Modularity of a new cementless acetabular revision cup system based on research of the anatomic variability of the pelvis

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Abstract

There is a growing need for specific revision implants to meet the increasing occurrence of failed total hip arthroplasties displaying massive deficiencies in acetabular bone stock. The developed acetabular revision cup presented in this study is aimed at individual patient solutions using a multi-axial and angular stable fixation peg as well as a modular adaptable lateral flap. To obtain an optimum implant design, a database of computed tomography scans of 69 patients’ pelvis was collected and computational reconstruction of the pelvic bone morphology was conducted. Based on the anatomic measurements, the direction of the fixation peg of the revision cup was evaluated using custom software and the geometry of the lateral flaps was evaluated using rapid prototyping models of the pelvis. Furthermore, we conducted preclinical examinations of the acetabular revision system with regard to the safety of the angular stable locking mechanism of the fixation pegs and the mechanical stability of the lateral flap. The dynamic tests showed no mechanical failure of the fixation peg and its angular stable connection using a cyclic maximum torque of 24.5 Nm for one million cycles. The lateral flap and its fixation showed no mechanical failure using a cyclic maximum torque of 28.4 Nm for two million cycles. In conclusion, a promising solution to satisfy the requirements for adequate anatomical fit in a wide range of acetabular defects is presented.

Keywords: acetabular revision cup; anatomic measurement; preclinical testing; total hip replacement.

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Introduction

The growing number of primary total hip arthroplasties (THAs) in connection with the persistent implant loosening rate [18] caused a doubling of the amount of THA revisions in the United States from 1990 to 2002 [17]. Revision of the endoprosthetic cup poses a particular challenge to the orthopedic surgeon because acetabular bone defects of various sizes and shapes necessitate sophisticated surgery techniques [8]. Primary implant stability and avoiding of periprosthetic infection and total hip dislocation [3, 4] are crucial for the long-term function of total hip revision implants. The acetabular defect classification differentiates between different defect sizes. This underlines the great variance of defect size and severity. Larger defects often correlate with cranial protrusion of the implant caused by osteolysis in combination with implant loosening. Small defects can be filled with a primary acetabular cup [11], whereas larger defects require special revision implants.

In addition to cementless revision systems, several cemented acetabular rings and cups are available [5, 6]. As bone cement does not allow for biological fixation of the surrounding bone, there is a trend towards cementless fixation aimed at biological ongrowth and generation of new bone material around the implant.

Cementless solutions include jumbo cups [25], oval-shaped cups [7, 9], pedestal cups [22, 23] and modular adaptable revision systems [20, 24]. The implantation of jumbo cups is technically less demanding, but reaming a large cavity sacrifices too much bone in the anterior and the posterior acetabular column [19, 25]. Oval-shaped cups are designed to fit the oval bone defect, but the preparation of oval bone stock is technically demanding. The pedestal cup is equipped with a large fixation peg which is located in the Os ilium and directs towards the sacrum. The fixation peg provides enhanced fixation, but the monoblock design of the implant does not allow for arbitrary cup positioning. The group of modular adaptable acetabular revision systems comprises advantages of patient individual fixation; however, considering the modular implant systems on the market, the modularity is rather limited on the one hand, and on the other hand, the locking mechanisms between the cup and the fixation elements bear the risk of implant breakage [24].

A lateral flap as realized in the ESKA-CL-cup (ESKA Implants GmbH & Co. KG, Lübeck, Germany) provides good clinical results [12]; however, the flap in the monoblock design of the cup is not adaptable to the great variety of the patient’s bone morphology. To achieve an adequate anatomical fit of
the flap, the cup position might have to be altered resulting in an unfavorable combination of inclination and antever- sion. The fixation peg included in the ESKA system provides additional stability, but the direction of the peg is fixed. An angular stable fixation peg with multi-axial directional adjustment would allow for a wider range of patient individual pelvic morphology.

A recent biomechanical study into enhanced primary stabili ty of cementless acetabular cups in revision arthroplasty shows the benefits of additional fixation elements attached to the cup [14]. A computational analysis of the implant bone compound showed strongly decreased micromotion if additional fixation pegs and a lateral flap are applied.

By summarizing clinical studies of the different acetabular revision solutions, we found that most revision systems are applied in a small range of defects only [14]. A survey of the literature together with our own surgical and clinical experiences resulted in a proposed classification of design features which an adequate acetabular cup revision system should comprise:

- Oval-shaped metal back to fit the defect morphology and to save bone in the anterior and posterior column [7, 9].
- Modular adaptable fixation elements to allow for individual patient solutions [20, 24].
- Fixation peg with multi-axial adjustment and angular stable locking mechanism.
- Convertible lateral flap with different angles.
- Ability to implant the cup first and subsequently place additional fixation elements.

To design such a revision cup system comprising adequate anatomical fit in the varying bone defects and pelvic morphology, research of the anatomic variability has to be conducted. Data about bone morphology has been published by different researchers [2, 21]. These publications aim at generating statistical shape models for different groups (e.g., small female, large male [21]). If the design of the revision cup was based on these models, the required variability for example of the fixation peg could not be reproduced, because averaging of the shape had been conducted already before virtual implantation. To be able to recognize the required variability of the implant system according to different implant sizes and individual cup positions, one has to conduct the virtual implantation first and to calculate the average values afterwards [10].

The objective of the present study is to develop a concept for a new cementless acetabular revision cup system based on a survey of anatomical fit and preclinical testing.

**Materials and methods**

**Database for research of the anatomic variability**

For research of the anatomic variability of the human pelvis, we collected 69 computed tomography (CT) scans of the pelvis (41 white male/28 white female patients, age: 53.4 years, range: 16–92 years). All of the CT scans were carried out for diagnostic purposes independent of this study. The scans were created using a LightSpeed Plus CT (GE Medical Systems Deutschland GmbH & Co. KG, Solingen, Germany) with a resolution of 512\(\times\)512 (pixel spacing 0.703 mm) and a slice distance of 3.0 mm.

Using the software AMIRA (Mercury Computer Systems, Chelmsford, MA, USA), a three-dimensional reconstruction of the pelves was conducted and the geometry was saved as a tessellated surface in STL format [15]. Afterwards, the pelves were reoriented in a standardized coordinate system with the x-axis connecting the right and left spinae iliacae anterior superior (SIAS), the z-axis touching the pubic symphysis and pointing cranially, and the origin located in the sagittal plane between the SIAS [16]. The 69 reconstructed and reoriented pelves were classified by acetabular diameter to achieve groups fitting different acetabular cup sizes.

**CAD construction of the acetabular revision cup system**

The design of the new acetabular revision cup system (Figure 1) was created using SOLIDWORKS 2008 (Dassault Sys-

![Figure 1](image) Three-dimensional CAD construction of the newly developed acetabular revision cup system before (A) and after (B) assembly of the modular fixation elements; prototype made of Ti6Al4V implanted in artificial hemipelvis (C).
The body of the cup is oval shaped to fit the acetabular defect without sacrificing too much bone in the posterior and anterior column of the pelvis. The cup system features a modular lateral flap which can be attached during surgery, thereby the surgeon can decide which flap fits best to the patient’s pelvic morphology and the individual defect size. The attachment of the flap on the body of the cup is firstly realized by a dovetail which accounts for stable form fit. Secondly, two screws are inserted with an additional locking ring to prevent loosening of the flap.

In addition to the flap, a modular adaptable, angular stable fixation peg can be attached to the cup. The fixation peg is impacted into the intramedular region of the Os ilium superior of the acetabulum after the revision cup has been implanted. Moreover, the fixation peg provides an angular stable locking mechanism within a rotation angle of 16°. The locking mechanism consists of a hemisphere located on a metric screw thread M14 locking screw which interferes with a hemispheric cavity at the back end of the fixation peg. When the locking screw is tightened, the hemisphere of the screw penetrates the cavity of the fixation peg and a stable connection is established. The fixation peg was modeled in three different lengths: 30 mm, 50 mm and 70 mm.

For trabecular screw fixation in the Os ischii, the Os pubis and the anterior Os ilium, screw holes were added in the design of the cup.

Software for evaluating the proper direction of the fixation peg

Custom-made software was developed to analyze the proper direction of the fixation peg in the posterior volume of the Os ilium. At first, the STL file of the pelvis generated in AMIRA was loaded and visualized in an OpenGL environment. Then, the acetabular revision cup constructed in SOLIDWORKS was virtually implanted into the pelvic geometry. The placement of the fixation peg at the surface of the cup was entered by assigning the vector pointing from the rotation center of the cup to the origin of the fixation peg. Following placement, the peg was visualized in the OpenGL environment (Figure 2). Finally, using two scroll bars, the direction of the peg was altered with two angles (theta and phi) until a proper position in the posterior volume of the Os ilium was achieved. The final position of the peg was recorded and the procedure was repeated on the other side using a mirrored implant. Afterwards, the next pelvic geometry from the same group with equivalent acetabular diameter was analyzed.

Rapid prototyping of pelves for flap development

In addition to the position of the pegs, the geometry of the lateral flaps was determined based on the anatomic database. Therefore, three pelves from the entire group with average diameter of the acetabulum comprising (i) the greatest distance of the left and right SIAS, (ii) the medium distance, and (iii) the smallest distance of the SIAS were chosen for rapid prototyping (RP). Acetabular defects were generated at the RP models according to the classification system of D’Antonio et al. [8]. An RP model of the acetabular revision cup was implanted into the RP models of the pelves. Subsequently, lateral flaps were modeled over the RP models of the pelves and hardened in an oven. After hardening, the flaps were detached and geometric registration was conducted using a laser scanner (MicroScribe G2, Immersion Corp., San Jose, CA, USA). The scanned point cloud data was loaded in GEOMAGIC (Raindrop Geomagic, Research Triangle Park, NC, USA) and converted to a NURBS (non-rational b-spline surface)-based IGES file. The IGES file was imported to SOLIDWORKS and was adapted to the previously constructed geometry of the acetabular revision cup system.

Preclinical testing of the flap and the fixation peg

A series of experimental analyses was conducted to guarantee the safety of the angular stable locking mechanism of the fixation pegs as well as the safety of the lateral flap.

The maximum loads that the modular fixation elements might have to bear in the worst case were calculated using
the equilibrium of forces and the equilibrium of moments. The worst case was defined such that only one fixation element (flap or peg) is used, the cup is solely supported by the upper cortical rim of the acetabulum, the patient does not use crutches for support and in the case of the lateral flap, only the upper bone screw is set. For the calculation, a cutting plane was constructed covering the hip force vector and the locking mechanism of the flap and the fixation peg. Within this plane, the equilibrium equations for the bony bearing and the hip force were solved. Considering the maximum load during gait, the lateral flap would have to bear a bending moment of 27 Nm and the fixation peg would have to bear a bending moment of 16 Nm.

To test the modular fixation elements experimentally, functional models of the locking mechanism of the fixation peg as well as functional models of the lateral flap with geometry and material (Ti6Al4V) equal to the original design were manufactured. The functional models were assembled and mounted in a steel frame placed in the testing machine. Static testing was conducted using an electromechanical universal testing machine (Z50, Zwick GmbH & Co. KG, Ulm, Germany), dynamic testing was conducted using a servohydraulic universal testing machine (FastTrack 8874, Instron Deutschland GmbH, Pfungstadt, Germany).

For testing of the fixation peg, the indenter of the testing machine was placed at the tip of the peg 70.0 mm apart from the locking mechanism, according to the longest variation of the peg. The locking screw was fixed with a torque of 20 Nm. During static testing, the indenter was driven downwards with a velocity of 5 mm/min and the reaction force developed by the locking mechanism was measured. As soon as inelastic rotation of the peg inside the locking mechanism occurred, the maximum resisting moment was recorded. For dynamic testing, sinusoidal repeated load with one million cycles was applied at the tip of the peg using the same test setup. Three tests with newly unused models were conducted using amplitudes of \( F_{\text{min}} = 10 \text{ N} \) to \( F_{\text{max}} = 150 \text{ N} \); \( F_{\text{min}} = 10 \text{ N} \) to \( F_{\text{max}} = 300 \text{ N} \); and \( F_{\text{min}} = 10 \text{ N} \) to \( F_{\text{max}} = 400 \text{ N} \). The dynamic tests of the peg were aborted as soon as one million load cycles were reached or otherwise when the maximum displacement of the tip of the peg exceeded 6.0 mm. As seen in the static tests, a displacement of 6 mm results in inelastic rotation of the peg inside the locking mechanism and hence counts as mechanical failure. To evaluate the influence of the initial alignment of the peg, two test setups using firstly a horizontally oriented peg and secondly an 8° tilted peg were realized. Each experiment was conducted three times.

The lateral flap was tested dynamically only with the indenter placed 40.6 mm apart from the attachment site. The two screws for fixation of the flap were tightened with a torque of 10 Nm. Fatigue testing was conducted with the following sinusoidal repeated loads, each repeated three times with newly assembled, unused functional models:

1. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 2000 \text{ N} / F_{\text{Average}} = 1025 \text{ N} \)
2. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 1500 \text{ N} / F_{\text{Average}} = 775 \text{ N} \)
3. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 1000 \text{ N} / F_{\text{Average}} = 525 \text{ N} \)
4. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 800 \text{ N} / F_{\text{Average}} = 425 \text{ N} \)
5. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 750 \text{ N} / F_{\text{Average}} = 400 \text{ N} \)
6. \( F_{\text{min}} = 50 \text{ N} / F_{\text{max}} = 700 \text{ N} / F_{\text{Average}} = 375 \text{ N} \).

The dynamic tests of the flap were aborted as soon as one million load cycles were reached or otherwise as soon as the indenter was displaced more than 6.0 mm from its neutral position.

**Results**

The measurements of the acetabular diameter of all reconstructed pelves from CT data showed a typical Gaussian distribution (Figure 3). The pelves were classified by acetabular diameter and divided into five groups according to the predefined sizes of the acetabular revision cup system.

Based on our custom-made software, the examination of the optimum direction of the fixation peg was defined by the two angles required for peg alignment. The visualization of the results was conducted by defining the angles theta and phi on the x-axis and the y-axis and assigning the number of pelves fitting these combinations of theta and phi on the z-axis. An example of this evaluation is shown in Figure 4 for the revision cup size of 58 mm. The optimum combination of theta and phi to cover the maximum amount of pelves with regard to the peg directions and the additional 8° multi-axial adjustment were chosen for the final design of the revision system.

Three different designs of the lateral flap were generated in SOLIDWORKS based on the RP models of the revision cup implanted in the RP models of the pelves. Prototypes of the final design of all implant components were manufactured from titanium alloy (Ti6Al4V) to be used in a preclinical trial implantation in cadaveric bone.

Static testing of the locking mechanism of the fixation pegs showed inelastic rotation of the horizontally aligned pegs not until an average force of 385 N, corresponding to...
a maximum resisting moment of 27 Nm. When the peg was aligned 8° apart from the horizontal axis, the locking mechanism could withstand average forces of up to 340 N, corresponding to a maximum resisting moment of 24 Nm. A typical development of the reaction force during displacement of the tip of the peg is shown in Figure 5. Note that, even the locking mechanism starts to allow inelastic rotation of the peg at maximum load, the resisting force stays almost steady, which means the peg does not loosen during inelastic rotation. Dynamic testing of the locking mechanism showed no mechanical failure (inelastic rotation of the peg with tip displacement of more than 6.0 mm) at force amplitudes both of $F_{\text{max}} = 150$ N and $F_{\text{max}} = 300$ N over a total of one million load cycles. An amplitude of $F_{\text{max}} = 400$ N caused break-off of the test after a few cycles due to inelastic tip displacement. As an additional examination, we conducted two single tests with $F_{\text{max}} = 350$ N using a horizontally aligned and an 8° tilted peg and found no mechanical failure over a total of one million load cycles. A maximum force of 300 N corresponds to a resisting moment of 21 Nm, 350 N correspond to 24.5 Nm.

The dynamic test of the lateral flap was evaluated using a Woehler curve (Figure 6). There was no mechanical failure of the lateral flap and the corresponding fixation (dovetail and screws) at a maximum cyclic load of $F_{\text{max}} = 700$ N over two million load cycles. Considering the lever arm of 40.6 mm, the assembled lateral flap could withstand 28.4 Nm for two million cycles without any mechanical failure.

**Discussion**

Owing to the growing number of revisions of failed total hip replacements, research towards optimum revision implants becomes more and more important. With regard to half a million primary total hip arthroplasties being accomplished throughout Europe each year [1] and unsolved associated long-term complications such as aseptic loosening, there is a tremendous need for adequate revision options for the acetabular as well as for the femoral component. The acetabular revision cup system presented in this study was developed with the intention to provide one solution for a wide range of acetabular defects and varying pelvic morphologies. Hence, as a basis of the development, we collected CT data of 69 patients and we conducted a computational three-dimensional reconstruction of the pelvic morphology. The acetabular revision cup system was designed to meet various requirements drawn from the literature, such as oval shaping of the body of the cup and application of additional fixation elements [7, 9, 12, 23].

Compared to cemented acetabular rings and cages which are usually designed relatively thin, the new modular revi-
sion system seems rather stiff. However, as shown in our calculations and experiments, the modular connections need a minimum thickness to withstand the occurring loads. Especially with regard to a stable modular connection, a compromise has to be drawn between a sufficiently stiff system and the risk to compromise the bone remodeling in the long-term due to elevated implant stiffness. However, a certain stiffness of the implant has to be provided to achieve primary stability. Sufficient primary stability is crucial to reduce micromotion and to promote osseointegration.

The fixation elements were previously evaluated in a computational study of the implanted components [14], revealing a strong decrease of micromotion in the implant-bone interface. Modular adaptable flaps and fixation pegs, in contrast to monoblock implants, yield the ability to provide patient individual solutions. The developed revision cup is impacted first, the lateral flap and the fixation peg can be attached afterwards if the surgeon decides additional fixation is required to establish sufficient primary stability. Therefore, differently shaped lateral flaps and fixation pegs in different lengths are provided. The fixation peg is attached by a locking mechanism which allows multi-axial adjustment of the peg with an angular stable screw coupling. The optimum direction of the peg was determined using the reconstructed pelvises from the CT database. Furthermore, the lateral flaps were modeled using two extreme morphologies and one medium morphology of the pelvis with regard to the distance of the SIAS.

In contrast to monoblock designs, modular adaptable implants bear the risk of disconnection and failure of the mechanical joint between the body of the cup and the fixation element [24]. That is why extensive preclinical testing has to be conducted during the development of modular implants. We accomplished several static and dynamic tests of the fixation peg and the lateral flap. Therefore, we transferred the original design of the joint from the cup onto functional models, maintaining the original geometry of the joint and the original implant material. The dynamic tests showed no mechanical failure of the fixation peg and the adjacent angular stable connection using a cyclic maximum torque of 24.5 Nm for one million cycles. One million load cycles are usually assumed to correspond to an in situ duration of approximately 1 year [13]. Over the course of this period, stable osseointegration of the implant is expected, subsequently the main load is then transferred through the adjacent bone while the fixation elements are less mechanically loaded.

The lateral flap and the screw-dovetail combination of its fixation showed no mechanical failure using a cyclic maximum torque of 28.4 Nm for even two million cycles. This value is fairly close to the calculated moment the flap has to withstand under absolute worst case loads. Consequently, such high loads in the flap should be avoided by applying more than one bone screw or using the fixation peg additionally if the cup is solely supported by the upper cortical rim as assumed in our worst case calculations.

Following mechanical testing, prototypes of the acetabular revision cup system and the required surgical instruments were manufactured for the first cadaver implantation. The handling of the acetabular revision cup system and the fitting of the fixation elements were satisfying.

In the further development of orthopedic implants, we are planning to expand the anatomic database to encompass further bony regions (femur, knee, shoulder). Moreover, the developed software for discovering the optimum direction of the fixation peg yields further possibilities in improved implant design. For example, the location of screw holes in acetabular cups can be optimized to enhance the safety of screw placement in the future.

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