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**COOP-CT-2005-017806**

**ENHIP**

**ERGONOMIC INSTRUMENTS DEVELOPMENT FOR HIP SURGERY  
AN INNOVATIVE APPROACH ON ORTHOPAEDIC IMPLANTS  
DESIGN**

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Instrument: Co-operative Research Project.

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**PUBLISHABLE FINAL ACTIVITY REPORT**

**WP5\_075\_TEC\_IBV\_FIN\_PUBLISHABLE\_REPORT**

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Project coordinator name: Carlos Atienza

Project coordinator organisation name: IBV

Revision: Final



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## 1. PROJECT EXECUTION

Nowadays surgical procedures for implanting hip prostheses are going from traditional protocols, where instrumentation and product design provoke an important time and effort to surgeons in operating theatre, to a new scenario where minimally invasive surgery is substituting progressively old techniques. In both cases designs of instruments are relevant to simplify tasks to be done during the intervention as well as to improve working conditions of surgeons.

Nevertheless, although the great importance of instrumentation, low efforts have been devoted in the past to improve design of instruments, so surgeons are obliged to work with instruments which do not fulfil basic ergonomic criteria.

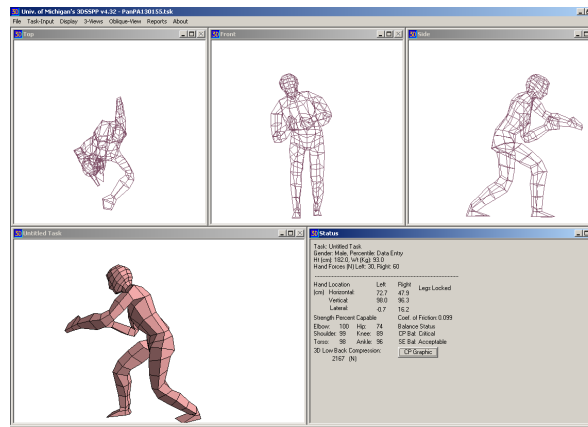


Computer models of the Rongeur tool holding method during a surgical operation in sitting position.

The aim of the project ENHIP was to design instruments for hip surgery under a new point of view, the ergonomics. These new designs were obtained thanks to a list of specifications that had been generated during the project. Therefore, the application of these design guidelines assure the accomplishment of basic ergonomics rules, and this way to improve working conditions of surgeons during the operation.

### The main objectives of ENHIP were:

- To develop new instruments for surgery that will provide an **important advantage to the implant manufacturers**, thanks to the added value obtained through the ergonomic features applied to them.
- To improve **surgeons' working conditions** by developing a new generation of instruments to be used in hip surgery. These instruments should be designed under ergonomics design criteria to improve current tools, which are based only on functionality and durability.
- **To improve patients' quality of life thanks to a reduction of the operation length** due to an easier use of instruments designed ergonomically.
- **To improve patients' quality of life by offering a new generation of MIS instruments to implant manufacturers** that will reduce postoperative problems of the patients.



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



To achieve these objectives it was necessary to create a consortium formed by partners who covered the industrial chain of innovative surgical instruments, RTD centres, SMEs, instruments distributors and hospitals.

**The consortium was formed by** six SMEs from five different countries (Spain, France, Portugal, Germany and United Kingdom), by two RTD centres from two countries (Spain and Poland), and by two hospitals (from Spain and Poland). The designed consortium covers accurately all the value chain which is necessary to fulfil successfully the project.

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- **End user:** HOSPITAL de SAGUNT (Spain), SILESIA (Poland).
- **Surgical implants and minimally invasive surgery:** LAFITT (Spain), EVOLUTIS (France), EROTHITAN (Germany).
- **Distribution of implants and instrumentation:** SALGADO (Portugal).
- **Biomaterials applicable to surgical instruments:** VBM (France).
- **Minimally invasive surgery instrumentation:** LANDMARK (United Kingdom).

In September 2007 project ENHIP finished its 24-months existence under the funding of European Commission. Next, [work performed and results achieved are described.](#)

First step to fulfil the objectives of this project was to gather all necessary information to understand the problems in surgical instruments related to ergonomics. After that, ergonomic and mechanical requirements were identified by means of different point of views:

- Surgeons opinion
- Analysis of current instruments
- Analysis of ergonomics during surgery

As a result of these studies generic ergonomic design guidelines were obtained. These general guidelines allowed generating specific ergonomic design guidelines for each instrument studied that were applied in order to redesign eight instruments for MIS and open surgery.

Instruments were modelled by means of 3D-CAD tools, they were analysed due to Finite Element Method and their weights were reduced thanks to optimization procedures. After that, stereolithography prototypes were manufactured; and finally, preindustrial pre-series of six of them were manufactured.

Assessment by ergonomics, mechanics, surgical and manufacturing point of view was carried out after each development stage. Meetings, questionnaires and workshops allowed the consortium to perform a continuous evaluation of the instruments in order to ensure that every subject was taken into account. Furthermore, a clinical assessment group was created during the project. This group was in charge of giving the clinical



information needed to generate the guidelines, performing clinical tests in operating theatre and laboratory and analyzing the features of the new instruments.

Finally, to ensure that new procedures for ergonomic design allow developing better instruments than current ones, an ergonomic validation of instruments pre-series was carried out. A new methodology of ergonomic validation, also generated during the project, concluded that new instruments improve the working conditions of surgeons during their surgical procedures.

Regarding the **expected impact** of the results obtained in the project, new instruments developed and knowledge generated will allow companies of the consortium to increase their market share. In fact, the SMEs enhanced their competitiveness because of the following reasons:

- An innovative design criteria was generated allowing SMEs to offer improved products, surgical instruments, to their potential clients.
- Partners worked together in order to obtain a unique result, the ergonomic instruments, that allowed them to establish transactional contacts with different European organisations. By means of these contacts SMEs involved in the project will be able to operate in the European market as a whole and have a global vision of the market.
- New generation of products was developed. Therefore, SMEs are pioneers in their sector by introducing new design concepts that will allow them to differentiate their instruments from the competitors.
- SMEs obtained a new methodology of developing surgical instruments. This knowledge involves skills from areas such as biomechanics, orthopaedic surgery, ergonomics and implant and prosthesis manufacturing that were studied deeply during the project.

For more information, go to

<http://www.enhip-project.net>





dissemination in the technical environment and among the enterprises. Of course, the dissemination of the results of the project has been and will be restricted to those results that are not confidential.

**In the first half of the project**, dissemination of the information about the project was limited to the distribution of publishable abstracts, as contractually required for EU RTD projects, in order to don't endanger the industrial interests of the industrial partners. Furthermore, an easy-to-use Internet Website was created.

Finally it was also designed a poster that was delivered to all partners in order to be used to promote the project during all congress, trade fairs and commercial exhibitions they attended.

**During the second half of the project**, the RTD performers have continued providing support in the preparation of general articles about the objectives of the ENHIP project, and working on the results achieved to be published in scientific magazines.

The project has been presented in different forums, as European congresses of the field and other forums related to orthopaedic surgery and joint biomechanics.

At the end of the project one workshop has been organized between Lafitt and IBV. In this congress (SECOT 2007) a selected panel of leader surgeons of different European hospitals from different countries have been introduced to the new ergonomics instruments. With this action, the project has been made more visible to the potential users outside the consortium.

During all duration of the project, the public side of the web site has been used as a dissemination platform, where all the public information coming from the project has been also accessible to third parties.

Besides these specific actions, the participation of the Information and Communication Area of IBV, as well as Office for Transfer of Technology of the centre has been essential to disseminate the project to general public and some specific groups (especially Medical Sector), taking advantage of their previous experience and contacts within press media.

Major dissemination activities developed are the following ones:

- More than 20 articles, press releases were published in mass media.
- Different articles and press releases were written and published in specialized journals in order to start exposing the product.
- Partners assisted to congresses, scientific meetings and oral communications (SOFCOT 2006 in France, SECOT 2006 in Spain, SOTOCV 2006 in SPAIN, SOFCOT 2007 in France, SECOT 2007 in Spain, Fair "Implants 2007" in France).

As a summary, dissemination activities were addressed to different purposes. RTD members prepared scientific papers in order to publish main knowledge and results obtained during the project. SMEs and distributors performed workshops with their commercial staff to teach them how to explain to their clients the innovative improvements incorporated to new instruments. Hospitals informed their surgeons about results of the project and benefits that these results can bring to their work. Posters, demonstrators and workshops were prepared to advertise the project during congresses to introduce the instruments to surgeons and commercial staff from SMEs companies, and finally, different papers were prepared in order to disseminate results of the project to the scientific community.