

PROCESS FOR REALISATION OF A CAGE ADAPTED TO PATIENT FOR SPECIFIC ACETABULAR DEFECTS IN THA REVISION*

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Although the procedure of revision of hip prosthesis has a high success rate, covering large defects present after extraction of the old prosthesis is a difficult task for the surgeon, because he must adapt a standard acetabular cage to the acetabular defects by using bone grafts and bone cement. Using a custom acetabular cage allows better contact between prosthesis and bone, and a better positioning of the centre of rotation, and also an easier and safer installation. This paper presents a parameterized process for making a custom acetabular cage, based on a study case (patient MI).

Keywords: customized prosthesis, acetabular cage, bone 3D modelling, FEM, FEA, acetabular cage design

1. Introduction

For THA (Total Hip Arthroplasty) revision there are more options available to the surgeon: liner exchange, the use of hemispheric cup porous-coated, the use of highly porous metal cup or modular revision systems that use porous metal augments (Tantalum implants), antiprotrusion cage (APC) or a customized triflange prosthesis. The choice for one of the presented options is made considering patient characteristics, the amount and position of bone loss, the capacity of the columns to support biologic fixation, and the presence of pelvic discontinuity [1, 2]. In the case of considerable acetabular defects (Paprosky II C or III) [3], the last 3 options are preferred. Standard acetabular cages achieve good results with small costs (in comparison with the other two solutions), but can also cause failure and usability problems (related to the operation itself - laceration of the femoral artery, sciatic nerve problems or biomechanical-related insufficient

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resistance in acetabular fractures, septic loosening due to breakage bending or screws loosening, poor fixation due to the fact that the ischium is not engaged by the inferior flange, issues of graft resorption and collapse) [4-6]. For this reason, the results of APC solution are weaker when it comes to bigger acetabular defects (Paprosky II C or III). The customized triflange implant, porous metal cup or modular revision systems that use porous metal augments (Tantalum implants) are better suited for this kind of cases, but have the drawback of being expensive and, in the case of customized implants, they have a long production time, so they cannot be used in urgent cases [2, 7]. This paper proposes a patient specific acetabular cage design that attempts to improve the standard cage results by addressing problems that standard cages sometimes do not fix, and in the same time tries to remain an affordable solution by using a minimal design and standard components where possible. A process approach was tried for the realisation of the customised cage and will be presented on the bases of a real patient case study. The process was developed first on artificially generated acetabular defect and then improved on a real case [8]. This is the second real case.

2. Patient information

The patient is a man, 48 years old, suffering from bilateral coxarthrosis with prostheses in both hips. On the right side, a standard APC cage is present, fixed with two screws, and on the left side a polyethylene (PE) cup is present, which migrated upwards (Fig. 1). The last one will be replaced with a personalized cage.

The information required for the Pelvis 3D model was obtained from the patient through computerised tomography (CT) scan. The parameters used were slice thickness of 0.60, a resolution of 512x512 pixels and a field of view of 354.99 mm.

3. Pelvis 3D model reconstruction

The images resulted from the CT scan were segmented so that each element was a separate 3D model (pelvis bone, prosthesis stem and acetabular screws, APC). This process had two parts: an automated segmentation made by choosing a range of grey (or a range of Hounsfield values) for each type of object and a manual segmentation. Pelvic bone was segmented with 180-2000 HU interval, screws with 2600-3072 HU, APC with 2250-3072 HU, and prosthesis stem with 2600-3072 HU.

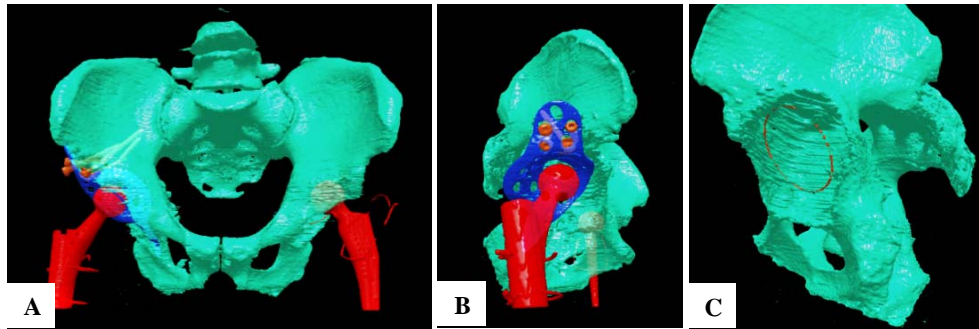


Fig. 1. A - 3D reconstruction pelvis, prosthesis, screws, femur (partial), B - Right hip enlarged C- medial lateral view of the left hip (prosthesis not displayed).

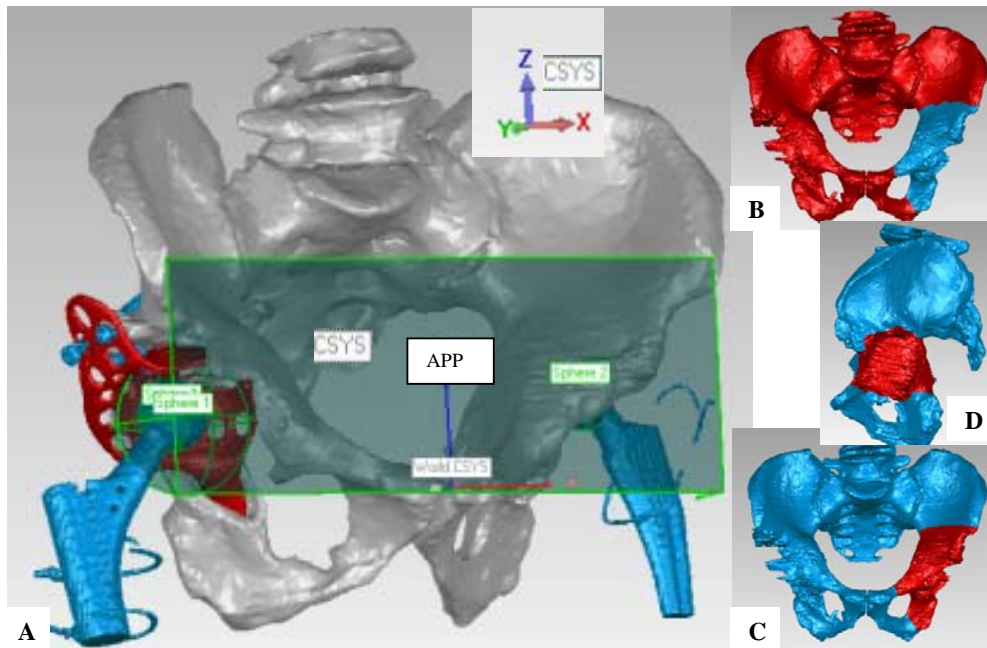


Fig. 2. A - Image of the model used for symmetry calculation and CoR parameter extraction (The plane is APP, CSYS is the coordinate system, the spheres on the left are used for CoR determination), B - Less important area (the number of triangles was reduced to approx. 10% while maintaining a 2.7 mm accuracy), C - Prosthesis contact area, important area optimization with a 0.1 mm accuracy, D - Important area but with no flange contact, optimization with a 0.6 mm accuracy -includes the 0.1mm from C

With the help of segmented images the pelvis was reconstructed (Fig. 1), with the help of specialized software (Slicer 4D, 3D Doctor). Because the hip is not always correctly oriented on the CT table, an orientation procedure [8] was used to bring the pelvis in a symmetrical and usable position. Symmetry is

required, as part of the methods used for centre of rotation (CoR) determination copies geometrical features from one side of the pelvis to the other. In this case, the symmetry was calculated by considering especially the parameters obtained from distal ischial bone and top of the iliac bone. The pelvis model was also referenced to a new coordinate system (Fig. 2A), according to the same procedure form [8]. The pelvis was rotated 0.6 degrees for symmetry and the coordinate system (Fig. 2A) was placed with X and Z axis in anterior pelvic plane (APP). Before optimizing the 3D Model of the pelvis, important parameters for the cage design were extracted: CoR for both hips, maximum allowed cup insert dimension, and the areas that presented a high risk regarding cage-bone fixation were identified. The CoR was determined by copying the CoR from the opposite hip (94.3; 54.8; 36.4 mm) and by 3 predictive methods, Bell et. al [9], Ranawat et. al [10], Dandachli et. al [11] , (83.03; 53.5; 21.77 mm *mean value*). The copied CoR could not be used because it was badly positioned when compared to the predictive methods. There for the mean value was optimised in the sense that was placed symmetrically between the two acetabular columns and also fine adjusted to allow optimal construction for the cage. The next step was optimization of the 3D mesh. This meant clearing the model from self-intersecting surfaces, spikes, and small holes, crested edges and reducing the number of triangles from 1811354 to 160710, so that the model is easy to work with. This was done differentiated, in steps, depending on the surface that needed to be optimized (Fig. 2B, C, D). Using specialized software (Geomagic Studio, GOM inspect) a surface body was generated that can be used further for the cage design in SolidWorks.

4. Parameters for cage design

For the design of the prosthesis a parameterized and repeatable process was tested, which can be easily adjusted to improve performance of the cage. The parameters were divided in two categories: patient specific and general parameters. Patient specific parameters are generated by the design engineer from the analysis of the 3D model and approved/modified by the surgeon or they can be directly generated by the surgeon. General parameters are generated by the design engineer and are to be used as standard building blocks for every cage regardless of the patient data.

Patient specific parameters are: CoR (85.03; 56.9; 21.77 mm); cup anteversion and inclination angle 20°, 40°; Cage outer diameter (mm) 54; area selection for superior flange (SF) and inferior flange (IF); Number of holes (Fig. 3B), 3 for SF , 2 for IF, one for the cup; position of the holes; insertion direction of the cage: x 13°, y 83°, z 101° (obtained from a SolidWorks undercut analysis); patient weight 75 kg and assessment of the risk for double acetabular column fracture (low risk). After the approval of the surgeon the parameters were used as

input patient specific parameters. The rest of the parameters will be described in following two chapters.

5. Cage design

The hip centre of rotation and the setting up of the inclination and anteversion of the acetabular face are the starting point of the part.

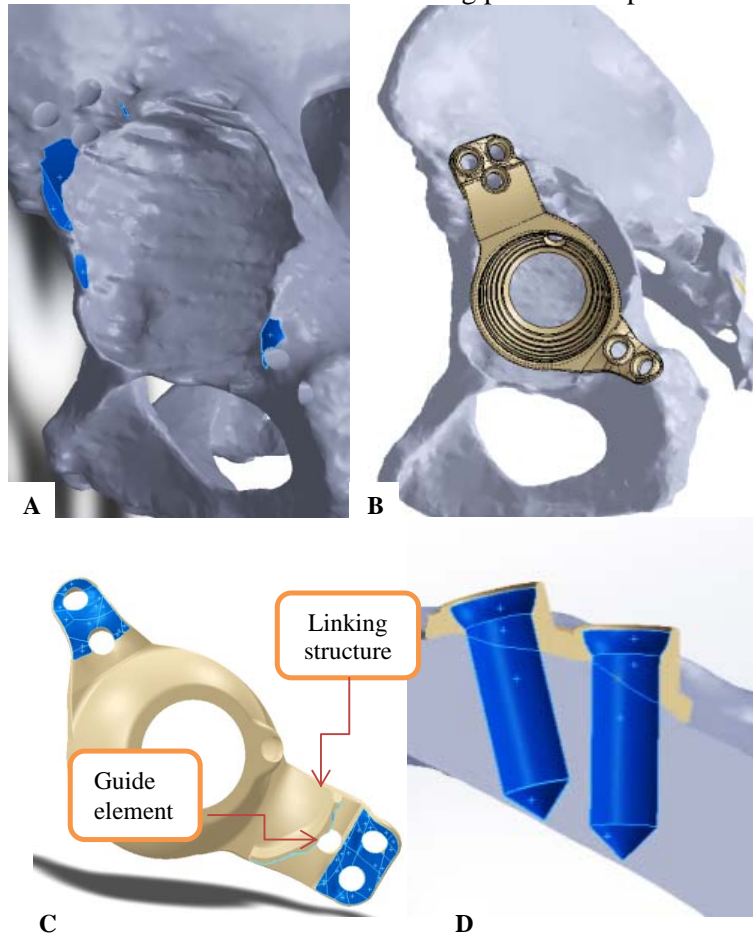


Fig 3 A - Bone defect with cut out part area, B - Cage mounted on the pelvis, C - Cage back surface (the highlighted area is in direct contact with the bone), D - Screw through cage and bone

Once this is set, the cup is generated with the previously agreed dimensions (54 mm exterior diameter, 49 mm - interior so that it can accept an insert cup with 42 mm outer diameter). For this dimension and for other features of the cage a small part of the pelvis bone was cut (Fig. 3A, B). On the bone surface selection the flanges are build, they match exactly the bone surface of the bone model and have a thickness of 2.5 mm (Fig. 3D). In the case of the superior flange, this is linked to the cup through a structure that is 3 mm thick. This follows the bone as close as possible. In order to ensure correct positioning to the acetabular defect, an element (Fig. 3C, 4B) was designed in addition to the two flanges that fit the bone. This was used to give the prosthesis a unique fit to the pelvis and acetabular defect, so that the surgeon cannot mount the cage in other position than the right one (Fig. 3D).

The flange screw holes are inserted at such an angle to the flange, so that a minimum screw length is fixed in the bone. Because the cage is built directly on the pelvis model, the screw length can be determined at this point (Fig. 3C). The cup screw hole is designed along an axis that passes through the CoR and is inclined 16° in relation with the sagittal plane and 16° against the coronal plane (Fig. 4C). The holes are designed for screws with 6.5 mm thread diameter. Optimization of the cage was carried out in order to round all sharp edges, this was done with minimum 0.5 mm radius and the cup upper rim was rounded with a 1 mm radius.

6. Screw guide design

For helping the surgeon to place correctly positioned and oriented screws, a guide for drilling was designed that will be removed after drilling (Fig. 4). This will be implemented through 3D printing out of a plastic sterilizable material. If the screws are not correctly oriented, there is a risk of sciatic nerve problems or femoral artery laceration.

The guides are 10 mm long and have a hole diameter of 3.3 mm. The cup guide is longer (20 mm), because the screws are longer, and every error in direction will be amplified. The ring that is placed in the cup has a small contact area to the cup (Fig. 4 B). The design was made so that the debris found in the cage dose not influence the guide fixation and position. Besides the ring, the fixation of the guide to the cage is ensured by two anti-rotation features (Fig. 4 D, E, A). They are positioned around the cup upper edge, where the flanges begin. For the same reason two anti-movement flange keys are present and fix the guide to one hole feature on every flange (Fig. 4 E). The guide directional precision was measured and calculated in [12] for two types of plastic materials at maximum 2° .

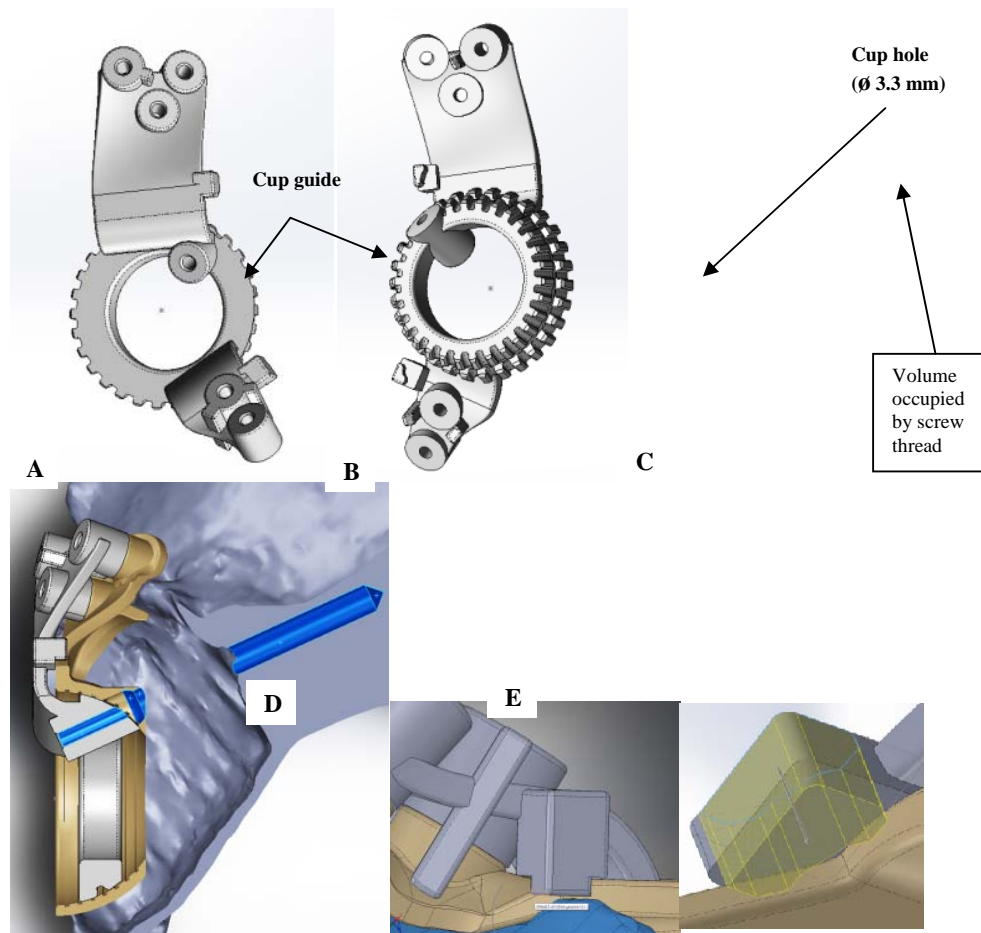


Fig. 4. A - Guide front view, B - Guide back view C - Cage cup hole through assembly D - Anti-rotation cup key E- Anti-movement flange key

7. Finite element analysis (FEA)

As the cage is different for every patient, it has to be tested for the stresses that are specific to that patient. We designed 3 tests 2 for fatigue using the maximum forces for walking and stair climbing and one for accidental big forces (stumbling). The forces were obtained by Bergmann et al. [13] from in vivo measuring with a sensor equipped femoral stem. Their values were increased with 25% and only the absolute maximum force for each activity was considered, so that the test has a good margin of error [13]. The forces were: for walking 390% of Bodyweight (Bw) or 2869 N with the components x, y, z, -364 N, 157 N, 2840 N; for stair climbing 470%Bw (3457 N), -277 N, 587 N, 3395 N; for stumbling

1100%Bw (8085 N), -1027 N, 444 N, 8012 N)[13]. The presented forces are adapted to patient weight (735N) and presented reference system. The testing assembly included: patient specific cage, PE cup, prosthetic head and a bone cement layer between cup and cage. The used material properties were: for cage and head - Ti6Al4V ELI (grade 23) - Young's modulus 111 GPa, yield strength ($R_p 0.2 \%$) 1050 MPa, Poisson's ratio 0.296; for cement (PMMA), 2.7 GPa, 48 Mpa, 0.35; for PE cup (UHMWPE) -690 MPa, 21 MPa, 0.49. Fatigue limit used for Ti6Al4V ELI at $N=10^8$ was 615 MPa. Only compression supports (Fig. 7A-F) were added to the cage, one for each healthy bone contact area (Fig. 3C) and one for each screw head contact surface (Fig. 7C, 7D). The force was applied perpendicular to the end face of the round cut in the prosthetic head (Fig. 7F, 8).

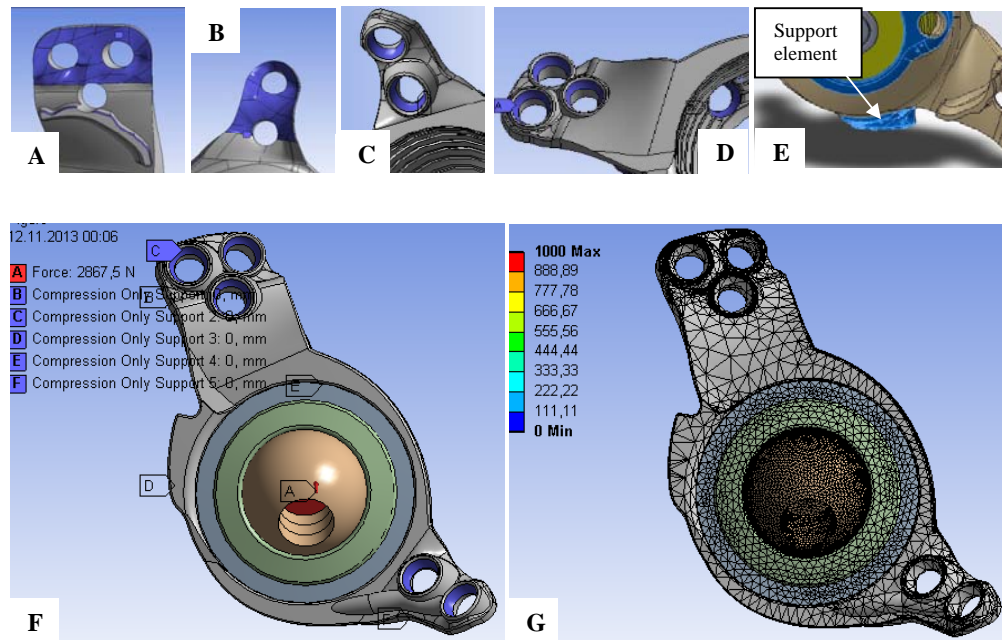


Fig. 7. Fixation: A, B - Superior and inferior flange bone contact, C, D - Screw heads contact surface, E - Support element was added that allows fixation on the acetabular anterior column, F - Forces and supports acting on assembly, G – Finite element model (10 nodes tetrahedral elements –SOLID 187 and TARGE170, CONTA174 elements for contact modelling, totalising 255000 nodes and 157000 elements)

The contact between cage cement and PE cup was set to “bounded” and the contact between head and cup was a frictional one with 0.2 friction coefficient and 0.132 mm radial clearance (Fig. 8, 7G). The following parameters were analysed: maximum tension, maximum displacement, factor of safety (theory: max equivalent stress, stress limit type: tensile yield per material) for stumbling

test and factor of safety (FoS) for fatigue (Equivalent Stress - Von Mises), for the other two tests. The initial test of the cage reveals the following results (Table 1, Fig. 9).

Table 1

	Tests results							
	Initial Model			Optimized Model				
	Max. Stress MPa	Max. total deformation (mm)	Min FoS	Max. Stress MPa	Compared to initial model	Max. total deformation (mm)	Compared to initial model	Min FoS
Test 1	650	0.279	1.61	261	-60%	0.049	-82%	3
Test 2	798	0.317	1.28	332	-58%	0.061	-81%	2.35
Test 3	1638	0.762	0.64	633	-61%	0.129	-83%	1.66

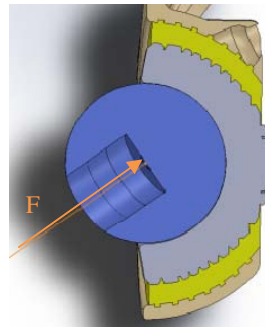


Fig. 8. Section through the testing assembly

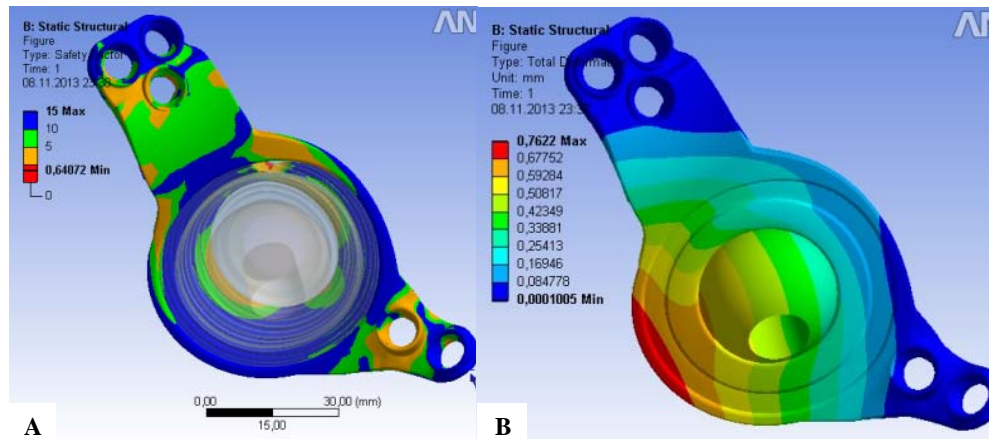


Fig. 9 A - Maximum deformation, test 3 - first model B- Factor of safety, test 3 - first model (FoS <1 red, 1-5 orange, 5-10 green, >10 blue)

The results from the first test did not meet the limits for total deformation (any deformation larger than 0.15 mm [14] restricts bone integration of the prosthesis) and the stress in test 3 was above the yield strength of the material. Also the values for the FoS for fatigue for the two tests were small. As the test forces were already increased by 25% an absolute minimum FOS for all tests was 1. Therefore, the model was optimised by adding the following elements: the inferior part of the cup was thickened (1 mm), the cup border was enlarged for a smoother transition to the flanges, the extrudes for screw holes were thickened at the base as much as the flange surface allowed, a rib (4.5 mm diameter) was added to the inferior flange and a support element was added that allows fixation on the acetabular anterior column (Fig. 7E).

The results for the optimised model (Table 1 Fig. 10) meet now all the requirements. It is interesting to notice that the maximum deformation moved from the anterior side to the posterior side of the cage, and that the maximum stress is now on the new support element instead of the cup hole.

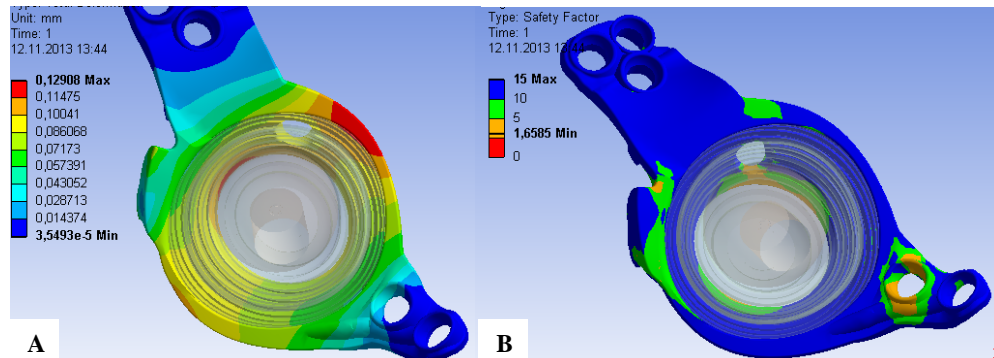


Fig. 10. A - Maximum deformation, test 3 stumbling - optimised model B - Factor of safety test 3 stumbling- optimised model (FoS <1 red, 1-5 orange, 5-10 green, >10 blue)

8. Final steps

The final steps of the procedure are building a plastic prototype, presenting it to the surgeon for a final check along with all the necessary implantation information. After the surgeon approves the design, the cage is printed in titanium through a direct metal laser sintering (DMLS) process. The cage can be then covered with a bone porous surface for fixation and sterilized along with the drill guide.

9. Conclusion

The analytical study highlights the stability of the equivalent surface under bending and compression loadings for different cage parameters (linking element

width varying from 27.2 mm to 40.8 mm). The FEA test emphasizes the mechanical performance of the cage under normal (test 1 and 2) and accidental stresses. We achieved a 60% decrease of the maximal stress points and an 80% decrease in total deformation by adding 1.657 cm³ (13.5%) of material through different construction elements. We believe that the presented process is able to produce a real usable cage. The process can be improved by making a dimensional analysis of a 3D printed titanium cage, in order to adapt the design parameters for the specific printing technology and also to test the results of the FEA on a real part. Also the modelling and simulation can be improved by modelling the pelvic bone accordingly to the local bone density and strength (different material properties for different points on the pelvis).

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