

# Effect of hydroxyapatite coating on risk of revision after primary total hip arthroplasty in younger patients

## Findings from the Danish Hip Arthroplasty Registry

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**Background** The effect of hydroxyapatite (HA) on implant survival in the medium and long term is uncertain. We studied the effect of HA coating of uncemented implants on the risk of cup and stem revision in primary total hip arthroplasty (THA).

**Patients and methods** Using the Danish Hip Arthroplasty Registry (DHR), we identified patients less than 70 years old who had undergone uncemented primary THA during 1997–2005. 4,125 HA-coated and 7,737 non-HA-coated cups and 3,158 HA-coated and 4,749 non-HA-coated stems were available for analysis. The mean follow-up time was 3.4 years for cups and 3.2 years for stems. We estimated the relative risk (RR) of revision due to aseptic loosening or any cause, and adjusted for possible confounders (age, sex, fixation of opposite implant part, and diagnosis for primary THA) using multivariate Cox regression analysis.

**Results** The adjusted RRs for revision of HA-coated cups and stems due to aseptic loosening were 0.89 (95% CI: 0.37–2.2) and 0.71 (95% CI: 0.27–1.9) with up to 9 years of follow-up, compared to non-HA-coated implants. When taking all causes of revision into consideration, the risk estimates were 0.85 (95% CI: 0.68–1.1) and 0.81 (95% CI: 0.61–1.1) for HA-coated cups and stems, respectively.

**Interpretation** In this medium-term follow-up study, the use of HA-coated implants was not associated with any clearly reduced overall risk of revision compared to non-HA-coated implants.

Plasma-sprayed coatings on metal implants have been used in dentistry and orthopedics since the mid 1980s (Furlong and Osborn 1991). Their clinical use was justified by experiments in animals showing acceleration of bone healing and enhanced implant fixation due to the osteoconductive properties of hydroxyapatite (HA), increasing the bone ingrowth to the implant surface, as well as by converting the fibrous tissue membranes to bone (Søballe et al. 1993A). Later, studies using radiostereometric analysis (RSA) showed reduced migration of HA-coated prosthetic components (Søballe et al. 1993B, Karrholm et al. 1994). Some clinical studies have shown good radiographic and clinical results with HA-coated stems and cups (Theis and Ball 2003), and better radiographic results and survival rates with HA-coated stems than with identical press-fit components (Donnelly et al. 1997). Another study showed that HA-coated femoral stems gave excellent long-term results in young patients with high demands (Singh et al. 2004). However, there is still uncertainty concerning the effect of HA on implant survival in the medium and longer term.

We evaluated the effect of HA coating in uncemented primary THA on the risk of revision in patients younger than 70 years of age.

Table 1. Characteristics of the study population (1997–2005) from the Danish Hip Arthroplasty Registry. No difference between patients receiving HA-coated components and those receiving non-HA-coated components was found

	Uncemented cups				Total		Uncemented stems				Total	
	+ HA		– HA				+ HA		– HA			
	n	%	n	%	n	%	n	%	n	%	n	%
Sex												
Female	2,006	49	3,869	50	5,875	50	1,601	51	2,233	47	3,834	48
Male	2,119	51	3,868	50	5,987	50	1,557	49	2,516	53	4,073	52
Age (years)												
0–49	644	16	1,021	13	1,665	14	534	17	878	18	1,412	18
50–59	1,403	34	2,646	34	4,049	34	1,201	38	1,781	38	2,982	38
60–69	2,078	50	4,070	53	6,148	52	1,423	45	2,090	44	3,513	44
Primary diagnosis												
OA	3,114	75	5,887	76	9,001	76	2,409	76	3,383	71	5,792	73
Other	1,011	25	1,850	24	2,861	24	749	24	1,366	29	2,115	27

## Patients and methods

### Sources of data

#### 1. The Danish Hip Arthroplasty Registry (DHR).

The DHR is a nationwide clinical database on primary THAs, revisions, and postoperative complications in Denmark since the beginning of 1995. All 44 orthopedics departments performing THA in Denmark report to the DHR. Since 1995, 61,506 primary total hip arthroplasties and 10,394 revisions have been recorded (Annual Report 2006, available at URL: <http://www.dhr.dk/>). The registration of whether or not HA coating was used started at the beginning of 1997.

#### 2. The Danish Civil Registration System (CRS).

The CRS was established in 1968. By using the personal identification number, which is unique for each Danish citizen, the CRS contains electronic information on all changes in vital status for the entire Danish population, including changes of address, date of emigration, and the date of death. Changes are updated without old data being deleted; it remains on file as historical data. We used data from the CRS to obtain data on vital status of all patients included in the study.

### Study population (Table 1)

All patients with primary uncemented THA registered in the DHR between 1997 and 2005, who were less than 70 years of age at surgery and who had received a frequently used component (i.e. component brands with more than 3,800 cases, in order to get more than 500 cases in each subgroup) that was available both with and without HA coating, were

Table 2. Brands of components used for uncemented primary total hip arthroplasty in the patients younger than 70 years of age included in the present study

	+ HA		– HA		Total n
	n	%	n	%	
<i>Cups</i>					
Trilogy	1,406	17	6,640	83	8,046
Mallory-head	2,719	71	1,097	29	3,816
Total cups	4,125	35	7,737	65	11,862
<i>Stems</i>					
Bi-Metric	3,158	40	4,749	60	7,907

included in the study (Table 1). Of the cups, Trilogy and Mallory-head were included, corresponding to one-third of the total number of uncemented cups (Table 2). The remaining uncemented cups registered in the DHR comprised 32 component types, and they were not included in this study. The Trilogy cups are hemispherical (NMS; Zimmer Inc., Warsaw, IN), are made of titanium alloy, and are porous-coated. The porous coating is sintered onto the cup surface and consists of a fibermesh made of pure titanium. The HA coating is plasma-sprayed (thickness: 40  $\mu$ m, 70% HA, 30% TCP) on top of metal porous coating. The Mallory-head cups are hemispherical (Biomet Inc., Warsaw, IN), are made of titanium alloy, and are porous-coated. The porous coating is plasma-sprayed with a thickness of 700  $\mu$ m and a porosity of 36%. The pore diameter is 480  $\mu$ m. The HA coating is plasma sprayed (thickness: 50–75  $\mu$ m, crystallinity: 75–90% (not < 62%), purity: 95–97%) on top of metal porous coating. We only included uncemented Bi-Metric

stems, corresponding to half of the total number of uncemented stems (Table 2). The remaining uncemented stems comprised 40 component types, and were not included. The Bi-Metric stem (Biomet, Bridgend, UK) is made of titanium alloy and is porous-coated on the proximal one-third and has the same porous coating as present on the Mallory-head cup (and on top of that, the same HA-coating). The distal two-thirds is grit-blasted.

### Outcome

The outcome was time to implant failure, defined as a new surgical intervention (revision) including partial or complete removal or exchange of the implant. Causes not requiring surgical intervention, for example a closed reduction of a dislocation, were not regarded as failure. Only the first revision of each hip was included in the analyses.

### Statistics

Follow-up started on the day of primary THA and ended on the day of revision, death, emigration, or December 31, 2005, whichever came first. We used Cox's regression analysis to estimate the relative risk (RR) of revision and 95% confidence interval (CI) adjusted for age (< 50 years, 50–59 years, and 60–69 years), sex, diagnosis for primary THA (idiopathic osteoarthritis (OA), fresh fracture of proximal femur, late sequel from fracture of proximal femur, fracture of acetabulum, traumatic hip dislocation, atraumatic necrosis of femoral head, rheumatoid arthritis, Mb. Bechterew, congenital hip dislocation, Mb. Calvé-Legg-Perthes, epiphysiolysis, acetabular dysplasia, and other), and status of the other component in the hip (uncemented with or without HA coating).

Separate analyses were done for revision due to aseptic loosening and revision for any reason. Any reason was defined as aseptic loosening, osteolysis/granuloma, deep infection, fracture of the femur, dislocation, component failure, pain, and other, in accordance with the DHR registration form. We performed additional stratified analyses on the components, age groups (< 60 years and 60–69 years), and sex. Furthermore, all analyses were done for all patients, i.e. irrespective of diagnosis for primary THA, and separately for patients with idiopathic OA. We used the uncemented group without HA as a reference.

All analyses were performed using SAS software version 9.1.3.

## Results

There was no difference between the patients who received HA-coated implants and the patients who received non-HA-coated implants regarding age, sex, and diagnosis for primary THA (Table 1). The median follow-up time was 3.1 (0–9.0) years for cups and 2.7 (0–9.0) years for stems (Table 2).

### Risk regarding revision of the cup

350 (3.0%) of 11,862 cups were revised for any reason, most usually because of dislocation (40%), aseptic loosening (23%), and deep infection (17%) (Table 3). For cups with HA coating, the adjusted RR for deep infection was 1.01 (95% CI: 0.61–1.7), compared to the non-HA-coated cups. The adjusted RR for revision of HA-coated cups due to aseptic loosening was 0.89 (CI: 0.37–2.2), when considering "all diagnoses", compared to non-HA-coated cups (Table 3). Separate analyses for OA, sex, age groups, and 2 components showed no difference. When taking all causes of revision into consideration, and including all patients irrespective of diagnosis, the adjusted RR was 0.85 (CI: 0.68–1.1) for the HA-coated cups compared to the non-HA-coated cups (Table 3). The adjusted RR regarding revision for any reason was 0.67 (CI: 0.47–0.95) in females and 1.1 (CI: 0.77–1.4) in males for all diagnoses. Separate analyses for OA, age groups, and 2 components showed no statistically significant difference. In patients with HA-coated stems, the adjusted RR for cup loosening was 0.82 (CI: 0.62–1.1) for any reason, and 0.91 (CI: 0.31–2.7) due to aseptic loosening, compared to the patients with non-HA-coated stems. The absolute survival concerning cup revision for aseptic loosening was 99% (CI: 98–100) with HA coating and 99% (CI: 99–100) without HA coating. The survival concerning cup revision for any reason was 96% (CI: 94–97) and 95% (CI: 94–96) with HA-coating and without HA-coating, respectively.

### Risk regarding revision of the stem

229 (3%) of the 7,907 stems included were revised for any reason, most commonly because of dislo-

**Table 3. Relative risk (RR) of revision of uncemented HA-coated cups and stems for any reason and for aseptic loosening only, for up to 9 years of follow-up**

All diagnoses	No. of patients <sup>a</sup>	No. of revisions	Crude RR (95% CI)	Adjusted RR <sup>b</sup> (95% CI)
Endpoint: any reason				
Cups – HA	7,737	246	1.0 (ref.)	1.0 (ref.)
+ HA	4,125	104	0.85 (0.68–1.1)	0.85 (0.68–1.1)
Stems – HA	4,749	154	1.0 (ref.)	1.0 (ref.)
+ HA	3,158	75	0.79 (0.60–1.0)	0.81 (0.61–1.1)
Endpoint: aseptic loosening				
Cups – HA	7,737	17	1.0 (ref.)	1.0 (ref.)
+ HA	4,125	7	0.89 (0.37–2.1)	0.89 (0.37–2.2)
Stems – HA	7,737	14	1.0 (ref.)	1.0 (ref.)
+ HA	4,125	6	0.69 (0.26–1.8)	0.71 (0.27–1.9)

Stems: only Bimetric was included. Cups: Trilogy and Mallory-Head were included.

<sup>a</sup> All patients younger than 70 years of age registered as having primary uncemented total hip arthroplasty (THA) in the Danish Hip Arthroplasty Registry were included.

<sup>b</sup> RR mutually adjusted for age, gender, diagnosis for primary THA, and status of the other component if THA was done.

ation (45%), aseptic loosening (13%), fracture of the femur (13%), and deep infection (11%). For stems with HA coating, the adjusted RR for deep infection was 0.91 (CI: 0.40–2.0) compared to the non-HA-coated stems. The adjusted RR for revision of HA-coated stems due to aseptic loosening was 0.71 (CI: 0.27–1.9) when considering “all diagnoses”, compared to non-HA-coated stems (Table 3). Separate analyses for OA, sex, and age groups showed no statistically significant difference. When taking all causes of revision into consideration and looking at “all diagnoses”, the adjusted RR was 0.81 (CI: 0.61–1.1). Separate analyses for OA, sex, and age groups showed no difference. In patients with HA-coated cups, the adjusted RR for stem loosening for any reason was 0.78 (CI: 0.63–0.97), and 0.53 (CI: 0.31–0.92) due to aseptic loosening, compared to the patients with non-HA-coated cups. The absolute survival concerning stem revision for aseptic loosening was 100% (CI: 99–100) for the stems both with and without coating. The survival concerning stem revision for any reason was 96% (CI: 94–97) and 96% (CI: 95–96) for stems with HA-coating and without HA-coating, respectively.

## Discussion

The limitations of our study include the follow-

up period of 3 years, which is short when aseptic loosening is the issue. However, the main goal in using HA-coated components is to enhance early bone repair around the implant, thus accelerating secondary implant fixation (Overgaard 2000). Thus, the first aim of using HA-coated implants should be fewer early revisions; the second is supposed to be the long-term effect—by a potential sealing of the effective joint space (Schmalzried et al. 1992), thereby reducing the frequency of aseptic loosening. A second limitation of our study is that, although we adjusted for a range of possible confounders, we cannot entirely exclude the possibility that other factors may have influenced our findings, e.g. bearing material (both head and cup insert), the use of screw fixation of the cup, and bone grafting. In addition, patient-related factors such as co-morbidity were not adjusted for, which might be of importance (Johnsen et al. 2006).

The strength of our study was access to prospectively collected data from a validated population-based nationwide hip arthroplasty registry. The registry was validated in 2003, and completeness of primary THAs and/or revisions was found to be 94%. There was a lower degree of completeness for revisions than for primary THAs (81% as opposed to 94%); however, excluding hemiarthroplasties from the analyses, the degree of completeness for revisions increased to more than 90% (Pedersen 2006). Moreover, we included only 2 groups

of acetabular components (Trilogy and Mallory-head) and 1 femoral component (Bi-Metric), the main purpose being to get a homogenous material, and to exclude the potentially confounding effects of the relatively uncommon prostheses. In addition, we were able to account for a number of possible confounders including age, sex, diagnosis for primary THA, and fixation of components in the data analyses. Finally, none of the groups had less than 500 patients, to avoid small subgroups. However, some of the risk estimates for the subgroups were based on few revisions, resulting in statistical imprecision.

We found no difference in the risk of revision of cups between patients with HA-coated stems and those with non-HA-coated stems; thus, the use of HA-coated stems does not seem to increase cup survival. However, there was a significantly reduced risk of revision of stems in patients with HA-coated cups, compared to the patients with non-HA-coated cups. This indicates that the components may influence each other and that the use of HA-coated cups may increase stem survival—which is difficult to explain, however. It may also be a chance finding. We found no difference in risk of deep infection between coated and non-coated components, as has been suggested already by experimental studies (Ganguli et al. 2005).

We found excellent medium-term survival of both HA-coated and non-HA-coated cups (96% and 95%), which contrasts with the results of studies from the Norwegian Arthroplasty Register (Havelin et al. 2000). Follow-up in these studies was longer than in our study, and a relatively small number of cups in our study have been followed for the entire follow-up period, which may account for our superior results. The Norwegian studies included HA-coated cups with grit-blasted surfaces ("ATOLL"), which have been shown experimentally to give implant fixation and coating delamination that are inferior to those of porous-coated implants (Overgaard 2000). Indeed, inferior results have also been found for these implants in the Norwegian Arthroplasty Register (Furnes et al. 2005). In the Finnish Arthroplasty Register, the 10-year-survival of HA-coated, uncemented cups was found to be 93% (95% CI: 88–98) (Eskelinen et al. 2005), although the 10-year-survival of the HA-coated ABG I cup (with

grit-blasted surface) was only 79% (CI: 70–88) (Eskelinen et al. 2006).

Several series of HA-coated stems have shown 75–100% survival after 5–13 years of follow-up; however, these studies included rather few patients and/or did not include control groups (Capello et al. 2003, Reikerås and Gunderson 2003, Duffy et al. 2004, Eskelinen et al. 2005, Eskelinen et al. 2006). Publications from the Norwegian Arthroplasty Register showed that one brand of HA-coated stem had better survival than some non-HA-coated components (Havelin et al. 2000). However, data from a control group with the identical stem but without HA coating have not been presented. Thus, the improved survival may be due to the prosthetic design, including the surface macro- or microstructure, and not the HA coating itself.

Our study showed stem survival of 96%. We found no evidence to suggest that use of HA coating on uncemented components in patients undergoing primary THA will reduce the risk of revision in patients younger than 70 years of age. For cups in women, however, HA-coated components had a statistically significantly lower RR regarding revision, compared to non-HA-coated components. This absolute difference is small and may reflect a chance finding due to multiple comparisons, as the difference was only found for revision for any reason and not for revision due to aseptic loosening. It cannot be excluded, however, that specific factors in women, such as poorer bone quality and poorer bone healing capacity, may play a role. It has been reported that HA may dissolve and be resorbed with time (Overgaard 2000), or delaminate (Røkkum et al. 2002). A concern in the long term is failure of the coating—causing delamination or release of particles, which might accelerate third-body wear. This has mainly been observed after more than 5–7 years of follow-up (Reikerås and Gunderson 2002, Blacha 2004).

In a randomized clinical trial (RCT), Sharp et al. (2000) found no effect of HA coating on the survival of C-Fit uncemented prostheses, which is in accordance with our results. In addition, some RCTs and matched-pair studies have shown no statistically significant clinical or radiological advantages in the use of HA coating; however, the power of these studies was low (Rothman et al. 1996). In contrast, in an RCT Incavo et al. (1998) found that

HA-coated stems had superior Harris hip scores than identical uncemented, non-HA-coated smooth stems. Unfortunately, we were not able to report clinical outcome from the DHR.

Due to the lack of RCTs with large patient populations, examining the long-term survival of HA-coated components, it is difficult to make conclusions on the effect of HA coating. A high rate of failure of HA-coated cups, and early polyethylene wear and osteolysis after 7–10 years have been reported (Reikerås and Gunderson 2002, Capello et al. 2003). Both the ABG I cup (Blacha 2004) and the total ABG I prosthesis (Duffy et al. 2004) have poor survival after 5–9 years.

An important issue when using HA-coated materials is that the coating itself cannot change a bad implant design, but can only contribute to accelerated secondary implant fixation during the first few months.

We conclude that the use of HA-coated implants was not associated with any overall reduced risk of revision compared to non-HA-coated implants, in this medium-term follow-up study of patients aged 70 years and less. There is still a need for longer-term follow-up studies—to show a possibly reduced risk of revision of HA-coated implants due to a sealing effect—in order to justify the use of HA-coated prosthetic components in daily clinical practice.

### Contributions of authors

SO and UL: conception of the study. SO, ABP, SPJ, UL, AR, and AP: contributed to the study design, interpretation of data, critical revision of the manuscript, and final approval of the version to be published. AR: contributed to the analysis of data. AP: had the main responsibility for writing up the study. AP, SO, and ABP: took responsibility for the integrity of the work as a whole.

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