

# Standard anatomical medullary locking (AML) versus tricalcium phosphate-coated AML femoral prostheses

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**Objectives:** To compare the preliminary rate and amount of bony ingrowth and calcar resorption between patients receiving either a standard anatomical medullary locking (AML) or a tricalcium phosphate (TCP)-coated AML femoral prosthesis and to compare preliminary clinical results. **Design:** A prospective, randomized, double-blind clinical trial. **Setting:** An acute care tertiary institution. **Patients:** Between January 1993 and March 1995, 92 patients underwent primary total hip arthroplasty (THA). They were randomized to 2 groups of 46 — a control group or a treatment group. Of the 46 subjects enrolled in each group, no significant differences were seen preoperatively with respect to age, sex, diagnosis, clinical and radiographic assessment. Seventy-one patients were followed up for 24 months. **Interventions:** Insertion of either a standard AML femoral implant (control group) or a TCP-coated AML femoral implant (treatment group). **Outcome measures:** The degree of hypertrophy, calcar atrophy and the number of spot welds on standard postoperative radiographs at 6, 12 and 24 months. Clinically, assessment according to the Société internationale de chirurgie orthopédique et de traumatologie (SICOT) scale and a 100-point visual analogue scale (VAS) for pain. **Results:** There were no prosthetic stem revisions in either group at the 24-month follow-up. Radiographically, bony ingrowth was not significantly different in the TCP-coated stem, by  $\chi^2$  analysis of the degree of hypertrophy and number of spot welds present. Also by  $\chi^2$  analysis, the degree of calcar atrophy was not significantly different between groups. The mean VAS score for pain at 24 months was 12.5 for the control and 12.1 for the treatment group. No significant differences were seen in any of the clinical categories of the SICOT Scale over the 24-month interval. **Conclusion:** The objective of TCP-coating — to increase the rate and amount of bony ingrowth while reducing the rate of calcar resorption in non-cemented THA — was not achieved by 24 months postoperatively in our study.

**Objectifs :** Comparer le taux préliminaire et le volume d'interposition osseuse et de résorption de l'éperon entre les patients recevant une prothèse à blocage médullaire anatomique (BMA) standard ou une prothèse fémorale BMA recouverte de phosphate tricalcique (PTC), et comparer les résultats cliniques préliminaires. **Conception :** Étude clinique prospective randomisée à double insu. **Contexte :** Établissement de soins tertiaires actifs. **Patients :** Entre janvier 1993 et mars 1995, 92 patients ont subi une arthroplastie totale de la hanche (ATH) de première intention. Ils ont été affectés par randomisation à deux groupes de 46 — un groupe témoin ou un groupe de traitement. Chez les 46 sujets inscrits à chaque groupe, on n'a constaté aucune différence significative avant l'intervention quant à l'âge, au sexe, au diagnostic, à l'évaluation clinique et radiologique. On a suivi 71 patients pendant 24 mois. **Interventions :** Insertion d'une pièce fémorale à BMA standard (groupe témoin) ou d'une pièce fémorale à BMA recouverte de PTC (groupe de traitement). **Mesures de résultats :** Degré d'hypertrophie, atrophie de l'éperon et nombre de points de soudure révélés par les radiographies postopératoires standards à 6, 12 et 24 mois. Sur le plan clinique, évaluation selon l'échelle de la Société internationale de chirurgie orthopédique et de traumatologie (SICOT) et selon une échelle analogique visuelle (EAV) de 100

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points. **Résultats** : Il n'y avait eu aucune révision de la queue de la prothèse dans les deux groupes au moment du suivi à 24 mois. Sur le plan radiographique, l'interposition osseuse ne présentait pas de différence significative au niveau de la queue de la prothèse recouverte de PTC, selon l'analyse  $\chi^2$  du degré d'hypertrophie et le nombre de points de soudure présents. L'analyse  $\chi^2$  a aussi révélé que le degré d'atrophie de l'éperon ne présentait pas de différence significative entre les groupes. Le score médian selon l'EAV à 24 mois s'est établi à 12,5 dans le cas du groupe témoin et à 12,1 dans celui du groupe de traitement. On n'a pas constaté de différence significative dans les catégories cliniques de l'échelle SICOT pendant les 24 mois. **Conclusion** : L'objectif visé par la couche de PTC — qui était d'accroître le taux et le volume d'interposition osseuse tout en réduisant le taux de résorption de l'éperon dans les cas d'ATH non cimentée — n'a pas été atteint 24 mois après l'intervention dans le contexte de notre étude.

**C**emented total hip arthroplasty (THA) has successfully improved quality of life in the elderly population for many years.<sup>1,2</sup> The survival rate has improved with technologic advances in cementing technique and implant design.<sup>3-7</sup> But even with these advances, the long-term success of cemented THA in healthy, young, active patients remains inadequate, and survivorship analysis of cemented fixation in all populations demonstrates a progressive loss of fixation over time.<sup>8-11</sup> In young, active patients who underwent THA, early aseptic loosening of the cement mantle and bone lysis were 2 factors that led to the development of cementless stems designed for bone ingrowth.

The fixation of femoral stems without cement relies on biologic fixation, which can be obtained through bone ingrowth onto porous-coated stems.<sup>12</sup> Press-fit stems rely on friction between the bone and the prosthesis to obtain mechanical interlocking (bone apposition).<sup>13-19</sup> Porous coating the stems increases the surface area available for osseous fixation. This can be achieved when correct pore size, close apposition and minimal movement of the bone and implant are present, conditions that have been optimized primarily through implant design and surgical technique.<sup>3,19-29</sup>

Initially developed as substitute bone grafting agents, calcium phosphate ceramics (CPCs) have also been found to be capable of use as a coating on porous implants to enhance implant fixation, particularly when the fit is suboptimal.<sup>13,15,19,30-35</sup> The 2 CPC materials considered most appropriate for this task are tricalcium phosphate (TCP) and hy-

droxyapatite (HA).<sup>19,28-30,32,36-41</sup> TCP and HA, bioactive materials with osteoconductive capabilities, are also biocompatible since they contain only elements present in bone.<sup>32,36,39,42-46</sup> Studies have reported minimal immune response from regional lymph nodes or local tissues and negligible systemic toxicity.<sup>36,47-51</sup>

Even under ideal conditions HA is considered to have minimal resorptive capacity, a trait that gives rise to 2 disadvantages.<sup>30,38,50,52,53</sup> As CPCs have a high radiodensity, the continued presence of HA impairs radiographic evaluation of bone healing and remodelling.<sup>36</sup> Because HA has bone-bonding capacity, if the coating does not resorb, the coating-metal interface becomes the weak link.<sup>30,38,54</sup> TCP, conversely, has been shown to undergo progressive degradation, with the rate of resorption in part contingent on the formation of new bone.<sup>36,43,50</sup>

Results from early and recent randomized and nonrandomized clinical studies show that while HA-coated porous-coated femoral stems give excellent clinical results, so do the non-HA coated porous-coated femoral stems up to 8 to 9 years after surgery.<sup>30,55-66</sup> Any differences noted are radiologic in nature and their significance in the survival of the THA is currently unknown.

Clinical studies of TCP-coated porous-coated femoral stems have not been reported in the English literature. Chae and associates<sup>67</sup> reported that plasma-sprayed TCP on porous-coated cobalt chromium tibial implants in rabbits enhanced osseous ingrowth.

The primary purpose of this randomized clinical trial was to deter-

mine if a TCP coating applied to a porous femoral implant enhanced bony ingrowth compared to a porous femoral implant without the TCP coating, in the first 24 months after a primary THA. The secondary purpose of the study was to compare the clinical outcome of patients in each of these 2 groups.

### A priori hypothesis

The TCP-coated femoral implants would enhance bone growth and reduce calcar atrophy compared with the non-coated femoral implants after 24 months.

### Materials and methods

#### Design

This paper reports the results of a prospective, randomized, double-blind clinical trial undertaken by 2 surgeons at the University of Alberta Hospitals, an acute-care tertiary institution.

#### Patients

Between January 1993 and March 1995, 92 patients scheduled to undergo primary THA volunteered to participate in the trial. Subjects older than 20 years who were willing and able to give informed consent and return for follow-up assessment were eligible for participation in the trial. Exclusion criteria included active infection, previous surgical procedures to the hip that could adversely affect the outcome, previous heterotopic ossification or any other systemic condition that could adversely affect healing or limit follow-up.

**Intervention**

After we had obtained informed consent from the patients and enrolled them in the study, they were equally randomized (46 patients/group) in blocks of 4 into 1 of 2 groups. The control group received a cobalt-chromium-molybdenum alloy porous-coated femoral implant (DePuy, Warsaw, Ind.). The stem was straight, collared, anatomical medullary locking (AML) and had a 5/8th coating with standard triangle or modified medial aspect configuration. The treatment group received the same femoral stem as the control group with the addition of TCP plasma-sprayed circumferentially on the proximal one-third of the stem. The TCP applied was beta-TCP, 98% pure and 100 ± 30 mm thick.

**Outcome measures**

Plain radiographs were obtained preoperatively, 3 days postoperatively and at 6, 12 and 24 months postoperatively. At the time of this study, dual energy x-ray absorptiometry and radiostereometric analysis techniques were not readily available for a reasonable cost at our institution. Evaluation of the radiographs included assessment of the following: spot welds to indicate bony ingrowth, radiolucent line formation or progression in the Gruen zones,<sup>68</sup> heterotopic bone formation,<sup>69</sup> stem subsidence,<sup>70</sup> stress shielding,<sup>70</sup> distal tip reaction,<sup>70</sup> component positioning,<sup>70</sup> new bone formation<sup>70</sup> and endosteal scalloping.<sup>70</sup> An experienced orthopedic surgeon who was blinded to the patient's grouping and was not involved in the study evaluated the radiographs.

Patients were clinically assessed preoperatively and at 6, 12 and 24 months postoperatively utilizing the Société internationale de chirurgie orthopédique et de traumatologie (SICOT) clinical hip evaluation,<sup>71</sup> and the 100-point visual analogue scale (VAS) for pain evaluation.<sup>72</sup>

Clinical assessments were performed by a physical therapist who was blinded to the patient's allocation. Data regarding the complication and survival rates were also collected.

Surgical technique and postoperative protocols of medication, weight-bearing as tolerated and inpatient physiotherapy were identical in both groups. All patients received warfarin anticoagulants postoperatively for a minimum of 42 days.

The 2 treatment groups were similar with respect to gender, age, weight and preoperative diagnoses (Table 1). Pre-existing medical conditions ( $p = 0.85$ ) and previous procedures or conditions of the operative hip ( $p = 0.28$ ) were also not significantly different between the 2 groups.

**Analyses**

SAS statistical software version 6.12 was used for all statistical analyses.  $\chi^2$  analysis or Fisher's exact test was used for categorical or frequency variables. When both of the categorical variables were ordinal, Mantel-

Haenszel  $\chi^2$  was used instead. The results of the VAS and other continuous variables were analyzed with a generalized linear model. Nonparametric analysis methods were used for confirmation of the parametric analyses. The level of significance was set at  $\alpha = 0.05$ . Further analysis was done, stratifying patients on the basis of age, gender, diagnosis, body mass index (BMI), function and location of pain.

**Losses to follow-up**

The 24-month follow-up was carried out in 71 patients. Of the 21 patients without 24-month results (9 from the TCP group and 12 from the control group [ $p > 0.05$ ]), 2 had died, 13 were lost to follow-up and 6 refused to return for their 24-month evaluation. This left 34 control patients and 37 patients in the treatment group available for analysis. A sensitivity analysis was performed to determine the effect on the results of those who were lost to follow-up or refused to return. In this analysis, all patients who did not return for a 24-month assessment in the TCP group

**Table 1**

**Demographic Features of the Control and Treatment Groups of Patients Who Underwent Total Hip Arthroplasty\***

Demographic feature	Control	TCP
Gender, no. (and %)		
Male, $n = 41$	23 (56)	18 (44)
Female, $n = 51$	23 (45)	28 (55)
Age, yr		
Mean (and SD)	59.1 (9.7)	60.5 (8.5)
Range	37-74	36-73
Weight, kg		
Mean (and SD)	84.1 (19.8)	81.5 (14.2)
Range	40-138	53-104
Body mass index		
Mean (and SD)	29.7 (6.2)	28.3 (4.6)
Range	15.6-41.6	21.8-38.4
Diagnosis		
Osteoarthritis	35	36
Post-traumatic arthritis	3	0
Rheumatoid arthritis	4	4
Psoriatic arthritis	1	0
Avascular necrosis	2	3
Epiphyseal defect	1	1
Diastrophic variant	0	1
Ankylosing spondylitis	0	1

\*Control = patients receiving a non-coated femoral implant, treatment = patients receiving a tricalcium phosphate (TCP) femoral implant.

were analyzed as having spot welds present and no calcar atrophy. All patients in the control group who did not return for the 24-month follow-up were analyzed as having calcar atrophy and no spot welds, representing a "worst case" scenario.

### Sample size

The power of the statistical analysis was calculated from the standard deviation of the scores on the modified Harris Hip Score from a previous study on non-cemented AML prostheses (unpublished data). Based on a 2-tailed level of significance of  $\alpha = 0.05$  and a power of 80%, a sample size of 90 participants was required to detect a difference of 8 points in the modified Harris Hip Score between the groups.

## Results

### Radiographic parameters

Spot welds were present in 17 (59%) of 29 control femoral implants and in 19 (54%) of 35 TCP implants. (Five patients from the control group and 2 from the TCP group were either lost to follow-up or did not have appropriate radiographs.) Sixteen (55%) control patients and 21 (60%) TCP patients showed signs of calcar atrophy on their 24-month radiographs. Three (10%) patients with non-coated implants and 1 (3%) patient with a TCP-coated implant demonstrated radiographic lines

around more than 50% of the coating on the 24-month radiographs. Pedestals at the stem tips were present in 9 (31%) of the control implants and 8 (23%) of the TCP implants. There was no subsidence of the femoral implant in either group at 24 months. None of these findings were statistically significant between the 2 groups ( $p > 0.05$ ). The distribution of heterotopic bone is noted in Table 2.<sup>69</sup>

The sensitivity analysis did not alter the results of the radiographic analysis, with the differences between the groups in terms of spot welds and calcar atrophy remaining non-significant ( $p > 0.05$ ).

### Visual analogue scale

The mean (and standard deviation) preoperative pain level as assessed by the VAS was 78.07 (19.8) ( $n = 44$ ) for the control group and 73.78 (12.1) ( $n = 46$ ) for the TCP group ( $p = 0.22$ ). The mean postoperative VAS pain score for the control group was 12.5 (17.3) ( $n = 33$ ) and 10.6 (10.8) ( $n = 36$ ) for the TCP group at 24 months ( $p = 0.58$ ). (One patient in each group was lost to follow-up.) Using analysis of covariance (ANCOVA), no difference was found between the 2 groups for the change in pain between the baseline measurement and the measurements at 24 months or more when controlling for any confounding effects of age, gender or BMI ( $p = 0.70$ ). At no measurement interval was a significant difference seen in pain measurement between the 2 treatment groups.

## SICOT clinical evaluation

### Pain

Pain frequencies between groups preoperatively and at 24 months or more are presented in Table 3. At the baseline and at the last follow-up the measurements for the 2 groups were not significantly different ( $p = 0.06$  and  $p = 0.15$ , respectively). Five patients in each group complaining of pain at the final follow-up stated that the pain occurred with "start-up." The incidence of thigh pain was not significantly different between groups ( $p = 0.63$ ).

### Function

No significant differences were seen in any of the clinical categories of the SICOT scale (putting on shoes or socks, sitting to standing, climbing stairs, limp, support required, time walked, range of motion, deformities) at any evaluation point over the 24-month interval ( $p > 0.05$ ).

### Complications

Perioperatively, 1 patient sustained a perforation of the acetabular floor. Postoperatively, there were 5 dislocations, all occurring in the first year after surgery. Three of these were in the TCP group. There was 1 wound problem in each group. In the TCP group, 1 patient had distal venous thrombosis and 2 patients had nerve palsies. The remaining complications were not related to the operation and were similarly distrib-

Table 2

Heterotopic Ossification (Brooker Classification<sup>69</sup>) Present at 24 Months in the Control and Treatment Groups\*

Degree of ossification	Control	TCP
Brooker I	7	10
Brooker II	7	4
Brooker III	2	3
None	13	18

\*Control = patients receiving a non-coated femoral implant, treatment = patients receiving a tricalcium phosphate (TCP) femoral implant.

Table 3

Measurement of Pain at Two Time Intervals in the Control and Treatment Groups of Patients Who Underwent Total Hip Arthroplasty\*

Time interval/degree of pain	Control	TCP
Preoperatively, no./total (%)		
Moderate	30/46 (65)	38/46 (83)
Severe	16/46 (35)	8/46 (17)
At 24 mo, no./total (%)		
None	23/34 (68)	20/37 (54)
Mild	8/34 (23)	16/37 (43)

\*Control = patients receiving a non-coated femoral implant, treatment = patients receiving a tricalcium phosphate (TCP) femoral implant.



uted between the groups. In neither group had there been stem revision at the 24-month assessment.

## Discussion

The use of TCP coating to enhance bony ingrowth was not radiographically or clinically advantageous in this randomized trial. Although these results can only be considered preliminary at 24 months postoperatively, the use of an implant that is more costly with no readily apparent clinical benefit is questionable, especially in this era of fiscal constraint. Although the long-term benefits are not currently known, there is no evidence to suggest that these coatings may prevent or reduce the failure of the implant at later dates.

Our results are similar to those in clinical trials examining the effectiveness of HA-coated femoral implants. Several studies that examined the effectiveness of HA-coated femoral implants have not found clinically significant differences between patients with coated versus uncoated femoral implants based on the Harris Hip Score over mid- to long-term follow-up.<sup>30,55-66</sup> Some studies suggested that radiologically there was an improved outcome with the use of HA coating, but this finding has not yet been proven to affect the clinical outcome. Our study did not detect either radiologic or clinical differences between the groups at the 24-month interval, indicating that the TCP coating did not result in earlier bony ingrowth than a non-coated implant.

It was theorized that the use of synthetic calcium phosphates would enhance implant fixation, thereby reducing the migration of wear debris distally.<sup>35</sup> Osteolysis could then be decreased, reducing progressive loss of fixation over time.<sup>57,59,61,64,73</sup> If the revision rate could be reduced, the savings would offset the increased cost of the implant. This theory was not, however, borne out in our findings to date. It is not anticipated that

the coating will have a greater effect at later intervals than it did in the initial postoperative period.

There are some indications from the basic science literature that current clinical treatments or the preparation of the implant may affect the synthetic calcium phosphates in their ability to enhance early bony ingrowth. Contributing factors to this lack of ingrowth include exposure to warfarin<sup>74</sup> or nonsteroidal anti-inflammatory (NSAID) medications<sup>75-77</sup> in the early postoperative period. In addition, the use of cobalt chrome rather than titanium and the process in which the coating is placed on the implant may also have reduced the effectiveness of the synthetic calcium phosphates to encourage early ingrowth.<sup>14,17,29,33,37,78,79</sup> It is, however, beyond the scope of this paper to determine if these factors played a role in our findings.

## Conclusions

The objective of the TCP coating — to increase the rate and amount of early bony ingrowth and fixation while reducing the rate of calcar resorption in cementless THA — was not achieved within 24 months of surgery in our study. Further follow-up of this population is warranted to determine if there are long-term benefits or detriments to the use of this coating. There does not appear to be justification based upon the current results to encourage health care providers to continue to use these more costly implants.

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