Published in final edited form as:

J Arthroplasty. 2013 June ; 28(6): 922–927. doi:10.1016/j.arth.2013.01.035.

Bone Ingrowth in Well-Fixed Retrieved Porous Tantalum Implants

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Abstract

While first generation porous coatings have had clinical success, aseptic loosening remains a leading cause of revision. The purpose of this study was to investigate the reason for revision and to assess the amount of bone ingrowth in retrieved porous tantalum components. In a prospective multicenter retrieval program, 76 porous tantalum acetabular shells, 5 femoral stems, 7 patellas and 36 tibial trays were collected from revision surgeries. A subset of the implants were analyzed for bone ingrowth. The main reason for revision was infection for acetabular shells (1.4 year implantation time) and instability for tibial trays (1.8 years implantation time). Two of the thirty primary surgery acetabular shells and one of the thirty-six primary surgery tibial trays were revised for implant loosening. We observed full depth penetration of bone into the porous tantalum layer for the acetabular shells and femoral stems.

Introduction

Total hip replacement (THA) and total knee replacement (TKA) have been successfully employed for the treatment of end stage arthritis, rheumatoid arthritis and fracture. Despite their success, there were an estimated 45,000 total hip revisions and 60,000 total knee revisions performed in the United States in 2009. A recent Nationwide Inpatient Sample (NIS) study that reviewed 51,345 revision THA procedures in the United States showed that the most common reasons for revision were instability/dislocation (22.5%), mechanical loosening (19.7%) and infection (14.8%). Infection (25.2%), loosening (16.1%) and implant failure/breakage (9.7%) were the most common reasons for revision in an NIS study that reviewed 60,355 revision TKA procedures. Thus, implant loosening remains an important concern both in THA and TKA. In an effort to reduce loosening rates caused by long-term breakdown of the cement mantle, manufacturers introduced cementless technologies to provide for biologic fixation by tissue ingrowth or ongrowth (osseointegration) at the bone-implant interface. Historically used porous coatings include cobalt-chrome-alloy sintered beads, Fiber Metal™, Cancellous-Structured Titanium™ and titanium plasma spray. Even

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though these materials have had excellent clinical results, several perceived limitations such as a relatively high modulus of elasticity, low coefficient of friction and low porosity exist.

Given these limitations, several orthopaedic manufacturers have introduced various highly porous metals (HPMs), to address aseptic loosening of hip and knee components. Porous tantalum coatings are designed with several important features: increased volume of tissue in-growth due to high porosity (75–85%), comparable elastic modulus to trabecular bone (2.5–3.9 MPa) to reduce stress shielding and favorable frictional characteristics ($\mu = 0.88$) to reduce micromotion. Animal studies using porous tantalum implants have shown bone ingrowth of: 40 – 50% bone ingrowth (dogs, femur implants, 4 weeks implantation time), 8.3% (pigs, intervertebral lumbar arthrodeses, 3 months implantation time) and 35.1% (goats, spinal fusion implants, 6 weeks implantation time). Initial large-scale clinical studies have been generally promising with well-fixed implants and limited loosening incidents, however focused on radiographic review after short-to-intermediate term implantation.

Previous retrieval studies aimed at characterizing human bone ingrowth into porous tantalum implants have been limited in population size or focused on only tantalum rods. Due to the limited number of retrieval studies, the characterization of bone ingrowth in humans remains poorly understood. The first objective of this study was to determine the reasons for revision of retrieved porous tantalum implants. The second objective was to characterize the bone ingrowth into retrieved porous tantalum components.

Materials and Methods

Porous tantalum (Trabecular Metal; Zimmer Inc, Warsaw, Indiana) implants were retrieved during revision surgeries under an IRB-approved multicenter retrieval program. The retrieved implants, collected between 2003 and 2012, consisted of 76 acetabular shells, 5 femoral stems, 7 patellas and 36 tibial trays. Of the retrieved tibial trays, 35 were monoblock tibial components (27 LPS Flex and 8 CR-Flex) and 1 was a modular tray. Acetabular shells consisted of 30 implants retrieved after primary surgeries and 40 implants retrieved after revision surgeries based on available clinical data. Three femoral stems were retrieved after primary surgeries. The patellas consisted of 5 implants from primary surgery and 1 implant from revision surgery. All the tibial trays were retrieved following primary surgeries.

Clinical data consisting of age, primary/revision surgery, implantation time and reason for revision was obtained. Revision operative reports were reviewed to determine if loosening was noted by the surgeon. Retrieved components were cleaned in a 10% DisCide solution for modular metal components or 10% bleach solution for monoblock implants, followed by soaking in an ultrasonicator. The average patient age varied from 56 ± 9 years for tibial trays to 64 ± 13 years for femoral stems. The average implantation time varied from 0.2 ± 0.1 years for femoral stems to 2.1 ± 1.2 years for acetabular shells (Table 1).

Out of the collection, a subset was chosen to be dehydrated, embedded, sectioned and analyzed for bone ingrowth. Acetabular shells were excluded from the bone ingrowth study based on the following criteria: found to be grossly loose, cemented, complex revision surgeries or shells exhibiting only fibrous fixation. A subset was randomly selected from the remaining shells. One femoral stem was excluded from the study because it was revised for femoral loosening. Two salvage patellas were excluded from the study. The tibial trays were selected with favor given to the trays which were retrieved together with their associated pegs. The 7 available, corresponding tibial tray pegs were also chosen for analysis. In total, 10 acetabular shells, 4 femoral stems, 5 patellas and 7 tibial trays were chosen for analysis.

Each implant was then dehydrated using increasing graded alcohols (40% ethanol to 100% acetone). Specimens were infiltrated and embedded using Osteo-bed resin and catalyst

(Polysciences and Sigma-Aldrich). Specimens were cut into 3–4 mm sections using a diamond cut-off saw (Isomet 1000, Buehler, Lake Bluff, Illinois). Each section was ground flat, polished and sputter-coated with platinum-palladium to facilitate imaging. The sections from each implant were imaged at 22× magnification using a scanning electron microscope (SEM, XL30 ESEM FEG, FEI, Hillsboro, Oregon and Supra 50 VP, Zeiss Peabody, Massachusetts) equipped with a BSE detector to facilitate bone-implant imaging. The number of sections analyzed for each component was: 8 sections per acetabular shell, 5–7 sections per femoral stem, 3 sections per patella and 6 sections per tibial tray, 1 section per tibial tray peg. Individual images from BSE were stitched to create a montage for each individual section. Image processing of each montage consisted of thresholding the montage image to identify areas of tantalum and bone followed by manual correction for areas of false signal (e.g., residual polishing media) prior to analysis (Figure 1A).

The analysis consisted of three measurements: bone volume fraction, extent of ingrowth, and maximum depth of ingrowth. The bone volume fraction represents the fraction of available pore space within the porous coating that was occupied by bone. The entire process was validated by comparing the results against a manual point counting analysis conducted by two operators. The extent of bone ingrowth provides a topological indication of the distribution of bone ingrowth across the surface of the implant. The surface of the implant was divided into linear sections of approximately 1 mm length. Each 1 mm linear field was assessed for evidence of bone ingrowth beyond the surface of the implant. The extent of ingrowth was calculated as the number of sectors with ingrowth divided by the total number of sectors and expressed as a percentage (Figure 1B). The maximum depth was defined at the deepest point where bone was present in the porous tantalum substrate in each analyzed section. The maximum depth of ingrowth observed in the each section was measured and expressed as a percentage of the available depth of trabecular metal available for ingrowth (Figure 1C).

The bone volume fraction, extent of bone ingrowth and maximum depth were averaged to calculate an overall implant value. Kruskal-Wallis with post-hoc Dunn tests were used to evaluate differences between anatomic location. Pearson Chi Square tests were used to compare differences in reason for revision between cohorts. All statistical tests were performed using PASW Statistics package (Version 19.0.0; IBM, Chicago, IL).

Results

The main reasons for revision of the retrieved porous tantalum implants were infection (35.5%, 44/124 components), instability (22.6%, 28/124) and loosening (17.7%, 22/124). The predominant reasons for revision for primary surgery acetabular shells were infection (30.0%, 9/30 components), instability (26.7%, 8/30 components) and hematoma (10.0%, 3/30 components, Figure 2). Of the primary surgeries for acetabular shells, only two were revised for acetabular loosening. The predominant reason for revision of acetabular shells, removed after revision surgery, were infection (52.3%, 21/40 components), acetabular loosening (25.0%, 10/40 components) and instability (7.5%, 3/40 components). Our results showed a significant increase ($X^2 < 0.04$) in the number of acetabular shells revised for acetabular loosening when comparing primary surgeries (6.7%) to revision surgeries (25.0%). Among the analyzed acetabular shells the reasons for revision were infection (6), femoral loosening (2), instability (1) and periprosthetic fracture (1). Femoral stems were revised for instability, infection, femoral loosening, periprosthetic fracture and one unknown reason. Patellas were revised for infection (2), instability (2), patellar loosening (2) and arthrofibrosis (1). All retrieved tibial implants were from primary surgeries. The two most prevalent reasons for revision of tibial trays were instability (38.9%, 14/36 components), infection (19.4%, 7/36 components) and pain (13.9%, 5/36 components). One was revised

for tibial loosening. The analyzed tibial trays were revised for instability (5), femoral loosening (1) and infection (1).

The measured bone volume fraction, extent of ingrowth and depth of bone ingrowth were measured based on implant location. The average bone volume fraction was lowest in the tibial trays ($1.7\% \pm 1.2$) and highest in the femoral stems ($4.6\% \pm 1.6$, Table 1, Figure 3A). The average extent of bone ingrowth was lowest in the tibial trays ($21\% \pm 12$) and highest in the tibial tray pegs ($52\% \pm 21$) (Table 1, Figure 3B). The average maximum depth of bone ingrowth was lowest for the tibial trays ($60\% \pm 10$) and highest in the patellas ($79\% \pm 21$) and (Table 1, Figure 3C). There was no detected significant difference in the bone volume fraction between anatomic location ($p = 0.071$). Additionally, no difference was detected between anatomic locations for extent of ingrowth ($p = 0.066$) or depth ($p = 0.707$). Five acetabular shells, one tibial tray peg and two femoral stems demonstrated localized bone growth spanning the full depth of the porous tantalum (Figure 4A). Our findings showed that the bone ingrowth in tibial tray pegs was trending towards higher amounts when compared with the tibial trays, but there was insufficient statistical power to confirm.

For acetabular shells with screw holes, bone ingrowth was observed surrounding the screw holes in 11/18 sections (Figure 4B). The femoral stems were implanted for a short duration and immature woven bone formation was seen in several implants (Figure 4C). Bone ingrowth was primarily located in curved medial and lateral portions of the stem. All 7 of the tibial trays showed an ongrowth layer just above the porous tantalum substrate (Figure 4D). All 7 tibial tray pegs demonstrated bone ingrowth.

Discussion

This retrieval study documents the reasons for revision and characterizes the amount of bone ingrowth in porous tantalum implants. Initial clinical studies have documented a limited incidence of loosening. They have been limited, however, to radiographic review after short-to-intermediate term implantation. Previous retrieval studies have been limited in population size or only focused on tantalum rods when characterizing the amount of human bone ingrowth. To the authors' knowledge, this is the first study that quantified the amount of bone ingrowth into porous tantalum acetabular shells, femoral stems, tibial trays and patellas. The results of this study showed that there is no significant difference for the amount of bone ingrowth based on anatomic location. There were two cases of primary acetabular shells removed for loosening and one case of primary tibial components removed for loosening.

This study had several limitations. We were able to collect a large number of acetabular shells and tibial trays; however, collected a limited number of femoral stems and patellar implants. Additionally, due to the nature of a retrieval program, we can only report the prevalence of loosening within our retrieved population of implants. Only 4.8% (6/124) of the implants had implantation times greater than 5 years and, thus, we are limited to observation of short-term implantation. The current removal procedure can cause mechanical damage which negatively affects (reduces) the amount of bone ingrowth observed in the substrate. In contrast, post-mortem studies allow for removal of well-functioning components, with limited affects on the bone ingrowth into the implants, allowing for a more accurate analysis. A power study of the bone ingrowth measurements showed that this study had a limited power (power < 0.5).

Our results showed that the two most prevalent reasons for revision of primary surgery acetabular shells were infection (30.0%) and instability (26.7%). These results are similar to the Swedish Hip Registry, which shows that short-term retrievals (0–3 years) have a higher

revision rate (21.7%), due to infection, when compared to long-term implants (4–6 years (5.0%), 7–10 years (2.6%) and >10 years (1.5%)). In our study, acetabular loosening increased when comparing primary (6.7%) to revision (25.0%) surgeries, which is similar to the Australian Registry (primary surgeries, 31.3% and all surgeries, 54.1%). Our results showed that the most prevalent reasons for revision of tibial trays were instability (38.9%), infection (19.4%) and pain (13.9%), which is similar to a previous study that showed the main reasons for revision of implants revised before 5 years were infection (38%, 105/279 components) and instability (27%, 74/279 components). Earlier uncemented tibial components showed a high loosening rate: 19% (21/108 components, porous-beads, 64 month follow-up) and 7% (8/108 components, Fiber Mesh™, 11 years average follow-up) than our 1 loosening case. Previous studies of porous tantalum tibial trays with short-term follow-up showed few to no cases of tibial loosening.

We compared our acetabular shell bone ingrowth results to historical porous coatings surfaces (Fiber Metal™, Cancellous-Structured Titanium™ (CSTi™) and porous beads). Our acetabular bone volume fraction ($3.5\% \pm 1.5$) was similar to a previous retrieval study of Fiber Metal™ ($3.8\% \pm 8$), however lower compared to postmortem studies that investigated CSTi™ ($12\% \pm 6$) and porous beads (13%). Our acetabular shell extent of bone ingrowth ($46\% \pm 20$) was higher compared to a retrieval study of Fiber Mesh™ ($15\% \pm 23$), however was lower compared to postmortem studies that evaluated CSTi™ ($84\% \pm 9$) and porous beads 32%.

Our measured bone ingrowth for patellas and tibial trays were compared to historical porous coatings. Our reported bone volume fraction ($3.5\% \pm 4.1$) and extent of bone ingrowth ($41\% \pm 30$) for the patellas was lower than a previous postmortem study of well functioning CSTi™ patellar implants (bone volume fraction, $13\% \pm 9$ and extent, $86\% \pm 12$). Our reported bone volume fraction ($1.7\% \pm 1.2$) for tibial trays was lower than a previously reported retrieval study of Fiber Metal™ (9.5%) and two postmortem studies that investigated CSTi™ (6%) and porous beads (6%). We found our tibial tray extent of bone ingrowth ($21\% \pm 12$) to be similar to a retrieval study of Fiber Metal™ ($27\% \pm 16$), but lower than previous postmortem studies that evaluated CSTi™ (73%) and porous beads (34%).

Our bone ingrowth values are lower than previously reported studies, possibly due to differences in materials properties and/or measurement methods. The porosity of Fiber Metal™ (40 – 50%), CSTi™ (51%) and porous beads (30 – 50%) are lower compared to porous tantalum (70–80%). Comparing bone ingrowth between porous tantalum, Fiber Metal™, CSTi™ and porous beads can be misleading due to differences in the porosity and substrate thickness resulting in substantial differences in the available porous space for bone ingrowth. For example, given 100 cm³ of porous tantalum and porous beads, both having a bone volume fraction of 3%, the porous tantalum would have 2.25 cm³ of bone ($3\% \times 0.75$ average porosity), while the porous beads would have 1.2 cm³ of bone ($3\% \times 0.4$ average porosity). Currently, there is no standard method for bone ingrowth analysis, allowing for variation between institutions. Additionally, the maximum depth of bone ingrowth can be affected by the thickness of the porous coating or substrate. The thickness of porous tantalum layer for bone ingrowth varies between component types. The approximate thicknesses observed in our retrievals were: acetabular shell: 3.9 mm, femoral stem: 1.4 mm, patella: 2.5 mm and tibial tray: 2.6 mm.

It is promising that there were only two cases of acetabular loosening after primary surgery and one reported tibial tray loosening case in our retrieval cohort as loosening continues to be a prevalent issue in cementless technologies. We present the reason for revision and amount of bone ingrowth in retrieved porous tantalum implants. Further investigation into

the amount of bone ingrowth necessary and evaluation of long-term implants will yield insight into the clinical performance of porous tantalum implants.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Institutional funding has been received from the National Institutes of Health (NIAMS) R01 AR47904; Stryker Orthopaedics, Inc.; Zimmer, Inc.; Stelkast, Inc.; and through the Wilbert J. Austin Professor of Engineering Chair (CMR).

Each author certifies that all investigations were conducted in conformity with ethical principles of research.

This work was performed at the Implant Research Center, Drexel University, Philadelphia, PA, USA.

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Fig. 1.

A–C (A) A grayscale montage of a retrieved porous tantalum femoral stem. (B) An example image shows 3 sectors out of 7 having bone ingrowth, or approximately 43% bone ingrowth. (C) An image of an acetabular demonstrating the maximum depth measurement.

Fig. 2.
Reason for revision for porous tantalum implants.

Fig. 3.
A–C Porous tantalum results based on implant for: (A) Average bone volume fraction, (B) Average extent of bone ingrowth and (C) Average maximum depth of bone ingrowth. Note: Circles represent outliers in the data.

Fig. 4.

A–C (A) A representative image of an acetabular shell showing bone spanning the full depth of the porous tantalum substrate. (B) A representative image of an acetabular shell showing bone formation around screw holes. (C) A representative image of woven bone found in retrieved femoral stems. (D) A representative image showing a layer of bone ongrowth on a retrieved tibial tray.

Table 1

Clinical information of the retrieved porous tantalum components.

Complete Collection			Implants Analyzed for Bone Ingrowth				
Implant Type	Patient Age (y)	Implantation Time (y)	Patient Age (y)	Implantation Time (y)	Bone Volume Fraction (%)	Extent Ingrowth (%)	Maximum Depth (%)
Acetabular Shell (N =76,10)	59 ± 12 (37 – 88)	1.4 ± 1.7 (0.0 – 7.4)	62 ± 9 (53 – 78)	2.1 ± 1.2 (0.3 – 4.2)	3.5 ± 1.5 (1.2 – 6.9)	46 ± 20 (20 – 83)	76 ± 28 (39 – 100)
Femoral Stem (N=5,4)	64 ± 13 (49 – 85)	0.2 ± 0.1 (0.1 – 0.4)	64 ± 15 (49 – 85)	0.2 ± 0.1 (0.1 – 0.2)	4.6 ± 1.6 (2.7 – 6.6)	45 ± 22 (27 – 77)	69 ± 24 (45 – 100)
Patella (N =7,5)	63 ± 10 (48 – 77)	1.0 ± 0.4 (0.5 – 1.6)	61 ± 11 (48 – 77)	1.0 ± 0.5 (0.5 – 1.6)	4.1 ± 4.3 (0.2 – 11.3)	47 ± 30 (7 – 87)	79 ± 21 (45 – 99)
Tibial Tray (N = 36,7)	56 ± 9 (36 – 77)	1.8 ± 2.3 (0.2 – 12.8)	61 ± 9 (51 – 77)	1.7 ± 1.0 (0.6 – 3.1)	1.7 ± 1.2 (0.4 – 4.2)	21 ± 12 (8 – 46)	60 ± 10 (48 – 77)
Tibial Tray Pegs (N=7)	56 ± 9 (36 – 77)	1.8 ± 2.3 (0.2 – 12.8)	61 ± 9 (51 – 77)	1.7 ± 1.0 (0.6 – 3.1)	2.9 ± 1.0 (1.6 – 3.8)	52 ± 21 (29 – 79)	75 ± 20 (58 – 100)

Values are expressed as mean ± SD, with range in parentheses.