The Journal of Arthroplasty 30 (2015) 1008–1013

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Performance of Porous Tantalum vs. Titanium Cup in Total Hip Arthroplasty: Randomized Trial with Minimum 10-Year Follow-Up

Julien Wegrzyn, MD, PhD, Kenton R. Kaufman, PhD, PE, Arlen D. Hanssen, MD, David G. Lewallen, MD

Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota

ARTICLE INFO

Article history:
Received 29 May 2014
Accepted 11 January 2015

Keywords:
total hip arthroplasty
porous tantalum monoblock cup
cementless fixation
osseointegration
aseptic loosening

ABSTRACT

Porous tantalum monoblock cups have been proposed to improve survivorship of cementless primary THA. However, there are few direct comparative trials to established implants such as porous-coated titanium cups. 113 patients were randomized into two groups according to the cup: a porous tantalum monoblock cup (TM) or a porous-coated titanium monoblock cup (control). At a mean of 12 years after THA, no implants migrated in both groups. Two TM patients (4%) and 13 control patients (33%) presented with radiolucency around the cup ($P < 0.001$). In the control group, 1 cup (2%) was revised for aseptic loosening. At 12 years post-implantation, porous tantalum monoblock cups demonstrated 100% survivorship, and significantly less radiolucency as compared to porous-coated titanium monoblock cups.

Despite substantial improvements in cementless total hip arthroplasty (THA) implants, periprosthetic osteolysis and subsequent aseptic loosening secondary to biologic reaction to polyethylene (PE) and metallic wear debris represent some of the leading causes of implant revision and account for 20% of the overall revision THA procedures [1–3]. In an attempt to reduce mechanical failures of implant fixation, monoblock acetabular components have been proposed as an alternative to cemented PE or conventional cementless modular implants [4,5]. The monoblock design combines advantages of no PE backside wear due to liner micromotions, no metallic debris generated by deficient locking rings, and no holes which decrease surface area for bone ingrowth and allow pelvic entrance pathways for wear debris [4,5]. Accordingly, a porous tantalum monoblock cup (Hedrocel, Implex Corp., Allendale, NJ) and a porous-coated titanium monoblock cup (Elliptical, Implex Corp., Allendale, NJ) have been developed. The rationale of the Hedrocel cup is to combine the advantages related to the monoblock design with the unique properties of porous tantalum implants: a high friction coefficient that increases interface shear stress and primary frictional stability, a high volumetric porosity that enables extensive tissue integration and bone ingrowth into the shell scaffold, and a subchondral bone-matched elastic modulus that results in a more physiological mode of load transfer to the host bone with decreased periacetabular stress shielding [6–9].

Short-term to mid-term follow-up series evaluating porous tantalum monoblock cups have shown encouraging results with excellent initial fixation, osseointegration and stability; no evidence of progressive radiolucent lines, osteolysis, migration or gross PE wear; and no reported acetabular component revision for aseptic loosening [10–17]. However, to our knowledge, no prospective and randomized study to date has been performed to compare these promising early results obtained with such implants to more conventional cementless monoblock acetabular components. Therefore, this randomized controlled trial (RCT) aimed to compare the clinical and the radiological outcome of a porous tantalum monoblock cup to a porous-coated titanium monoblock cup in primary THA with a minimum of 10-year follow-up. We hypothesized that the use of porous tantalum for acetabular component in THA would improve implant osseointegration and survivorship, and reduce revisions associated with periprosthetic osteolysis and fixation failure at long-term follow-up.

Patients and Methods

A randomized controlled trial (RCT) on primary THAs with cementless monoblock acetabular components made of either porous tantalum (Hedrocel) or porous-coated titanium-alloy (Elliptical) was initiated in January 1998 and completed in December 1999. The Hedrocel porous tantalum monoblock cup consists of ultra-high molecular weight PE (UHMWPE, GUR 1020, Perplas Medical Ltd, Lancashire, UK) directly compression-molded into a backing made entirely of porous tantalum [6] (Fig. 1). The porous tantalum is an open and fully interconnected tridimensional porous surface with porosity of 75%–80% and an average pore size of 550 μm [6,9,18]. The elastic modulus is 3 GPa, which is between elastic modulus of subchondral (2 GPa) and cortical (15 GPa) bone [6,9,18]. The UHMWPE is moderately crosslinked and sterilized in nitrogen with 30 kGy of γ-radiation from a 60Co source [6]. The direct compression molding results in PE intrusion into the

Level of evidence: Therapeutic Level I.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.01.013.

Reprint requests: David G. Lewallen, M.D., Department of Orthopedic Surgery, Mayo Clinic, 200 First Street SW, Rochester, MN 55905.

http://dx.doi.org/10.1016/j.arth.2015.01.013
0883-5403/

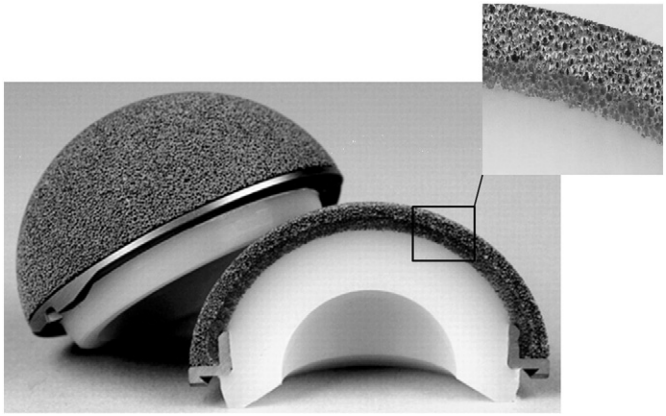

Fig. 1. The Hedrocel porous tantalum monoblock acetabular component. On the right and in the inset, a cross-sectional view of the monoblock cup showing the PE intrusion into the porous tantalum shell to a depth of 1 to 2 mm.

porous shell to a depth of 1 to 2 mm, leaving 2 to 3 mm of porous tantalum for bone ingrowth [6,7] (Fig. 1). The Elliptical porous-coated titanium monoblock cup consists of a compression-molded UHMWPE preassembled into a Ti6V4Al alloy shell [5,19]. The coating surface is made of 3 layers of 200 to 300 μm-diameter pure titanium beads [5,19]. The porosity of the coating surface is 30%–50% and the elastic modulus of Ti6V4Al alloy shell is 110 GPa [18,19]. The characteristics of the UHMWPE are the same as for the Hedrocel cups. The geometry of both cups is a hemi-ellipsoid designed for peripheral interference fit into an acetabular bone shaped with hemispherical reamers [5,6]. The equator diameter is 2 mm larger than the polar diameter allowing maximal coaptation and press-fit at the time of implantation [5,6].

Inclusion in the current RCT has been proposed to 278 patients during their preoperative visit to one of two senior surgeons at our institution (Fig. 2). The inclusion criterion was patient eligibility for primary cementless or hybrid THA with sufficient periacetabular bone stock for peripheral rim fixation. The exclusion criteria were acetabular segmental or rim non-supportive defect, severe acetabular dysplasia, and severe acetabular deformity related to acetabular fracture or advanced osteoarthritis. We excluded 167 patients who matched the inclusion criteria since they declined to participate in the study (Fig. 2). The assigned treatment was generated by a computerized randomization program administered by our Department of Biostatistics. For each patient, an opaque and sealed envelope containing the assignment to a group was chosen at random by the first assistant surgeon in the operating room before cup implantation. One hundred and eleven patients (111 hips) were randomized into the porous tantalum monoblock cup (TM, 56 patients) and porous-coated titanium monoblock cup (control, 55 patients) groups. Seven patients in the TM group and 9 patients in the control group were lost to follow-up due to failure to return for the postoperative evaluation and no response to phone calls or letters. Three patients in the TM group and 5 patients in the control group died before reaching a minimum 10-year follow-up. Therefore, 45 patients in TM group and 41 patients in the control group with a minimum 10-year follow-up of their THA were analyzed in this study (Fig. 2). No differences between groups were found in the following pre-operative parameters: age at surgery, gender ratio, BMI and preoperative Harris hip score (Table 1). Institutional review board approval and written informed consent were obtained from each patient before their enrollment in the study. A Hardinge's lateral transgluteal approach was performed in all the patients in both groups by one of two senior surgeons at our institution. Reaming was performed to the size of the acetabular component to be used. Positioning of the cup was in relation to the neighboring anatomic landmarks, seeking anteversion of 15° to 20°

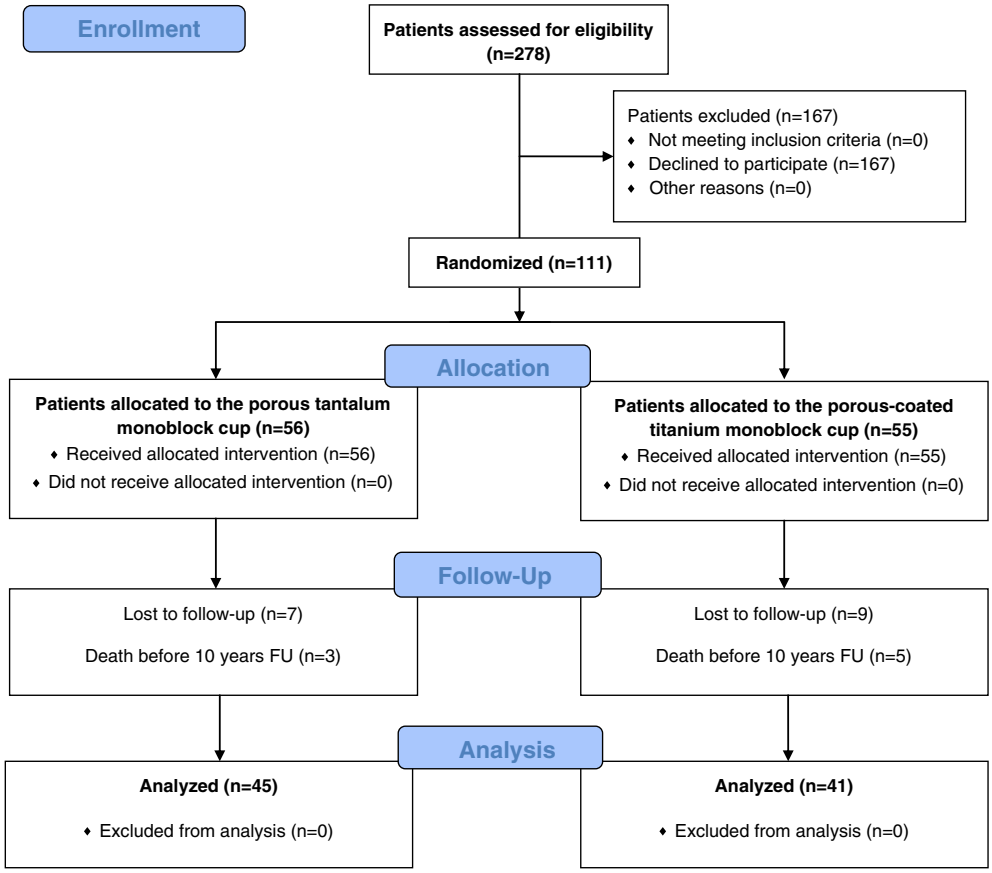

Fig. 2. Flow diagram illustrating patients' enrollment, allocation, follow-up and analysis [36].