Multicentre use of a porous tantalum monoblock acetabular component

Th. A. Xenakis · G. A. Macheras · K. S. Stafilas ·
A. T. Kostakos · K. Bargiotas · K. N. Malizos

Received: 12 December 2007 / Revised: 13 February 2008 / Accepted: 25 March 2008 / Published online: 29 May 2008
© Springer-Verlag 2008

Abstract The purpose of this study was to evaluate the minimum five-year prospective results from the multicentre use of a porous tantalum monoblock acetabular component for primary total hip arthroplasty (THA). A multicentre study was performed in 253 consecutive primary THAs in three separate surgical centres. All patients underwent identical postoperative protocols including radiological and clinical evaluation. The average preoperative total HHS score was 44.0 ± 13.8 and increased at one-year follow-up to 95.2 ± 4.8 ($p < 0.05$), remaining constant through the five-year follow-up at 97.0 ± 6.2 ($p < 0.05$). There was no radiographic evidence of gross polyethylene wear, progressive radiolucencies, osteolytic lesions, acetabular fracture, or component subsidence. From these results, we can recommend the continued use of this material for acetabular components in primary THA and that further review of the current multicentre population is warranted to determine the long-term durability of the acetabular composite.

Résumé Le propos de cette étude est d'évaluer, à cinq ans de suivi, les résultats d'une étude prospective multicentrique sur l'utilisation de composants acétabulaires ou monobloc

en tantalum lors de prothèses totales de hanche. Matériel et méthode: cette étude multicentrique concernait 253 prothèses de hanche consécutives dans trois centres différents. Tous les patients ont bénéficié du même protocole post-opératoire incluant une étude radiologique et une évaluation clinique. Résultats: le score HHS postopératoire a été de 44.0 ± 13.8 et s'est amélioré à un an postopératoire à 95.2 ± 4.8 ($p < 0,05$). Ce score demeure constant à 5 années de suivi 97.0 ± 6.2 ($p < 0,05$). Il n'y a pas de signe sur les radiographies d'usure grossière du polyéthylène, ni de liserés, ni de lésions ostéolytiques, ni de fractures de l'acétabulum ou de migrations des composants. En conclusion, à partir de ces résultats, nous pouvons recommander l'utilisation de ce matériel pour les composants acétabulaires de prothèses totales de hanche. Néanmoins, il sera nécessaire de faire d'autres études afin d'évaluer cette évolution sur un plus long terme.

Introduction

Successful acetabular component implantation in association with primary total hip arthroplasty (THA) requires correct component position, immediate component macro-fixation, component stability, and an optimum surface for biological on-growth (surface preparations such as plasma spray-coating) or biological in-growth (porous surfaces such as sintered beads or fibre mesh pads). The use of ancillary screw fixation may aid in overall component stability in weak or porotic bone but may lead to a pathway for polyethylene debris and subsequent osteolysis. Moreover, host bone congruence involving an intact acetabular rim for press-fit stability is necessary for immediate component macro-fixation [8, 9, 18, 23].

Th. A. Xenakis (✉) · K. S. Stafilas
Orthopaedic Department, University of Ioannina, Medical School,
Ioannina 45110, Greece
e-mail: kosmas@hol.gr

G. A. Macheras · A. T. Kostakos
2nd Orthopaedic Department, 1st I. K. A. Hospital,
Athens, Greece

K. Bargiotas · K. N. Malizos
Orthopaedic Department, University of Thessaly, Medical School,
Larissa, Greece

The mechanism of acetabular component failure is multifactorial and may include contributing factors such as bearing surface wear, osteolysis, and aseptic loosening. The avoidance of acetabular component failure involves both manufacturing and surgical/technical variables. Gaining optimum peripheral press-fit stability maximises initial component macro-fixation, allowing for subsequent biological fixation (in-growth/on-growth) and long-term acetabular composite durability. However, while the complications associated with acetabular composite durability and success have been identified and minimised, acetabular component failure due to aseptic loosening with or without osteolysis continues to arise [1, 19]. Tantalum metal for orthopaedic use was initially introduced in 1997, with a subsequent rapid evolution of orthopaedic applications [4–7, 9, 10, 21–25]. The use of tantalum metal for the acetabular component in THA was developed to enhance the fixation properties while eliminating aseptic loosening and the potential pathways for polyethylene debris into the peri-acetabular regions [12, 15, 16]. The purpose of this study was to monitor and report the minimum five-year prospective results from the multicentre use of a porous tantalum monoblock acetabular component for primary THA.

Materials and methods

Between 1997 and 2000 a multicentre study was performed in which 253 consecutive primary THA cases in 233 patients were undertaken in three separate surgical centres. Of the 253 total cases, the number contributed per centre included 102 hips (40.3%) from the first centre, 101 hips (39.9%) from the second, and 50 hips (19.8%) from the third. There was a 2:1 proportion of female ($n=166$, 65.6%) to male patients ($n=87$, 34.4%) with a similar average age between genders (female: 61.1 years $\pm$ 11.3, range 32 to 83; male: 57.2 years $\pm$ 14.1, range 24 to 86). Of these combined cases, osteoarthritis was the primary diagnosis in 116 hips (45.8%). Thereafter, congenital dysplastic hip (CDH) was seen in 80 hips (31.6%), avascular necrosis (AVN) in 33 hips (13.0%), femoral neck fracture in eight hips (3.2%), rheumatoid arthritis (RA) in three hips (1.2%), and other miscellaneous diagnoses in 13 hips (5.1%).

The procedures were performed by the leading co-authors in which a posterior surgical approach was used in all cases. A press-fit porous tantalum monoblock acetabular component (Trabecular Metal Monoblock Acetabular Component System, Zimmer Inc, Warsaw, IN) was used and has two distinct profiles: (1) solid, and (2) with peripheral screw holes for adjunctive fixation. There were only nine cases in which peripheral screws were used to gain additional acetabular component stability in cases of CDH (one with one screw, five with two screws, three with

three screws). The cup has a hemi-ellipsoid geometry shape; its equator diameter is 2 mm larger than its polar diameter. It is inserted using the press-fit technique, taking particular care to prevent soft tissue interposition between the implant and the acetabulum bone during the phase of implantation. The acetabulum is prepared with hemispherical reamers. The diameter of the final reamer is the same as the polar diameter of the acetabular component and 2 mm less than the equator diameter. The subgroup of acetabular components with screws was impacted with the same technique as that without screws. Three different non-cemented femoral components were used and included the Proxilock FT, the CLS Spotorno, and the Wagner Cone (Zimmer, Warsaw, IN). In all cases, no bone grafting was performed in the acetabular region. Intraoperatively, the initial stability of the acetabular prosthesis was assessed manually and was considered satisfactory in all cases of both subgroups.

The tantalum acetabular component has unique manufacturing and mechanical properties. The friction coefficient of porous tantalum on bone is approximately twice that of other porous surfaced biomaterials. The average pore diameter of the porous tantalum shell is 550 μ m and the polyethylene liner is compression moulded into the porous tantalum shell to a depth of 1–2 mm, thus leaving 2–3 mm of porous tantalum for tissue in-growth. This type of manufacturing process allows for a 48-mm acetabular component to incorporate a minimum total polyethylene thickness of 8.5 mm for a 28-mm head, while a 40 mm acetabular component allows a minimum total polyethylene thickness of 8 mm for a 22-mm head.

Trabecular metal has an unusually large and interconnecting porous surface, which corresponds to 75–80% of its total volume and an overall geometry, shape, and size similar to those of cancellous bone [6]. The high volume porosity enables extensive tissue infiltration and strong attachment strength. The strut microtexture is conducive to bone formation. Trabecular metal elasticity is 3 GPa, which is between that of cancellous (0.1 GPa), subchondral (2 GPa), and cortical bone (15 GPa). On the contrary, titanium alloys (110 GPa) and cobalt-chromium alloys (220 GPa) are materials with significantly less elastic properties.

All patients from the three surgical centres underwent identical postoperative protocols including immediate postoperative anteroposterior radiograph of the pelvis and anteroposterior and lateral radiograph of the affected hip. On the second postoperative day, the patients were mobilised with partial weight bearing for six weeks thereafter, followed by full weight bearing. All patients were evaluated clinically at six weeks, 12 weeks, 24 weeks, 12 months, and then annually thereafter for five years using the Harris hip score (HHS) and the Oxford hip score

Table 1 Summary of pre- and postoperative Harris hip scores (HHS), Oxford hip scores (OHS), and range of motion (ROM)

	Preoperative	One-year postoperative	Five-years postoperative
HHS (total)	44.0±13.8	95.2±5.8*	97.0±6.2*
HHS (pain)	14.0±6.7	42.4±2.0*	43.6±1.6*
OHS	43.3±6.5	15.2 ±2.3*	13.9±2.3*
ROM (flexion)	72.6°±13.8°	117.6°±10.2°*	106.9°±11.1°*
ROM (extension)	8.0°±3.0°	7.7°±2.5°*	9.2°±2.7°*

* Statistically significant change ($p<0.05$) when compared to preoperative measurements

(OHS). There were no patients lost to follow-up and all patients were evaluated at the minimum five-year follow-up (maximum follow-up at 8 years). At the same time intervals, all patients had radiological evaluation. Patient radiographs with evidence of peri-acetabular dome gaps were digitised and assessed using software that incorporates the Ein-Bild-Röntgen-Analyse (EBRA) digital measurement system for cup migration and wear [13]. The EBRA system, which is a method for measuring 2D migration and wear in horizontal and vertical axes from digitised plain radiographs, allows the user to compare image position in prospective radiographs over long periods of time excluding those with positioning errors that may influence the assessment.

All data were collected prospectively using standardised collection forms and entered thereafter into a Microsoft SQL Server database (Microsoft Corporation, Redmond, Washington, USA). Statistical evaluations included simple descriptive summary and survival analysis with an endpoint of re-operation for the acetabular component.

Results

All patients were evaluated for a minimum five-year period. Clinically, the average preoperative total HHS score was

44.0±13.8 (range, 4–86.75) which increased at one-year to 95.2±4.8 (range, 81–100) ($p<0.05$) and remained constant through the five-year follow-up at 97.0±6.2 (range, 58.85–100) ($p<0.05$). Similarly, the average preoperative HHS pain component was 14.0±6.7 (range, 0–44) which increased at one-year to 42.4±2.0 (range, 40–44) ($p<0.05$) and remained constant through the five-year follow-up to 43.6±1.6 (range, 30–44). The average Oxford hip score improved from a preoperative score of 43.3±6.5 to 15.2±2.3 at one-year postoperatively and 13.9±2.3 at five-years postoperatively. Preoperative range of motion (ROM) included an average flexion of 72.6°±21.3° (range, 0°–130°) which increased postoperatively at one-year to 117.6°±10.2° (range, 90°–135°) and slightly decreased through the five-year follow-up to 106.9°±11.1° (range, 80°–130°). The difference in average flexion between one year and five years was statistically significant ($p<0.05$). Preoperative extension was 8.0°±3.0° (range, 5°–15°) and was 7.7°±2.5° (range, 5°–10°) ($p<0.05$) at one-year and slightly increased through the five-year follow-up to 9.2°±2.7° (range, 5°–20°) ($p<0.05$) (Table 1).

Immediate postoperative radiographs revealed well fixed and positioned acetabular components. Acetabular component inclination in the initial postoperative radiograph was measured from 39.76° to 50.30° (mean 45.38°, SE 0.47°). In the initial postoperative radiographs, peri-acetabular dome gaps were observed in 25 hips (10%). Of the cases with initial acetabular dome gaps, radiographic evidence of gap filling was observed in all cases by 24 weeks (Fig. 1a–c). There was no further radiographic evidence of acetabular dome gaps at the five-year follow-up. Also, there was no radiographic evidence of gross polyethylene wear, progressive radiolucencies, osteolytic lesions, acetabular fracture or component subsidence.

The different subgroups of nine acetabular components with screws had the same excellent results as the main group and no further radiographic evidence of wear or osteolysis. Also, there was no difference in results between the three different subgroups with regard to stems.

There were four cases of long-term radiographic evidence of nonprogressive, radiolucent lines. Two cases had

Fig. 1 Postoperative radiographic evidence of dome gaps at 6 weeks (a), 12 weeks (b), and with gap filling at 24 weeks (c)

evidence of early acetabular radiolucent lines at 6–12 weeks. Of these, one case had an acetabular radiolucent line at one year and three years, but none at five years. This may be due to either patient positioning or gap filling. Another case had an acetabular radiolucent line only at three years and at five years. There are also two other cases with acetabular radiolucencies at five years but with no previous radiographic evidence of radiolucencies. In all four cases involving long-term evidence of radiolucencies, the acetabular component was deemed radiographically stable and the patients had no complaints of pain.

There was one case in which the acetabular component was revised at 50 months for recurrent dislocation and this patient (one hip) was removed from further study. At the time of revision, the component was well fixed, stable and, upon visual inspection, had extensive bone to component apposition (Fig. 2a,b). No other acetabular component was revised or needed revision at the last follow-up.

There were ten (4%) acute complications. Acute complications included intraoperative femoral fracture in six hips (2%) treated with cerclage wires, early dislocation in two hips (<1%) treated by closed reduction, peroneal nerve palsy in one hip (<1%), and pulmonary embolism in one hip (<1%) treated with low molecular weight heparin (LMWH). All acute complications were successfully treated.

There were seven independent postoperative complications (2.5%) in seven patients. Deep vein thrombosis occurred in three patients (two on the operated side, one contralateral side) (1.5%) and pulmonary embolism in one patient (one hip, <1%) which were successfully treated with LMWH. One acute dislocation in one hip (<1%) was treated by closed reduction without further incident. There was one recurrent dislocation in one hip (<1%) that required revision of a well-fixed and stable acetabular component. Aseptic loosening of the femoral component occurred in one hip (<1%) that required femoral component revision.

Fig. 2 a,b Case involving acetabular component revision at 50 months for recurrent dislocation. Upon visual inspection, the revised acetabular component had extensive bone to component apposition

Discussion

Acetabular component success in THA has evolved with changes in component design characteristics as well as surgical techniques. Initial noncemented acetabular component designs involving various material combinations, component conformity, and implantation techniques yielded only average results. More recently, intermediate results of noncemented acetabular components have shown significant decreases in failure rates attributed to aseptic loosening. However, radiographic evidence of radiolucencies adjacent to the acetabular component still exist and may be indicative of subsequent aseptic loosening and component failure [17, 20]. Common noncemented acetabular components have the design characteristics that include low volumetric porosity, low coefficient of friction, and surface preparations that involve bonding to a solid substrate. Latimer et al. [14], in an intermediate study of porous-coated acetabular components, reported no acetabular component failure with the endpoint being revision but found radiographic evidence of peri-acetabular radiolucencies. The design considerations and use of tantalum metal for the acetabular component in our study involved the goals of immediate stable component macro-fixation, an environment for optimum biological micro-fixation, the elimination of potential pathways for debris to the peri-acetabular regions of the pelvis, and thus the elimination of aseptic loosening with or without osteolysis.

The monoblock acetabular component used in this study incorporated direct fusion and compression of the polyethylene into the metal shell which has the advantage of no debris from the interface between the metallic shell and the polyethylene liner (backside wear). It also offers a more physiological acetabular bone loading due to the elasticity. The inherent quality of tantalum metal is that 75–80% of the total material volume is porous voids and, in combination with the osteoconductive material properties, is shown to be optimum for biological in-growth [6, 9]. Rahbek et al. [18] showed superior on-growth characteristics of tantalum metal over solid metal implants with grit blasting. Bobyn et al. [2] ascribed these findings to the high and interconnected porosity of the porous tantalum. Our study reveals both clinical and radiographic evidence of well-fixed and stable acetabular components, thus confirming our hypothesis of increased early stability from the high coefficient of friction and stable early macro-fixation of the tantalum acetabular component.

Rahbek et al. [18] showed superior biological fixation and subsequent radiographic evidence of “gap healing around the implant” in the reported trabecular metal model. Bobyn et al. [3] have also shown acetabular component stability and complete filling of large polar gaps. Radiographic review of our data has shown early series peri-

acetabular dome gaps in 25 hips (10%). However, at 24 weeks follow-up, there was gap filling and no further radiographic evidence of peri-acetabular gaps was noted [15]. Similarly, Gruen et al. [11] reported radiographic evidence of peri-acetabular gaps using the same acetabular component with complete gap filling at two years. A potential error associated with subjective radiographic assessment of gap resolution is subsequent patient positioning masking the original gap. In an effort to demonstrate gap filling without positional error, a subset of patient radiographs for our reported cohort were digitised and analysed using the EBRA-digital measurement system [13]. We found the radiographic evidence of gap filling was true and not a product of patient positioning or component subsidence. From the evidence of our reported radiographic findings we believe with certainty that the osteoconductive properties of tantalum metal allows for the resolution of most line-to-line components to host bone differences found following primary THA.

Radiographic evidence of acetabular gaps was noted for only one study site (site 2). The gaps seem to be related to the surgeon's ability to "bottom out" the acetabular component which contributed to the component insertion learning curve.

We need long term results and more actual data (wear, osteolysis) to support the long term durability of this acetabular component.

There are potential disadvantages to using this kind of cup. First of all, it is difficult to insert this in a proper way due to a "grabby" surface and dished contour. Second, it is difficult for an inexperienced surgeon to be sure about the presence of bottoming out due to monoblock characteristics. Third, we worry about the revision of this monoblock cup and especially for liner wear and exchange.

The advantages of the cup are less periacetabular stress shielding from a less stiff composite, low wear rate with elimination of debris and apparent osteolysis, and component stability and osseointegration due to higher coefficient of friction and geometry with peripheral rim press-fit technique.

In conclusion, we report the promising intermediate results of a monoblock acetabular component with no evidence of gross polyethylene wear, nonprogressive radiolucencies, no osteolytic lesions, and no cup migration. Overall, all the patients were very satisfied and reported no difference as compared to their normal hip. Clinical findings are similar to current reports of noncemented acetabular component systems, but the radiographic findings support the theoretical advantages of tantalum metal. We recommend continuing use of this component and that further review of the current multicentre population is warranted to determine the long-term durability of the acetabular composite.

References

1. Blumenfeld TJ, Bargar WL (2006) Early aseptic loosening of a modern acetabular component secondary to a change in manufacturing. *J Arthroplasty* 21:689–695
2. Bobyn JD, Stackpool GJ, Hacking SA, Tanzer M, Krygier JJ (1999) Characteristics of bone ingrowth and interface mechanics of a new porous tantalum biomaterial. *J Bone Joint Surg Br* 81:907–914
3. Bobyn JD, Toh KK, Hacking SA, Tanzer M, Krygier JJ (1999) Tissue response to porous tantalum acetabular cups: a canine model. *J Arthroplasty* 14:347–354
4. Chalkin B, Minter J (2005) Limb salvage and abductor reattachment using a custom prosthesis with porous tantalum components. *J Arthroplasty* 20:127–130
5. Christie MJ (2002) Clinical applications of trabecular metal. *Am J Orthop* 31:219–220
6. Cohen R (2002) A porous tantalum trabecular metal: basic science. *Am J Orthop* 31:216–217
7. Deglurkar M, Davy DT, Stewart M, Goldberg VM, Welter JF (2007) Evaluation of machining methods for trabecular metal implants in a rabbit intramedullary osseointegration model. *J Biomed Mater Res B Appl Biomater* 80:528–540
8. Fisher DA, Mallory TH, Kraus TJ, Mitchell MB (1990) Evaluation of the design and clinical performance of cementless acetabular components. *Semin Arthroplasty* 1:35–44
9. Gordon WJ, Conzemius MG, Birdsall E, Wannemuehler Y, Mallapragada S, Lewallen DG, Yaszemski MJ, O'Driscoll SW (2005) Chondroconductive potential of tantalum trabecular metal. *J Biomed Mater Res B Appl Biomater* 75:229–233
10. Gross AE, Goodman SB (2005) Rebuilding the skeleton: the intraoperative use of trabecular metal in revision total hip arthroplasty. *J Arthroplasty* 20:91–93
11. Gruen TA, Poggie RA, Lewallen DG, Hanssen AD, Lewis RJ, O'Keefe TJ, Stulberg SD, Sutherland CJ (2005) Radiographic evaluation of a monoblock acetabular component: a multicenter study with 2- to 5-year results. *J Arthroplasty* 20:369–378
12. Komarasamy B, Vadivelu R, Bruce A, Kershaw C, Davison J (2006) Clinical and radiological outcome following total hip arthroplasty with an uncemented trabecular metal monoblock acetabular cup. *Acta Orthop Belg* 72:320–325
13. Krismer M, Bauer R, Tschupik J, Mayrhofer P (1995) EBRA: a method to measure migration of acetabular components. *J Biomech* 28:1225–1236
14. Latimer HA, Lachiewicz PF (1996) Porous-coated acetabular components with screw fixation. Five to ten-year results. *J Bone Joint Surg Am* 78:975–981
15. Macheras GA, Papagelopoulos PJ, Kateros K, Kostakos AT, Baltas D, Karachalios TS (2006) Radiological evaluation of the metal-bone interface of a porous tantalum monoblock acetabular component. *J Bone Joint Surg Br* 88:304–309
16. Mulier M, Rys B, Moke L (2006) Hedrocel trabecular metal monoblock acetabular cups: mid-term results. *Acta Orthop Belg* 72:326–331
17. Muller U, Gautier E, Roeder C, Busato A (2003) The relationship between cup design and the radiological signs of aseptic loosening in total hip arthroplasty. *J Bone Joint Surg Br* 85:31–36
18. Rahbek O, Kold S, Zippor B, Overgaard S, Soballe K (2005) Particle migration and gap healing around trabecular metal implants. *Int Orthop* 29:368–374
19. Simank HG, Brocai DR, Reiser D, Thomsen M, Sabo D, Lukoschek M (1997) Middle-term results of threaded acetabular cups. High failure rates five years after surgery. *J Bone Joint Surg Br* 79:366–370

20. Sochart DH (1999) Relationship of acetabular wear to osteolysis and loosening in total hip arthroplasty. *Clin Orthop Relat Res* 363:135–150
21. Sporer SM, Paprosky WG (2006) Acetabular revision using a trabecular metal acetabular component for severe acetabular bone loss associated with a pelvic discontinuity. *J Arthroplasty* 21:87–90
22. Sporer SM, Paprosky WG (2006) The use of a trabecular metal acetabular component and trabecular metal augment for severe acetabular defects. *J Arthroplasty* 21:83–86
23. Stiehl JB (2005) Trabecular metal in hip reconstructive surgery. *Orthopedics* 28:662–670
24. Unger AS, Lewis RJ, Gruen T (2005) Evaluation of a porous tantalum uncemented acetabular cup in revision total hip arthroplasty: clinical and radiological results of 60 hips. *J Arthroplasty* 20:1002–1009
25. Zou X, Li H, Zou L, Mygind T, Lind M, Bunger C (2006) Porous tantalum trabecular metal scaffolds in combination with a novel marrow processing technique to replace autograft. *Adv Exp Med Biol* 585:197–208