The Journal of Arthroplasty 28 (2013) 922–927

Contents lists available at SciVerse ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Bone Ingrowth in Well-Fixed Retrieved Porous Tantalum Implants

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ARTICLE INFO

Article history:
Received 3 October 2012
Accepted 31 January 2013

Keywords:
aseptic loosening
bone ingrowth
porous tantalum components

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 reasons 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 was analyzed for bone ingrowth. The main reason for revision was infection for acetabular shells (1.4 years 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.

Total hip arthroplasty (THA) and total knee arthroplasty (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 [1]. 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%) [2]. 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 [3]. Thus, implant loosening remains an important concern in both 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 [4]. Even 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 [5].

Given these limitations, several orthopaedic manufacturers have introduced various highly porous metals (HPMs), to address aseptic loosening of hip and knee components [4]. Porous tantalum coatings are designed with several important features: increased volume of tissue ingrowth due to high porosity (75%–85%) [5–7], 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 [4]. Animal studies using porous tantalum implants have shown bone ingrowth of: 40%–50% bone ingrowth (dogs, femur implants, 4 weeks implantation time [5]), 8.3% (pigs, intervertebral lumbar arthrodeses, 3 months implantation time [8]) and 35.1% (goats, spinal fusion implants, 6 weeks implantation time [9]). Initial large-scale clinical studies have been generally promising with well-fixed implants and limited loosening incidents, however they focused on radiographic review after short-to-intermediate term implantation [10–17].

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 [18–21]. 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.

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.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2013.01.035.

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0883-5403/2806-0010$36.00/0 – see front matter
http://dx.doi.org/10.1016/j.arth.2013.01.035

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 were 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, 6 sections per tibial tray and 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 (Fig. 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 (Fig. 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 (Fig. 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, Fig. 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 ($\chi^2 < 0.04$) 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,

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.