Citation for the published paper:
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"Comparison of flanged and unflanged acetabular cup design."

Acta Orthopaedica 2010 81(5), 556 - 62

http://dx.doi.org/10.3109/17453674.2010.519167

Flanged versus unflanged acetabular cup design

An experimental study using ceramic and cadaveric acetabuli

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Abstract

Background and purpose: Adequate cement penetration depth and cement mantle thickness is important for the cemented cup durability. A flanged cup, as opposed to an unflanged, has been suggested to give a more uniform cement mantle and superior cement pressurization, thus improving cement penetration depth. This hypothesis was experimentally evaluated.

Materials and methods: The same cup design, with and without flange (both without cement spacers) was investigated regarding intra-acetabular pressure, cement mantle thickness and cement penetration depth. The cups were machine controlled inserted into open pore ceramic acetabular models (flanged=10, unflanged=10) and in paired cadaveric acetabuli (flanged=10, unflanged=10) with prior pressurization of the cement.

Results: No differences in intra-acetabular pressures during cup insertion were found, but unflanged cups tended to migrate more towards the acetabular pole. Flanged cups resulted in thicker cement mantles because of less bottoming out, whereas no differences in cement penetration into the bone were observed.

Interpretation: Flanged cups do not generate higher cementation pressure or better cement penetration than unflanged cups. A possible advantage of the flange, however, could be to protect the cup from bottoming out and a potentially better closure of the periphery around the cup, sealing off the cement bone interface.

Introduction

The main cause for aseptic loosening is inadequate surgical techniques and inferior prosthetic implants (Herberts and Malchau 2000). Sufficient cement penetration (3-5 mm) into cancellous bone and prevention of cup bottoming out, as seen by a uniform cement mantle (i.e., cement penetration excluded) with a minimal 2 mm thickness, have been stated to be crucial for cup fixation (Huiskes and Slooff 1981, Noble and Swarts 1983, Schmalzried et al. 1993, Mjöberg 1994, Ranawat et al. 1997, Lichtinger and Muller 1998). A clean bony surface with partly exposed cancellous bone together with cement pressurization before prosthetic implantation improves cement penetration depth, thus creating a stronger cement-bone interface (Krause et al. 1982, Rey, Jr. et al. 1987, Mann et al. 1997, Flivik et al. 2006, Abdulghani et al. 2007).

Absence of postoperative demarcation at the acetabular cement-bone interface has been related to a reduced risk of aseptic cup loosening (Ranawat et al. 1995, Garcia-Cimbrelo et al. 1997, Ritter et al. 1999, Flivik et al. 2005). The use of a flanged polyethylene cup has demonstrated both less postoperative demarcation at the above interface (Hodgkinson et al. 1993) and less loosening (Garellick et al. 2000). This may be due to its ability to increase cement pressurization at the time of implantation and thereby cement penetration depth, though conflicting experimental findings have been reported (Oh et al. 1985, Shelley and Wroblewski 1988, Parsch et al. 2004, Lankester et al. 2007). The previous studies addressing the use of flanged cups have all inserted the cups without prior cement pressurization, and only Parsch et al. (2004) implanted the cup into a porous material (cadaveric bone).

Accordingly, we decided to investigate the intra-acetabular pressures, cement mantle thickness and cement penetration depth obtained by a flanged versus an unflanged cup, inserted in an open pore ceramic acetabular model as well as in paired cadaveric acetabuli using pressurization of the cement before implantation.

Materials and methods

Ceramic study

20 ceramic acetabular models with a 49 mm diameter were produced from Sivex ceramic foam filter plates (filter grade 80, cell size 600-700 microns, Pyrotek SA, Sierre, Switzerland). 2 custom made pressure sensors (modified Entran, EPB, Entran Sensors & Electronics, Garston, UK) with a 3.6 mm diameter and a 100 mm shaft were inserted through a standardized drill hole located at the acetabular pole, and 2.5 cm from the rim, respectively (holes were drilled using a specially designed drill guide). The tip of each sensor was covered with tape to protect it from polymer induced damage, and was levelled with the acetabular surface. 20 cross-linked-polyethylene XLPE Opera cups (Smith & Nephew, Inc., Andover, MA, USA) with a 43 mm outer (flange excluded) and a 28 mm inner diameter and no orientation wire were used (Figure 1). 10 cups had the flange completely cut off (unflanged sockets), and the remaining 10 had the flange trimmed (flanged prostheses) to fit just on top of the acetabular model. To protect the brittle ceramic rim, the flange was not trimmed to fit inside the reamed hemisphere. Every cup was inserted with 40 g of prechilled (5º C) Refobacin-Palacos R cement (Biomet, Warsaw, IN, USA) using an Instron 851120 materials testing machine (Instron Corporation, Norwood, MA, USA). The room temperature was kept a 20º C, and the cement was removed from the refrigerator just before vacuum mixing in the Optivac mixing system (Biomet Cementing Technologies AB, Sjöbo, Sweden). 2.5 min after the onset of mixing, cement was applied in the acetabular model, and pressurized with 80 N for 1.5 min using a conventional pressurizer (Smith&Nephew, Andover, MA, USA) which was fitted into the Instron machine. 5 min after the onset of mixing, the cup was inserted position-controlled by the use of a femoral head and a specially designed device to avoid cup tilting during introduction. Thereafter the cup was held in place with force-control (25 N) until the cement had cured. The resultant forces, pressures and cup displacements were recorded continuously every 0.02 s during cementation using the Spider8 software (HBN, Inc., Marlborough, MA, USA). After the cementing procedures, all samples were cut longitudinally along the centre of

the cup with an electric saw, and digitized using an hp scanjet 4470c digital flatbed scanner (1200 dpi) to enable inspection of the cement mantle and penetration depth (Abdulghani et al. 2007).

Cadaver study

10 human cadaver pelvises embalmed in (v/v) 5% formalin, 45% ethanol, 27% glycerine, and 5% glyoxide-glutaraldehyde were obtained from the Anatomical Institute, Aarhus University, Århus, Denmark. All pelvises were from male donors (median 83 years, range 65–102) without any previous hip surgery or signs of osteoarthritis. The left and right acetabulum was randomly allocated to receive either a cup with or without flange. The flange was either trimmed to fit inside the acetabulum (flanged cup) or cut off (unflanged cup). All acetabuli were over-reamed according to the manufacturer's recommendations using a conventional reamer to provide a final cement mantle between 2.5 and 3.5 mm, depending on the size of the last reamer, and the most suitable cup size (40, 43, 47, 50 or 53 mm). Every acetabulum in a pair was equally over-reamed, and the same cup size was inserted on both sides. During reaming, the aim was to remove at least 75% of the subchondral bone plate area in order to optimize the possibility for cement penetration by exposing cancellous bone (Flivik et al. 2006). 9 anchorage holes with a 6 mm diameter and a 6 mm depth were drilled with a standardised distribution, i.e. 1 anchorage hole in os pubis and os ischii, respectively, and the remaining 7 holes drilled in os ilium. All acetabular preparations were performed by an experienced hip surgeon (GF). Afterwards, every acetabular bone was potted into Vel-Mix Stone (Kerr Italia S.p.A., Scafati, Italy) to ensure horizontal alignment of the acetabular opening during further handling, and finally, 2 additional channels for the later application of pressure sensors were drilled at the pole and 10 mm from the iliac rim (opposite the transverse ligament, using a special designed device). All acetabuli were then cleaned with pulse lavage, and before cementation, the acetabular bone bed was dried with gaze (Figure 2). Subsequently, the previously used pressure sensors were inserted (the sensor tips were again levelled with the cancellous bone surface), and a flanged or unflanged cup was implanted using 40 g of prechilled (5º C) Refobacin-Palacos R cement under identical conditions with pressurization of the cement before insertion as described for the ceramic study. After cementation, every cadaveric bone pair was

reversely aligned and CT scanned in the coronal plane using a Philips Mx8000 IDT 16 CT scanner (Philips Medical Systems, Andover, MA, USA) with the following settings: 120 kV, 158 mA, and a 0.8 mm slice thickness to enable estimation of the total cement volume and penetration depth. Bones were stored in a cold room between cadaveric handling.

Data management

Intra-acetabular pressures and cup displacements in ceramic and cadaveric acetabuli

Insertion forces and intra-acetabular pressure measurements were obtained during position-controlled cup insertion within the last 3 mm before the final cup position. Resultant intra-acetabular pressures and cup displacements were, in addition, assessed during force-controlled pressurization. Area under the curve (AUC) was computed for every insertion force and pressure measurement (with use of the trapezoid rule), and subsequently the calculated value was divided by the observed time period (Flivik et al. 2004). Cup displacements obtained under a constant force were evaluated for 45 and 150 s with a negative number indicating cup migration towards the acetabular pole.

Cement mantle thickness, penetration depth and areas in ceramic

A hemisphere template was created in Adobe Photoshop 7.0 to divide the acetabulum into three 60º segments (2 laterals and 1 central). Each segment was divided into 12 sub-regions by adding a radial test line for every 5 degrees (Figure 3). Cement mantle thickness and penetration depth were measured along every test line, with the exception of the central zone, where only 6 measurements were performed in the lateral part of the region to avoid uncertainty caused by the pole pressure sensor channel. Accordingly, the median mantle thickness and penetration depth could be calculated. The lateral and central mantle and penetration area for every 5 degrees were also estimated. Penetration was defined to begin at the base of a proximal penetration sprout, and to end at the most distal point of cement along a radial test line. All measurements were performed with the ImageJ software (ImageJ 1.31i, W. Rasband, NIH, USA).

Total cement volume and penetration in cadaveric acetabuli

The total cement volume (mantle thickness plus penetration depth) was estimated using Cavalieri's direct estimator (Gundersen et al. 1988). Basically, a grid containing points covering a known area was created (Adobe Photoshop 7.0), then the total upper right corner of the points overlaying the cement were counted in every 12th CT slide (Figure 4). The starting point was random, and 12 to 15 slides were analyzed in a sample using an equal number of slides for the other half of the bone pair. All analyses were performed blinded. When estimating cement penetration a medial and a lateral anchorage hole were localized for every sample on the CT sections, and the images visualizing the most prominent diameter were chosen. In the opposite cadaveric bone pair the corresponding anchorage hole was selected. The diameter of each chosen anchorage hole (i.e., the diameter of the drill hole plus penetration at both sides of the hole) was measured 3 times at its thickest location (with ImageJ). Penetration was subsequently calculated as the half of the difference between the median measured diameter and the known size of the drill hole (6 mm). All analyses were performed blinded.

Statistics

A minimum sample size of 8 in the cadaveric study was calculated to achieve sufficient power (>80%) based on published pressure variation data (Parsch et al. 2004) and assuming a 100 mmHg difference in the obtained median pole pressures between flanged and unflanged cups. STATA version 7 (StataCorp LP, Texas, USA) was used for all statistical analyses, with values for $p \leq 0.05$ being regarded as significant. Ceramic groups were compared with the Mann-Whitney U test, whereas cadaveric groups were compared using the Wilcoxon Signed Rank Test. Data is presented as median values with the 95% confidence interval in brackets, unless otherwise stated.

Results

Intra-acetabular pressures, forces and cup displacements in ceramic

Forces, pressures and cup displacements were collected in 3 flanged and 3 unflanged cups (Table 1). During position-controlled cup insertion no statistically significant differences were obtained between the insertion forces or intra-acetabular pressures when comparing a flanged with an unflanged cup. In addition, both cups produced similar intra-acetabular pressures (flanged p=0.5 and unflanged p=0.1) i.e. pole and rim pressures were similar. However, during force-controlled pressurization the unflanged cups showed deeper displacement in the direction towards the acetabular pole (p=0.05) and produced a higher pole pressure than the flanged cups did (p=0.05) (Table 1). In addition, the intra-acetabular pressures turned out to be unevenly distributed only in the unflanged cup, with a higher pressure obtained at the pole.

Cement mantle thickness, penetration depth and areas in ceramic

Mantle thickness, penetration depth and the respective areas were measured in 10 flanged and 10 unflanged samples (Table 2). The central and the lateral cement mantle thickness was statistically significantly thicker with a flanged cup than with an unflanged cup, and also the central and lateral cement mantle area was significantly larger when a flanged cup was used. The mantle thickness and area were equally distributed for the flanged cup (p=0.1 for thickness and p=0.2 for area), as well as for the unflanged cup (p=0.8 and p=0.3). The cement penetration depth and cement penetration area were similar between the two cups (Table 2). Both cups were observed to have deeper penetration central than lateral (p=0.002 for the flanged and p=0.003 for the unflanged cups), and similar findings were observed for the penetration area (p=0.003 and p<0.001).

Intra-acetabular pressures, force and cup displacements in cadaveric acetabuli

During position-controlled cup insertion, forces and pressures were collected in 10 paired samples (Table 3). The insertion forces were similar for flanged and unflanged cups. Unflanged cups produced higher intra-acetabular pole pressures than flanged cups, but both cups produced uneven intra-acetabular pressures with highest pressures obtained at the pole (p=0.02 for flanged and p=0.005 for unflanged cups). During force-controlled pressurization cup displacements were collected in 8 paired samples and pressures were obtained in 9 paired samples (Table 3). Again the unflanged cups migrated more towards the acetabular pole, and produced zhigher pole pressures than the flanged cups did. In contrast to the unflanged cups, only the flanged cups produced uniform pressures when comparing pole pressures with rim pressures.

Total cement volume and penetration depth in cadaveric acetabuli

Total cement volume and penetration were measured in 10 paired samples. Flanged cups were found to be enclosed by more cement than unflanged cups (70 cm^3 (58 – 76) *versus* 57 cm^3 (46 – 76), p=0.005), whereas the cement penetration was similar between the two cup types (0.92 mm (0.30 – 2.61) *versus* 0.99 mm (0.21 – 2.34), p=0.9).

Discussion

Increased cement penetration into the acetabular bone improves cup stability (Flivik et al. 2005). However, many factors influence cement penetration including magnitude and duration of the applied force, properties of the bone cement used, amount of bone bleeding, anatomy, porosity and not least preparation of the acetabular bone (Noble and Swarts 1983, Juliusson et al. 1994, Graham et al. 2003, Hogan et al. 2005, Flivik et al. 2006).

The possible advantage of a flanged cup has mainly been related to its hypothesized ability to increase cement pressurization at the time of implantation, thus improving cement penetration (Oh et al. 1985, Shelley and Wroblewski 1988). When we inserted a flanged and an unflanged cup position-controlled using equivalent forces the intra-acetabular pressures were similar between flanged and unflanged cups inserted in ceramic acetabuli, and both cups produced equal intra-acetabular pressures as well. When the cups were further pressurized (using force-control) the unflanged cups migrated more towards the acetabular pole than the flanged cup did when inserted both in ceramic and paired cadaveric acetabuli, despite of a minimal force application (25 N). Most certainly, however, the migration susceptibility observed for the unflanged cup was further increased due to the lack of cement spacers in this specific cup.

It has been suggested that the use of a flanged cup may correlate to a lower incidence of bottoming out (Oh et al. 1985). We know no consistent classification concerning bottoming out. Using a tentative definition being cement mantle thickness less than 1 mm along any of the 29 test lines (in the ceramic study), 9 of 10 unflanged cups, and just 2 of 10 flanged sockets demonstrated bottoming out (p=0.002). Close contact between polyethylene and bone has been related to reduced cup longevity (Wroblewski et al. 1987). It is thus tempting to suggest that the reduced cement mantle thickness observed in the unflanged cup experiments may reduce cup durability, but again the lack of cement spacers have probably influenced these results and highlights the importance of cement spacers in cup designs without a flange. It should also be considered that a flanged cup may risk an eccentric cement mantle (Sandhu et al. 2006), and care is needed when adjusting the flange to the particular acetabulum.

The porosity and preparation of the acetabular bone bed is related to the degree of cement interdigitation, and removal of the subchondral bone plate has been observed to improve the cement-bone interface and to lower the interfacial stresses without impairing prosthetic stability (Volz and Wilson 1977, Sutherland et al. 2000, Flivik et al. 2006). We are aware that all sockets inserted in both ceramic and cadaveric bone were implanted under good conditions due to a dry acetabulum without any blood or bone-marrow to disrupt cement penetration (Krause et al. 1982, Ranawat et al. 1995). However, all prostheses were inserted under the same conditions, and the errors are therefore systematic. To adjust for the improved conditions regarding a dry acetabulum we pressurized cement and prostheses with lesser force than usually performed in the clinic.

The overall cement penetration was higher in the ceramic study compared with cadaveric bone. The reason may lie in larger pore diameters and a completely open porous structure in ceramic. According to Poiseuille's law ($R = 8\eta L \times (\pi r^4)^{-1}$) where R denotes flow resistance, η viscosity, and

L length of the pores with radius r (Alkafeef et al. 2006), larger pore diameters give less flow resistance, thereby facilitating higher penetration. The deeper central penetration observed in the ceramic study can be explained by the higher pressure gradient at this location. In fact, this is confirmed by the second part of Poiseuille's law ($f = \Delta P \times R^{-1}$), in which the flow ($f$) of the liquid is governed by the pressure gradient (ΔP) and the flow resistance (R).

We found no differences in cement penetration depth between the cups tested when inserted in either ceramic or paired cadaveric acetabuli, which confirm earlier findings that cement penetration occurs primarily during cement pressurization before cup insertion (Abdulghani et al. 2007). Thus, when it is time to insert the cup the cement might simply be too viscous to permit further penetration even with a flanged cup design. It seems as if the flanged cup reduces cement leakage during insertion; at least when investigating a cup design lacking cement spacers, and the increased cement volume we observed around the flanged cup in the cadaveric study are most certainly caused by a thicker cement mantle. In most studies, however, cement penetration depth and cement mantle thickness are not differentiated, and the total is usually referred to as the cement mantle. If possible, both cement penetration depth and cement mantle thickness should be considered.

In conclusion we argue that as flanged cups do not seem to generate higher cement pressure or induce increased cement penetration, this is not the reason for the superior clinical outcome reported for some flanged cups (Hodgkinson et al. 1993, Garellick et al. 2000). Flanged cups, however, have been associated with less postoperative demarcation in the important cement-bone periphery around cups (Hodgkinson et al. 1993). It is in this periphery that joint fluid pressure and wear particles can act on the exposed interface and start and fuel the aseptic loosening process seen as a progressive radiolucent line (Schmalzried et al. 1992, Robertsson et al. 1997, Aspenberg and Van der Vis 1998, Van der Vis et al. 1998, McEvoy et al. 2002, Lankester et al. 2007). We suggest that apart from preventing the cup from botttoming out, the only advantage with a flange as regards cup longevity is its better possibility of closing the periphery around the cup and thereby protecting the cement-bone interface. The exact closure and fit of the flange to the acetabular rim is dependent on what shape the flange has and how well it is trimmed to fit by the surgeon.

Acknowledgements

The authors thank the Anatomical Institute, Aarhus University, Århus, Denmark for loan of the cadaveric pelvises. In addition, Mats Christenson, Mette Forseth, Eva Börlin, and Fred Kjellson, from the Departments of Medical Technology, Neuro-radiology and Biomechanics, Lund University Hospital, Lund, Sweden, respectively are acknowledged for their technical support. Opera cups were generously sponsored by Smith & Nehpew, Hørsholm, Denmark, and bone cement and Optivac mixing devices were kindly donated by Biomet Merch, Horsens, Denmark and Biomet Cementing Technologies AB, Sjöbo, Sweden. The study was supported by Göran Bauer's Grant and The Foundation for Health Research in Western Denmark.

Contributions of authors

MØ contributed in study design, data acquisition, data analyses and manuscript preparation. SA, IM and KS contributed in study design and manuscript revision. GF contributed in study design, data acquisition and manuscript preparation and revision.

Conflict of interest and funding

There are no conflicts of interest declared. The study received financial support from The Foundation for Health Research in Western Denmark and Göran Bauer's Grant.

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Table 1

Intra-acetabular pressures in ceramic.

	Flanged	Unflanged	p-value
Position-controlled cup insertion			
Force applied (N)	68 (65 – 74)	57 (43 – 83)	0.5
Pole pressure (mmHg)	353 (281 – 356)	402 (298 – 568)	0.3
Rim pressure (mmHg)	283 (282 – 292)	252 (189 – 331)	0.5
Force-controlled pressurization			
Cup displacement (mm)^a	-0.1 (-0.2 – 0.0)	-0.2 (-0.4 – -0.2)	0.05
Pole pressure (mmHg)	86 (0.0 – 108)	140 (114 – 160)	0.05
Rim pressure (mmHg)	76 (8 – 85)	25 (24 – 55)^b	0.5

Median values (95% confidence interval) are shown. [a] Negative displacement indicates cup migration toward acetabular pole. [b] $p<0.05$ for pole *versus* rim pressures.

Table 2

Cement mantle thickness, penetration depth and areas in ceramic

	Flanged	Unflanged	p-value
Cement mantle			
Lateral thickness (mm)	2.4 (1.7 – 3.8)	1.5 (0.9 – 2.0)	0.002
Central thickness (mm)	3.3 (2.0 – 4.2)	1.6 (0.6 – 2.1)	<0.001
Lateral area (mm^2/5º)	4.6 (3.2 – 7.1)	2.9 (2.1 – 4.1)	<0.001
Central area (mm^2/5º)	5.8 (3.7 – 7.7)	2.4 (1.0 – 4.1)	<0.001
Cement penetration			
Lateral depth (mm)	3.6 (3.2 – 4.0)	3.8 (3.2 – 4.2)	0.5
Central depth (mm)	4.2 (4.6 – 5.3)[a]	4.7 (3.2 – 5.9)[a]	0.6
Lateral area (mm^2/5º)	9.2 (7.9 – 9.5)	8.8 (8.3 – 9.6)	0.2
Central area (mm^2/5º)	10.2 (8.9 – 12.1)[a]	10.4 (9.1 – 11.6)[b]	0.4

Median values (95% confidence interval) are shown. [a] p<0.01, [b] p<0.001 for lateral *versus* central measurements.

Table 3

Intra-acetabular pressures in cadaveric bone.

	Flanged	Unflanged	p-value
Position-controlled cup insertion			
Force applied (N)	90 (12 – 196)	75 (0 – 138)	0.8
Pole pressure (mmHg)	218 (7 – 524)	470 (25 – 1656)	0.04
Rim pressure (mmHg)	156 (3 – 457) [a]	196 (2 – 596) [a]	0.4
Force-controlled pressurization			
Cup displacement (mm)[b]	-0.1 (-0.4 – 0.1)	-1.0 (-1.7 – 0.1)	0.01
Pole pressure (mmHg)	12 (3 – 100)	130 (21 – 1190)	0.008
Rim pressure (mmHg)	17 (3 – 80)	23 (4 – 123)[a]	0.6

Median values (95% confidence interval) are shown. [a] $p<0.05$ for pole *versus* rim pressures.
[b] Negative displacement indicates cup migration toward acetabular pole.

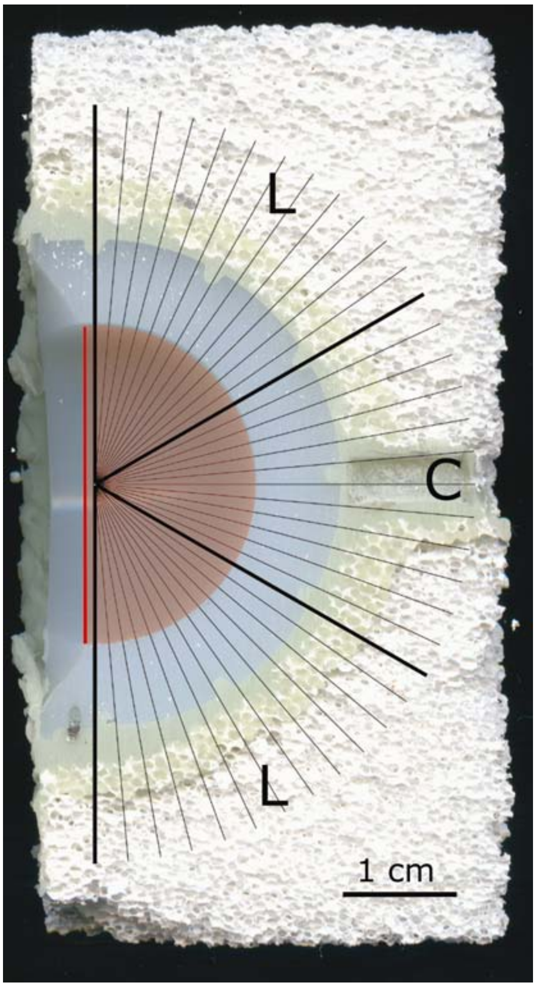
Figure 1

The inserted Opera cup (with flange)

Figure 2

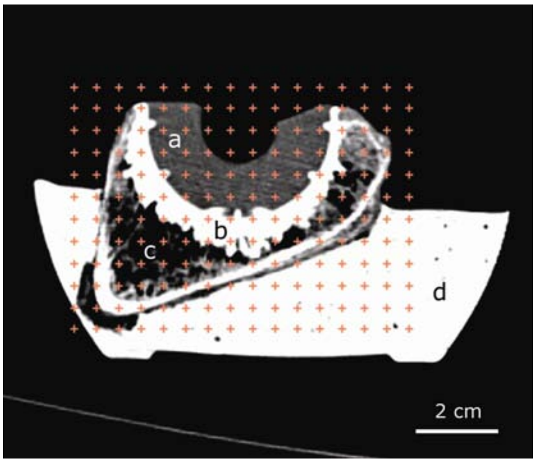
Prepared cadaveric acetabular bone bed with the cancellous bone exposed.

Figure 3



The template with test line placed on a ceramic sample (note the close contact between the unflanged cup and the ceramic). (L) lateral segments, and (C) central segment.

Figure 4



The counting grid placed on a CT cadaveric bone image. (a) Opera cup, (b) cement, (c) cadaveric bone, and (d) Vel-Mix Stone.