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SURGICAL TECHNIQUE

Can Porous Tantalum Be Used to Achieve Ankle and Subtalar Arthrodesis?

A Pilot Study

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Abstract A structural graft often is needed to fill gaps during reconstructive procedures of the ankle and hindfoot. Autograft, the current gold standard, is limited in availability and configuration and is associated with donor-site morbidity in as much as 48%, whereas the alternative allograft carries risks of disease transmission and collapse. Trabecular metal (tantalum), with a healing rate similar to that of autograft, high stability, and no donor-site morbidity, has been used in surgery of the hip, knee, and spine. However, its use has not been documented in foot and ankle surgery. We retrospectively reviewed nine patients with complex foot and ankle arthrodeses using a tantalum spacer. Minimum followup was 1.9 years (average, 2 years; range, 1.9–2.4 years). Bone ingrowth into the tantalum was analyzed with micro-CT in three of the nine patients. All arthrodeses were fused clinically and radiographically at the 1- and 2 year followups and no complications occurred. The American Orthopaedic Foot and Ankle Society score increased from 32 to 74. The micro-CT showed bony trabeculae growing onto the tantalum. Our data suggest tantalum may be used as a structural graft option for ankle and subtalar arthrodesis. All nine of our patients achieved fusion and had no complications. Using tantalum obviated the need for harvesting of the iliac spine.

Level of Evidence: Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

To achieve and maintain a desired correction, a structural graft often is needed to fill gaps during reconstructive procedures of the ankle and hindfoot (eg, in subtalar distraction arthrodesis, fusion after failed total ankle arthroplasty, lateral column lengthening) [50, 58]. Recognized options currently include autograft, allograft, and xenograft bone, each associated with certain disadvantages. Autograft, which is considered the gold standard for bone grafting because of its high healing potential, is associated with donor-site morbidity in 15% to 48% [17, 21, 24, 38, 42, 45], postoperative complications (hematoma, hypoesthesia, wound dehiscence) in 3% to 39% [24, 38, 42], limited quantity, and risk of graft collapse [24]. Allograft and xenograft carry the risk of infectious disease transmission, lower stability attributable to the preparation process, and potential failure to integrate, which can result in graft collapse and failure of surgery [6, 24, 35].

Porous tantalum is a trabecular metal that resembles bone in its microstructure (Fig. 1). It is 80% porous,

allowing two to three times greater bony ingrowth compared with conventional porous coatings, and is considered osteoconductive [3]. Its compressive strength and elastic modulus are similar to normal bone, which theoretically reduces stress shielding and stress concentration [3–5, 56]. Tantalum is biocompatible and its mechanical properties have been studied extensively [2, 25, 34, 56]. Owing to its biocompatibility, tantalum has been used safely in patients for years for pacemaker electrodes, cranioplasty plates, and as radiopaque markers [29, 30].

The osteointegration of tantalum was observed in a histologic canine study [4].

Bony microstructure also has been assessed in animal studies by micro-CT (high-resolution peripheral quantitative computed tomography) [10, 52, 53]. Micro-CT has become increasingly popular for in vivo assessment of osteoporosis in human bone [8, 9], and we presumed it could be used similarly with porous tantalum.

Porous tantalum has been used successfully as a structural graft for interbody cervical fusions. In two randomized controlled trials comparing tricortical autologous iliac crest graft and porous tantalum, similar clinical (SF-36, neck disability index, visual analog scale) and radiographic outcomes were found at 2 years. However, tantalum was associated with a lower complication rate than autograft as it avoided any donor-site morbidity [19, 54]. Tantalum also has been used successfully in primary and revision THAs and TKAs for reconstruction of large bony defects [20, 30, 36, 37, 40, 46, 47] and as a possible intervention for osteonecrosis of the femoral head [15]. Its use in the foot and ankle is new and only one case report exists [6].

Our pilot study had two purposes: (1) to evaluate the clinical outcome and complications after using tantalum for ankle and subtalar arthrodesis after a short trial period; and (2) to verify osseous incorporation of tantalum with micro-CT.

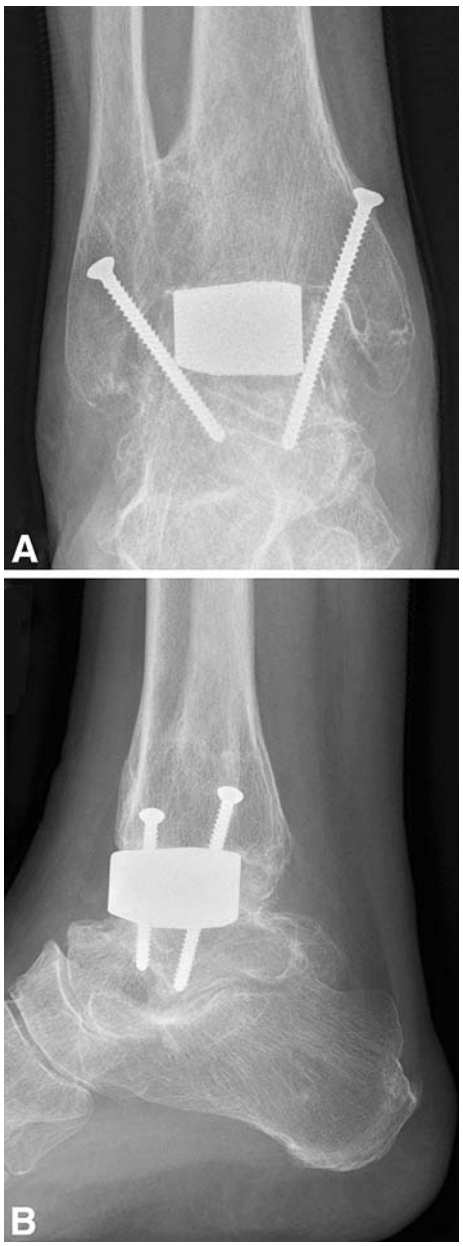

Fig. 1A–B (**A**) Anteroposterior and (**B**) lateral radiographs show an ankle fusion with a tantalum spinal fusion device after failed total ankle arthroplasty. The 14-mm high tantalum block bridges a large bony defect between the tibia and talus. The radiographs show signs of bony incorporation of the tantalum and fusion of the ankle.

Materials and Methods

We retrospectively reviewed nine patients with complex foot and ankle problems who underwent arthrodesis of the foot and ankle using a tantalum spacer (Zimmer Inc, Warsaw, IN) from June to November 2006. There were three men and six women, with an average age of 53 years (range, 19–74 years). Indications included patients with large bony defects (failed revision total ankle replacement [one patient] [Fig. 1]), osteonecrosis of the talus in a morbidly obese patient [one patient], subtalar nonunion in a pantalar fusion ([one patient] in a smoker), severe flatfeet in patients with poor bone quality (patients with rheumatoid arthritis with chronic prednisone use [two patients], one of them a smoker), or with morbid obesity to increase stability of the fusion to prevent possible collapse and loss of correction ([four patients] Fig. 2). The mean Charlson comorbidity score of these patients was 0.8 (range, 0–5) [13, 18]. Minimum followup was 1.9 years (average, 2 years; range, 1.9–2.4 years). Patients provided informed consent and the study was approved by the authors' University Ethical Review Board. The study was performed in accordance with the World Medical Declaration of Helsinki.

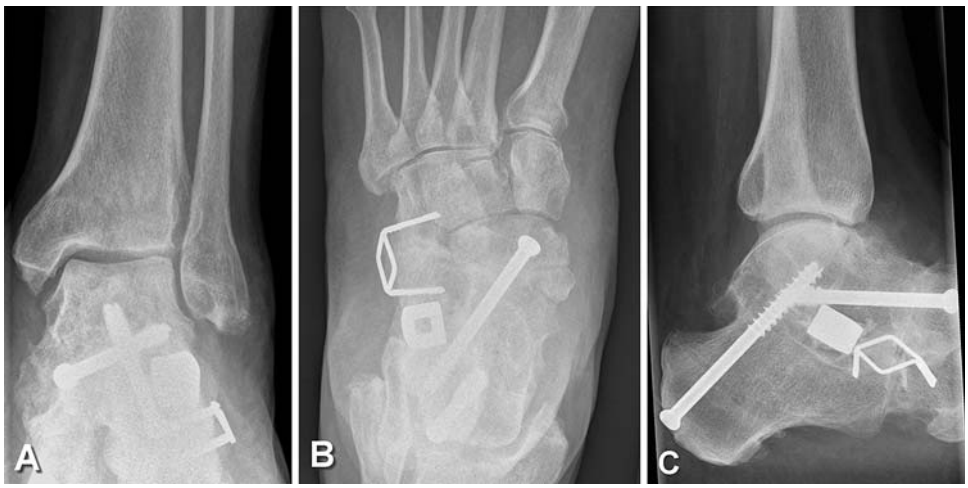

Fig. 2A–C (**A**) Anteroposterior, (**B**) dorsoplantar, and (**C**) lateral radiographs show a patient after triple-realignment arthrodesis using a tantalum cervical fusion device. The tantalum block was tamped into the sinus tarsi to achieve and maintain the desired correction. The radiographs show signs of bony incorporation of the tantalum and fusion of the subtalar joint.

The failed revision total ankle replacement was converted to an ankle arthrodesis using the existing anterior approach. After removal of the prosthesis, the tantalum block was inserted in the bony defect. A block for spinal surgery measuring 21 × 32 × 14 mm was used (Fig. 3A). To maintain the position of the ankle fusion, we used two 4.5-mm tibiotalar screws (one from the lateral side introduced from the posterior leg, one from the medial side [Fig. 1]), and an external fixator from the tibia to the calcaneus. The external fixator was removed at 6 weeks.

The subtalar fusions were performed as part of a triple or pantalar fusion over an extended lateral approach. After removing the cartilage, the alignment was observed and corrected using a lamina-spreader. It is our general practice for patients with complex foot and ankle problems as outlined above, to tamp a structural graft (usually allograft from the fibula or femoral head) into the sinus tarsi similar to a Grice-procedure [1, 7, 31, 32] to augment fixation of the subtalar arthrodesis, thus preventing collapse and increasing the chance of fusion. For this pilot study, we used a tantalum block instead. Tantalum blocks are available in various shapes, sizes, and heights (Fig. 3). A trial spacer was inserted in the sinus tarsi to determine the piece of tantalum needed. Reshaping the tantalum with a saw is not recommended as it seals the porous microstructure and puts the osteoconductive properties at risk. For the subtalar fusions, a cervical fusion device (Zimmer Inc), 14 × 14 mm (Fig. 3B) and height of 5 to 9 mm was tamped in the sinus tarsi and the subtalar joint then was tightened with the compression screws (Fig. 2). The subtalar arthrodesis was internally fixed with one to two screws (6.5 mm screws from the heel, across the subtalar joint, into the talus), or in patients with complex revisions with previously fused ankles, a retrograde intramedullary nail was inserted.

Postoperatively, all patients wore a cast and were nonweightbearing using crutches. After 2 weeks, the sutures were removed and the cast was changed. At 6 weeks, the cast was exchanged, radiographs were taken, and patients were allowed touch weightbearing. At 12 weeks, the cast was removed and radiographs again were taken. If we judged satisfactory union had occurred, the patient was permitted full weightbearing or if the union was unsatisfactory the patient was allowed partial weightbearing. Clinical and radiographic followups were obtained at 3 to 4-week intervals until we judged the presence of union. Radiographic criteria for fusions were complete bridging of the joint line/osteotomy site by trabeculae and absence of a visible joint line or gap. The treating surgeons (HD, IR) and the hospital radiologist independently determined the occurrence of fusion radiographically, or with CT if needed.

After the fusion had been verified, all patients were followed clinically and radiographically during the postoperative course with radiographs 1 and 2 years postoperatively and with further clinic visits if indicated by problems. At the 2-year followup, the AOFAS score [26] was assessed by the treating physician. Main outcome measurements were the clinical outcome (fusion rate) and complications in the 2-year period.

To assess the microanatomy, we obtained micro-CT scans (Scanco Medical, Brüttisellen, Switzerland) at the 2-year followup, but owing to artifacts from previous hardware [28, 51], it was limited to use in patients with fewer than three screws and a distance greater than 1 cm between tantalum and screws. Four of the nine patients qualified, but one declined to participate in the study, which resulted in three micro-CT scans. We used 60 kVp, 1000 μamp, 100-millisecond integration time for each micro-CT scan. The total time for each measurement was approximately 4 minutes and resulted in 150 slices or a 12-mm-long three-dimensional representation of the foot. The effective radiation dose from one scan was approximately 4 μSv, which was well below the recommended annual dose limit (approximately 1 mSv) for the general

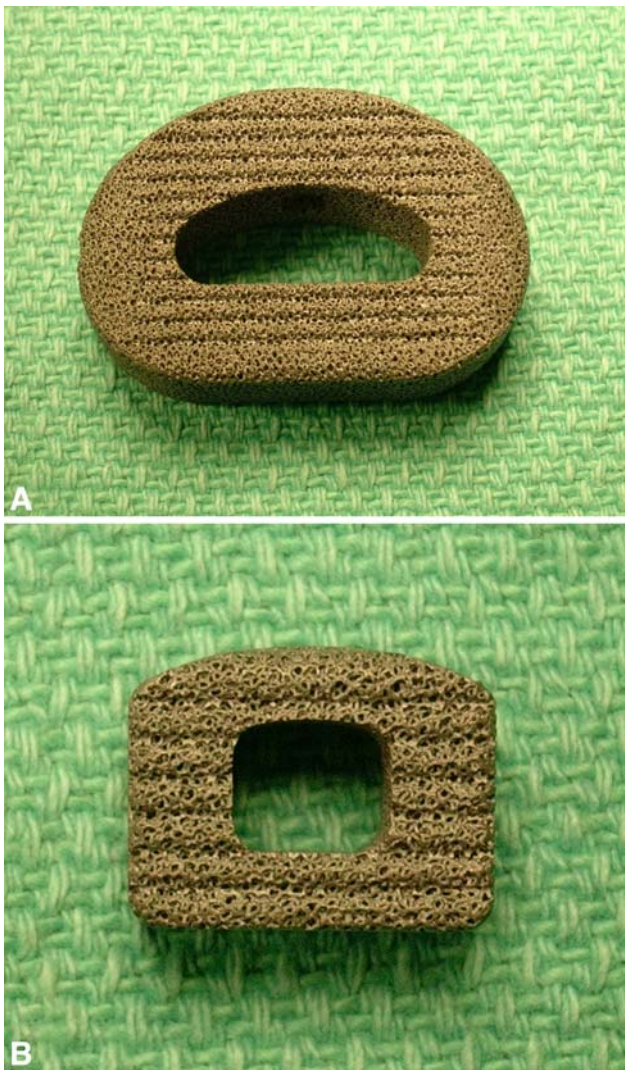

Fig. 3A–B The photographs show (**A**) a tantalum spinal fusion device used as a spacer for ankle fusion after failed total ankle arthroplasty and (**B**) a cervical fusion device used as a spacer for subtalar arthrodesis. After using a trial spacer in the operation, a tantalum block can be selected from various shapes, sizes, and heights to achieve the most optimal fit. Tantalum should not be cut with a saw as this would seal its porous microstructure and jeopardize its osteoconductive properties.

public (International Commission on Radiological Protection) [23].

Results

At 1 and 2 years followup, all nine arthrodeses were fused. We observed no patients with collapse, loss of correction, or infection. The AOFAS score increased from 32 (range, 8–62) preoperatively to 74 (range, 37–100) at the 2-year followup.

In the three patients with micro-CT, we observed condensation of bony trabeculae on the tantalum (Fig. 4) with

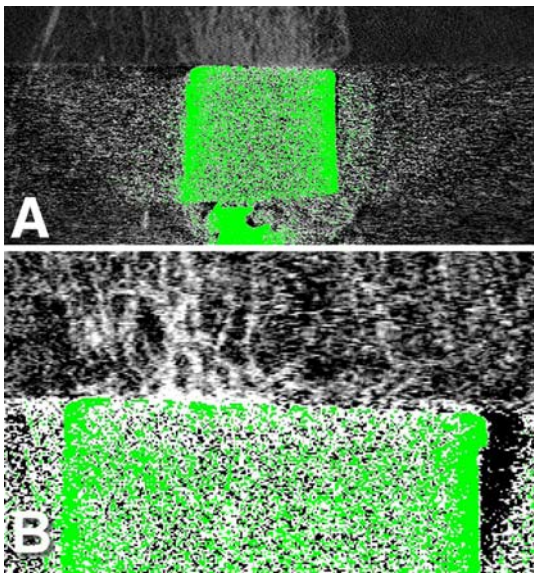

Fig. 4A–B (**A**) A sagittal view micro-CT shows condensation of trabeculae on the tantalum block, which means the force transmission from the tibia to the talus flows through the tantalum block. (**B**) A frontal view micro-CT shows ingrowth of trabeculae on the porous structure of the tantalum. Artifacts in the tantalum make interpretation of bony ingrowth in the tantalum impossible.

bone ingrowth in the bone-implant interface. Bone ingrowth in the tantalum could not be evaluated owing to artifacts of the metal.

Discussion

Tantalum has been used successfully in cervical interbody fusions and primary and revision total hip and knee replacements [19, 20, 30, 36, 37, 40, 46, 47, 54]. Its use in foot and ankle surgery has not been documented. We therefore evaluated the clinical scores and complications after using tantalum for ankle and subtalar arthrodesis after a 2-year period. As the use of tantalum is new in foot and ankle surgery, we questioned whether osseous incorporation of tantalum could be verified with micro-CT. The second purpose of our pilot study, therefore, was to investigate osseous incorporation of tantalum in vivo using micro-CT.

Our pilot study has certain limitations. First, the number of patients was small and conclusions comparing tantalum with autograft or allograft are not possible. A randomized controlled prospective trial would be needed [19, 54]. A larger series of 50 to 100 patients originally was planned with approval from the authors' local institution, but our plans subsequently were modified by the Provincial Health Technology Assessment Committee to include a limited number of patients who would be reviewed after a short

trial period before exposing more patients, despite the fact that porous tantalum already was used in spinal surgery. A similar situation was reported by Wigfield et al. when starting to use tantalum in spine surgery [54]. Second, the imaging of tantalum by CT or micro-CT is associated with artifacts in the tantalum and in the direction of the xray beam [28, 51]. When the bone-tantalum interface was parallel to the xray beam, artifacts were minimal. However, other hardware such as screws, plates, or intramedullary nails in the region of the tantalum created artifacts which made precise assessment of bone ingrowth impossible in most of these patients with complicated foot problems. Third, we do not know the long-term outcome of these procedures and whether long-term complications would develop, or the difficulties in revising these procedures (eg, in case of secondary infection) should that be necessary.

All of the hindfeet or ankles of our nine patients with porous tantalum have fused and we observed no complications. These observations are consistent with those reported with the use of tantalum in spinal fusion and treatment of bony defects in revision and primary THAs and TKAs [30, 36, 40, 47]. Tantalum has the advantage that it avoids donor-site morbidity of harvesting the iliac crest graft and the possibility of disease transmission. Harvesting autograft at the iliac crest has a reported donor-site morbidity rate of 15% to 48% (postoperative hematoma, infection, hypesthesia, increased postoperative pain, wound dehiscence, cosmetic defect, prolonged pain in the long term, and impairment in ambulation, work, and activities of daily living [17, 21, 24, 38, 42]). The cost of tantalum (approximately $1000 per block in the US) is comparable to allograft ($850, plus approximately

Table 1. Summary of advantages and disadvantages of structural graft options reported in the literature

Graft option	Stability	Healing potential	Disadvantages	Advantages	Quantity	Costs
Autograft	Gold standard	Gold standard	Donor-site morbidity up to 48%, postoperative complications up to 39%, possible collapse [17, 21, 24, 38, 42, 44, 45]	Best healing potential	Limited	Approximately 20 minutes OR (approximately $600–$700)
Allograft	Less owing to the preparation process [19, 24, 54]	Less [33, 41, 47, 48]	Possible infectious disease transmission, possible collapse [33, 41, 55]	No donor-site morbidity	Limited	Approximately $850
Tantalum	Similar to normal bone [3, 4, 56]	Similar to gold standard [19, 54]	Difficult radiographic assessment of fusion [28, 51, 54]	No donor-site morbidity, no reported complications [19, 20, 36, 37, 54]	Unlimited	Approximately $1000 per piece

Table 2. Possible operations for management of a failed total ankle replacement

Study (year)	Followup (years)	Operation	Graft	Fusion rate (n/n)	Graft/operation-related complications
Thomason and Eyres (2008) [49]	2.7	Intramedullary nail	Femoral head allograft	3 of 3	None reported
Carlsson (2008) [11]	1.6	Intramedullary nail	Titanium cage with autograft	0 of 3	Subtalar joint sacrificed, all nonunions
Schill (2007) [43]	1–3	Intramedullary nail	Autograft from fibula or iliac crest	14 of 15	None reported
Culpan et al. (2007) [16]	3.7	Compression screws	Iliac crest autograft	15 of 16	None reported
Kotnis et al. (2006) [27]	1	Intramedullary nail	No	9 of 9	None reported
Hopgood et al. (2006) [22]	2.4	Intramedullary nail or compression screws	No	17 of 23	None reported
Zwipp and Grass (2005) [57]	1	Compression screws and plates	Iliac crest autograft	3 of 4	None reported
Carlsson et al. (1998) [12]	4–15	External fixation	No	17 of 21	None reported

Table 3. Published studies of iliac crest autografts used for hindfoot fusions

Study (year)	Followup (years)	Operation	Graft	Fusion rate (n/n)	Graft/operation- related complications
Trnka et al. (2001) [50]	5.7	Subtalar distraction arthrodesis	Iliac crest and femoral head allograft	32 of 37	None reported
Pollard and Schuberth (2008) [39]	2.3	Subtalar distraction arthrodesis	Iliac crest autograft	21 of 22	None reported
Chen et al. (1998) [14]	5.4	Subtalar distraction arthrodesis	Iliac crest autograft	35 of 36	None reported

5 minutes of preparation time in the operating theater) or harvesting iliac crest autograft (estimated at $600 to $700, as it involves approximately 20 minutes of operating time, suture material, sponges, and dressing) (Table 1).

The treatment of a failed total ankle replacement is challenging with only a few reports of outcomes (Table 2). Ankle arthrodesis without structural grafting results in considerable shortening of the leg, donor-site morbidity with the use of autograft, and intramedullary nailing sacrifices the subtalar joint (Table 2). Using a porous tantalum block in conjunction with external fixation could avoid these problems. It is our general practice to augment subtalar fusions in patients with complex foot and ankle problems with a structural graft (usually allograft) tamped into the sinus tarsi similar to a Grice-procedure [1, 7, 31, 32]. For this pilot study, a block of tantalum was used instead. Other studies using structural grafts in foot surgery are limited to autograft from the fibula or iliac crest with a union rate of 87% to 100% (Table 3) [1, 7, 14, 31, 32, 39, 50]. Donor-site morbidity was not reported in these studies, but we presume the rates would be similar to those reported for spinal surgery.

We observed condensation of trabeculae in the tantalum block in three of our nine patients. However, owing to artifacts from surrounding hardware in many patients, we believe micro-CT generally is not suitable to assess osseous integration of tantalum.

Our data suggest porous tantalum may be used as a structural graft for ankle and subtalar arthrodesis. All nine of our patients achieved fusion without any complications, corresponding to the findings reported when tantalum has been used in spine and primary and revision total hip and knee replacements. Harvesting of graft from the iliac spine was not necessary, thus eliminating donor-site morbidity. We believe tantalum is useful in complex cases such as revisions when a high healing potential is desired to achieve fusion or in morbidly obese patients when a graft with greater stability is required.

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