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Comparative *in vitro* assessment of the primary stability of cementless press-fit acetabular cups

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Long-term stable osseointegration of porous-coated acetabular cups depends on bony ingrowth within their porous surface. For ingrowth to take place, one must ensure rigid initial fixation of the implant, by means of screws or by impaction or using a threaded ring. Primary stability is a prerequisite for long term stability through bony ingrowth.

We tested several cups commonly used in our department to assess their primary stability. The study was done using synthetic EP-Dur polyurethane resin blocks (Bayer, Leverkusen, Germany). The blocks were fixed at a 45° angle to the horizontal. They were subsequently reamed using the appropriate reamers and the cups tested were impacted into the resin blocks. Eleven 52-mm cups were tested. The pull out force necessary to extract each cup was measured.

The pull-out strength ranged from 7.63 to 55.46 Nm. We noted that the closer the cup was to a hemisphere, the better was the initial stability. The contact zone was at the periphery, and the greater the contact was with the resin, the better was the stability.

Micromovements exceeding 150 microns prevent any bony ingrowth *in vivo*. Solid osseointegration can thus only be achieved if movements between implant and bone can be prevented. Our study indicated that initial fixation is essentially peripheral and that those cups that demonstrated the highest pull-out values also had the best peripheral contact. Our observations suggest that the geometry of the cup is more important than its surface macrostructure in terms of primary stability. To achieve stable fixation, we recommend using an oversized cup with a flattened dome to allow maximum peripheral contact.

INTRODUCTION

Long-term stability of acetabular implants depends on their resistance to important mechanical stresses. The implants must therefore have primary stable fixation (*6, 9*). Long-term stable osseointegration of porous-coated acetabular cups depends on bony ingrowth within their porous surface. For ingrowth to take place, one must ensure rigid initial fixation of the implant (*12, 15*), by means of screws, impaction or using a threaded ring. Screws can provide strong fixation (*17, 24*) but they carry a risk of vascular complications. Impaction may be the best option to achieve firm fixation. In order to achieve natural retention of the cup within the bony acetabulum, the implant must be hemispherical with a flattened dome (*1, 19, 20, 29*). The contact area between the implant and bone must be maximal to achieve an optimal distribution

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Fig 1. — A resin block mounted in its support

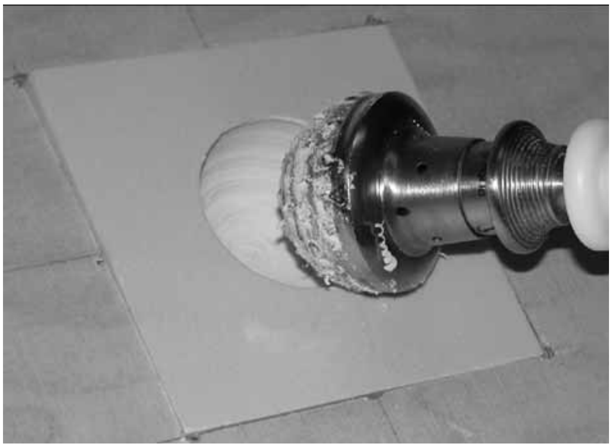

Fig. 2. — A 52-mm cup is impacted in a resin block after drilling at 51 mm.

of stress. Reaming (*1, 16, 17, 24, 25-28, 31*) must preserve the subchondral bone, because the latter will be the source of the bony ingrowth (*19*), which ensures definitive stability, by colonising the pores, after initial rigid fixation has been obtained (*2, 3, 8, 23*). Secondary stability depends on various factors, Hulbert *et al* (*11*) and Bobyn *et al* (*4, 5*) have determined the ideal diameter of the pores that allows ingrowth. Experimental studies in dogs (*9, 10, 12-14*) have confirmed the good quality of ingrowth when the pore diameter is between 200 and 450 µm. The porous surface must be at least 40% of the total surface area of the cup.

We tested various cups commonly in use in our department to assess their primary stability.

MATERIAL AND METHOD

The study was done using synthetic EP-Dur polyurethane resin blocks made of modified diphenylmethandiisocyanate (Bayer, Leverkusen, Germany) whose density and mechanical characteristics closely replicate those of bone. The blocks were fixed at a 45° angle to the horizontal. They were subsequently reamed using the appropriate reamers, starting with 48-mm reamers up to the appropriate size (fig 1).

Reaming instructions given by the implants designers were complied with (fig 2 and table I).

All the cups were impacted in the resin blocks by the same investigator. Impaction was checked to insure correct positioning i.e. good in-depth contact and peripheral contact (fig 3). One pull-out test was performed on every cup.

Eleven cups were tested : the Biomex® acetabular cup from BIOMET, the Albi®+ from CREMASCOLI, the Reflection® cup FSO 5 and Reflection® Interfit from SMITH AND NEPHEW, the Duraloc® cup from DEPUY, the Fitmore® with screws and the Fitmore® with fins, the Press-fit Cédior® and the Spotorno® cup from CENTERPULSE, and finally, the TMT® and the Trilogy® from ZIMMER. The chosen diameter was 52 mm, the most commonly implanted size in our department. The pull-out force necessary to extract the cup was measured for each of them. We first intended to pull on a 50-cm metal rod screwed into the cup, but we noted that the elasticity of the rod resulted in measurement errors, as the pull-out force could exceed 24 kgf. We finally decided to measure the pull-out force applied to the impactor with a cable connected to the tip of the impactor and pulling down at a 45° angle to the vertical. The force was applied with 250 g increments (fig 4, 5). The varying length of the impactors used was taken into account to calculate the pull-out force . Considering the forces applied, the mass of the impactor is negligible.

Table I. — Reaming instructions and subjective feel

CUP	DRILLING	SUJECTIVE FEEL, INCIDENTS
Biomex® BIOMET	Size to size	Good stability
Albi+® CREMAS COLI	2 mm press-fit	Easy impaction
Reflection® SMITH & NEPHEW	1 mm press-fit	rupture of the block for a 2 mm press-fit
Reflection® Interfit SMITH & NEPHEW	Size to size	Easy impaction
Duraloc® option DEPUY	2 mm press-fit	Good stability
Fitmore® (without fins) CENTER PULSE	Size to size	1.5 mm oversizing
Fitmore® (with fins) CENTER PULSE	Size to size	1.5 mm oversizing
Press-fit Cedior® CENTER PULSE	Size to size	1 mm oversizing
Spotorno® CENTER PULSE	Size to size	Expansion cup
TMT® ZIMMER	Size to size	Easy impaction
Trilogy® ZIMMER	2 mm press-fit	Good stability

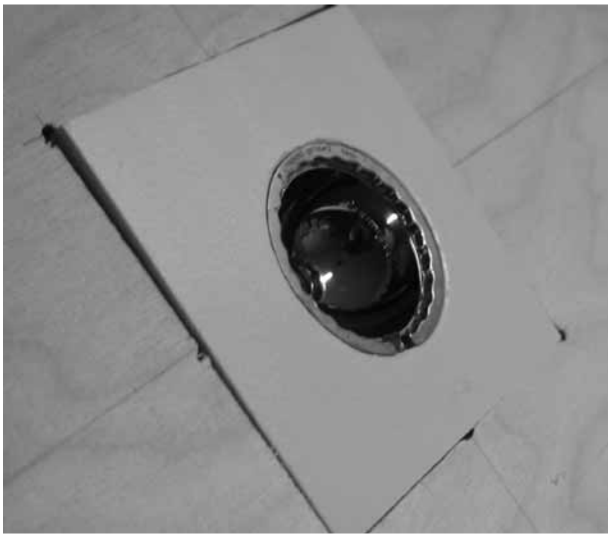

Fig. 3. — View of a cup after it has been impacted in a resin block.

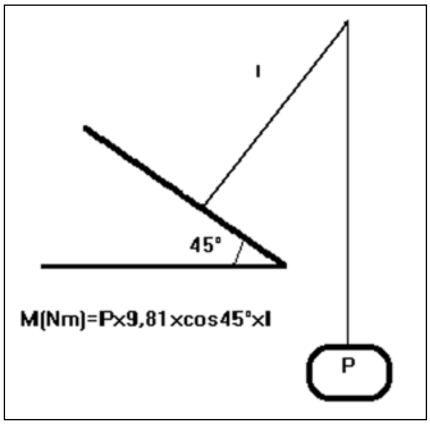

Fig. 4. — Diagram of the pull-out equipment

RESULTS

We achieved complete impaction with solid fixation for each of the cups. The feel of the impaction in the resin blocks was very close to that in the operating theatre, and primary stability was subjectively good for all cups. However, the pull-out strength did show variations between the implants tested. Biomex® cups were set in line to line and could be pulled out at 31.32 Nm. The Albi® cups were 2 mm oversized according to the manufacturer's recommendations ; pull-out was at 43.96 Nm. Reflection® cups demonstrated the best primary stability. In clinical practice, they are oversized 1 or 2 mm with respect to the reamer size, depending on the quality of the bone stock. In our *in vitro* study using resin blocks, 2 mm press-fit resulted on two occasions in rupture of the block (fig 6) : the cups were therefore tested with a 1- mm press fit. Under these conditions, the pull out force was 55.46 Nm. The Cedior® press-fit cups, from Centerpulse, only had a pull-out force of 20.62 Nm. The Spotorno®

Fig. 5. — Experimental pull-out equipment

Fig. 6. — Rupture of the resin block

Table II. — Pull-out force needed to extract each of the cups tested

CUP	PULL-OUT FORCE (NM)
Biomex® BIOMET	31.32
Albi+® CREMASCOLI	43.96
Reflection® SMITH&NEPHEW	55.46
Reflection® Interfit SMITH&NEPHEW	37.87
Duraloc® option DEPUY	49.79
Fitmore® (without flaps) CENTERPULSE	7.63
Fitmore® (flaps) CENTERPULSE	32.60
Press-fit Cedior® CENTERPULSE	20.62
Spotorno® CENTERPULSE	54.94
TMT® ZIMMER	28.72
Trilogy® ZIMMER	44,40

cup from Centerpulse was the second best with a pull out force of 54.94 Nm. Its concept is different from the other cups : it is supposed to expand within the reamed acetabulum when the polyethylene insert is screwed into it. Primary stability was excellent but the pulled out cup was deformed, a fact not observed with any of the other cups. The Reflection® Interfit cup, set in line to line, could be avulsed at 37.87 Nm. The Duraloc® press-fit cup, 2 mm oversized, required 49.79 Nm for pull out, an excellent result for primary stability. Fitmore® cups come in two varieties, both of which have the same geometry and have the same titanium mesh over their convex surface, but one also has fins whereas the other does not. The pull-out strength was different with (32.60 Nm) or without (7.63 Nm) these retaining fins. Furthermore, these fins oppose rotational forces, which were not tested in this study. The last two cups tested were the TMT® and the Trilogy® from Zimmer. They scored at 28.72 and 44.40 Nm respectively. The Trilogy® cup thus obtains a good value, as shown in table II and fig 7.

We noted that the closer the cup was to a hemisphere, the better was the initial stability. The initial contact was at the periphery and the larger the contact with the resin, the better the stability. We noted that the resin mark left on the implants after extraction was of very uneven width : it was wider for those cups having the best resistance to pull-out.

DISCUSSION

The number of cups tested in this study was limited, but lack of responsiveness of several manufacturers limited our possibilities. The pull-out equipment was hand-made and low-tech, which may have lead to calculation errors. The procedure was however identical for all tested implants and it was easily reproducible. Primary stability is conditioned by press-fit and, in turn, it conditions bony ingrowth (*22*). It has been shown that micromovements exceeding 150 µ prevent any bony ingrowth (*6, 24*). Strong osseointegration can thus only be achieved if movements between implant and bone can be prevented. Primary stability thus conditions the quality of clinical results. Nègre and Henry (*21*) stated that osseointegration is also conditioned by an even distribution of forces between the cup and bone. Our study indicates that initial fixation is essentially peripheral and that those cups that demonstrated the highest pull-out values also had the best peripheral contact. Flattening the dome of the hemisphere and oversizing the implant will result in good distribution of stress on the periphery of the cup. This has been confirmed by Adler *et al* (*1*). On the other hand, rupture of a resin block when a 2-mm press-fit was attempted must stir reflexion. Post-operative pain after implantation of a press-fit cup may in some cases indicate fractures or microfractures of the acetabulum, difficult to objectivate intra-operatively. Such fractures may secondarily jeopardise osseointegration (*7*). This has been demonstrated by Kim *et al* who observed 18 fractures from 30 cadaver acetabular cup impactions with a 4-mm press-fit in cadaveric bones (*16*). The deformation of the Spotorno cup noted after pull-out is surprising : it may be related to a faulty implantation technique, but it is also possible that application of the pull-out force on this specific cup may induce uneven deformation of its flaps.

CONCLUSION

Many factors influence the quality of osseointegration of cementless acetabular cups, among which primary stability seems to be the cornerstone. Implant choice and amount of press-fit needed must take into account the quality of the bone stock. However we believe that the shape of the cup is more important than the macrostructure of its

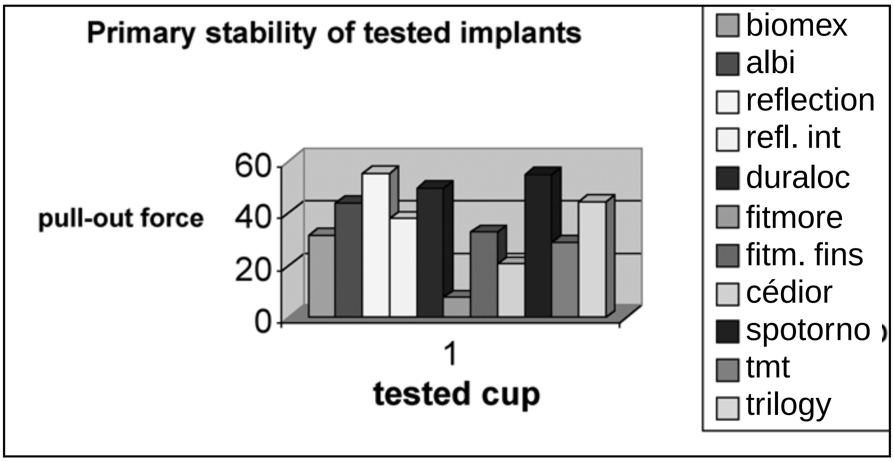

Fig. 7.

Fig. 8. — The larger the contact was with the resin – traces of which can be seen on the cups after pull-out –, the better was the stability.

convex surface in terms of primary stability. Primary fixation must be stable. This implies in our view, the choice of an oversized cup whose dome is flattened to allow maximum peripheral contact. This determines whether or not micromovement will interfere with osteointegration. The possibility of adding screw fixation to impaction of the cup certainly limits the possibility of micromovement. Some authors recommend a period of non weight-bearing after implantation (*18*). In the future, it would be interesting to assess the necessary press fit effect required according to bone quality. Finally, rotational stability should also be tested to mimick the mechanical stresses of deambulation.

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