



Method of cooperation between orthopedists and engineers during designing surgical tools for hip surgery

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Summary

The way of interdisciplinary collaboration between surgeons and engineers was presented in the paper. The collaboration was carried out within the European project ENHIP (*Ergonomic Instruments Development for Hip Surgery an Innovative Approach on Orthopaedic Implants Design*). The project concerned a development of new tools used in hip surgery. The tools underwent the assessment process within technical and anthropotechnical criteria. New instruments was made in Rapid Prototyping technology. The project was directed towards a development of small and medium enterprises, which manufacture surgical instrumentation and endoprotheses

Key words: surgical instruments, anthropotechnical model, ergonomics analysis, FEM analysis, Rapid Prototyping

1. INTRODUCTION

Each year more than 500.000 arthroplasties are performed in the world to recover hip joint functions of individuals [9, 10], and each year this number is increased because of the ageing of population in developed countries. Only in Europe the market of hip prosthesis is 380.000 units and 760 Million € per year in Europe, and it is expected that the rate of last years will be increased for next decades [10]. Total hip replacement (THR) consists in the hip joint substitution by both a femoral component (femoral head and stem) and by acetabular component. For the last 40 years in which THR has been performed, the associated surgical technique has not substantially changed [16]. If THR is compared to other surgical fields, it is surprising that surgical instruments have not been improved despite of their importance. During last decades, biomechanics, surgeons and hip prosthesis companies have focused their efforts on improving the patients' quality of life by improving the prosthesis clinical behavior and consequently making the prosthesis life longer. Nevertheless much lower effort has been applied to the development of the associated instruments.

In 2005 the project entitled: Ergonomic Instruments Development for Hip Surgery (ENHIP) financed from funds of 6 FP. One of the most important objective of the ENHIP project was to develop "Better surgical instruments, which will allow surgeons to reduce time required for surgery and to improve working conditions of surgeons by a reduction of physical effort required, and the consequent effect in the on health expenditure reduction".

The method of collaboration between orthopedists and engineers of different domains, which are involved in designing of surgical tools for hip operation is presented in the paper.

2. CHARACTERISTICS OF THE PROJECT PARTICIPANTS

Consortium consisting of RTD (Research to Development) organizations, hospitals and producers of surgical tools for hip operation was established for realization of the ENHIP project. Spanish Biomechanical Institute of Valencia (Instituto de Biomecánica de Valencia IBV) was a coordinator.

Project participants were divided into three groups:

- users of surgical tools, i.e. orthopedists from two hospitals:
 - Katedra i Oddział Kliniczny Ortopedii i Traumatologii Śląskiej Akademii Medycznej, Poland,
 - Hospital de Sagunto, Sagunto, Spain,
- surgical tools manufacturers:
 - LAFITT S.A., Spain,
 - Artur Salgado LDA, Portugal,
 - Erothitan, Germany,
 - Landmark U K,
 - EVOLUTIS, France.
- RTD organizations:
 - IBV, Spain
 - KOMAG Mining Mechanization Centre, Poland.

The group of users was uniform as regards competences and consisted of orthopedists. The groups of manufacturers and RTD were more diverged as regards competence and were represented by engineers of different specialties: mechanics, biomechanics, production engineers and biomaterial engineers.

Manufacturers were accounted to Small and Medium Enterprises (SMEs) as regards their production potential.

3. DESCRIPTION OF THE METHOD

The method consisting of the following stages was used in the project:

- an assessment of existing tools:
 - questionnaire inquiry of existing tools,
 - photo and video recording of hip alloplasty,
 - computer modelling of surgical tool and surgeons anthropometric features,
 - computer visualization of recorded activities,
 - ergonomic evaluation of activities,
 - analysis of tools design features,
- tools improvement:
 - modeling of design features,
 - testing the virtual prototypes,
 - Rapid Prototyping,
 - assessment of material prototypes.

4. ASSESSMENT OF EXISTING TOOLS

4.1. QUESTIONNAIRE INQUIRIES

Clinical assessment group consisted of 11 orthopedists: 1 from France (Sarrebouurg Hospital), 6 from Poland (St. Barbara Hospital in Sosnowiec), 3 from Spain (Hospital de Sagunto) i 1 from Great Britain (Prince Philip Hospital).

An assessment was conducted on the basis of questionnaire form submitted to the members of assessing group. The method of personal interview, when the form is filled during the interview, was used in the assessment.

Questions about each instrument were related to the following items:

- level and cause of pain during use of the tool,
- assessment of pain causes
- instrument assessment: assessment of grasping part, tool dimensions, shape as well as safety of use,
- assessment of the instruments' design factors

Pain assessment

Eight main tools for hip alloplasty, given in Table 1 were selected for assessment. The same presents the results of the questionnaire section referred to pain.

Numbers in cells refers how many surgeons have felt harmful in each body part during the use of each surgical instrument.

After analyzing the answers it is possible to observe that four instruments (rongeurs, reamer driver, hammer and femoral head extractor) are more problematic than the rest. Furthermore, focusing the answers in the body

Table. 1. Pain assessment

PAIN (body parts)	Rasps Impactor	Hammer	Rongeur	Socket Impactor	Self-Retaining Retractor	Self-Retaining Retractor	Reamer Drive	Raspator
Shoulder-arm	1	1	0	0	0	2	2	0
Elbow-forearm	0	2	3	1	0	2	2	3
Wrist-Hand-finger	0	4	4	0	0	2	4	4
Neck	1	0	1	0	0	0	0	1
Upper back	0	0	1	0	0	0	0	0
Lower back	1	0	0	0	0	0	0	0
Total	3	7	10	1	0	6	8	8

parts, the joints where more surgeons identify pain and discomfort are the wrist and the elbow.

Assessment of pain causes

It can be observed a relation between the discomfort produced by each instrument and the amount of possible causes of this discomfort. This demonstrates that surgeons can identify the causes, which produce pain. Nevertheless, this relation cannot be observed with the femoral head extractor. In that case surgeons state that this instrument produces pain but they cannot identify the cause.

Regarding which actions produce more discomfort in surgeons, it can be observed, that the highly repetitive movements and the excessive force are the main causes of pains, followed by maintaining joint postures in the extreme of the range of movement or maintaining static postures for prolonged periods.

Assessment of the instruments' design factors

Next, surgeons assessed several design factors in order to match discomfort sources when the instruments are used. It can be observed that surgeons do not agree with the design of four instruments (Hammer, Rongeur, femoral Head Extractor and Rasp Impactor), and they have identified clearly which aspects must be improved. We can emphasize that six from seven surgeons consider that the handle shape of Rongeurs is not appropriate, and five from seven coincide in saying that femoral head extractors have inadequate shape and volume. Results of questionnaire interviews enabled a selection of tools, which cause pain in a given part of locomotive organs. Then the tools underwent ergonomic analysis, which aim was to point out the reason of ailment and discomfort during their use.

4.2. VIDEO RECORDING DURING OPERATION

Three video recordings of hip operation were conducted to carry out ergonomic analysis. The operations were recorded in Wojewódzki Szpital Specjalistyczny im. św. Barbary in Sosnowiec, Poland (St. Barbara Hospital) and in Hospital de Sagunto in Spain. In St. Barbara Hospital

a women at 52 underwent hip alloplasty operation, was placed on back with front-side access. The operation was carried out by standing surgeons. Recording time was 55 min. Two video cameras and a digital photo camera were used for recording. The first camera was placed on the stand in front of operation field. The second one was used by operator to film freely the operation – he recorded manual activities of surgeons and their positions during operation. The video recording on that camera was taken from different parts of the operation room. Digital camera was used to record selected body positions of surgeons.

Operational team consisted of the following persons:

- head surgeon (man, 42, weight 93kg, height 182 cm),
- three assisting surgeons (men),
- instrumenter (woman),
- anesthesiologist (woman),
- manager of operating suite (woman).

Identification of body posture and manual activities of surgeons was the recording objective. Body posture identification was made in relation to the whole body and upper limb area.

4.3. MODELLING OF WORK ENVIRONMENT / CREATION OF VIRTUAL WORK ENVIRONMENT

Virtual work environment was created basing on the recorded operation and using modelling methods of design features of the material objects and anthropometrical features of human body.

Methods and software listed in Table 2 were used for modelling and assessment of virtual work environment.

Models of the equipment of the operational room and surgery tools were made in the software developed to support CAD (Computer Aided Design). Anthropos – Ergomax [1] were used to create the models of anthropometrical features, Fig. 1. The models describe:

- external anthropometrical features a),
- clothing and equipment b),
- skeletal system, c).

In Human Body Models the proportions of body, mass distribution on body length, somatic types and differences in body building of men and women are recreated. Locomotion organs are recreated by 6 kinematics chains

including 86 articulating joints. There is a possibility to select model for 10 types of nationality from 19 regions of the world [1, 17].

Table 2. Particular methods for virtual working environment analysis

Methods	Software
Geometrical modelling	AutoCAD, Inventor, Mechanical Desktop
Multi-Body System (MBS)	MSC.Visual Nastran 4D
Finite Element Method (FEM)	MSC.Patran/Nastran/Dytran
Human Body Modelling	ErgoMAX
Biomechanical Analyses	3DSSPP
Computer visualisation	3D Studio MAX
Reverse Engineering	Photomodeler

Computer animation enables to position the models of body segments in a space relating to real body postures during operation.

Awkward postures, taken by surgeons during operation, are especially difficult for map. For that purpose super-positioning of photos and models were used in the project. When surgeon’s anthropometrical features are known, it is possible to match it with the photo of respective human body model.

Anthropometrical features taken from [6]. Fig. 3a) shows a surgeon (Surgeon 3 from the Fig 2a) during “driving in” using Rasp Impactor.

After calibration of photo and model, the models of body segments are located in a position referring to the recorded body posture, Fig. 3b).

Activity realized in a sitting position by the female surgeon of anthropometric features given in Fig. 4a) (surgeon 5, Fig. 2b) was analyzed.

Fig. 1. Models of anthropometrical features [1]

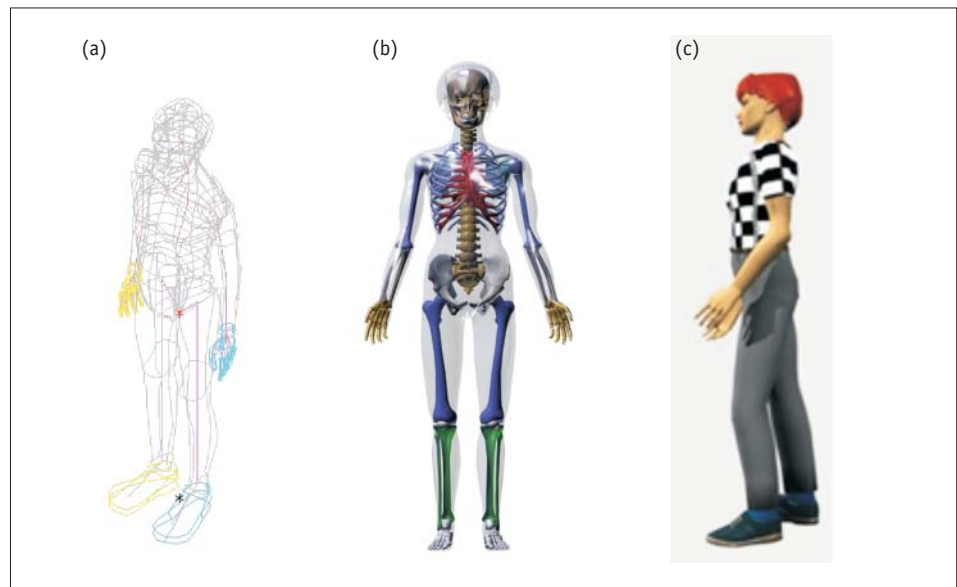


Fig. 2. Surgeon’s anthropometrical features: for man a) and woman b).

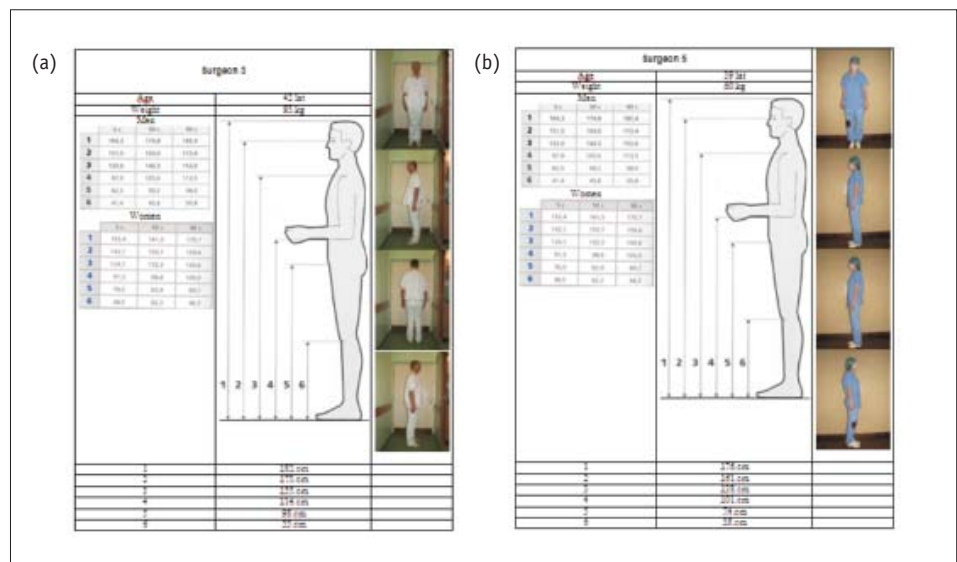
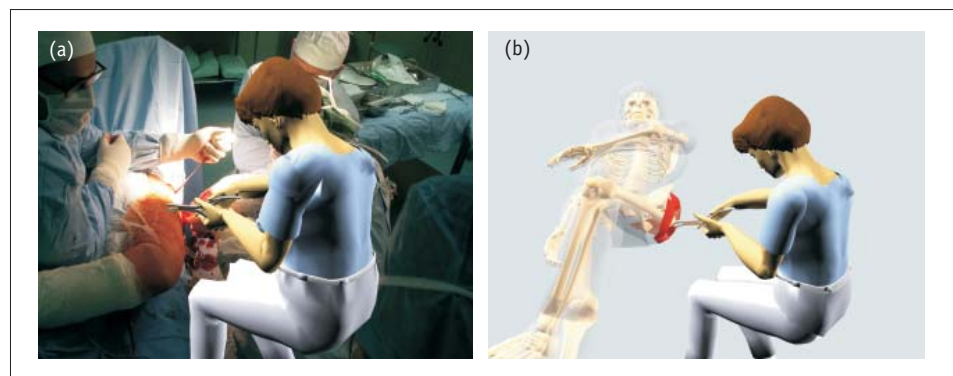


Fig. 3. View of surgeon's position during "driving in" using Rasp Impactor



Fig. 4. Photo-recording of activity realized in a sitting position during the surgical operation when using Rongeur a), and computer models of the surgeon, patient and tool b)



In this case both: surgeon and patient are super – positioned by the human body models, Fig. 4b). Photo-recording of activity realized in a sitting position during the surgical operation when using Rongeur tool has been shown.

4.4. ERGONOMICS ANALYSIS

Two methods were used for ergonomics analysis. In ErgoMAX program static discomfort coefficient, which is a measure of the locomotion system load, calculated on the basis of three factors [1]: torque in joints, range of joint movement loss ability, movement resistance in joints, is determined for the given body posture.

Results of static discomfort coefficient calculations for the given position of body segments are expressed in percent and are presented in a form of bar charts in which:

- green colour means the value below 75% and lack of hazards to locomotive system,
- yellow colour means the value between 75% - 90% and it says that overload of locomotive system is possible if the method of work will not change,
- red colour means the value above 90% and the necessity of change of working method due to overload of locomotive system.

This method is used for comparison of body postures and for their classification as regards approximate load in joints.

Ergonomics analyses were carried out using 3D SSPP software (3 Dimensional Static Strength Prediction Program), developed at the Michigan University, [4]. The method of load assessment of the locomotive system used in the 3D SSPP software belongs to so called biomechanical methods [8] and it is based on NIOSH (National Institute of Occupational Safety and Health) algorithm. The algorithm has been developed for manual work in a standing position associated with lifting activities, pulling and pushing of loads. In the 3D SSPP software the simplified human anthropometrical model is defined by angles in joints [4]. For that purpose the angles read from the models made in ErgoMAX were used in the projects, Fig. 4a. This is the software that enables the determination of the load to the skeletal system that results from the realized work. The software is designed to calculate the forces and torques that act on the selected joints and that result from the following:

- body segments weight,
- realized work,

- exerted forces,
- holding the weight.

The results are presented in a form of diagrams placed in an Analysis Summary reporting window, Fig. 5. Indicators that facilitate the interpretation of biomechanical calculation results are determined in that software. The Percent Capable PC [%] is the percentage of the population with the strength capability to generate a moment larger than the resultant moment. It is calculated as a function of the resultant moment, mean strength, and standard deviation of the mean strength using a normal distribution. For that indicator the software determines limiting values: SDL and SUL. SDL (Strength Design Limit) indicator informs when the population capable to transfer calculated torques is fewer than 99% for men and 75 % for women. SUL (Strength Upper Limit) indicates that this population is below 25% in case of men and 1% in case of women. The lower percentage values, the higher is a load to the locomotion system. Values between SDL and SUL are the indicator for managing board to take measures which should improve work conditions.

Required Coefficient of Ground Friction is useful in analyzing pushing and pulling tasks for risk of falls due to slippage, this is the coefficient of static friction between

the floor and the shoe soles required to prevent slippage given this specific combination of posture and load.

Use of both programs will be presented on the examples presented in point 2.3 of this paper.

Ergonomics Analysis for the pair: Hammer & Rasp Impactor

During driving in and driving out of Rasp Impactor awkward positions, which some selected cases were included to the ergonomics analysis were identified.

The following body posture is the subject of analysis (Fig. 6):

- bended back,
- trunk inclined to right side and slightly twisted,
- legs deeply bended,
- right leg significantly put forward and left one backwards,
- right hand holds the hammer and hits the tool.

Assessment of the locomotion system load is given in Fig. 7.

For the following joints: hip, knee, ankles and trunk, SDL coefficient appeared, what means the intensified load of those joints. The load amount in a lower part of spine is over 2000N. Back inclination and twisting decide about that amount. In case when the back is only bended forward, without twisting and side inclination, the load reduces to about 1700 N, when the back is straight the load reduces to about 550N.

Ergonomics Analysis for the Rongeur

The following arrangements of locomotion system segments were identified:

- both arms slightly lifted up,
- a left hand holding the tool, forearm lifted up, hand twisted,
- a right arm and forearm raised to the shoulder level, hand is bended and twisted.

In the analysis a special attention was paid to a method of tool holding, which computer model was shown in few shots in Fig. 8a.

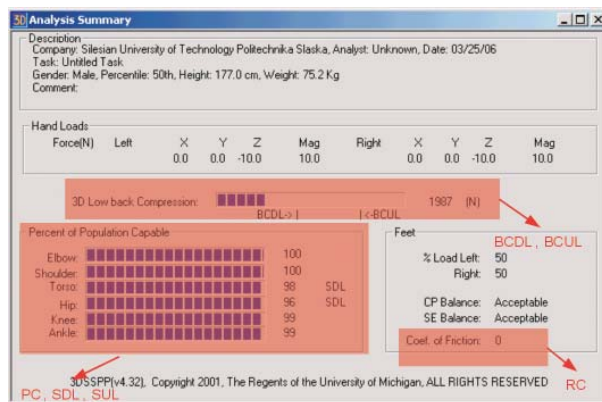


Fig. 5. Indicators of work arduousness in the 3D SSPP software

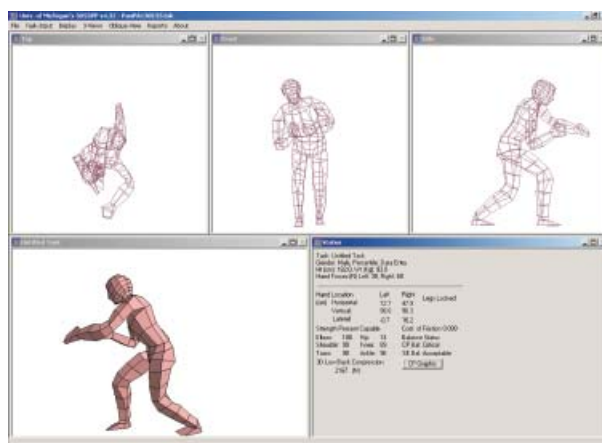


Fig. 6. Computer model of the surgeon posture which he took during the Rasp Impactor (a tool) driving in made in the 3D SSPP software

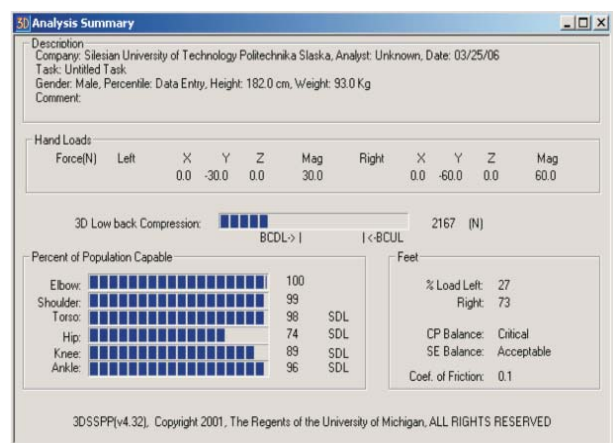


Fig. 7. Assessment of the locomotion system load for the posture which the surgeon taken during the Rasp Impactor driving in.

During activity realized in the sitting position a hand, in which the tool is held, is lifted higher comparing to the standing position. It causes an awkward method for the surgeon to realize operational activities, what in connection with twisting each segment of upper limbs can cause pain (see 4.1). First of all it results from high values of depletion of moving ability in joints. The static discomfort coefficient shown in Fig. 8b confirms the arduousness of analyzed activity.

4.5. ANALYSIS OF DESIGN FEATURES OF TOOLS

Analysis of design features of tools was made using the FEM method [18]. In that method, the geometric model of the analyzed tool is covered by a meshing consisting of big number of small elements (finite elements). Under the impact of external load the finite elements meshing is deformed. But the meshing elements still adhere to each other. The deformed meshing is the image and a measure of stresses, which are in the tested tool. The tool keeps its useful properties under a condition that neither stresses nor deformations in a tool material exceeded the specified limitations. Also vibrations caused by the load of dynamic character can not exceed amounts dangerous for health. Further discusses are carried out for the pair Rasp Impactor – Hammer. In Fig. 9a) calculation model, which apart the analyzed pair includes the model of femoral bone can be seen. Geometric form of tools and their dimensions were given by the producers. Material properties of tools were taken from the work [15]. The geometrical form and dimensions of femoral bone of white female, age 41-50, are taken from [5], Fig. 9b). Mechanical properties of bone are taken from [2].

Basing on video recording, the linear velocity of the hammer end was determined, and it is about 1.5 m/s. The hammer rotation centre, is marked in the drawing. Value

of the initial rotation velocity equals 7.28 rad/s, which responds to the determined linear velocity of hammer's end. Between the rasp and the femur there is an initial contact defined. In the analytical model two models of the material were needed: nonlinear elasto – plastic for the steel and orthotropic elastic material for the cortical bone.

In Fig. 10 results obtained from FEM dynamical analysis were given. The following can be seen:

- map of reduced stresses, Fig. 10a),
- diagram of contact force between hammer and the Rasp Impactor during “driving in”, using of the Rasp Impactor – Hammer, Fig. 10b),
- diagram of acceleration in a direction perpendicular to the surface of grasping part of vibrating Rasp Impactor, Fig. 10c).

Impact analysis shows, that acceleration at places of Rasp Impactor holders are higher than accelerations in the hammer's holder. In both cases the accelerations may cause a pain, what has been indicated in the questionnaire forms. Calculated values of the contact force during driving out are close to the values obtained during experimental measurements. Less conformity in the value of contact forces was obtained in case of driving in. It results from different form of deformations in an analytical model of the Rasp Impactor.

5. IMPROVEMENT OF TOOLS

5.1. OPTIMIZATION OF TOOLS GEOMETRIC FORM

Reduction of a tool weight, which do not reduce its stiffness and do not increase vibrations, is one of the form of tool improvement. Searching for proper geometric form is aided by the FEM method. Maximal contact force between Hammer and Rasp Impactor, determined in the

Fig. 8. Assessment of upper limbs load as the measure of coefficient of static discomfort for activity realized in a sitting position

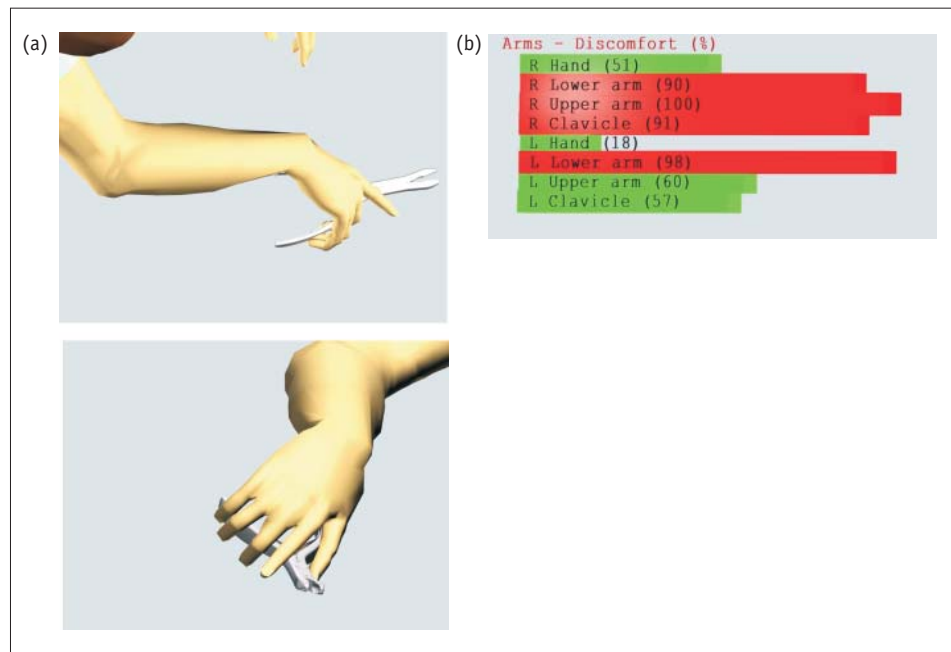


Fig. 9. Calculation model during “driving in” using pair Rasp Impactor – Hammer

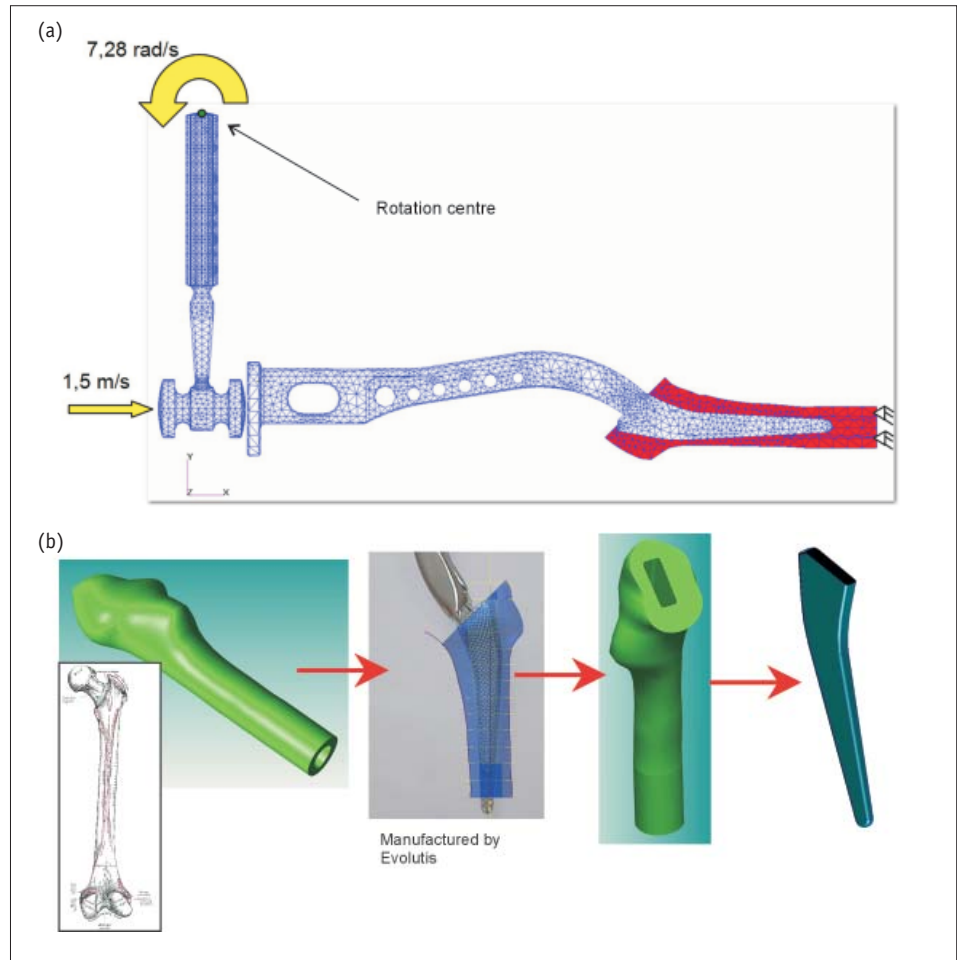
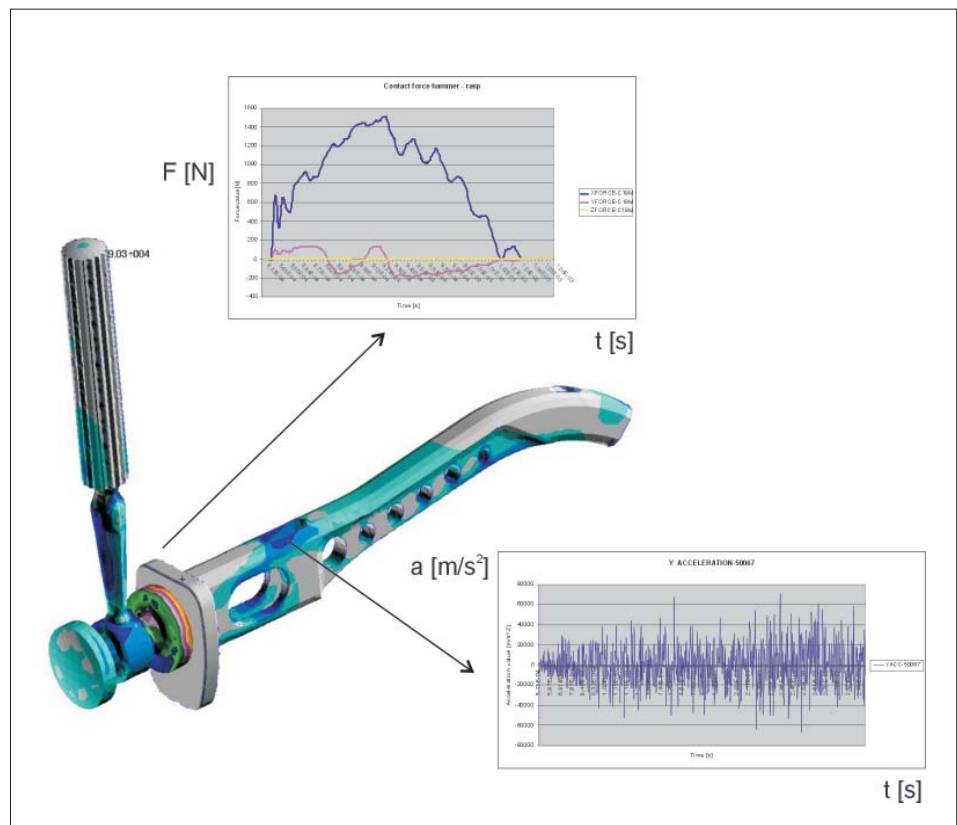


Fig. 10. Results of the FEM analyses



previous FEM analyses, is applied to Rasp Impactor model. This time we assume that the force is acting on the tool in a static way. Besides, we assume that elements, in which reduced stresses are below the given value has to be removed from the finite elements meshing. In Fig. 11 geometric forms, in which elements of reduced stresses below 5 MPa (Fig. 11a) and below 10 MPa (Fig. 11b) were removed, were given. Due to manufacturing possibilities, part of the tool of removed material was divided by ribs. View of the modified tool is in (Fig. 11 c). Mass of the rasp impactor was reduced by 30% in relation to the primary version.

Modified Rasp Impactor once again underwent FEM analysis. In Fig. 12 map of reduced stresses for modified Rasp Impactor was given. The active load was equal to a contact force between Hammer and Rasp Impactor, which was determined in dynamic analysis (see item 4.5).

New rasp impactor has a greater stiffness, what results in increase of dynamic forces, during placing the endo – prosthesis in a bone at the same speed of the hammer Fig. 12a). To reduce effects of dynamic action of the tool on surgeon’s hand, new Rasp Impactor should be extended by the grip plate, made of non metallic material, Fig. 12b).

The following conclusions were drawn on the basis numerical analyses:

- asymmetric load has no impact on increase of the Rasp Impactor effort,
- reduced masses of the Rasp Impactor improve its functionality for the ergonomic criterion.

5.2. RAPID PROTOTYPING

Main objective was a detection of necessary modifications in the design of the instruments before starting with pre-industrial manufacturing. For that purpose “hard copies” of computer models of surgical tools were made using Rapid Prototyping technology. Computer models are transferred into material elements made of thermo-setting resins in special numerically controlled devices [3]. Tool prototypes are made in a natural size and they have all components together with their connections, Fig. 13. Thus, they enable to carry out assessment from ergonomics and manufacturing points of view.

Tool prototype does not enable to assess the properties of material from which a tool will be made as well as to assess the behavior of the material during operation. However it is possible to assess the functionality of modified tools.

5.3. ASSESSMENT OF MATERIAL PROTOTYPES OF MODIFIED TOOLS

Ergonomics analyses were carried out both experimentally and in a virtual environment. Experimental tests

Fig. 11. Removal of finite elements in which reduced stress was below a) 5 MPa, b) 10 MPa. Modified version of the tool c)

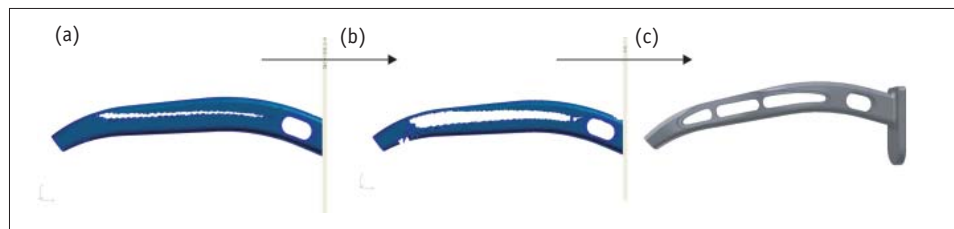


Fig. 12. FEM analysis of modified tool a) and design changes of grasping part b)

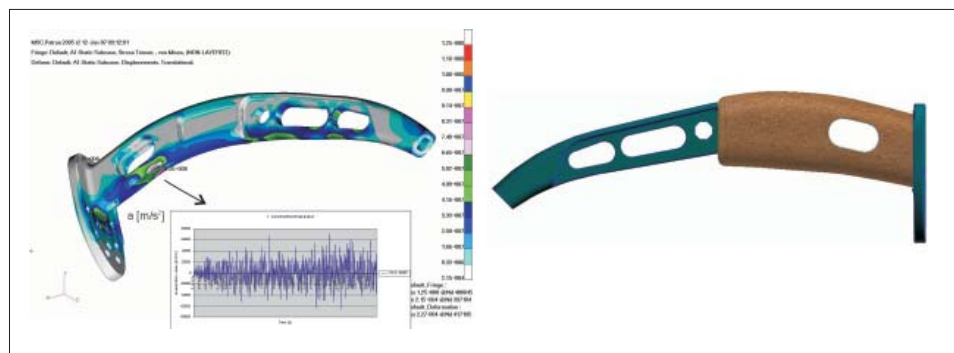


Fig. 13. Physical prototype of the Rasp Impactor made in the Rapid Prototyping technology



were conducted with using a synthetic model of lower limb. Conditions, in which the tests were carried out were reconstructed in a virtual environment.

The results of analysis made in a computer environment indicate for significant improvement of work comfort of the surgeon when using new Rasp Impactor, Fig. 14. In all spine vertebrae the static discomfort coefficients were within the permissible range.

Functionality of modified tools has been assessed by an assessing group consisting of surgeons (see point 1). Only external geometric features, especially of grasping part were assessed. Attention has been drawn to Comfortable handle Longitudinal curved shape (avoids the contact with major trochanter).

Easy assembly of the Rasp Impactor and the Rasp in operation field, Fig. 15. (easy maintenance, what is an unquestionable advantage).

Possibility of fixing a holder, which maintains proper rotation during driving the rasp into femur, is indispensable (Tommy bar (transversal bar)). The holder should be fitted with thread joint. Tommy bar should be

massive (diameter at least 20mm) and it should be placed in the area of grasping part. Two types of Rasp Impactors should be used for driving in, to enable approaching to the patient both from the right and left sides.

6. CONCLUSIONS

Nowadays, the SMEs use to follow the trend opened by multinational companies and they concentrate their efforts in what they are more competitive. For a single SME is very difficult to innovate due to the lack of resources and personnel dedicated to R&D activities. This can be solved by collaborating with RTD Centers that can support and transfer knowledge to SMEs thanks to their facilities and high skilled personnel. To attack so huge market by on single SME is not feasible. Only the establishment of cooperation with other companies can guarantee a prominent position and to reach greater market share avoiding isolated national efforts.

A project like this is not affordable by one single SME because it requires top skills of both different knowled-

Fig. 14. Body position investigations when using modified Rasp Impactor a), static discomfort coefficient for the spine joints b)

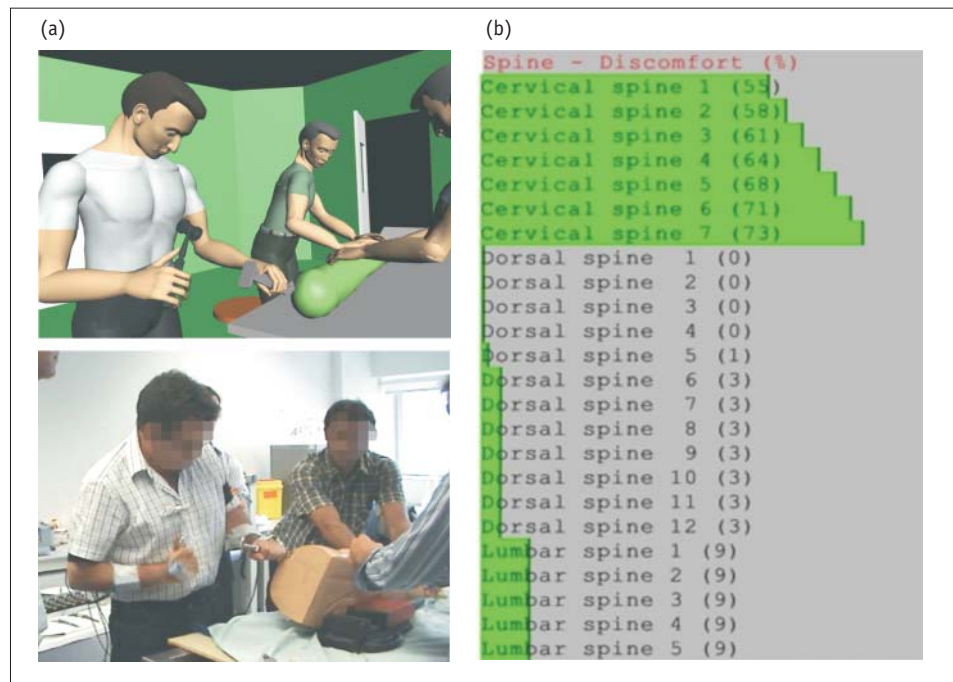
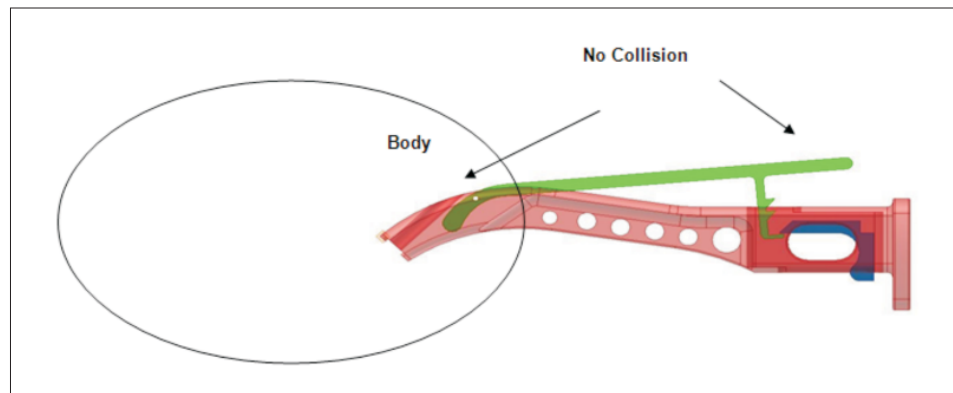


Fig. 15. Modified tool: easy assembly of the Rasp Impactor and lack of collision in operation field



ge areas biomechanics and ergonomics, and cooperation between different sectors like hip implant industry, surgical instruments manufacturers, and orthopedic hip surgeons, which are complementary. Information flow between surgeons and engineers was identified. The designing environment of surgical tools is geographical dispersed and diversified from competence point of view: surgeons, SMEs Engineers (designers, manufacturing engineers, biomaterial engineers), RTD Researchers (ergonomics, analytics) During the project an collaborative design mode of surgical tools was established. The next step is an participation design mode with direct an

online collaboration of all participants of designing process. Increasing complexity of tools needs new knowledge how to operate with them and maintain them. It is to consider to develop and disseminate an Knowledge Repository for surgeons and nurses, using the knowledge generated in the project.

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