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ORIGINAL STUDY

Hedrocel trabecular metal monoblock acetabular cups : mid-term results

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The most important factors for long-term survival of cementless prostheses are the initial fixation, the osteoconducting properties of the metal shell and the bony response. Porous tantalum, a new biomaterial with a geometric structure similar to trabecular bone, was reported in animal studies to allow for bone ingrowth even when 3-mm gaps exist between the implant and the bone. This new material may improve the durability and stability of hip arthroplasties.

We analysed the behaviour of the underlying acetabular bone, based on radiographs taken 46 months or longer after implantation of monoblock cementless acetabular cups made of porous tantalum. Clinical evaluation was done by means of the Harris Hip Score. The acetabular ARA-score, ranging from poor to excellent, was excellent in 80 % of the cases, 46 months or longer after implantation. The clinical condition of the patients as assessed with the Harris Hip Score was excellent for 65 % of the patients.

Keywords : Hedrocel acetabular cups ; osteoconductivity ; porous tantalum ; Harris Hip Score ; ARA score ; mid-term results.

INTRODUCTION

The most important factors for long-term survival of cementless hip prostheses are the initial fixation, the osteoconducting properties of the metal shell and the bony response. They contribute to an appropriate fill of the gaps between the prosthesis and the bone by stimulating bony penetration into the porous surface of the implant and osseointegration of the metal shell. These two mechanisms are respectively known as prosthesis bone penetration and prosthesis bone overlapping.

It is generally accepted that every implanted total joint prosthesis generates wear products, which are likely to cause periprosthetic osteolysis (*2, 11, 18*). Osteolysis around the femoral stem is however caused predominantly by mechanical factors whereas osteolysis around the acetabular cup is the result of a cellular reaction to wear products. This cellular reaction can be decreased by preventing the penetration of wear products into the gaps between the bone and the cup. For this reason, optimising bony ingrowth into the porous surfaces of the prosthesis in cementless arthroplasties is required (*3, 8, 9, 12*). The use of a monoblock construct will reduce the production of wear debris. The Hedrocel cup is a monoblock prosthesis,

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which eliminates any backside micromotion between the polyethylene and the metal shell.

During the last 20 years several materials have been tested to optimise the metal shell of cementless cups. Most of these are made of titanium and cobalt-chromium alloys. The external porous surface of these metal shells stimulates bone ingrowth into the shells, which ensures long-term biological fixation of the implant (*3, 8, 9, 14, 15*). Different techniques like overlapped nodules, plasma sprays, microporous surfaces and metallic fibre meshes are used to process the external surface of the shell. The goal is to achieve a good biological implant fixation by providing a porous surface into which the bone can grow and penetrate.

Porous tantalum, a new biomaterial that came into use in orthopaedic surgery since 1997, is not a coating but a truly structural porous biomaterial. Its overall geometry is similar to that of trabecular bone (*3, 5, 7*). The combination of the large porous surface of tantalum and its elasticity allows for a larger bone penetration volume, which results in a faster and stronger biological fixation of the implant (*1, 4, 5, 7, 8, 20*). The porous surface, the bone contact during the implantation and the peroperative stability are of vital importance because they can improve bone ingrowth (*6, 8, 19*). Therefore a complete contact between bone and prosthesis is sought. It has however been shown that bone ingrowth in currently used prostheses can take place in the presence of gaps up to 2 mm (*5, 7, 11, 16*). In experimental trials with dogs and mice, bone ingrowth has even been demonstrated in porous tantalum implants with gaps up to 3 mm (*4, 5, 7*).

In order to evaluate the biomechanical behaviour of the tantalum monoblock cups, the radiographs of 24 cups with a minimum follow-up of 46 months were analysed. The clinical outcome was assessed in 38 patients using the Harris Hip Score.

MATERIAL AND METHODS

Between September 1998 and September 2000, 48 patients (50 hips) underwent a primary hip arthroplasty including an Hedrocel acetabular cup (Implex Corp, Allendale, NJ 07401, USA). All operations were performed by one single experienced surgeon. The Hedrocel cup was implanted in anteversion (15°) and abduction (40°), using the press-fit technique. The anterolateral access was used for all patients. During insertion of the cup, any contact between soft tissue and the implant was meticulously avoided. The stability of the implant was checked intraoperatively in each case. All patients were evaluated radiologically immediately after the operation. X-ray imaging included a weight bearing anteroposterior film of the pelvis and hips and a lateral view of the operated hip in the supine position.

Patients were invited for a follow-up consultation in July 2004, i.e. at least 46 months post-operatively. During this visit the Harris Hip Score (HHS) (*16*) was calculated and radiographs were taken. Patients who were unable to attend the clinic for consultation were contacted by telephone to evaluate their pain and function.

All radiographs were scanned with a high-resolution scanner and stored digitally in the database program, Orthowave™ (licenced product to Stryker-Howmedica-Osteonics). The digitised films of the first and the latest postoperative evaluation were then compared, looking for radiological changes.

For evaluation of the radiographs, the acetabular region was divided into 4 zones (fig 1) allowing precise localisation of clinically relevant signs such as osteolysis around the implant, gaps between the implant and the acetabular bone, reactive lines, radiolucencies and cancellous bone densifications.

The use of four different acetabular zones, as described in the Orthowave™ program (*13*) was preferred to the classic acetabular division in 3 zones, as described by Charnley and De Lee (*10*). The division into 4 zones was necessary to generate a more detailed and specific topographic evaluation of the gaps between the prosthesis and the acetabular bone. It offered the possibility to characterise balloon expanding osteolysis, which is sometimes seen around cementless cups. The acetabular ARA-scoring method, from poor (1 point) to excellent (6 points), was used as a radiographic evaluation of the status of the cup (*13*).

The Hedrocel cup (fig 2), implanted in all patients, is a porous tantalum cup in which the polyethylene is embedded by direct fusion and compression (monoblock construction). It allows the polyethylene to penetrate 2 mm into the shell (fig 3). This eliminates backside micromotion.

The total thickness of the polyethylene can be limited to 8.5 mm (2 mm fused into the shell itself and another 6.5 mm 'not fused') for an external diameter of 48 mm and a head diameter of 28 mm. If on the other hand the

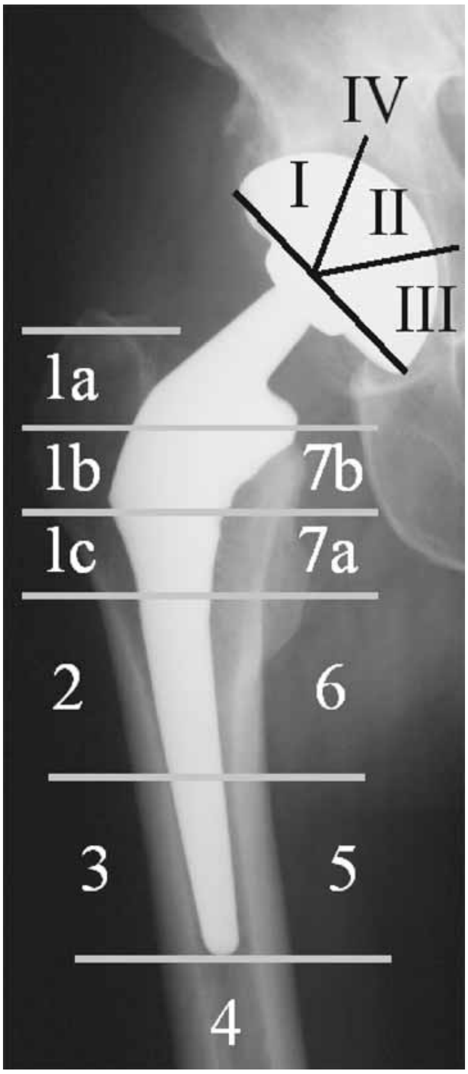

Fig. 1. — The 4 zones in which the acetabulum was divided (Orthowave program).

Fig. 2. — The Hedrocel tantalum acetabular cup

Fig. 3. — Hedrocel acetabular implant in cross-section, showing the bonding between the polyethylene and the tantalum shell.

external diameter is only 40 mm and the head 22 mm, the polyethylene thickness can be further reduced to 8 mm (2 mm fused into the shell itself and another 6 mm 'not fused').

The cup's shape is a widened hemisphere (fig 1). The diameter of the tantalum shell pores is 550 µm with a dodecahedron structure, which is within the optimum pore size of 400 to 500 microns. The porosity of tantalum is 75 to 80% of its total volume, it has an elasticity of 3 GPa and its friction coefficient is twice the friction coefficient of other biomaterials with a porous interface.

RESULTS

Fifty acetabular prostheses were implanted in 48 patients, 37 men and 11 women. The mean age at operation was 47.7 years (range : 31 to 64 years). The aetiologies were idiopathic osteoarthritis, aseptic necrosis, rheumatoid arthritis, and osteoarthritis secondary to congenital hip dysplasia. No revision was needed for wear or loosening ; one patient required re-operation for recurrent dislocation and infection. One of the 48 patients died during the follow-up period ; he was not included in this study. Nine patients were lost to follow-up.

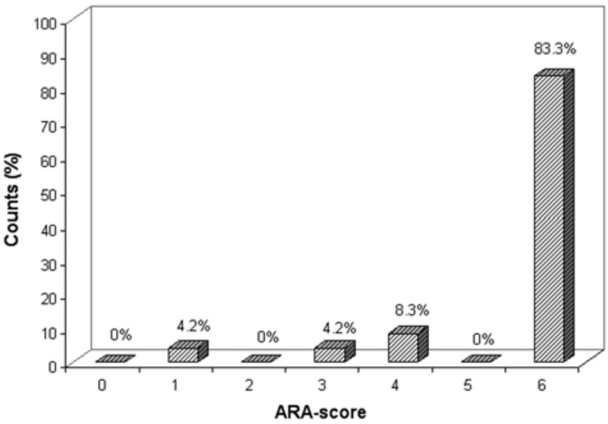

Fig. 4. — Distribution of the ARA-cup scores after a follow-up of at least 46 months.

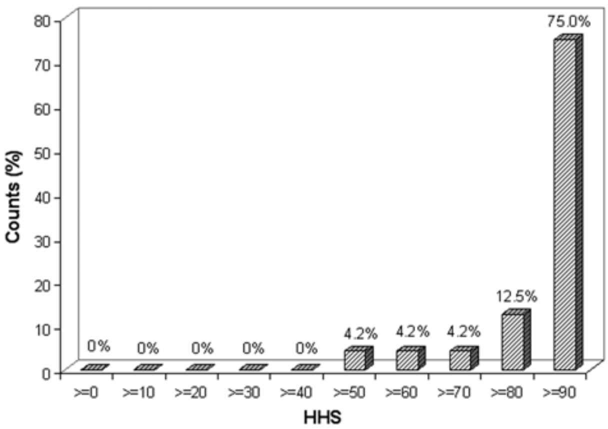

Fig. 5. — Distribution of the individual values of the HHS of the 23 patients (24 cups) with a radiological and clinical evaluation.

The results of the remaining 38 patients were evaluated in this study. Twenty-three patients with 24 implanted cups were evaluated clinically and radiologically. Fifteen other patients provided a telephone interview. The results are divided into two parts :

1) The results of the patients who had a radiographic and clinical evaluation (23 patients and 24 cups).
2) The results of all patients with a clinical evaluation (38 patients and 40 cups).

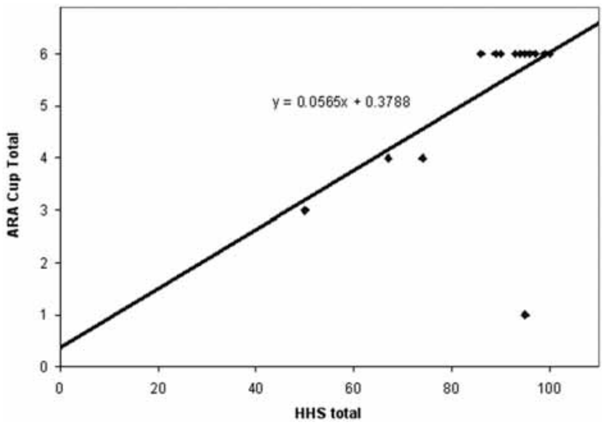

Fig. 6. — Cross correlation between the HHS and the ARA-score for the 23 patients (24 cups) with a radiological and clinical evaluation. The outlyer is the patient with a low ARA-score. Regression line : y= 0.0565x + 0.3788 ; Sigma HHS = 11.52 ; Sigma ARA = 1.22 ; CMin HHS = 79.1 ; Cmin ARA = 4.3 ; CMax HHS = 102.1 ; CMax ARA = 6.7 ; LS slope = 0.057 ; Correlation = 0.729).

Results of the 23 patients with a clinical and radiological evaluation (24 hips)

Radiological evaluation of the 24 hips showed an excellent ARA-score and an excellent HHS. The poor ARA-score was due to migration of the cup.

Cancellous bone densification was seen in 79% of the cases in zone 1 and in 58% of the cases in zone 3. None of the cups showed balloon-expanding osteolysis. Typical radiographs of a patient with a Hedrocel cup just after the operation and 63 months later are shown in fig 7.

Two patients had a radiolucent line in zone 2, and the acetabular bone in two other patients appeared to remain unchanged since the operation, although their cups were stable.

Results of all 38 patients (40 cups) with a clinical evaluation

An excellent HHS (> = 90 points) was obtained by 65% of all 38 patients (fig 8).

One patient, whose pre-operative diagnosis was secondary osteoarthritis due to septic arthritis in the neonatal period followed by avascular necrosis,

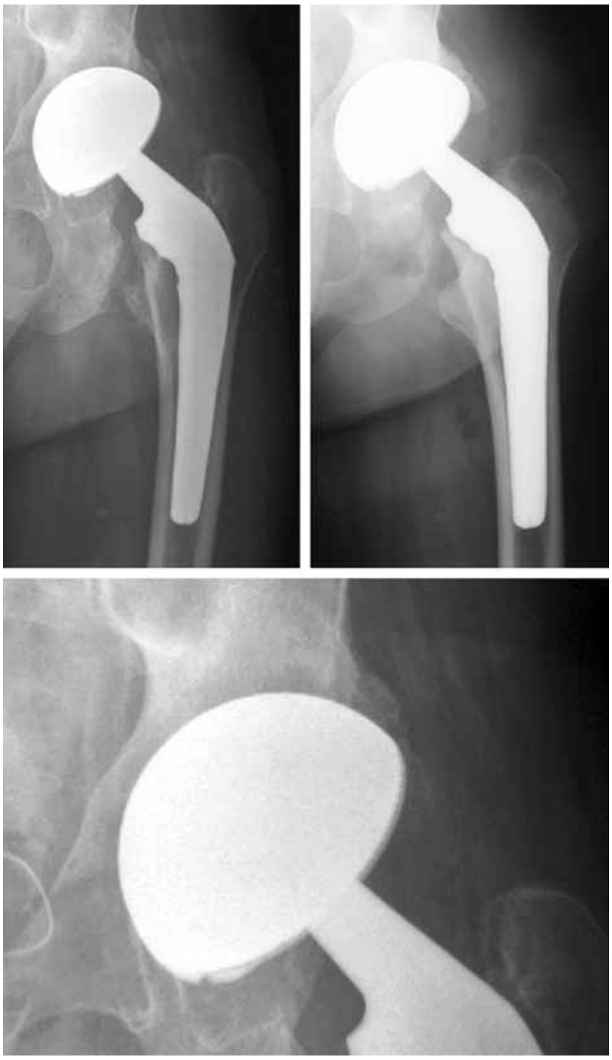

Fig. 7. — Typical example of an implanted Hedrocel cup (and femoral stem) after a total hip arthroplasty. AP radiograph of the left hip shortly after the operation (a) and at follow-up 63 months later (b) and (c).

needed a reoperation to replace the prosthetic head for recurrent dislocation. He also had a deep culture that was found positive for coagulase negative S*taphylococcus*. The reoperation was successful and the patient subsequently had no further problems. This was reflected in an HHS of 82 points at follow-up.

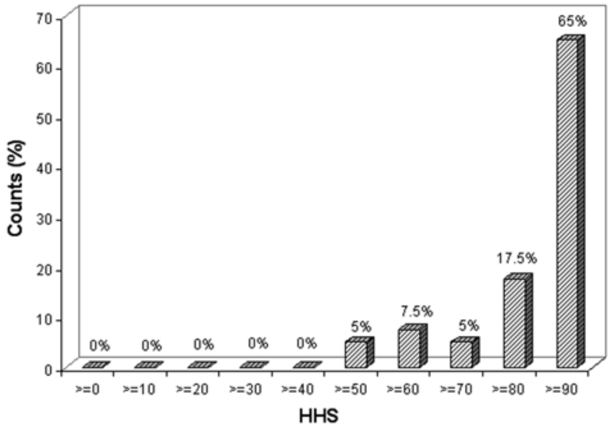

Fig. 8. — Distribution of the Total HHS at follow-up of all 38 patients (40 cups).

DISCUSSION

The vast majority of the patients showed an excellent clinical and radiological evaluation. Although one cup had migrated, this patient still had an excellent HHS. The cancellous bone densification that was seen after 46 months in most patients, especially in zone 1 and 3, reflects an attempt by the local bone to improve the stability of the implant by replacing the elastic cancellous bone by rigid endosteal bone tissue. This may have been enhanced by the specific features of the porous tantalum cups. The friction coefficient of porous tantalum against bone is twice the friction coefficient of other biomaterials with a porous interface (*3, 5*). This is very important for the initial stability of the porous tantalum cups (*17, 18*). A further advantage is the porosity of tantalum, which is 75 to 80% of its total volume. This is much higher than the porosity of titanium or cobalt-chromium alloys. The absolute volume of bone ingrowth is consequently also higher for porous tantalum than for conventional porous coatings. Tantalum further offers a good load transfer because of its physiological elasticity of 3 GPa. This is comparable with the elasticity of bone (cancellous bone : 0.8 GPa, subchondral bone : 1.5 GPa and cortical bone : 15 GPa) and more physiological than the elasticity of titanium (110 GPa) or cobalt-chromium

(205 GPa). The good load transfer of tantalum helps to maintain the bone density and support which preserves the bony architecture. It has probably facilitated the filling of bone defects, especially in zone 1 and 3. This reduces the possibility for wear products to penetrate between the cup and the bone, which can lead to mechanical failure in the long term. The monoblock construction of the cup additionally reduces this risk by eliminating any possibility of backside wear.

All these properties of tantalum have helped the tantalum cups to act as an osteoconductive material and to restore the bony deficiencies. Because of the remarkably good evolution of the vast majority of the implants, we feel we may be optimistic about the long-term results with these cups.

CONCLUSIONS

The use of porous tantalum monoblock cups provided good results in this mid-term follow-up study. They may be advantageous to address the issues of initial instability, early migration, wear of the polyethylene and the associated osteolysis. A longer follow-up will have to confirm these results.

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