Original Research

Behavior of the Femoral Stem in the Bihapro Hip Prosthesis

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ABSTRACT

This study evaluated the hydroxyapatite-coated femoral stem of the Bihapro hip prosthesis (Biomet Ltd, Bridgend, United Kingdom) using radiography, TC-99 scintigraphy, and bone densitometry. Thirty stems with >2 years of follow-up (mean: 31 months) were evaluated. No loosening or changes in the position of the implant were seen, and the mean subsidence was 2.2 mm. Radiography revealed a densification in the metaphyseal zone with reconstruction of the trabecular lines in 21 cases, while in 22 patients, radiolucent lines in the distal area of the femoral component were observed. Scintigraphy showed a diaphyseal normo-captation in 19 cases and a hypercaptation <1.4 with a mean index of 1.1 in 10 patients. Metaphyseal hypercaptation >1.4 was seen in 24 patients. Bone densitometry revealed increased density in the metaphyseal zones in 29 patients with a periprosthetic/normal bone quotient of 1.4.

The femoral stem of the Bihapro hip prosthesis (Biomet Ltd, Bridgend, United Kingdom) is made of titanium with a hydroxyapatite coating covering a porous coating along the proximal half (Fig 1). The metaphyseal area of the stem is thick whereas the diaphyseal area is extremely thin with a polished surface without hydroxyapatite coating.

The Bihapro stem is designed to achieve initial stability without distal contact to prevent the inadequate transfer of forces that give rise to the so-called phenomenon of stress shielding. Metaphyseal filling is a requisite for immediate stability and for reconstruction of the loading lines, while the application of an hydroxyapatite coating ensures long-term fixation of the implant. Sufficient practical experience with arthroplasties coated with hydroxyapatite exists, and excellent clinical results have been reported with the absence of pain in 90% of cases and survival rates at 7 years similar to those of cemented arthroplasties.

One way of predicting the long-term results of femoral stems is to study early radiographic migration and densitometric changes that occur in the first years after hip arthroplasty. In some instances, if migration and changes had been observed, the failure of other implants, some around 50% after short-term follow-up, could have been avoided. This study used three diagnostic techniques to evaluate the present situation and future prospects of the Bihapro femoral stem.

MATERIAL AND METHODS

From August 1992 to July 1996, a total of 692 Bihapro stems and 821 Bihapro cups were implanted in patients in a prospective multicenter study involving three Spanish university teaching hospitals. The surgical technique was similar in all cases. Preoperative radiographs were obtained, and overreaming of the distal area was performed systematically to avoid fixation in the diaphyseal area.

Patients were evaluated clinically using a modified Johnson's protocol and radiographically using the protocol of Kobayashi and Gruen. Patients also completed a questionnaire in the immediate postoperative period and at 3, 6, and 12 months, and annually thereafter.

The objective of this study was to analyze the behavior of femoral stems in 30 cases with at least 2 years of follow-up (average: 31 months; range: 24-34
months). In addition to radiographs, bone scintigraphs with TC-99 were obtained to quantify the diaphyseal area in respect to the normal bone. densitometric analysis also was performed with CADIA (computer-assisted densitometric image analysis). Clinical results were not studied, as it was impossible in many cases to separate the symptoms for the stems from those secondary to the acetabular component.

Six measurements were evaluated from the radiographs, namely, the amount of subidence, calcar resorption, and varus-valgus mobility in relation to the immediate postoperative period (Fig 2). Radiolucency and sclerosis in each of the seven areas as described by Gruen also were noted.

**RESULTS**

In the 30 cases analyzed, no movements or changes in the stem position were noted radiographically. In 6 patients, some degree of varus was noted radiographically at the distal part of the implant; no contact with the femoral cortex was evident in any of these.

Radiographic evaluation at 1 year postoperatively revealed a mean subidence of 2.2 mm. Thirteen stems showed no degree of subidence, while in the remaining 17, a mean subidence of 4 mm (range: 1-8) (P<.001) was observed. At 2 years postoperatively, the figures were the same, and subidence was not observed in the 13 cases that had no subidence at 1 year.

On analyzing the bone response in Gruen's areas (Table 1), increasing densification in areas 1 and 2 was observed in 13 cases with reconstruction of the trabecular lines that join the femoral cortex with the stem. Eight patients also showed a densification in areas 6 and 7 (Fig 3). However, radiolucent lines were seen in 22 cases (in areas 3 and 5); this coincided with the polished surface of the stem without hydroxypapite. None of the patients showed sclerosis in area 4, which is situated at the distal end of the stem.

In 24 cases, scintigraphic studies conducted 2 years postoperatively showed an increase in captation of radionuclide TC-99 with an index >1.4 in the metaphyseal area (Table 2). In 11 cases, an increase in captation in the diaphyseal area was found with a mean quantification index in respect to normal bone of 1.2 (range: 1-1.6); this was always less than that in the metaphyseal area (Fig 4) (P<.001). Only one patient showed a hyper-captation >1.4 in the distal area of the implant. The mean index of diaphyseal captation was 1.1, and no cases of hypercapition were found in the infraprosthetic area.

Densitometric studies showed an increase in density in areas 1, 2, 6, and 7 in 29 patients. The mean in these areas was 1.4 (periprosthetic bone/normal bone quotient). Hypodensity was present in areas 1 and 7 in 1 patient who presented pathologic diaphyseal scintigraphic hypercaptation. Hyperdensification in areas 3, 4, and 5 was not observed.

**DISCUSSION**

The main goal of hip arthroplasty is articular reconstruction with artificial implants. To accomplish this, in addition to respecting articular morphology, material biocompatibility and sufficient bone fixation must be obtained. The past decade saw the introduction of cementless implants with different coatings to help periprosthetic bone growth. It was believed that a surface that secured bone growth in the whole femoral implant could be the solution for eliminating the need for cementing the femoral component. This kind of arthroplasty, however, has not reached expectations.

It is currently accepted that rigid fixation with good bone growth throughout the implant is not a guarantee of good clinical results. The failures using stems with a porous surface are due, among other causes, to the destructive transmission of forces, which is the origin of pain in the thigh as well as the morphological and mechanical changes in the upper extremity of the femur.

Surgeons have reported a high fre-
quency of pain at mid-stem (between 25% and 50%) and bone reinforcement in the distal area of the stem in 30% of the cases 5 years after surgery. Some authors linked this pain with unnoticed femoral shaft fractures, but in the majority, the pain could be due to hypertrophy of the distal cortical area combined with bone resorption in the upper area. The abnormal transfer of forces that produce a rigid stem with diaphyseal fixation create a remodeling with trabecular thickening, which provide protection against these forces and proximal resorption stress shielding. A nonphysiologic transfer of stress therefore occurs due to the greater rigidity of the implant compared with bone.

To avoid this complication of unforeseen consequences, new prostheses have appeared that aim to achieve only a metaphyseal fixation. The Bihapro stem attempts to correct the abnormal transmission of force by making the implant thicker at the superior end with a porous-coated surface of hydroxyapatite, while the distal end is thinner, shorter, and smoother.

Long femoral stems increase proximal micromovements and subsidence of the implant, while short ones increase proximal contact as shown by Noble et al on comparing stems of 90, 130, and 170 mm. Munuera et al also found a statistically significant difference in the amount of osteoporosis produced in the proximal area by stems of greater thickness. A sufficient metaphyseal filling, on the other hand, increases initial stability and avoids the resorption of hydroxyapatite, which is less in fixed implants.

The Bihapro prosthesis is collarless and anatomical in shape. Although exact morphology can only be determined through axial tomography, reconstruction of the normal anteverision of the neck is recommended to avoid twisting movements. The presence of a collar could favor the resorption of the femoral calcar.

In fixation of the implant to the bone, three stages similar to the healing of a fracture have been described: inflammation, repair, and remodeling. In certain fractures, primary healing is possible under ideal conditions without the formation of fibrocartilage. This could also occur in arthroplasty if there is mechanical stability, which the Bihapro stem possesses, and a sufficient biocompatibility of the materials used in its manufacture.

Both the considerable clinical experience and large number of investigations demonstrate the osteoconducting properties of hydroxyapatite that favor both centripetal and centrifugal growth. Hydroxyapatite facilitates early and solid fixation of the implant.

Oonishi et al have shown that 2 weeks after surgery, hydroxyapatite-coated arthroplasty results in fixation 14 times more often than noncoated ones. In a comparative study, Kroon demonstrated migration of the implant is less with hydroxyapatite coating in the metaphyseal area. Migration was 0.12 mm per year in implants with hydroxyapatite coating and 0.99 per year in implants without hydroxyapatite coating; this difference was statistically significant.

Soballe et al compared two types of stem and found migration was similar at 3 months. However, while migration continued in noncoated stems, it did not occur in stems coated with hydroxyapatite; this difference was significant for both radiographic subsidence and clinical evaluation. The authors theorized the reason for the better evolution of the hydroxyapatite-coated implants was the formation of a fibrocartilage membrane that would become bone, while in those without hydroxyapatite coating, the connective tissue would stay the same over time.

There is also evidence on the conversion of fibrous tissue into bone when the implant has some degree of motion. Our findings coincide with this; the mean subsidence seen 1 year postoperatively was 2.2 mm; this had not changed 2 years postoperatively. It

<table>
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<th>Gruen Area</th>
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<th>Resorption</th>
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<td>0</td>
<td>22</td>
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**TABLE 2**

<table>
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<th>Results of scintigraphic studies</th>
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<td>Diaphyseal Zone</td>
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<td>----------------</td>
</tr>
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<tr>
<td>Increase &lt;1.4</td>
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<td>Increase &gt;1.4</td>
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Fig 4: Bone scintigraphic study with Tc-99 2 years after surgery shows no changes in the diaphyseal area.
appears that minimal subsidence is the general behavioral guideline of this type of stem, and the subsidence becomes stable after time while in other models subsidence appears to continue over the years.

The thickness of hydroxyapatite coating has been the subject of several studies, and a coating between 50 and 150 μm is recommended, bearing in mind that the resorption is three times greater when the thickness is 200 μm.24 In clinical studies, hydroxyapatite has caused less postoperative pain, and a rough surface under the hydroxyapatite coating,25 such as that in the Bihapro prosthesis, is recommended.

In stems with metaphysial fixation, good integration of the implant in the proximal area should be seen, included with reconstruction of the lines of force. The radiolucency in the distal zone22 show the absence of bone growth. As previously described, this is a frequent finding on analyzing the Bihapro stem; trabecular lines that originate in the external and internal metaphysial cortex of the femur are highly visible. These images are similar to the "crane" of Culman26,27 and appear early and remain without modification during the study period.

On the other hand, in 22 patients in this series, periprosthetic radiolucent lines were found in the distal polished area without hydroxyapatite coating. This radiolucency, which could be a problem in prostheses with hydroxyapatite coating over the whole stem, is a favorable sign for the survival of Bihapro stems. Kroon and Freeman23 affirmed this on analyzing other prostheses with similar characteristics. They postulated this could be the result of the absence of distal fixation and the micro-movements that develop in this area, and demonstrate the correct transmission of forces toward the metaphysial zone and not toward the diaphyseal zone.

Furthermore, this also may be due to the elasticity of the titanium in a thin structure, like the Bihapro stem in its distal area. No cases of stem mobilization, radiolucent lines in the metaphyseal area, or radiographic densification in the distal stem were noted in this study.

Hwang and Park28 analyzed three cementless stems with metaphysial fixation; osteolysis of the neck occurred in 8% to 15% and distal hypertrophy was seen in 14% to 15%. Femoral migration correlated statistically with pain in the thigh in >20% of the three prostheses studied.

Bone scintigraphy studies of the Bihapro stem have shown data similar to radiographic studies. An increase of the radionuclide deposit in the metaphysial area was seen in 24 cases. In the case of diaphyseal hypercaptation (11 cases), this was less than in the femoral metaphysis. Only one patient showed excessive captation in the distal zone, which coincides with the areas where the stem has a smooth surface to avoid fixation in the modular canal. These findings corroborate the design achieves its objective of metaphysial fixation. Hypercaptation was not seen in zone 4, the distal part of the stem, which also supports this finding.

Densitometry recently has been used to evaluate the bone near articular implants.29,30 It is the only technique capable of accurately showing the response of the bone to the implant, as for some authors,31 radiography only detects variations >30% and scintigraphy does not allow the study of precise quantitative changes.

In a previous study by our group on the densitometry of hip arthroplasties,32 some stem models with hydroxyapatite coating over the whole surface, or with a greater thickness in the diaphyseal area, showed an increase in the density in this area, which we attribute to incorrect distal fixation of the bone. Hein et al29 compared two prostheses and found densification in zones 2 and 6 without proximal resorption in the prostheses with metaphysial fixation. In prostheses with total fixation, densification was found in areas 3 and 5 with resorption in the upper femoral areas.

Kilgus et al33 also found less bone density loss in the trochanteric portion in prostheses with metaphysial fixation when comparing these models to prostheses with metaphysial-diaphyseal fixation. They found that changes in bone density after implant fixation with metaphysial filling were equal to the densitometric variations that occur in the nonoperated femur. Maugars et al34 have shown that bone density loss in the trochanteric portion is less if the stem possesses a metaphysial fixation. Stems with small diameters in the diaphyseal area cause smaller densitometric losses. Minuesa et al35 compared prostheses with thick and thin stems, both with hydroxyapatite coating in the proximal half, using densitometry with digital imaging and found a decrease in density in zones 1 and 7 in all cases, but the loss was greater in the thicker stems.

Vidal et al31 studied stems with proximal porous covering using DEXA and found metaphysial atrophy around 31% in the calcar area 6 months after surgery. This supports the concept previously outlined that not only metaphysial fixation is necessary but also ablation of contact with the cortex in the distal area.

We have used computer-assisted densitometric image analysis to study the behavior of Bihapro stems. This technique analyzes the radiographic images through a video camera and adds a special treatment that quantifies, with the use of the computer, the bone density in seven areas corresponding to Gruen's areas in the femoral stem.3 The density is evaluated comparatively with the preoperative radiographs and a zone with a thickness of 3.5 mm around the implant. Hyperdensity was not seen in areas 3, 4, or 5 in any of our cases. However, a common finding in 29 cases was increased density in zones 1, 2, 6, and 7 with a mean increase of 1.4 in the periprosthetic/normal bone quotient.

**CONCLUSION**

The Bihapro prosthesis yields excellent short- and medium-term radiographic results. However, only period-
ic radiographic follow-up and densitometric studies can predict the long-term outcome.

REFERENCES


EDITORIAL DISCUSSION ORTHOPEDICS: How were the 30 patients analyzed selected? Hernández-Vaquero: The 30 patients analyzed were randomly selected from patients with >2 years of radiographic follow-up. ORTHOPEDICS: You measured subsidence in the movement of the component but did not mention rotation. Is it possible to do so? Hernández-Vaquero: It is difficult to measure rotational changes of the femoral stem. With standard radiographs, this would only be possible with good quality axial radiographs or roentgen stereophotogrammetric analysis. Computed tomography with special programs and other complex techniques also could be useful. Rotatory instability of the stem would demonstrate an absence of bone integration in the metaphyseal zone with images of periprosthetic radiolucency and no trabecular lines in the external and internal metaphyseal cortex of the femur. The subsidence also would be produced in a short period of time. The design of the upper part of the Bihapro stem restricts the rotation due to the sufficient metaphyseal filling.