Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jor

Original Article

A short-term follow-up study of a surgeon-customised fully-coated hydroxyapatite femoral stem using a nation-wide joint registry

Aneesh Dave^a, Bob Jang^b, Warwick Bruce^{c,*}^a Faculty of Medicine, The University of Sydney, NSW, Australia^b Department of Orthopaedic Surgery, Concord Hospital, NSW, Australia^c Hip and Knee Clinic, Sydney Olympic Park, NSW, Australia

ARTICLE INFO

Article history:

Received 29 October 2015

Accepted 14 December 2015

Available online 28 February 2016

Keywords:

Hydroxyapatite

Fully-coated

Arthroplasty

Cementless

ABSTRACT

Objective: To compare revision rates between otherwise-identical fully-coated and proximally-coated hydroxyapatite (HA) femoral stems using a nation-wide registry.

Methods: 249 proximally-coated stems (50 μ m HA) and 225 fully-coated stems (100 μ m HA and 50 μ m titanium) were followed over a mean of 34.9 and 23.2 months respectively.

Results: Four proximally-coated (rate: 1.61%) and five fully-coated stem revisions (rate: 2.20%) were reported, with no statistical difference between groups ($p = 1.0$, OR 0.90, 95% CI 0.20–3.97). Registry data showed no difference in performance between fully-coated and proximally-coated stems nationwide (rate: 2.22%, $p = 0.82$).

Conclusion: There is no statistical difference in survival between fully-coated and proximally-coated HA prostheses in the short-term.

© 2015 Prof. PK Surendran Memorial Education Foundation. Published by Elsevier, a division of Reed Elsevier India, Pvt. Ltd. All rights reserved.

1. Introduction

Since its development by Furlong and Osborn¹ in 1985 and by Geesink² in 1986, hydroxyapatite (HA) coating has become a widely used form of fixation in total hip arthroplasty (THA). The development of this technique has sought to improve performance of implants in younger, more active patients in

whom cemented stems tend to fail.^{3–5} Given this benefit, the use and research of cementless fixation in THA has increased in the last decade. Most notably, in 2014 the Australian Orthopaedic Association National Joint Replacement Registry⁶ (AOA NJRR) reported that cementless fixation had a lower rate of revision 3 years after surgery compared to cemented THA, particularly in younger patients. A significant volume of literature has been dedicated to laboratory-based studies

* Corresponding author.

E-mail address: Prof.Bruce@hipandkneeclinic.com.au (W. Bruce).

Abbreviations: HA, hydroxyapatite; THA, total hip arthroplasty; AOANJRR, Australian Orthopaedic Association National Joint Replacement Registry; SOCRATES, Standardised Orthopaedic and Cartilage Repair and Treatment Evaluation Software; SD, standard deviation; CI, confidence intervals; OR, odds ratio.

<http://dx.doi.org/10.1016/j.jor.2015.12.001>

0972-978X/© 2015 Prof. PK Surendran Memorial Education Foundation. Published by Elsevier, a division of Reed Elsevier India, Pvt. Ltd. All rights reserved.

investigating the use of HA as a coating material. In histological analysis, HA coatings have been shown to achieve early implant stabilisation,⁷ and compensate for stem micromotion⁸ by encouraging bone formation across large gaps.

In contrast, the clinical role of HA coatings is still under some debate, with several trials reporting a potential clinical benefit,^{7,9–11} whereas others report no significant difference in stem performance.^{12–15} In 2015, a meta-analysis¹⁶ was performed to compare proximally-coated HA and porous-coated non-HA femoral stems. It showed a significant improvement in Harris Hip Scores and patient reported thigh pain in favour of HA-coated stems, though no difference in rates of aseptic loosening.

Evidently, most of the literature is focussed on the use of proximally-coated HA stems. A comparatively small level of research has been dedicated to the impact of fully-coated HA stems on implant survival. The fully-coated HA stem may provide potentially significant clinical advantage over a proximally-coated stem by increasing distal stability, reducing stem micromotion and improving performance in poor quality bone. There are several long-term studies reporting on the success of these stems, however there is a paucity of literature which directly compares implant survival between partially- and fully-coated HA stems. Hence, this study aims to directly compare implant survival of a novel, surgeon-customised fully-coated HA stem to a widely-used proximally-coated HA stem, using a surgeon's database. The AOA NJRR was also used to minimise loss of patient follow-up, examine nationwide implant survival and to verify the accuracy of the surgeon's database.

2. Materials and methods

2.1. Operative methods

445 patients received 474 primary hip replacements, either a standard or modified Anthology Primary Hip System femoral stem (Smith & Nephew Inc., Memphis, USA) using standard operative procedure. All operations were performed by a single surgeon under spinal anaesthesia using a standard posterior approach in an operating theatre with laminar flow. A femoral neck osteotomy was performed, followed by reaming of acetabulum and broaching of the femoral canal. Trial implants were inserted and the joint was reduced. Final implants were then inserted and the wound was closed in a traditional fashion over a drain. Patients were routinely allowed to weight bear from day 1 post-operatively, and underwent a rehabilitation programme before discharge.

2.2. Follow-up and data collection

249 proximally-coated HA femoral stems were inserted in 233 patients between June 2006 and October 2013 (Group A). 225 modified fully-coated HA femoral stems were inserted in 212 patients from May 2008 to May 2013 (Group B). Implants were inserted consecutively, except in the rare instance where an appropriate implant size was not available. Patients followed up with the surgeon at standard post-operative intervals (6, 12, 24, 52 weeks and then annually). Mean follow-up in Groups A

and B were 34.9 months and 23.2 months respectively. Using the AOA NJRR, there was complete follow-up of patient revisions in both stem groups.

Ethics approval was obtained from Sydney Local Health District Human Research Ethics Committee, Concord Hospital (Reference Number: CH62/6/2014-07). Data were collected from the surgeon's database, SOCRATES (Standardised Orthopaedic and Cartilage Repair and Treatment Evaluation Software, Ortholink, Sydney, Australia). Patient demographics, procedural records, intraoperative notes and post-operative follow-up consultation information were recorded for each implant inserted. The primary outcome measured was revision surgery. As per the AOA NJRR, revisions were classified as major revisions (removal of femoral stem or acetabular cup) or minor revisions (removal of any prosthesis not directly fixed to bone). These data were then forwarded to the AOA NJRR for verification. Any discrepancies between the two databases were recorded.

2.3. Stem design

The standard stem features a 50 μm HA coating as well as a 300 μm sintered bead coating along its proximal surface (Fig. 1A). The primary surgeon led a design team of orthopaedic engineers to modify the existing femoral implant with the aim of improving implant survival. The modified stem (Fig. 1B) is composed of a titanium alloy (Ti-6Al-4V). It is the first cementless stem design to the best of our knowledge that has a Taperloc blade stem design with extensive HA coating. The coating features a combination of 100 μm HA and 50 μm titanium along the entire stem surface, both applied by plasma spray. This dual layer is thought to enhance adhesive properties of the coating. Horizontal steps were inserted onto all faces of the stem to convert hoop tension into compression. Vertical grooves at the distal stem were inserted to allow give of medullary contents during stem insertion. This stem has a narrower cross-sectional profile than other fully-coated HA stems, giving better torsional stability. Most notably, both the stems used in this study had an identical geometrical footprint, such that one broach could be used on either stem.

2.4. Patient demographics

There was no statistically significant difference in patient demographics using standard T-tests (Table 1).

3. Results

3.1. Revision rates

According to the primary surgeon's database, there were 4 revisions of the 249 primary procedures in 233 patients within Group A (revision rate: 1.61%). One of these revisions was not recorded on the surgeon's database as it was performed by another surgeon. Of these, two were major revisions (major revision rate: 0.80%), and only one required removal of the femoral stem (femoral stem revision rate: 0.40%). In Group B, there were five revisions of the 225 primary procedures in 212 patients (revision rate: 2.20%). Of these, there was only one

Fig. 1 – Photographs and radiographs of femoral stems. (A) Standard proximally-coated HA femoral stem: 50 µm HA coating and a 300 µm sintered bead coating along proximal surface only. (B) Modified fully-coated HA femoral stem: 100 µm HA and 50 µm titanium along the entire stem surface. Horizontal steps and vertical grooves inserted. (C) Radiograph of modified fully-coated femoral stem.

major revision, which involved removal of a femoral stem (femoral stem revision rate: 0.44%). There was no statistically significant difference in revision rate between the two groups ($p = 1.0$, 95% CI 0.20–3.97, OR 0.90). Using the AOANJRR, the primary surgeon's revision rate per observed years for Group A was 0.33 (95% CI 0.09–0.84) revisions/100 observed years, whilst revisions per observed years for Group B were 0.61 (95% CI 0.17–1.57) revisions/100 observed years.

The revision rate of the standard stem used by surgeons Australia-wide was 0.65 revisions/100 observed years (95% CI

0.52–0.80). All THA performed in Australia have a revision rate 0.77 revisions/100 observed years (95% CI 0.76–0.79). There was no statistically significant difference in revision rates between the modified stem inserted by the primary surgeon and all standard Anthology stems recorded on the AOANJRR (revision rate: 2.22%, $p = 0.82$) or all primary total hip replacements in Australia, independent of stem type and implant fixation (revision rate: 3.98%, $p = 0.23$).

The cumulative revision rates for Group A and Group B were 0.4% (95% CI 0.1–2.7) and 1.0% (95% CI 0.3–4.0) at 1 year, and 1.3% (95% CI 0.4–4.1) and 2.9% (95% CI 1.0–8.0) at 4 years respectively (Table 2), and this rate was lower than all THA Australia wide in the first 4 years of follow-up (Fig. 2).

3.2. Revision diagnoses

In Group A, there were four revisions performed, with two known major revisions. In one major revision, there was femoral stem loosening 2 years after primary surgery. In this patient the stem was loose to hand which suggested stem under-sizing. In the second major revision, metallosis developed secondary to edge loading 3 years after primary surgery. Only the acetabular component was removed at revision, and the femoral component showed successful bone ingrowth. One minor revision was performed 3 weeks post-operatively due to infection. One revision was performed by another surgeon, and the revision diagnosis was reported as hip pain.

In Group B, there were five revisions performed. Of these, only one revision was a major revision involving replacement of a femoral component, performed 1 month after primary surgery. Revision diagnosis in this case was periprosthetic fracture secondary to trauma, sustained when the patient fell off a golf buggy. This patient reported good hip function in all prior assessments. At the time of revision, the surgeon noted

Table 1 – Patient demographics.

Patient parameter	Group A	Group B
Age ± SD	64.5 (±11.5)	63.3 (±10.7)
Range	22–88	37–90
BMI ± SD	28.8 (±5.0)	28.8 (±5.0)
Range	19–49	19–43
Gender	Male 46.5%	Male 52.9%
	Female 53.5%	Female 47.1%
Side	Left 48.8%	Left 47.8%
	Right 50.4%	Right 51.3%
	Simultaneous 0.8%	Simultaneous 0.9%
Primary diagnosis	91.7%	92.0%
osteoarthritis		
primary		
Secondary ^a	85.7%	64.3%
	6.0%	27.7%
Bone quality ^b	Type A 2.4%	Type A 4.0%
	Type B 80.5%	Type B 69.6%
	Type C 17.1%	Type C 26.4%

^a Indicates diagnoses of femoro-acetabular impingement or slipped upper femoral epiphysis.

^b Bone quality defined by Dorr classification. Standard deviation (SD) shown when appropriate.

Table 2 – Cumulative revision rate of fully-coated stem versus proximally-coated stem.

Years since primary procedure	Cumulative revision rate (%)	
	Group A (95% CI)	Group B (95% CI)
1	0.4 (0.1–2.7)	1.0 (0.3–4.0)
2	0.8 (0.2–3.3)	1.0 (0.3–4.0)
3	0.8 (0.2–3.3)	1.7 (0.6–5.3)
4	1.3 (0.4–4.1)	2.9 (1.0–8.0)

excellent bony ingrowth onto the prosthesis. Three minor revisions requiring replacement of the head and liner were performed for metal related pathology and one minor revision was performed due to infection. There were no cases of aseptic loosening or prosthesis integration failure in the fully-coated stem group.

4. Discussion

Our study reports short-term results of a surgeon customised fully-coated HA stem compared to a widely used proximally-coated HA stem. There is a paucity of research in the literature directly comparing the differences between fully-coated and proximally-coated HA femoral stems. In our short-term study we found that there was no statistically significant difference in revision rates between the modified fully-coated stem and the proximally-coated stem used by the primary surgeon.

A recent prospective randomised controlled trial by Sandiford et al.¹⁷ also compared proximally-coated and fully-coated HA stems. They reported three femoral revisions in 103 patients in the fully-coated stem group at mid-term follow-up. They found no statistical difference in implant survival between the groups, which is consistent with the findings in our study. However, this study used two different femoral implants for comparison and several surgeons were involved in the trial, contrasting to our study which involved stems with identical geometric footprints and broaching sizes, as well as a single surgeon who performed all the procedures.

Similarly, a study by Argenson et al.¹⁸ reported on 598 consecutive procedures comparing fully-coated and proximally-coated HA stems. They reported only one femoral revision

in the fully coated HA stem group after 38 months follow-up. In direct contrast to our findings, they reported statistically significant improvement in revision rates due to aseptic loosening in favour of fully-coated HA stems. However, when we considered aseptic loosening of the femoral stem alone, our revision rates were comparable to those reported in this study, with only one major femoral revision secondary to trauma and no cases of aseptic loosening. Vidalain¹⁹ reported the survival probability of the cementless fully-coated HA DePuy Corail stem (DePuy, Warsaw, IN) as 96.8% at 20 years. This suggests the clinical performance of our stems in the short term is in keeping with the success of similar stems reported in long-term follow-up.

The fully-coated HA femoral stem may provide significant clinical advantage over a proximally-coated femoral stem. It is well established HA coated stems display enhanced early fixation, and osseointegration can occur within 10 days post-operatively. Furthermore, full HA coatings may seal the potential space between implant and bone, preventing movement of particles from cup wear into the periprosthetic and joint spaces.²⁰ In our study, we report no cases of resultant osteolysis or granuloma development requiring revision in the fully-coated stem. Fully-coated HA stems may also compensate for poor broaching technique, with osseointegration shown to occur even in the presence of stem micromotion²¹ using HA coated stems. Preliminary studies have also shown that HA-coated prostheses allow for bone growth across gaps of up to of up to 2 mm,^{22,23} far greater than porous coated comparators.²⁴

HA-coated stems may provide benefit in patients with Type C bone (Dorr Classification). Cementless prostheses are generally not used in these patients because of poor bone ingrowth potential. Kelly et al.²⁵ reported no femoral stem revisions in 13 patients with Type C bone using a proximally-coated HA stem. To the best of our knowledge, the effect of a fully-coated HA stem in Type C bone is undetermined. We can report that two patients with Type C bone received a revision of their fully-coated HA implant. Both were minor revisions, due to infection and metal-related pathology. In both cases, excellent osseointegration was noted at the time of revision. There were no cases of stem loosening in any patients with Type C bone at any stage of follow-up. In the short term, a

Fig. 2 – Cumulative revision rate of femoral stems. Cumulative revision rate for the standard stem (diamond) and modified stem (square) are shown. Cumulative revision rate for the standard stem used Australia wide (triangle) and all total hip arthroplasty in australia (cross) are also represented.

fully-coated HA stem appears to provide effective osseointegration in Type C bone, however longer term studies are required.

5. Limitations

A limitation of this study was its retrospective and non-randomised nature. Despite the femoral stems being inserted prospectively and consecutively, the data were collected and analysed retrospectively. We cannot therefore exclude selection bias or confounders in interpreting the results. Furthermore, this study only reports a short-term follow-up of a single (standard and modified) stem by a single surgeon. Longer term studies in a multi-surgeon and multi-centre context may be required in the future. Finally, given the differences in implants, patients and surgeons, any comparison with other studies examining the use of fully-coated HA stems remains difficult.

6. Conclusions

This study reports the use of a surgeon customised fully-coated HA femoral stem for uncemented THA. In the short-term follow-up period, there was no statistically significant difference in implant survival between a modified fully-coated HA stem and a standard proximally-coated stem. Future studies should focus on the performance of these stems to elucidate any long-term benefit in implant survival.

Conflicts of interest

The authors have none to declare.

REFERENCES

- Furlong RJ, Osborn JF. Fixation of hip prostheses by hydroxyapatite ceramic coatings. *J Bone Jt Surg Br.* 1991;73:741-745.
- Geesink RG. Experimental and clinical experience with hydroxyapatite-coated hip implants. *Orthopedics.* 1989;12:1239-1242.
- Chandler HP, Reineck FT, Wixson RL, et al. Total hip replacement in patients less than thirty years old. A five-year follow-up study. *Bone Jt Surg.* 1981;63:1426-1434.
- Dorr LD, Takei GK, Conaty JP. Total hip arthroplasties in patients less than forty-five years old. *Bone Jt Surg.* 1983;65:474-479.
- Collins DK. Cemented total hip replacement in patients who are less than fifty years old. *Bone Jt Surg.* 1984;66:353-359.
- Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide: Australian Orthopaedic Association; 2014.
- Søballe K, Toksvig-Larsen S, Gelineck J. Migration of hydroxyapatite coated femoral prostheses. A roentgen stereophotogrammetric study. *J Bone Jt Surg Br.* 1993;75:681-686.
- Søballe K, Hansen ES, Rasmussen H, et al. Hydroxyapatite coating enhances fixation of porous-coated implants. *Acta Orthop Scand.* 1990;61:299-306.
- Palm L, Jacobsson SA, Ivarsson I. Hydroxyapatite coating improves 8- to 10-year performance of the link RS cementless femoral stem. *J Arthroplasty.* 2002;17:172-175.
- Geesink RCT. Osteoconductive coatings for total joint arthroplasty. *Clin Orthop.* 2002;395:53-65.
- D'Antonio J, Capello W, Maley M. Remodelling of bone around hydroxyapatite-coated femoral stems. *J Bone Jt Surg.* 1996;78:1226-1234.
- Rorabeck C. Tapered hydroxyapatite-coated press-fit stems: any added value? *J Arthroplasty.* 2006;21:85-88.
- Kim Y, Kim JS, Oh SH, et al. Comparison of porous-coated titanium femoral stems with and without hydroxyapatite coating. *J Bone Jt Surg Am.* 2003;85:1682-1688.
- Yee AJ, Kreder HK, Bookman I, et al. A randomized trial of hydroxyapatite coated prostheses in total hip arthroplasty. *Clin Orthop.* 1999;366:120-132.
- Parvizi J, Sharkey P, Hozack W, et al. Prospective matched-pair analysis of hydroxyapatite-coated and uncoated femoral stems in total hip arthroplasty. A concise follow-up of a previous report. *J Bone Jt Surg Am.* 2004;86:783-786.
- Chen Y, Lin T, Liu A, et al. Does hydroxyapatite coating have no advantage over porous coating in primary total hip arthroplasty? A meta-analysis. *J Orthop Surg Res.* 2015;10:21.
- Sandiford NA, Skinner JA, East DJ, et al. Primary total hip arthroplasty with hydroxyapatite coated titanium femoral stems. Does design philosophy influence long term outcome? Results of prospective randomised controlled trial with follow-up of 10-15 years. *Acta Orthop Belg.* 2014;80:372-379.
- Argenson J, Ettore P, Aubaniac J. The extent of hydroxyapatite coating: proximal versus full coating with customs stems using compacted bone preparation. In: Einette J, Manley L, eds. *Fifteen Years of Clinical Experience with Hydroxyapatite Coatings in Joint Arthroplasty.* Paris: Springer; 2004:139-145.
- Vidalain JP. Twenty-year results of the cementless Corail stem. *Int Orthop.* 2011;35:189-194.
- Kraemer WJ, Maistrelli GL, Fornasier V, et al. Migration of polyethylene wear debris in hip arthroplasties: a canine model. *J Appl Biomater.* 1995;6:225-230.
- Søballe K. Hydroxyapatite ceramic coating for bone implant fixation. Mechanical and histological studies in dogs. *Acta Orthop Scand Suppl.* 1993;255:1-58.
- Geesink R, de Groot K, Klein C. Chemical implant fixation using hydroxyl-apatite coatings. *Clin Orthop.* 1987;225:147-170.
- Kligman M, Kirsch G. Hydroxyapatite-coated total hip arthroplasty in osteoporotic patients. *Bull Hosp Jt Dis.* 2000;59:136-139.
- Harris WH, White RE, McCarthy JC, et al. Bony ingrowth fixation of the acetabular component in canine hip joint arthroplasty. *Clin Orthop.* 1983;176:7-11.
- Kelly S, Robbins C, Bierbaum B, et al. Use of a hydroxyapatite-coated stem in patients with Dorr Type C femoral bone. *Clin Orthop Relat Res.* 2007;465:112-116.