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Construction of a Cementable Modular Inlay Cup (C-MIC) for Total Hip Arthroplasty

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Abstract: In Total Hip Arthroplasty (THA) there is so far no device on the market that enables surgeons to use a cemented acetabular component with the possibility of different inlays. We present an acetabular metal backed shell that has been specifically developed for this purpose. Basis of our approach was to gain all profits from the cement-less method of hip replacement where, after press-fit fixation of the metal-cup, a great variety of inlays can be attached. Polyethylene, ceramic- or snap-inlays-even with different geometries (straight or asymmetric) - can be combined with different head-diameters (28/32/36 mm). The presented modular cementable acetabular component system (C-MIC), newly developed and utility patented in collaboration with ESKA Implants GmbH (Luebeck, Germany), combines the advantages of both methods.

Key words: (C-MIC), Total Hip Arthroplasty (THA), cemented acetabular

INTRODUCTION

In 1963 Charnley replaced the first generation of the acetabular component made of Teflon with high-density polyethylene which is still been used until today. After this, there has been no further significant evolution concerning cemented acetabular components (Crowninshield *et al*., 1983; Harris, 1984). Basis of our approach is to gain all profits from the cementless method of hip replacement also in a cemented cup where, after pressfit fixation of the metal-cup, a great variety of inlays can be attached (Rorabeck *et al*., 1996). Polyethylene, ceramic-or snap-inlays-even with different geometries (straight or asymmetric)-can be combined with different head-diameters (28/32/36 mm).

This facilitates the adjustment to characteristics like patients-age, the individual amount of activity or anatomic varieties. Furthermore, in correction of false-positioned cups with the risk of dislocation there is a large amount of flexibility by the use of asymmetric or snap-inlays. Due to this implant-safety is considerably increased (Rorabeck *et al*., 1996).

Until now for a cemented hip prothesis there were three versions of a polethylene cup with a diameter of 28 mm available (standard-shape, asymmteric or snap-cup). After completion of bone-cement hardening no subsequent changes of cup-position was possible.

In case of dislocation-after reposition and motion-testing-the surgeon was obliged to replace the cup looking for a better position. This process was associated with an extended operating time, additional bleedings and an increased risk of infections (Gaffey *et al*., 2004).

Our modular cementable acetabular component system (C-MIC), newly developed and utility patented in collaboration with ESKA Implants GmbH (Luebeck, Germany), combines the advantages of both methods.

MATERIALS AND METHODS

After conceptual work was done (Fig. 1) we crafted a cementable hemispheric metal-cup in all common sizes. Its

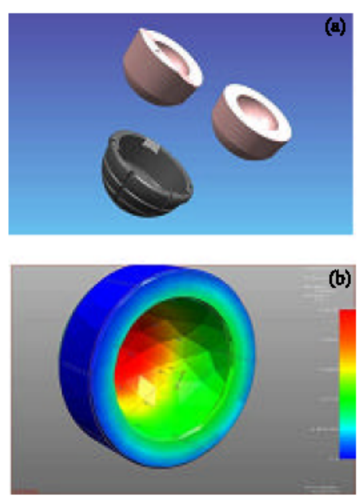

Fig. 1: Shell and different inlays (a) based on FE testing (b)

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Fig. 2: Available cup placement-tools including MIS instruments

Fig. 3: CMIC-cup with different inlays

material (chrome-cobalt-molybdene-metalcast) is configured to the needs of cementation using newest material-science.

The outer side shows defined arranged narrow-channels which facilitate an optimal allocation and adhesion of bone-cement. The winded apex-cone acts as a spacer and permits a constant bone-cement thickness in the same way.

The front view shows the polished cup-flange with six notches and three drilled kerfs. These kerfs allow the replacement of an inlay anchored in the cone, using an specially-built lever. The central-winding is located in the middle of the metal-cup, facilitating a simple and easy anchoring of the cup placement-tool. The development of the placement-tool also includes MIS-instruments scheduled for minimally-invasive hip-endoprosthetic (angled placement-tool) (Fig. 2).

We used Polyethylene (PE) and ceramic-inlays with a diameter of 28. 32 and 36 mm allowing an optimal range of motion combined with a very low risk of luxation.

Furthermore, there is the possibility for the use of special-inlays like asymmetric inflated inlays (10°, 20°) or snap-inlays (Fig. 3).

Fig. 4: CMIC-Tray with different sample-inlays

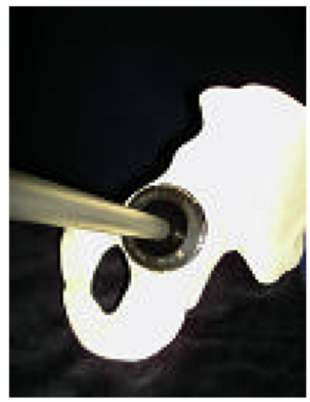

Fig. 5: Cup placement-tool with sample-inlay, protecting the cone of the metal-cup

The results of these options are an increased safety throughout the operation (e.g., in conventional inlays with tendency of dislocation) and a broader range of indications for revisions in endoprosthetics.

For the selection of the optimal inlay all common sample-inlays and sample-heads with different diameters and lengths-as known from the cement-free method-are available. To avoid contamination with bone-cement the sample-inlays are developed in a way that they protect the cone of the metal-cup during insertion (Fig. 4).

All components are accredited according to the European community (CE-label) allowing an immediate clinical application (Fig. 5). The mechanical stability of the metal-cement-bone interface was tested using a standardized experimental design.

Pullout testing of CMIC: The biomechanic experiments were done in the laboratory of ESKA Implants GmbH (ESKA-LAB) with a hydraulic testing machine (Schenk Hydropuls PA 40A) and a nominal force of 40kN. Basic principle of this experiment was blocs of polyurethane

Fig. 6: PU-bloc with the cemented C-MIC-cup

Fig.7: Testdevice for pullout-test

foam, fixed to clamping jaws on the plate of the testing machine. After drilling hemispheric cavities by using a riffle-trephine the sample-bodies with a diameter of 54 mm were cemented in the cavity using PMMA bone-cement (without gentamycine, normal viscosity) (Fig. 6).

After hardening was completed a pulling-tool was attached to the central-thread of the cup. Controlled by force the maximum amount of traction was measured until the failure of the anchorage. Three cups with a diameter of 48mm (Cup A), 50mm (Cup B) and 52mm (Cup C) where used (Fig. 7).

RESULTS AND DISCUSSION

In each individual experiment (CMIC-pullout and CMIC-torsion) the foam-block was fractured, there was no case of loosening. The test results showed no statistical difference in the 3 test body sizes ($p = 0.64$). Results of all experiments are displayed in Table 1.

Table 1: Results of biomechanical testings CMIC-cup-pullout Test

Test-No.	Sample-body	Traction-force[N]
1	Cup A	1666
2	Cup A	1487
3	Cup A	1802
4	Cup A	1566
5	Cup A	Machine failure
6	Cup B	1670
7	Cup B	1857
8	Cup B	1980
9	Cup B	1799
10	Cup B	1900
11	Cup C	1787
12	Cup C	1532
13	Cup C	1676
14	Cup C	1567
15	Cup C	1454
	Mean-value	1695.93
	Std.deviation	162.43

The significance of pull-out testings remains a controversial issue, because no comparable forces occur *in vivo* (Alder *et al*., 1992). Nevertheless, it is assumed that these testings allow a general statement concerning the safety of certain types of anchorage (Szivek *et al*., 1993; Tradonsky *et al*., 1993).

The usage of PU-foam or Simulated Cortical Bone (E-glass-filled Epoxy) seems advantageous, because it eliminates anatomically or biologically variations of cadaver-bones. The results of these biomechanical experiments has proven an extremely high primary stability for the anchorage of this newly developed CMIC-cup. Maximal-forces ranged clearly above these of other cement-free cups (ESKA-cups approx. 800N, other cementless-cups approx. 400-600N) (Tradonsky *et al*., 1993). The advantages of the CMIC-system are versatile as numerous inlays are now available to the orthopaedic surgeon, which were only provided by cementless systems until today. Through the usage of sample-inlays the surgeon is able to select the optimal and safest solution. If a tendency of hip dislocation occurs, the option of an asymmetric or snap-inlay is able to solve the problem without time-consuming additional operative work.

The use of modern femoral head diameters (32 and 36 mm) is also possible, increasing the range of motion for the joint and reducing the risk of luxation.

The CMIC-cup system provides even more advantages: Even in cemented cup systems, high-value combinations will now become available by using ceramic inlays. This means lower abrasion on gliding interfaces and less undesirable reactions of the body from abrasion-particles (foreign-body granuloma, early loosening of the components caused by remodeling-processes, toxicity) after total hip replacement. The result is a significant lengthening of life-time of the artificial hip joint.

The metal-cement-bone interface of the CMIC-cup indicates considerably advantages of cup-durability compared to the polyethylene cups used up to now, because of lower micro-movements and less cup deformations caused by its rigid metal-hull (Vandenbussche *et al*., 1997). This form-stability also reduces abrasion of the head-inlay interface.

After implantation an immediate full-load of the leg is possible, advantageous especially for elder patients. Through cementation and its high modularity the CMIC-system is applicable for complex interchange operations or special indications (e.g., hip-dysplasia-operations). Furthermore, improved inlays with optimised material-features or new glide-pairings can be integrated effortlessly into the CMIC-system.

The CMIC-system allows an extent of variability, safety in application and a patient-comfort so far reserved only to cementless cup-systems. We will proceed to cadaver testing now before first controlled trials on human hips.

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