ENHANCED FIXATION OF UNCEMENTED KNEE REPLACEMENT WITH HYDROXYAPATITE

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ABSTRACT

The increasing trend for uncemented joint prostheses has led to some concerns regarding fixation and the search for methods that may enhance it. Of the currently available bioactive ceramics, Hydroxyapatite (HA) remains the one with the most clinical use. We report early results of an uncemented total knee arthroplasty demonstrating excellent fixation at 2 *and 5 years*. Early clinical results are promising and no complications attributable to the HA or fixation are seen. There has been no early loosening. Comparison with a similar series of implants with similar geometry shows increased osseointegration with HA coating. With fluoroscopic imaging, the HA coated bone-prosthesis interfaces are seen to reliably fill in with bony tissue by 2 years. There are less lucent lines visible, if any, in the HA coated prosthesis.

1. INTRODUCTION

Early results with bioactive coatings on arthroplasty prostheses have been encouraging [1]. Most information to date however concerns total hip arthroplasty, with few reports regarding the knee. Although the published results of cemented knee arthroplasty are good [2,3,4], growing concerns with cement fixation have lead to an increasing trend for cementless fixation [4,5,6,7]. Certainly cementless fixation has some theoretical advantages; less third-body wear, maintenance and better restoration of bone stock, and safer implantation after bacterial arthritis. Simple press-fit total knee prostheses however have not demonstrated enough intrinsic stability, and ingrowth into porous coated implants is inconsistent, possibly because of inexact bone cuts. Preliminary reports by, Epinette, [8], have suggested that Hydroxyapatite coated implants may improve stability & fixation of total knee arthroplasty, but no studies to date have examined the bone prosthesis interfaces by accurate, screened radiology. The purpose of this study was to prospectively examine the role of HA in promoting osseointegration into knee prostheses.

2. MATERIALS & METHODS

Standardized radiographs of patients receiving the uncemented, HA coated Motus prosthesis were compared to those taken of patients receiving the non-HA coated Miller-Galante (MG) implant. The Motus and MG systems have similar geometry making comparison between groups possible.

We examined standardized radiographs of 105 patients with 161 uncemented, HA coated total knee replacements performed sequentially. 67 patients (64% of patients, 44% of prostheses) were male. The mean age was 68.8 years (Range 51-88).

All patients were operated on by a single surgeon, with a consistent operative technique using the Motus™ (Osteo, Switzerland) arthroplasty in all patients. All knees have been uncemented regardless of diagnosis, age of patient and bone quality. There has been no preoperative selection of patients against a cementless technique.

The Motus prosthesis is coated with Hydroxyapatite (crystallinity 75%, Porosity 20%, thickness 70 microns). The distal surface of the femoral prosthesis and tibial plate are coated with heat sintered beads (size 0.4-0.6mm). These patients all received thromboembolic prophylaxis in the form of low molecular weight heparin.

A comparison group of 98 patients receiving 151 non-HA coated cementless Miller-Galante™ implants formed the control group. The mean age was 70.06 years (Range 51-83). 57 (58.1%) patients were male, receiving a total of 73 implants (48.3%). The operating surgeon's technique, including the use of tourniquets and drains, remained unchanged during the study period, though choice of DVT prophylaxis did change, with the majority of the non-HA group receiving unfractionated heparin.

2.1 Surgical Technique

Bone cuts are made with the manufacturer's jigs and any bone defects grafted with autogenous bone from the patient. After sizing and trial insertion, the definitive components are press fitted onto femur and tibia. Four screws are used to obtain immediate stabilization of the tibial tray.

All patients are mobilized fully weight bearing on the second postoperative day and then begin active flexion and extension exercises. Patients are permitted to discard any walking aids whenever they feel confident.

The selection of patients, surgical implantation technique and rehabilitation regime has remained unchanged between the two groups, and with similar demographics in the two groups (See Table 1), comparison between the groups is justified.

Table 1: Patient Data

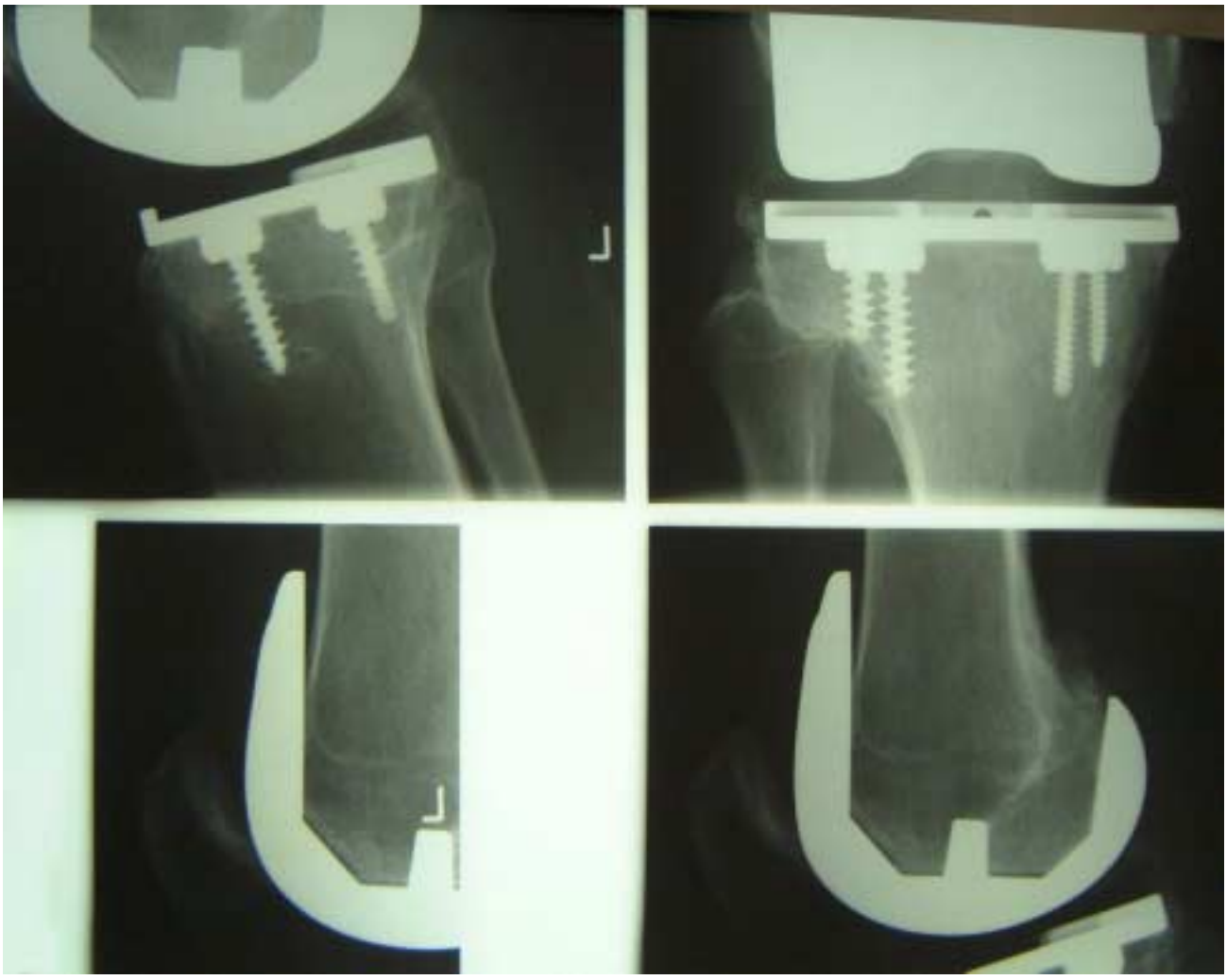
	Miller-Galante (Non-HA)	***Motus (HA coated)***
Number of patients	98	105
Number of knees	151	161
Mean Age in years (Range)	70 (51-83))	69 (51-88)
Sex (% Male knees)	48%	44%
Mean Follow Up	2.83 years	2 years
Diagnosis: OA (excl. HTO)	126	132
RA	17	18
Post HTO	5	8
Other	3	3

2.2 Radiographic Assessment

Being an uncemented prosthesis, the quality of the fixation is of paramount importance. In order to examine this, screened views of the bone-prosthesis interface were taken under fluoroscopic positioning (figure 1) immediately postoperatively, and at 2 years. To our knowledge few studies have examined the interfaces in this way [5,9,10]. Because of the minor malpositioning that invariably occurs a true AP or Lateral view of the knee is unlikely to be a true AP or lateral of the prosthesis itself. An apparently true lateral X-ray, for example, when screened into perfect position may then show lucent lines [10] (figure 1). In the few published series, many of the radiographs illustrated are not in fact true laterals or true AP views under close scrutiny and this may hide lucencies.

In a further attempt to standardize the radiographs, the same two experienced radiographers examined all patients in the same fluoroscopy suite. Screened radiographs having been obtained, the position and presence of lucent and also sclerotic lines were noted independently by two independent orthopaedic surgeons unconnected with either the development of the prosthesis or with the clinical management of the patients. A line was said to be present if noted by *either* of the two observers ensuring the false negative rate was as low as possible.

Figure 1. Interface Views



2.1 Clinical Assessment

Each patient was evaluated prospectively using the clinical scoring system of the Knee Society [11] as well as prospective recording of any complications that may have occurred. The total score (200 points) is compiled from two sub-scores: The Knee sub-score (100 points) which measures pain, range of motion, stability and alignment; and the Function sub-score (100 points), which scores points for walking and stair climbing.

3. RESULTS

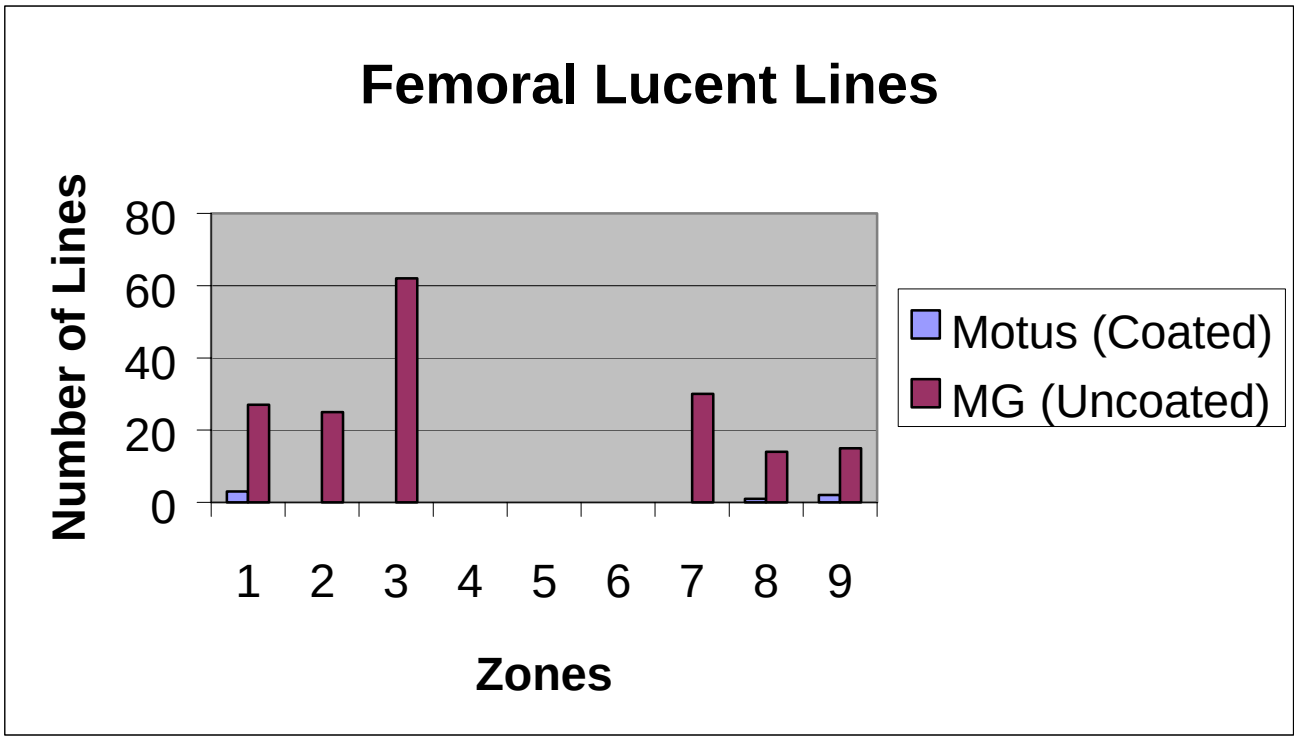
Clinical results of patient assessment using the knee society score are shown in Table 2. The median knee score at 2 years postoperatively in the HA coated knee was 188, versus 181 in the uncoated knee.

Table 2: Clinical Results

	MG (uncoated)	***Motus (HA coated)***
Mean Preoperative ROM	7°-116°	6°-112°
Mean Postoperative ROM	1°-105°	1°-115°
Mean Postoperative knee score	181	188

The radiographic results are shown in Figure 2 and the lucent zones locations are displayed in Figure 3. The assignment of zones is in the manner suggested by the Knee Society [12], to standardise the reporting of roentgenographic evaluations and scoring.

Figure 2 a) & b): Number of lucent lines in each zone (see Fig. 3 for zone location)



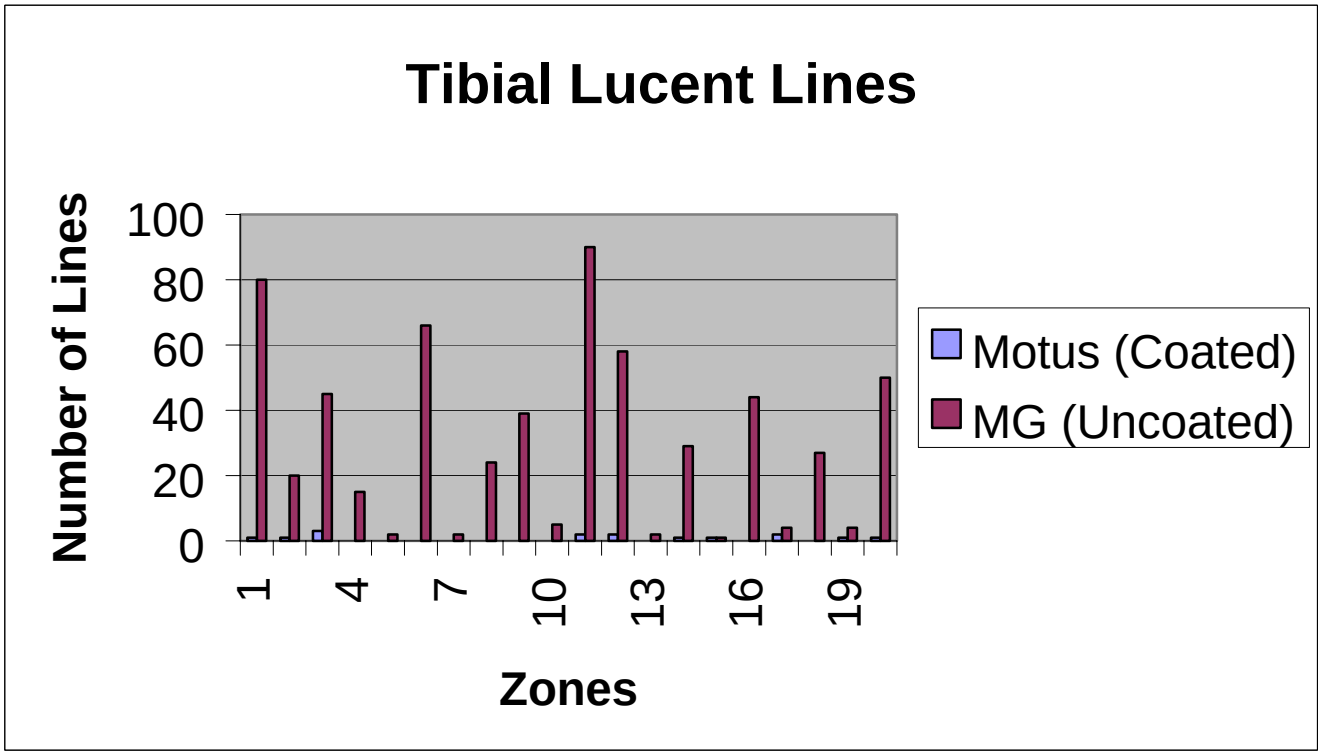
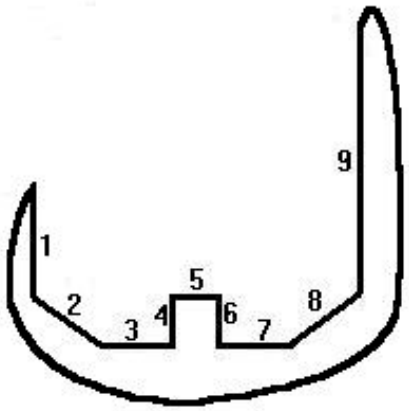
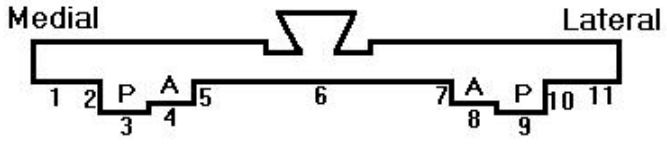


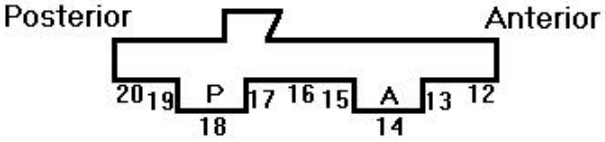
Figure 3. a) and b) Zone Location

a) Femoral Component



b) Tibial Component





Sclerotic lines were noted to be present around some HA coated implants although their significance is unknown. Epinette [8] suggests that they represent "An adaptation of host bone to the altered stress transfer pattern" because of an elasticity gradient between bone and implant. They were seen to be present infrequently, and mainly in the anterior and posterior zones of the femur in this study, and were not seen to have any clinical correlation.

No sclerotic lines were noted around the tibial component in the HA implant. Epinette [8] noted these around 3% of the HA coated areas of the tibia, but in up to 37% of the uncoated keel areas. The absence of a keel in the tibial component used in this study may be responsible for the difference observed.

4. DISCUSSION

The authors agree that the presence of lucent lines can be benign, as shown by the 2 year knee function scores (188 HA coated vs. 181 uncoated) which are similar despite the marked differences in the lucent line rate. However, although the presence of a lucent line does not necessarily indicate either osteolysis or a loose component, it does signify an absence of osseointegration, which is the goal in any cementless arthroplasty. Only by collecting data in this way can the extent of osseointegration be monitored over time.

Despite one's best efforts, gaps will inevitably be present after the press-fit implantation of the cementless knee implant. The presence of a hydroxyapatite coating is seen to reliably fill in these gaps (Figure 4). It is extremely unlikely that the decrease in lucent lines could be accounted for by inaccuracies in the follow-up fluoroscopy as the technique and radiographers performing the procedure remained the same.

There has been suggestion [8] that HA coating of a beaded surface can lead to bead shedding. None has been seen in this study, although it was specifically examined for. The prosthesis used has beads only on the distal femoral surface, where there should be no shear, and the authors therefore believe that a coated, beaded distal surface should not pose a problem. The single retrieval specimen that has been obtained shows osseointegration within the beaded surface (Figure 5).

The findings of this paper provide radiographic support for that of Onsten [1], which concludes that HA improves the fixation of the tibial component. It provides evidence that excellent early clinical results can be obtained with the unselected use of a cementless implant when augmentation with HA is used, although it is accepted that these results are no better than many published results with cemented prostheses.

Long-term follow-up continues, and aims to answer the question of whether HA may be a source of third-body wear particles, and whether there are any long-term advantages or disadvantages to this technique.

Figure 4. Osseointegration within the beaded surface

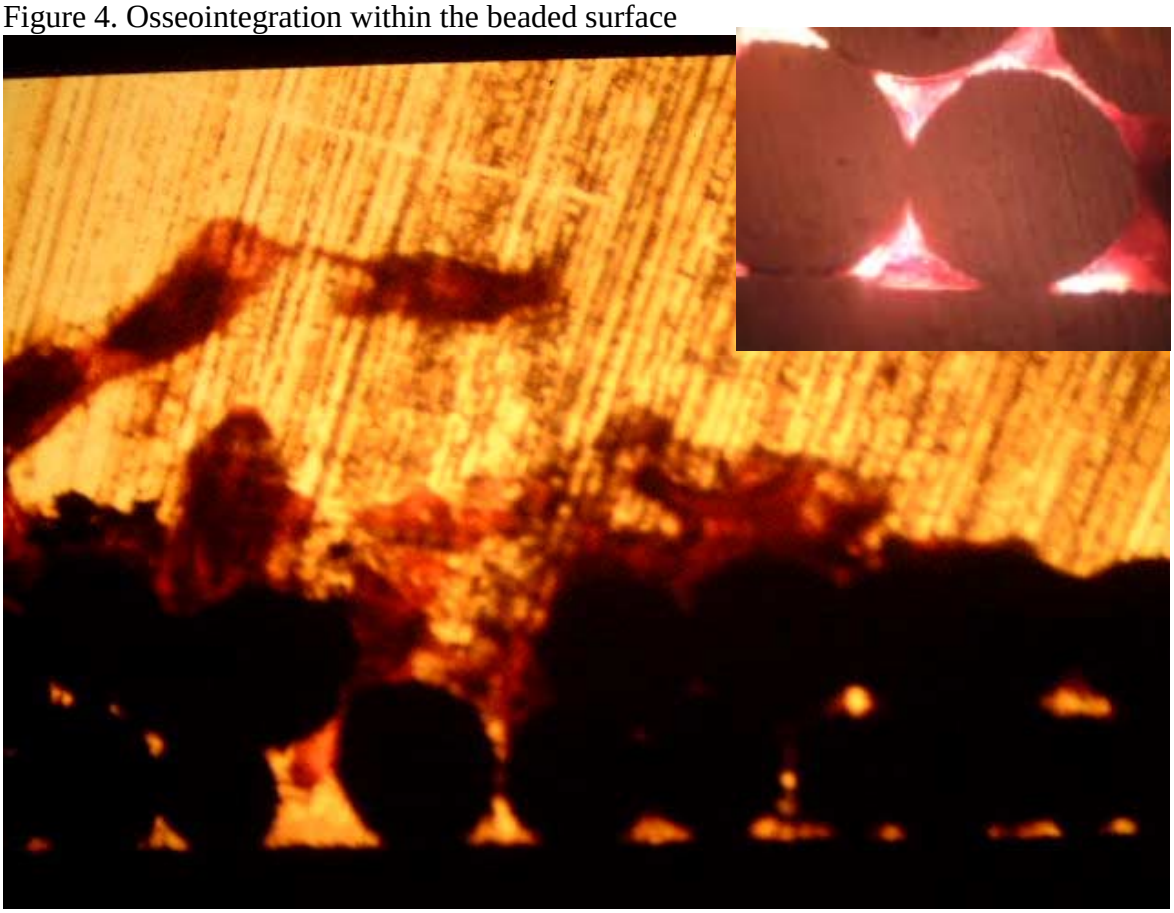


Figure 5. Retrieval prosthesis displaying osseointegration within the beaded surface

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