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Biomechanical Inlay Testing of a Cemented Modular Inlay Cup (C-MIC) for Total Hip Arthroplasty in the Elderly

Andreas Paech, Arndt P. Schulz, Johannes Kiene, M.M. Kaiser and Christian Jürgens
Department of Orthopaedics and Trauma, University Hospital Schleswig Holstein/Campus Lübeck,
Ratzeburger Allee 160, 23538 Lübeck, Germany

Abstract: The biomechanical inlay testing of a newly developed modular cemented acetabular component system is under investigation. The aim of this study, was to determine how strong the bondage of the inlay with the metal shell is in in-vitro testing. A Cementable Metal-Cup (C-MIC) was crafted in the commonly used sizes. Its material (cobalt-chromium-molybdenum alloy) was configured to the needs of cementation. For biomechanical inlay testing standard test methods for determining the axial disassembly force of a modular acetabular device were used. Push in/out and Torsion as well as lever-out inlay tests were performed. The mean maximal push-out force for the 28mm inlay was: 1.140 kN; for the 32mm test inlay was 2.483 kN. Mean results for the lever-out torque for test inlay 28 mm were 14.40 Nm, for the test inlay with 32 mm it was 45.93 Nm. The test results for the torsion tests: Inlay 28 mm: 17.545 Nm and 53.252 Nm for test Inlay 32 mm. The results of these biomechanical experiments have proven a high stability for the anchorage of the inlays in this newly developed C-MIC-cup.

Key words: Total hip arthroplasty, cementing technique, metal back, biomechanics

INTRODUCTION

Until now for a cemented hip prosthesis three versions of a polyethylene cup are commercially available (standard-shape, asymmetric or snap). After completion of bone-cement bonding no subsequent changes of cup-position is possible.

We developed a modular cementable acetabular component system (C-MIC) in collaboration with an implant manufacturer (ESKA Implants GmbH, Luebeck, Germany). We report the development and biomechanical testing of a new acetabular cup system that has the advantages of the cementless method of hip replacement in a cemented cup. After fixation of the metal-cup a great variety of inlays can be attached. Polyethylene-, ceramic- or polyethylene “snap-inlays“, even with different geometries (straight or asymmetric), can be combined with different head-diameters. This facilitates the adjustment to characteristics like patient-age, the individual amount of activity or anatomic varieties. Furthermore, after suboptimal positioned and cemented cups, correction is possible by the use of asymmetric or snap-inlays. The question of this study was how strong the bondage of different sized standard PE inlays with the metal shell is in *in-vitro* testing.

MATERIALS AND METHODS

After conceptual work regarding the design of implant and possible inlays (Paech *et al*., 2007) a hemispheric metal-cup for cemented fixation was crafted in the commonly used sizes. Its material (cobalt-chromium-molybdenum alloy) was configured to the needs of cementation (Fig. 1).

Fig. 1: The developed implant

Corresponding Author: Andreas Paech, Department of Orthopaedics and Trauma, University Hospital Schleswig Holstein/Campus Lübeck, Ratzeburger Allee 160, 23538 Lübeck, Germany

Fig. 2: Construction details of the inner side

Fig.3: Torsion and axial disassembly force test setup

The concave side shows narrow-channels which facilitate an optimal allocation and adhesion of the bone-cement. The apex-cone acts as a spacer and thereby permits a constant cement layer thickness.

On the femoral side its features include the polished cup-flange with six notches and three milled chamfers (Fig. 2). The chamfers allow the removal of an already anchored inlay, for this a specific lever was developed. This design is very versatile as it allows different customized inlays. We developed Polyethylene (PE, ultra-high molecular weight) and ceramic-inlays with an internal diameter of 28, 32 and 36 mm.

Fig. 4: Specimens tested

Furthermore, specific inlays like asymmetric (10°, 20°) and snap-inlays were developed. This would enable the surgeon to react on different intra-operative situations e.g. dislocation or subluxation without the need for cup removal and re-implantation.

All components are accredited according to the European Community (CE-label) allowing an immediate clinical application. The mechanical stability of the inlay-cup interface is tested using a standardized experimental design.

Torsional force tests were performed with a servomotoric testing machine (Schenk Hydropuls PA 40A, Carl Schenck AG, Darmstadt, Germany), axial force tests were done with a hydraulic testing machine (Schenk Hydropuls PA 40A, Carl Schenck AG, Darmstadt, Germany, Fig. 3). We used C-MIC outer diameter 48 and 66 mm (internal diameter 28 and 32mm) metal cups with the following specimen (Fig. 4):

15 pcs. PE-Inlay C-MIC, ID = 28 mm for OD = 48 mm
15 pcs. PE-Inlay C-MIC, ID = 32 mm for OD = 66 mm

Test procedure:: Push in/out: Standard test method for determining the axial disassembly force of a modular acetabular device was the American standard test procedure (ASTM F 1820-03) To determine the resistance against inlay loosening, the axial force required to push the inlay out of themetal back was determined. The inlay was pressed into the metal back using a ball head1 at a constant feed rate of 0.04 mm min^{-1} (max. load 2000N, Fig. 3).

Fig. 5: Test set-up for the inlay press-in (left) and press-out (right)

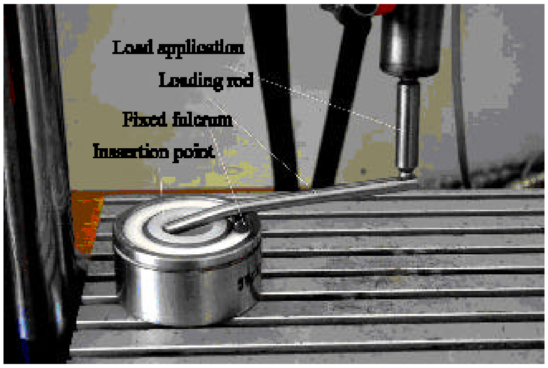

Fig. 6: Test set-up for the inlay lever-out test

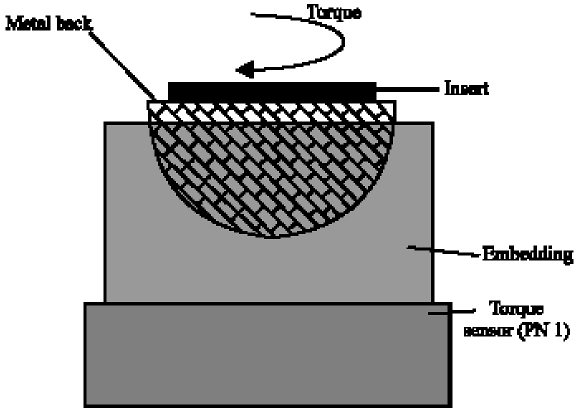

Fig. 7: Sketch of the test set-up for the inlay torque test

All specimens were assembled dry at room temperature. The metal back was placed upside down on an idler ring with appropriate clearance against the inlay. Thepush out load was applied by means of a cylindrical punch through a bore on the backside of the metal shell at a constant feed rate of 0.04 mm min^{-1} (Fig. 5).

Lever out: This test procedure is based on a test method described by Tradonsky *et al*. (1993). To determine the resistance against inlay loosening, the lever-out force required to tilt the inlay out of the metal back was determined. The inlay was pressed into the metal back using a ball3 head at a constant feed rate of 0.04 mm min^{-1} (max. load 2000N). All specimens were assembled dry at room temperature (Fig. 6).

To determine the lever out force, a small hole (5.5 mm diameter) was drilled into the inlay about 6 mm below the rim. As a lever arm a metal rod was inlayed into the hole and loaded. The lever arm vs. the fixed fulcrum was set to 88 mm (ID 28mm specimens) and 81 mm (ID 32mm specimens). A metal loading rod was used to apply the test force at a constant feed rate of 2 mm min^{-1}. Prior to the static torsion test the inlay was pressed into the metal back using a ball head (D28 Biolox delta 28-12/14, D32 Biolox delta D12/14) at a constant feed rate of 0.04 mm min^{-1} (max. load 2000N). All specimens were assembled dry at room temperature (Fig. 7).

The load was applied versus a ceramic ball that has been glued into the Polyethylene inlay. For statistical analysis the program SAS, Version 8.2 (SAS Institute, Cary, USA) was used.

RESULTS

Push in/out: The test results for the push-out force of 28 and 32 mm internal diameter inlays shown in Table 1.

Lever-out test: The resulting torque has been calculated by the applied force and the lever arm between the force application and the fixed fulcrum (81 mm for the ID 28 inlay and 88 mm for the ID 32 mm inlay).

The test results for the lever-out torque testing were shown in Table 2.

Finally the the torsion testing gained shown in Table 3.

Table 1: The test results for the push-out force of 28 and 32 mm

Test	Insert ID 28	Metal back ID28	F max [kN]
1	968501	972501	1.025
2	968401	972601	1.132
3	969001	972501	1.117
4	968601	972601	1.169
5	967901	972501	1.259
		Mean	1.140
		Std dev	0.085
Test	Insert ID 32	Metal back ID32	
1	970501	972800	2.412
2	970701	972700	2.622
3	970601	972800	2.337
4	969401	972700	2.518
5	970201	972700	2.526
		Mean	2.483
		Std dev	0.110

Table 2: The test results for the lever-out torque testing

Test	Insert ID 28	Metal back ID28	Torque [Nm]
1	968801	972601	13.11
2	968001	972501	12.41
3	967801	972601	15.66
4	968101	972501	15.93
5	969201	972501	14.87
		Mean	14.40
		Std dev	1.56
Test	Insert ID 32	Metal back ID32	
1	970301	972800	46.41
2	969301	972700	49.82
3	970401	972800	42.93
4	969601	972700	47.14
5	969701	972800	43.34
		Mean	45.93
		Std dev	2.85

Table 3: The torsion testing

Test	Insert ID 28	Metal Back ID28	Torsion [Nm]
1	968201	972501	16.032
2	969101	972601	17.921
3	968701	972501	19.286
4	968901	972601	17.234
5	968301	972601	17.251
		Mean	17.545
		Std dev	1.188
Test	Insert ID 32	Metal back ID32	
1	969501	972800	51.921
2	970001	972700	47.200
3	969901	972800	54.652
4	970101	972700	56.053
5	969801	972800	56.435
		Mean	53.252
		Std dev	3.819

DISCUSSION

It can be stated that the push-out force achieved by the ID 28mm inlay tested here is above the average range of modular hip implants tested by Tradonsky *et al.* (1993) and Blömer (1997). The push-out force achieved for the 32 mm inlay was above the 90% percentile of the above mentioned studies. It can be stated that the lever-out moment achieved by the 28 mm inlay tested here is close to the median of modular hip implants tested by Tradonsky *et al.* (1993) and Blömer (1997).

The lever-out moment achieved by the 32mm inlay tested herein is above the mean of modular hip implants tested before Tradonsky *et al.* (1993) Blömer (1997). The mean torsional fixation strength of the inlays tested was found to be 17.55 Nm for the 28mm inlay and 53.25 Nm for the 32mm inlay after specimen assembly with a preload of 2000 N, when compared to the literature this is close to the median value of modular hip implants tested before Tradonsky *et al.* (1993) and Blömer (1997).

We have developed a acetabular cup implant that should combine the advantages of both cemented and cementless implants. A minimized risk of acetabular fracture, immediate full weight bearing and a versatility of numerous different inlay types could be gained at the same time. 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.

CONCLUSION

The results of these biomechanical experiments have proven a high primary stability for the anchorage of the inlays in this newly developed C-MIC-cup.

The CMIC-system could also be used for complex revision or specific indications (e.g. hip-dysplasia), acetabular revision with a cemented metal-backed component using a cup that is manufactured for cement free use has been reported in a large series (Wang *et al.*, 2006). To further reduce the risks of failure by the PE inlay wear, ceramic inlays could also be used with this acetabular shell.

REFERENCES

Blömer, W., 1997. Design Aspects of Modular Inlay Fixation. Proceedings of the 2nd Syposium on Ceramic Wear Couple. Stuttgart, pp: 95-104.

Paech, A. and F. Renken *et al.*, 2007. Construction of a Cementable Modular Inlay Cup (C-MIC) for Total Hip Arthroplasty. Surg. J., 2: 25-28.

Tradonsky, S. and P.D. Postak *et al.*, 1993. A comparison of the disassociation strength of modular acetabular components. Clin. Orthop. Relat. Res., pp: 154-160.

Wang, J.W. and C.Y. Fong *et al.*, 2006. Acetabular revision with morsellised allogenic bone graft and a cemented metal-backed component. J. Bone Joint Surg. Br., 88: 586-591.