PATIENT SPECIFIC INSTRUMENTS FOR TOTAL HIP REPLACEMENT SURGERY

Drstvensek, I.; igor.drstvensek@um.si
Brajlih, T.; tomaz.brajlih@um.si
Paulič, M.; matej.paulic@um.si
Balic, J.; joze.balic@um.si
Tomazic, T.; tomaz.tomazic@zpiz.si

Abstract: *Plastic laser sintered parts are nowadays used in many different applications ranging from basic prototypes to demanding end user products as airplane parts, automotive industry products etc. Since Additive Manufacturing methods fit very well into the markets demanding low volume or even bespoke production of parts medicine is one of the main potential users or consumers of individualized plastic products. The use of plastic jigs for endoprosthetic operations has been studied and clinically tested to prove the usefulness of individualized operating equipment. The aim of the modern endoprosthetic is the optimal imitation of the individual human biomechanics. This is achieved by determination of a real 3D-mechanical joint axis and joint kinematics. Preoperative 3D-CT scan of degenerated joint enables a creation of a virtual 3D-joint-model with the determination of optimal and exact joint resection levels. A standardized CT-protocol for joint images with minimum irradiation was created, supported by the specific computer program for trusty segmentation of the CT images, to create a 3D model of the affected joint. Upon this model the planed resection lines were incorporated into an individual joint model with belonging jigs.*
Personalized joint jigs for Hip endoprosthesis have been developed through the presented study. They enable for accurate bone cuts and preoperative determination of component placement, without modifying the common OP-technique. The postoperative analysis of endoprosthesis positioning confirmed easier, quicker and more precise procedure.
Key words: *Laser Sintering, Total Hip Replacement, Resection Guides.*

1. INTRODUCTION

Additive Manufacturing technologies has been extensively used in medicine since the beginning of 21st century. Their applications mostly range from serial implants to custom models for surgical planning, custom implants and prosthetics and patient specific instruments for surgical procedures. Selective laser sintering and melting and electron beam melting are at the moment mostly used technologies used to produce medical implants and instruments. Laser sintering of PA12 based materials is a common choice of engineers and medical doctors looking for a reliable solution to provide them with instruments such as surgical guides and models that can be used inside the OP theatre and in contact with the OP field.
Orthopedic surgeons usually deal with a problem of defining the anatomical kinematics of their patients that needs to be retained after putting the joint prostheses into place. The problem can be effectively solved using modern CAD techniques based on CT scans and Additive Manufacturing technologies to produce patient specific instruments. Modern CAD techniques enable for reliable definition of mechanical axis in virtual 3D space, which is much preciser than clasical X-ray based planning methods. The main problem of virtual surgical planing is how to retain the calculated and simulated geometry when moving from virtual models to the patients in OP theatre. Nowadays it can be solved using special jigs, fixtures and guides that are designed inside the virtual CAD environment and produced using the Additive Manufacturing technologies. This way the orientation of anatomical features in the global coordinate system of the body can be transferred to the so called Patient Specific Instrument using special features of the patient's hard tissues (osteofits, etc.). These features assure that the jig fixture or guide will fit to the body part in only one position thus preserving the anatomic angles defined in the virtual coordinate system.
The aim of the presented study was to develop new resection guides for hip - endoprosthetic. Our clinical trial was carried out on 4 patients, with implantation of 4 conventional hip endoprosthesis implanted using the new resection guide technique (jig technique).

1.1 Total Hip Replacement Guides

This individual resection and bone stock preserving technique should enable the optimal prosthesis fit and positioning, with less postoperative complications due to quicker and less demanding procedure. The development of resection gudes starts by the determination of exact preoperative CT-joint anatomy with clear segmentation of CT-scans to get an individual joint model. The second step is the detection of individual anatomical parameters with center of the joint rotation and determination of inclination and version angles. Using the determined individual anatomy and disposable bone stock, the optimal endoprosthesis size and position were determined.

The ability to measure different relevant lengths and angles of the lower limb in 3D space is essential in the analysis of lower limb anatomy and biomechanics. A CT scan was performed on each joint with 1 mm slice thickness. The images were stored in DICOM format and transferred to a workstation running EBS ver. 2.2.1 software (Ekliptik, Slovenia) to generate a 3D reconstruction model for the targeted joint. Upon this preoperative 3D-CT scan of degenerated joint, a virtual and individual plastic 3D-joint-model with the determination of optimal and exact joint resection levels for Endoprosthesis placement has been created. The resection guides (joint jigs) were designed and produced at the Faculty of Mechanical Engineering Maribor on their EOS Formiga laser sintering machine. The material used was CE-certificated PA2200 polyamide material. Together with the guides the joint models were made to enable better communication and preoperative planing (Fig. 1).

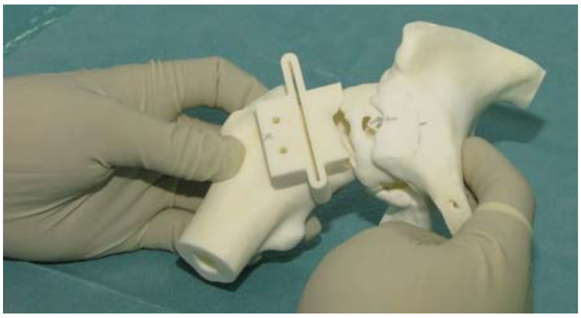

Fig.1. Guides and joint model in the OP theatre at the biginning of the operation.

The presented resection guide technology is unique at the moment of writing and is aimed at:

- determination of exact preoperative CT-joint anatomy with individual joint model
- manufacturing of personalized resection guides and facilitation of surgical technique
- optimal planning of bone cuts and positioning of the Endoprosthesis components
- estimation and prediction of operation pretentiousness
- less invasive approach and shortening of operative time
- diminishing of Endoprosthesis position outliers
- reduction of intraoperative and postoperative complications
- less instrumentation with consecutive diminishing of sterilization costs
- optimization of joint kinematics with better long term results.

1.2 HipCut project

The presented technology is not dedicated to specific endoprosthesis types, but to specific patients' anatomy and their individual bone stock.

To create the individual 3D-CT model of patient hip, the new French imaging method, the low-dose digital stereoradiography [Dubousset et al., 2007] has been used. This technique is based on the multiwire proportion chamber for particle detectors and was transformed into a low-dose system named EOS™ [Dubousset et al., 2007]. The classical radiographic dose efficient is around 3 mSv and the EOS™ CT- doses around 3,7mSv. Specially designed software included in the workstation allows three-dimensional (3D) modeling of the bone envelope. Using the individual CT Hip-model anatomic parameters important for endoprosthesis placement have been determined, supported by computer programs with self-dependent segmentation technology and planning of implantation geometry [Shapurian et al., 2006].

For each patient the femur length, i.e. the length between the center of the femoral head and the center of the femoral notch, the tibia length i.e. the length between the center of the tibia plateau and the center of the tibia plafond and the total length i.e. the length between the center of the femoral head and the center of the tibia plafond have been determined. Additionaly the femoral head diameter, representing the optimal circle diameter fitting the femoral head has been determined.

Definition of the exact acetabular inclination and anteversion angles was important for the acetabular cup placement. Using the 3D-CT model the inclination and the anteversion of original acetabulum have been defined. The optimal spherical surface covering the real acetabulum has been determined to predict the optimal size of acetabular cup. The optimal depth of selected cup has been determined according to the geometry of available bone stock. The femoral part of the hip has been used to determine an anteversion of the original femoral head. Considering the acetabular anteversion we tried to determine the optimal combined anteversion of acetabular and femoral endoprosthesis parts. Detecting the optimal cylinder volume fitting the femoral canal a femoral steam axis, its size and position have been determined. Regarding to the hip biomechanics the center of rotation for femoral head has been determined and the optimal offset for the femoral component set.

Considering the 3D-CT model of the patient hip the position and the size of the resection guides for acetabular and femoral cuts have been defined. Due to the limited operative field the jigs have to be shaped in a way that they do not disturb the surgeon's view, or forcing him to modify his operative approach.

For the acetabular component a central jig has been developed that fits optimally to the acetabular fossa, without brushing the acetabular ream, or fully remove the capsule (Fig. 2). The acetabular jig should be placed to the acetabular fossa, some millimetres below the capsular attachment on the acetabular ream (Fig. 3).

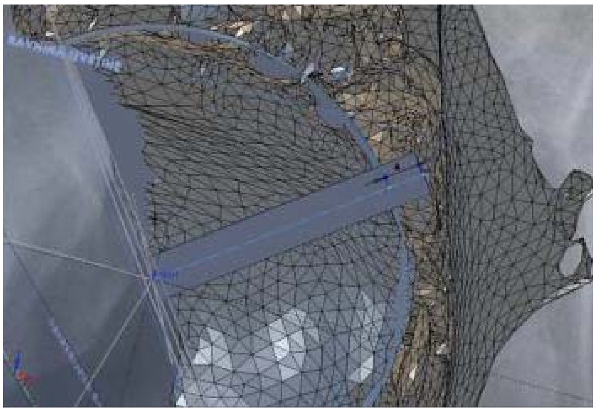

Fig.2. Acetabular jig construction. The position of the pin hole has been set in the direction of sufficient bone stock.

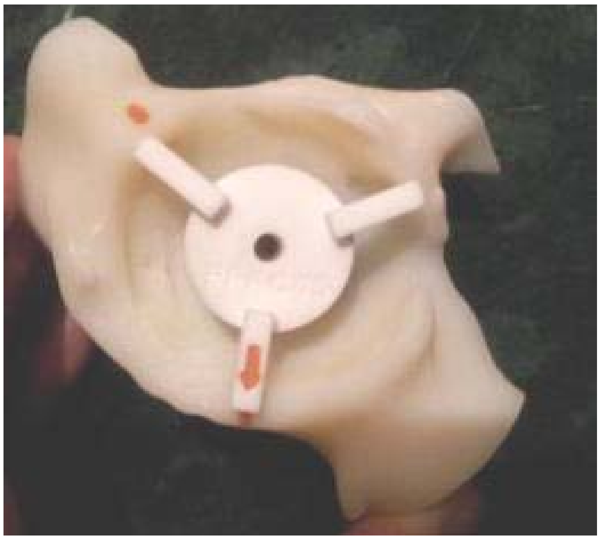

Fig.3. Smaller acetabular jig designed to avoid the capsule and cartilage.

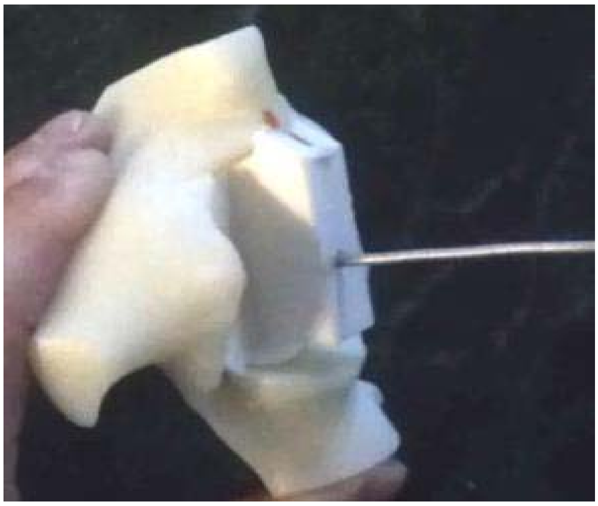

Fig.4. Reaming the central acetabular pin hole through the jig into the model of acetabulum.

In case of larger symmetrical cartilage rests an additional jig with 2 mm offset to the original bone stock to neglect the cartilage mantle has been developed (Fig. 4).

In case of complete asymmetrical cartilage mantle its removal for original bone fitting jig was required. After the jig is clicking into the bone stock, it has been fixed with the central pin, determining the center, depth, inclination and anteversion of the original acetabulum. It has been reamed off with the cannulated reamer, with optimal preoperatively determined reamer-size. The last step is the positioning of the acetabular component into the prepared bone stock with optimal size, anteversion and inclination of the cup.

After placing the femoral jig the femur has been resected and the line above the lesser trochanter for the optimal leg length and off set determined.

The resection lies in the right inclination and anteversion for the best femoral compound stability due to the combined anteversion (Fig. 5).
The procedure is completed by femoral component placing according to the resection lines and testing the stability of the hip Endoprosthesis (Fig 6).

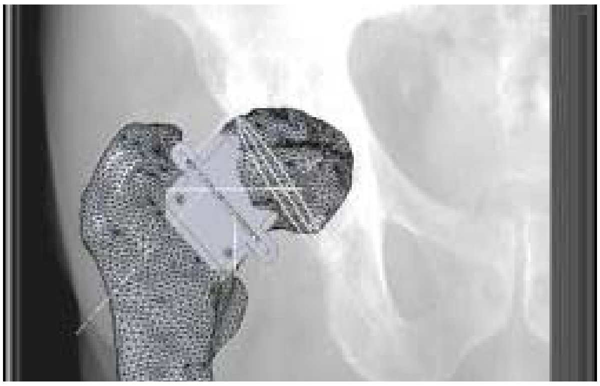

Fig.5. Femoral jig determining the right height, inclination and anteversion of the femoral resection.

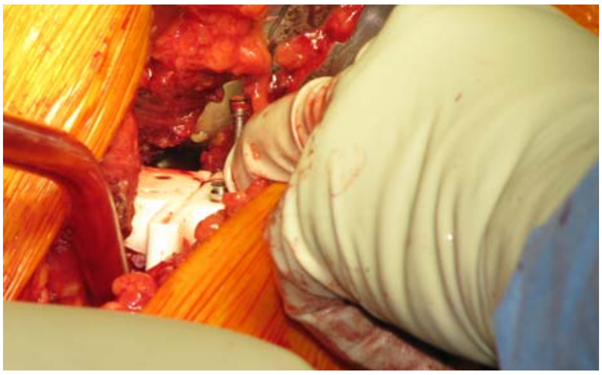

Fig.6. Femoral jig fixed with 2 pins for the intertrochanteric fixation and the resection slot for the femoral cut.

2. RESULTS AND DISCUSSION

Four total hip replacement operative procedures have been performed for the preliminary verification of the new procedure with detection of possible advantages over the conventional technique. The postoperative endoprosthesis positioning has been analyzed by comparing the planed and performed resections on CT images. The results confirmed easier, quicker and more precise procedure, with reasonable postOP-3D-CT mechanical axis outliers within the ±3° and ±5° for the Version Angles. The measured functional outcome due to Harris Hip score were comparable to the conventional technique.
Important for Hip Endoprosthesis stability is especially the determination of the optimal acetabular angle values. Due to our first data, the ideal acetabular inclination was around 40°, dependent to the available bone stock between 30° and 50°. The ideal anteversion of acetabular part was around 15°. Due to available bone stock the anteversion should be between 10° and 20°. The optimal combined anteversion of acetabular and femoral component has been determined with respect to femoral anteversion (optimal 15°). The value of combined anteversion should be between 25° to 45°, with our optimal value of 35°.

3. CONCLUSION

The aim of the project was to develop a new technology of patient specific resection jigs, created for individual total hip replacement operations. A real 3D model of patient anatomy was created using a method of CT 3D reconstruction with computer segmentation that enabled accurate, patient specific bone cuts. The low-dose EOS™ imaging method was used to reduce the CT-radiation almost comparable to the classic radiogram series for joint endoprosthetic.
A specific design of polyamide resection jigs has been developed and a specific surgical technique, customized to the patient anatomy has been created, that can be performed without conventional instruments. The intraoperative applicability of the jigs and the postoperative outcome of Endoprosthesis positioning has been preliminary tested. These first tests promised optimal endoprosthesis placement due to the available bone stock, with less surgical complication and better postoperative joint kinematic.

4. REFERENCES

►Dubousset, J.; Charpak, G.; Skalli, W.; Kalifa, G.; Lazennec, J. Y.; EOS™ stereo-radiography system: whole-body simultaneous anteroposterior and lateral radiographs with very low radiation dose Rev Chir Orthop 2007; 93 (Suppl. 6) : 141-143
►Shapurian, T.; Damoulis, P.D.; Reiser, G. M.; Griffin, T. J.; Rand, W. M.; Quantitative evaluation of bone density using the Hounsfield index. *Int J Oral Maxillofac Implants*. 2006 *21*(2):290-7