS score was 33.8 (12–72). Radiographs were taken with A/P (Méary view) and lateral views to analyze the presence and location of the subchondral cysts. All patients had visible tibial and talar subchondral cysts. A computed tomography (CT) scan was done preoperatively to measure the height of the bone defects, which averaged 29 mm (15–50 mm). The preoperative and intraoperative data are summarized in Table 1.

2.2. Surgical technique

The revision procedure was done by reopening the anterior approach at the ankle. The TAR implants were removed, the subchondral cysts were curetted and the interposed membranes were sent for anatomical pathology analysis. This showed macrophage-dominant infiltration against the material. Samples of the bone and periarticular soft tissues were taken for microbiological analysis in order to rule out an infection. The height of the bone defects measured intraoperatively was 33 mm (25–70). A Trabecular Metal™ Ankle Interpositional Spacer (Zimmer®) was used to fill the defect and reinforce the arthrodesis. We used implants of three different widths (5 small, 3 medium, 3 large) and four different heights (8 of 25 mm, 1 of 30 mm, 1 of 35 mm and 1 of 45 mm) to match the height and shape of the bone defects. Autograft was added to all the TM implants. This was harvested by reaming the anterior iliac crest using an acetabular reamer in 9 patients. This technique provides large quantities of osteogenic corticocancellous graft material [17]. In the two other patients, autograft was harvested from the posterior iliac crest. The autograft was combined with lyophilized bone allograft chips (Osteopure™, EFS Auvergne-Rhône-Alpes, France) (Fig. 1).

Ten patients underwent TTC arthrodesis fixed with a non-locked retrograde nail (AFN611TM, Tornier, Bloomington, USA), diameter 10 mm (9 cases) or 12 mm (1 cases), with a lateral angle of 6° (7 cases) or 12° (3 cases). One patient underwent tibiotalar (TT) arthrodesis fixed with two locking plates (Tibiaxys® Ankle Plate [anterolateral/anteromedial], Integra, Plainsboro, USA), while preserving the subtalar (ST) joint (Fig. 2). The average operative time was 192 minutes (135–240). The average tourniquet time was 110 minutes (82–130).

2.3. Follow-up

The patients' ankle was immobilized for 2 months in a removable posterior resin splint and they were not allowed to bear weight on the operated limb. Gradual return to weight bearing was allowed after 2 months with a removable walking boot. The patients were reviewed postoperatively at 21 days, then 2, 4, 6, 12 and 18 months, then annually with radiographs (weight bearing A/P and lateral views) of the ankle. The functional outcomes after the revision were evaluated at the final follow-up visit using the AOFAS and SF36 scores [18]. A CT scan was done after 6 and 18 months. Ankle fusion was determined on the CT scan using axial, sagittal and coronal slices. If fusion was visible on less than 30% of slices, the patient was said to have a nonunion. If fusion was visible on more than 70% of slices, the patient was said to have definitive fusion. The fusion was doubtful in the other cases. The same procedure was used to

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