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Porous-coated femoral components with or without hydroxyapatite in primary uncemented total hip arthroplasty: a systematic review of randomized controlled trials

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Abstract The purpose of this systematic review was to determine the clinical and radiologic benefit of hydroxyapatite coating in uncemented primary total hip arthroplasty. A database of Medline articles published up to September 2007 was compiled and screened. Eight studies involving 857 patients were included in the review. Pooled analysis for Harris hip score as a clinical outcome measure demonstrated no advantage of the hydroxyapatite coating (WMD: 1.49, $P = 0.44$). Radiologically, both groups showed equal presence of endosteal bone ingrowth (RR: 1.04, $P = 0.66$) and radioactive lines (RR: 1.02, $P = 0.74$) in the surface area of the prosthesis. This meta-analysis demonstrates neither clinical nor radiologic benefits on the application of a hydroxyapatite coating on a femoral component in uncemented primary total hip arthroplasty.

Keywords Systematic review · Uncemented hip arthroplasty · Porous coating · Hydroxyapatite coating · Harris hip score · Long term follow-up · Radiologic outcome

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Introduction

Reports of high rates of failure of cemented femoral components in younger and more active patients have stimulated the development of implant fixation without cement [1, 2]. In the late 1980s, hydroxyapatite was applied on the implant surface in uncemented total hip arthroplasty because of its biocompatibility and osteoconductive potential [3]. As opposed to the porous-coated variant with identical geometry, matched pair trials [4–7] and (bilateral) randomized controlled trials [8–15] remain ambiguous about the clinical and radiographic advantages of the hydroxyapatite coating. To determine the clinical and radiologic benefit of hydroxyapatite coating in uncemented primary total hip arthroplasty, we performed a meta-analysis of all high-quality randomized controlled trials on this subject.

Methods

We attempted to identify all relevant published and unpublished randomized trials that compared porous-coated femoral components with hydroxyapatite coating (HAC) or without an applied hydroxyapatite surface coating (Porous Coated, PC) of identical geometry. The QUOROM guidelines for reporting meta-analyses of randomized trials [16] were adhered to. We searched the MEDLINE and EMBASE electronic databases for studies published between January 1980 and September 2007, using the keywords "hydroxyapatite coating", "primary uncemented total hip arthroplasty", "porous coating", "prosthesis", "hip", "clinical outcome", "radiologic (or radiographic) outcome". Only articles (or abstracts) written in the English, German and French languages were considered. Bibliographies of journal articles were hand-searched to trace additional studies. We assessed relevance using a hierarchical approach based on title, abstract and the full manuscript.

Methodological quality

Two investigators independently assessed studies for possible inclusion, and any disagreements were resolved by discussion or referred to a third investigator for arbitration. To be included, studies had to be properly randomized, be based on a total hip prosthesis (HAC and PC) with one identical geometry, and have used objective, validated clinical and radiographic outcome measurements.

To ensure high quality, we used the methodological criteria outlined by Tulder [17]. This list adheres to the following 12 mean criteria: adequate randomization procedure; allocation concealment; baseline similarity; care provider-blinded; control for co-interventions; acceptable adherence; relevant, reliable and valid outcome measures; patient-blinded; acceptable number of withdrawals and missing values; outcome assessor-blinded; identical timing of outcome measurement; and intention-to-treat analysis.

Statistics

Percentage of observed agreement between reviewers was determined and interrater reliability of individual scores established using Cohen's Kappa statistics. Reviewers were blinded to author(s), institution(s) or journal. Methodological criteria scores of 9 (maximum 12) points or higher were classified as "high quality", studies with less than 5 points were classified as "low quality". We used Cochrane Collaboration software (Review manager 4.2.9) to conduct the statistical analysis and applied fixed-effects or, if necessary, random-effects model to pool results from the individual trials. We calculated the weighted mean difference (WMD) risk ratio (RR) and 95% CI. To demonstrate statistical heterogeneity we used the I^2 statistic. An $I^2 > 30\%$ was considered to denote heterogeneity. The Mantel–Haenzel method was applied to pool observed study effects.

Results

Our search identified 1,113 potentially eligible citations. Initially, 1,070 studies were excluded on screening for inclusion criteria. After further scanning their titles and abstracts, 35 citations were excluded on the basis of language, similar data published elsewhere, use of two (or more) prostheses with a different geometry, or application of a non-validated radiographic or clinical outcome measurement. Thus a total of eight trials involving 857 patients met the inclusion criteria (Fig. 1). Observer agreement was 94%, interobserver reliability $K = 0.799$ (0.611–0.987); $P < 0.001$. Table 1 shows the characteristics of the study design. There was considerable variation in number of operated hips and follow-up period. In one study, the patients received a HAC and a PC prosthesis bilaterally after randomization [13]. In all studies, proper methods were used to generate the randomized treatment allocation and had sufficient methodological criteria scores. One study showed an inadequate or uncertain concealment of treatment allocation and lack of blinding of observer because the surgeon who implanted the prosthesis also conducted the clinical evaluation at each follow-up visit [11]. The treatment and control groups were comparable at baseline in all eight studies. In three studies, patient-blinding was uncertain [8, 10, 13]. In four studies, the medical personnel involved in the care of study subjects was not blinded [8–11]. Two studies provided only mean and range information for their outcome measures [13, 15]. No standard deviation can be deduced from this information, so we were unable to calculate weighted effect sizes and pooled these studies for Harris hip score [18].

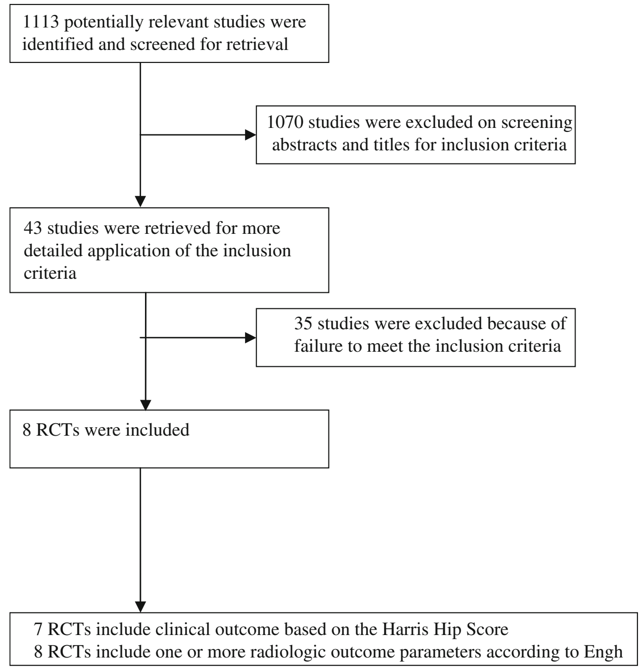

Fig. 1 The QUORUM statement flow diagram

Figures 2 and 3 show the pooled analyses on HAC versus PC. Because of statistical evidence of moderate heterogeneity among the studies on the Harris hip score ($I^2 = 32.1\%$), a random-effects model was applied for analysis of the Harris hip score. With respect to the Harris hip score, we were able to pool five studies [8–11, 14]. No difference between the coatings was observed (WMD: 1.49, CI: −2.32 to 5.31, $P = 0.44$) (Fig. 2).

Table 1 Study characteristics

Trial	Prosthesis	Number of hips (HA:PC)[1]	FU (years) HA:PC	Age (years) HA:PC	M:F	Clinical outcome[2]	Radiographic outcome[3]
Hamadouche [11]	Profile (DePuy)	50 (24:26)	8.7	65:64	41:19	HHS	A
Incavo [9]	Profile (DePuy)	50 (24: 26)	4	55	NR	HHS	A, B, C, D
Kim [13]	IPS (DePuy)	100 (50:50)	6.6	45	36:14	HHS	A, D, F
Rasquina [12]	Ranawat-Burstein (Biomet)	174 (82:92)	4.8:4.6	55:56	114:38	Postel d'Aubigne	A, B, F
Søballe [8]	Bi-Metric (Biomet)	28 (15:13)	1	57:59	NR	HHS	A, B, C, D
Tanzer [14]	Multilock (Zimmer)	318 (159:159)	3.1	65:63	165:153	HHS	B, C, F
Yee [10]	Mallory-Head (Biomet)	62 (35:27)	4.4:4.9	48:50	40:22	HHS	A, B, C
Yoon [15]	Multilock (Zimmer)	75 (37:38)	10.5	45:46	49:14	HHS	A, B, C, D

[1] *HA* Hydroxyapatite-coated; *PC* porous-coated

[2] *HHS* Harris hip score

[3] *A* Subsidence, *B* radioactive lines, *C* endosteal bone ingrowth (Spot Welds), *D* pedestal formation, *E* cortical hypertrophy, *F* bone ingrowth according to Engh

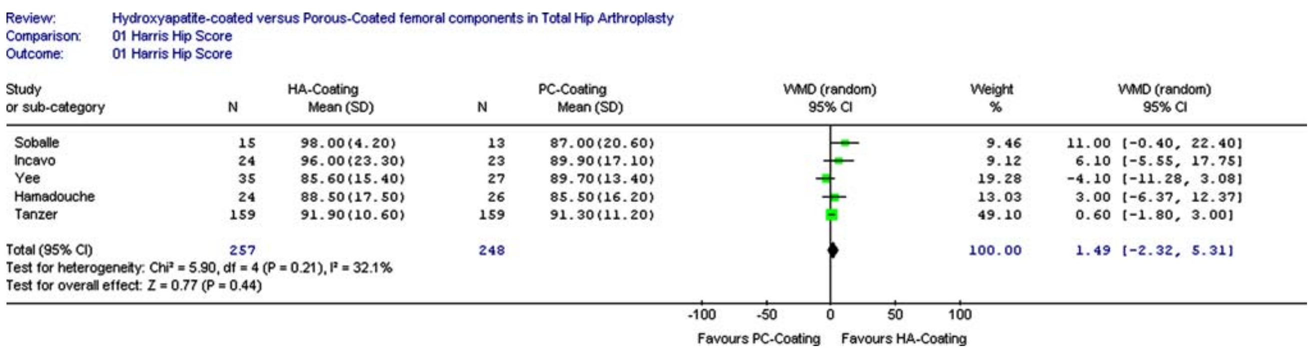

Fig. 2 Weighted mean difference (WMD) estimate for Harris hip score

Standard radiographs and one or more parameters of implant stabilization and fixation according to the criteria of Engh [19] were recorded in all studies. Five studies [8, 9, 12, 14, 15] recorded the presence of radioactive (lucent or dense) lines, which constitutes an unfavorable factor for implant stability and could be a sign of micromotion and component loosening [19]. Pooled analysis on radioactive lines could not demonstrate a difference between both coatings (RR: 1.02, CI: 0.90 to 1.16, $P = 0.74$) (Fig. 3a). The presence of endosteal condensation (spot welds), which is considered a sign of endosteal bone ingrowth on the surface of the prosthesis, is listed as a favorable factor for implant fixation [19]. This parameter was observed in five studies [8–10, 14, 15]. Pooled analysis showed that spot welds were equally present in both coatings (RR: 1.04, CI: 0.88–1.23, $P = 0.66$) (Fig. 3b). The studies included for pooled analysis on radioactive lines and endosteal condensation were statistically homogenous ($I^2 = 0\%$). Stem subsidence was measured in seven studies [8–13, 15], albeit with three different techniques and variable definitions. As a result, pooling on subsidence was not feasible.

Discussion

Hydroxyapatite is the crystalline portion of natural bone mineral. Synthetic HA is biocompatible and osteoconductive, and in contact with bone often develops a mechanically tight bond. These potentials were postulated as theoretical advantages of hydroxyapatite coating on femoral components in uncemented total hip arthroplasty [20]. Human retrieval studies have shown that the formation of newly woven bone adjacent to the HA layer does not pass through an intermediate stage of fibrous tissue, therefore secondary fixation is enhanced in this prosthesis [21]. Coathup et al. [22] investigated human retrievals on the implant-bone interface around the HAC and PC femoral stem, and observed significantly more ingrowth and attachment of bone to the HAC surface.

Although one study [8] showed a higher Harris hip score in those patients treated with a HAC compared with a PC femoral component, no difference was observed between the two groups in our meta-analysis. Contrary to our results, which are predominantly based on RCTs performed

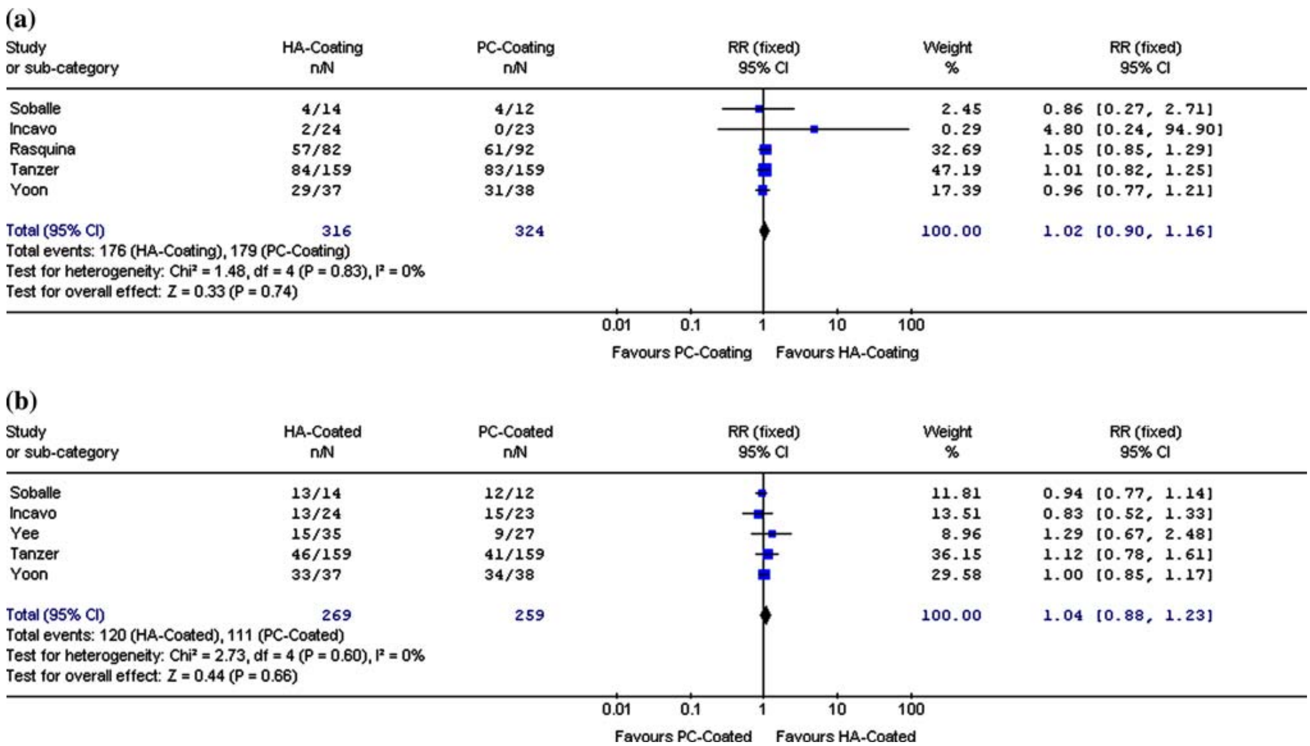

Fig. 3 Relative risk (RR) estimate for radioactive lines (**a**) and endosteal condensation (**b**)

in the early 2000s, the first (retrospective) studies after the introduction of HAC in uncemented total hip arthroplasty showed more favorable Harris hip scores in the HAC group, but these studies suffered from inferior methodology [23–25].

Radiologically, we could not differentiate between the HAC and PC femoral stems for presence of radioactive lines around the prosthesis or endosteal bone ingrowth. Contrary to our findings, earlier matched pair and bilateral radiologic studies report an improved bony ingrowth and fixation when using HAC [4, 5]. Based on absorptiometry analysis on three bilaterally operated patients (HAC on one side and PC on the other), the bone surrounding the HAC femoral components showed a higher bone mineral density, which suggests an improved fixation [5]. McPherson et al. [4] stated that 90% of the 42 HAC femoral components achieved stable bony fixation compared with the 83% of the 42 PC stems after a 3-year follow-up, according to the criteria of Engh [19].

Unfortunately, we were unable to pool the included RCTs on marked subsidence, because these studies used different measurements. Søballe et al. [8] observed less subsidence in the HAC compared with the PC femoral components after 1 year follow-up, using Roentgen-stereophotogrammetric analysis on 28 primary total hip replacements (1.7 vs. 3.9 mm, $P < 0.05$). In this group, the patients with an HAC femoral component also showed a better Harris hip score (98 vs. 87, $P < 0.05$). Hamadouche et al. [11] also demonstrated less subsidence in 24 HAC compared with 26 PC femoral stems (1.95 vs. 2.32 mm, $P = 0.04$), using EBRA after a follow-up of approximately 5 years. In the other reports included in this analysis, subsidence was measured using plain radiographs, and no difference was found on subsidence between the HAC and PC femoral stems [9, 10, 12, 13, 15].

Finally, a meta-analysis remains retrospective research that is likely to suffer from publication bias, methodological deficiencies and heterogeneity. However, we kept the likelihood of bias to a minimum by developing a detailed protocol before starting this study, undertaking a meticulous search for both published and unpublished studies, and using the appropriate methods for study selection, data extraction and data analysis.

In conclusion, this meta-analysis established no clinical or radiologic evidence of benefits of the application of hydroxyapatite coating on a femoral component in uncemented total hip arthroplasty, although this conclusion is based on only eight randomized controlled trials as a result of the stringent entry criteria. Studies reporting on the clinical and radiologic advantages of hydroxyapatite application that were based on inferior methodological designs were excluded from our meta-analyses. The randomized controlled trials included in our meta-analysis were predominantly conducted in the last 10 years.

Conflict of interest statement The authors declare that they have no conflict of interest.

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