ORTHOSIM: the European Simulation Service Provider (SSP) for Orthopaedic Surgery

Alfonso OLTRA[1], Ana Cruz GARCÍA[1], Carlos M. ATIENZA[1], Rubén LAFUENTE[2], Marc CLIMENT[2], Ignacio BERMEJO[1], Jose Luis PERIS[1], Carolina ÁVILA[1] , Jaime PRAT[1]

[1]*Instituto de Biomecánica de Valencia, Universidad Politécnica de Valencia-Edificio 9C Camino de Vera s/n, Valencia, 46022, Spain*

Tel: +34963879160, Fax: +34963879169, Email: ana.cruz@ibv.upv.es

[2] *ADAPTING S.L., Cl. Nicolás Copérnico, 6 Valencia Parc Tecnologic, PATERNA, 46980, Spain*

Tel: + 34961318244, Fax: + 34961318246, Email: info@adapting.es

Abstract: The objective of this paper is to present a new service concept of Simulation Service Provider for orthopaedic surgery (ORTHOSIM), aimed at the health community and implant industry. ORTHOSIM service shall offer virtual analyses the implant behaviour after implantation in a customized implant-patient configuration. ORTHOSIM is based on a highly sophisticated human body Finite Element Model (FEM). FEM models offer the possibility to analyse the mechanical properties of implants and implant-human set. With this service the orthopaedic surgeons will accomplish a better preoperative planning and will reduce the failures risk due to the implants. The manufacturing companies will reduce manufacturing costs and will obtain more reliable implants. The Hospitals and health administrations will be interested in improving quality of health service. Finally, the research teams, who are owners of validated biomechanical models, will integrate their models within the service in order to make a rapid exploitation of their models.

1. Introduction

Each year more than 600.000 of knee, hip and spine surgical interventions that require surgical implants are performed in Europe. Each operation represents a mean expense of 15.000 € with an average expense per implant of 1.800 €. A significant amount of these interventions are re-operations needed to repair an unsatisfactory clinical result. A better pre-operation planning will reduce uncertainty and consequently the number of failures and related sanitary expenses at European scale. A considerable amount of them are due to failures that could be prevented with a better preoperative analysis such as the one proposed by ORTHOSIM.

Virtual modelling offers the possibility to analyse the mechanical properties of implants and implant-human system. These techniques permit to minimise technical failures due to inappropriate configurations through a better preoperative planning, and optimises design process of implants by reducing failure due to bad design, thus improving competitiveness of the European implant industries. There are many research teams in Europe that have validated Finite Element Method (FEM) models of different parts of the body that are only used for scientific purposes. This is a clear example of the European Paradox which 'ORTHOSIM' wants to reduce: excellence in research that is not used for economic or health purposes. ORTHOSIM is aimed to enlarge the service to any other human joint or

other spine section models. The platform is intended to host any new model by performing a small adaptation of the new model in order to connect it to the interface portal-user.

With this service, a surgeon or implant engineer can effectively call on the expertise of the best people in any field of orthopaedic surgery, where biomechanical simulation can offer new insights for patient care. It targets three basic stakeholders in the health sector:

- It offers to orthopaedic surgeons scientifically validated models for clinical simulation of customized cases.
- It offers to implant manufacturers a tool to evaluate new product concepts without costly procedures.
- It offers to students and researchers a relevant and accessible tool for learning and investigating.

ORTHOSIM service will meet actual and acknowledged existing demands as:

- The surgeons nowadays make preoperational planning using X-ray films or/and CT scan to identify injuries. If they are not experienced, they select the implant system and configuration recommended by the manufacturer. If the surgeon has experience, s/he selects the implant according to his/her experience, but with no objective biomechanical information about the behaviour of the assembly joint-implant.
- The manufacturing SMEs can generally only study the behaviour of the fixation systems by in vitro tests, at the final stage of the development. At this stage of product development, the introduction of variations is very costly.
- Existing FEM models require highly qualified staff to be used, and they are normally hosted in research centres, so that their use is restricted to a limited number of users and very rarely clinical users.

1. Objectives

The latter facts joined to life expectancy that has increased from 19% in 2000 to 24% in 2020 for people aged over 60 [1], has made implant manufacturing an area with major expectations to develop innovative products to enhance the human life quality and reduce risk failures.

Besides, the process of development of new implants is a slow process, due to the amount of tests required to check the proper behaviour of these implants. To verify the quality of the designs, the manufacturing companies must perform many laboratory tests to check the mechanical behaviour on physical prototypes as well as *in vitro* tests whose cost is very high. All this necessary experimentation slows the process of development of new implants and also increases their final cost.

The **objective** of this paper is to present a new telematic service concept: the **Simulation Service Provider** (SSP) for orthopaedic surgery (ORTHOSIM), mainly aimed at the **hospitals and health administrations**, the **orthopaedic surgeons** community, the **orthopaedic manufacturing companies** and biomechanical **research teams**.
The services provided by ORTHOSIM are:

1. **Simulation** services. The possibility of simulating a personalised instrumented human joint in different situations.
2. **Integration services** of existing simulation models. Biomechanical models can be integrated on the ORTHOSIM platform service to make them available for any user. The model has to follow an adaptation process before being integrated in the service.
3. **Promotional** services. Those industrial firms interested in promoting their products related to orthopaedic surgery or biomechanical simulation would find in ORTHOSIM a suitable environment to do it.

4. **Information** services. Creating a database of clinical cases accessible for any accredited user and a virtual community of high skilled professionals. The users will be able to acquire better knowledge and comprehension of the biomechanical behaviour of the instrumented human joints by simulating many configurations and conditions or by consulting the database or by communicating with a virtual community of highly specialised users.

2. Methodology and Technology Description

ORTHOSIM consists on the development of a Simulation Service Provider for orthopaedic surgery where simulation models are hosted linking orthopaedic surgeons and manufacturing companies with research teams who have developed the models.

ORTHOSIM is based on the developments from a prior IST Craft project called: DEVASPIM [8]. Mywebspine is a service platform that resulted from the DEVASPIM project. This service via internet is based on a highly sophisticated Finite Element Model (FEM) of the lumbar spine. The preliminary validation of the tool, including the user experience, has been performed at a rigorous scientific and technical level by surgeons and implant designers. ORTHOSIM is the next step of *Mywebspine* service, where the service has been evaluated by means of tests with the stakeholders related to the service, and has been upgraded including more implants and models.

A user – a surgeon planning an operation, or an engineer working for an implant manufacturer – calls up the service website and orders a simulation service from among those models available. He or she enters the appropriate input data (information about the patient and the surgical technique proposed) in the user-friendly interface.

The **SSP** connects to a simulation-model server and initiates the simulation computation using a customised and validated model (Figure 1). Once the job is complete, the SSP uploads the resulting report to the portal and notifies the user. For the surgeon, the output indicates whether the proposed technique and instrumentation are likely to be effective and suggests improvements if not. For the implant designer, the simulation replaces what would otherwise be a much more time-consuming laboratory experiment requiring preparation and testing of real implant models.

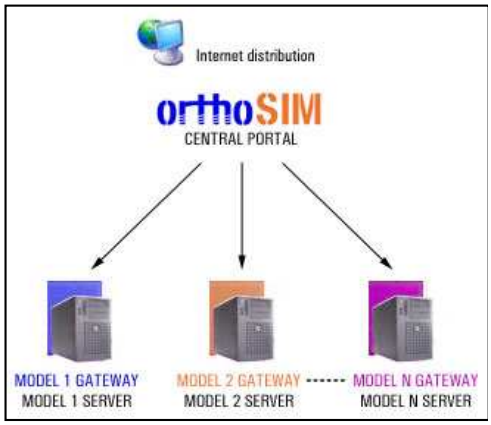

Figure 1. ORTHOSIM Simulation-models.

Hence, the generic characteristics of the ‘e-health’ oriented service platform may be used not only for lumbar spine implants, but also for other types of implants where preoperative simulation and planning may improve the clinical results. It will be a matter of business excellence of the future SSP to engage new validated and sound models (for instance, by sharing exploitation benefits with the model’s owner), which can improve the appeal and usefulness of the overall service for the customer targets.

The **main elements of the portal’s** architecture are the following:

1. Web server. Located at a remote ISP. It hosts all web pages visited by the end users, the application and the central database.

2. Simulation gateway. This server controls and triggers the technical simulation cycle, acting as an interface between the web server and the ANSYS simulation machine. It is located within the local area network of research center.

3. The server that hosts the FEM simulation software together with all necessary biomechanical modelling tools. It provides the results in form of text and/or image files.

The simulation process will be conducted in six consecutive and iterative steps.

1. The simulation gateway detects a pending simulation job at the web server's input tray.

2. The simulation gateway downloads the configuration file and any other relevant information for launching the simulation.

3. The simulation gateway provides the ANSYS machine with all necessary data and triggers the start of simulation.

4. The ANSYS machine finishes the simulation and downloads the result files and any other relevant information into an output tray within the simulation gateway.

5. The simulation gateway (a) detects the results and (b) transfers them to the web server, notifying the end of the simulation job.

6. Eventually, the simulation gateway asks the portal to notify the client of the availability of the results.

Hence:

- Step 1 has to verify new simulations pending so will use TCP/IP SQL-SERVER port 1433 to verify if there are simulations.
- Step 2 has to download the XML file containing the simulation. It can be done using port 21 or 80, and probably port 1433 to update the state of the simulation from "pending" to "in process".
- Step 5 has to upload the results of the simulation in XML through ports 21 or 80, update the state and some database data (1433) and upload some files.

No specific requirements are necessary for the simulation gateway server except full access to Internet in all ports, full access to ANSYS server (connected in the same LAN) and NAT access from the outside world (VNC).

The **FEM models** offer the possibility to analyse the mechanical properties of implants and the implant-human configuration [2], [3], [4]. These techniques permit to optimise the design process of implants by reducing failure due to bad design, thus improving competitiveness of the European implant industries as well [5], [7]. There are several research teams in Europe that have validated FEM models of different parts of the body that are, at present, only used for scientific purposes. This is a clear example of the European Paradox, which 'ORTHOSIM' wants to reduce. There are many software vendors which provide generic simulation packages for service providers usually for traditional industries (Arena, Witness, ANSYS, Promodel, Simul8, Simprocess, etc). The application of simulation to orthopaedics or biomechanics in general is limited to demonstrators for students or junior surgeons at universities. We could not find commercial equivalents to ORTHOSIM, the simulation service provider whose aim is not excellence in computing methods, but in the application of validated and renowned finite element method models to solve concrete orthopaedic problems.

Although there are currently different simulation models, none of them has been provided to the health community as an open consultation system for surgeons or manufacturers. The models currently available require the individual implementation of

each model's variations and instrumentation sets, and therefore the costs and expenses make their application unadapted to a reliable and rapid routine use for the above mentioned purposes (Figure 2).

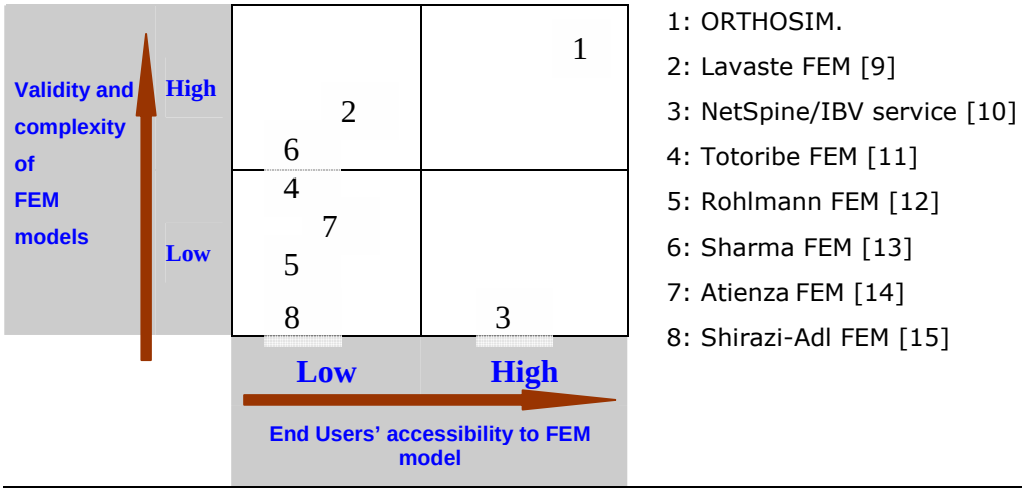

Figure 2. Relation between complexity and end users' accessibility to FEM models.

3. Results

After having launched the simulation, this will be treated as a new request by the model. This request will stand "in queue" until the model is free to handle the next request .The request will be "simulating" until the calculation is finished and afterwards the results will be transferred to the portal. These are the steps afterwards:

1. Receive email notification

Depending upon the model server conditions and the input configuration chosen, about 30-60 minutes after having launched the simulation, the user will receive an e-mail indicating that the process has been completed with success (or aborted due to a failure).

2. View output report

The output report obtained from the simulation will be displayed to the user containing three parts:

2.1. Input data summary: Showing the main input data inserted by the user for the simulation and also the obtained 3D reconstruction of the lumbar spine of the patient from the digitalized X-rays. With this geometric reconstruction and the input data it was obtained the personalised FEM model.

2.2. Motion and loads in the intervertebral discs of the FEM model:

2.2.1. Sagittal rotation of each of the intervertebral levels. It is shown the rotation, in degrees, for a sagittal bending motion of the number spine, of each of the intervertebral levels (purple bars) compared with the reference values (blue bars).

2.2.2. Maximal equivalent von Mises stress in the disc matrix. It is shown the maximal stress, in MPa, in each of the Intervertebral levels of the model (purple bars) compared with the reference values (blue bars).

2.2.3. Maximal force in the disc fibres. It is shown the maximal force, in MPa, in the Intervertebral levels of the model (purple bars) compared with the reference values (blue bars).

2.3. Stress distribution on the screws of the FEM model: As results, it is obtained three graphs per instrumented level concerning the stress distribution on the screws:

2.3.1. Axial force of the screw along the screw length. The axial load is the main responsible of the pull-out effect.

2.3.2. Shear force of the screw along the screw length. The shear load is the main responsible of the loosening effect.

2.3.3. Bending moment of the screw along the screw length. The bending moment is the main responsible of the breakage of the screw.

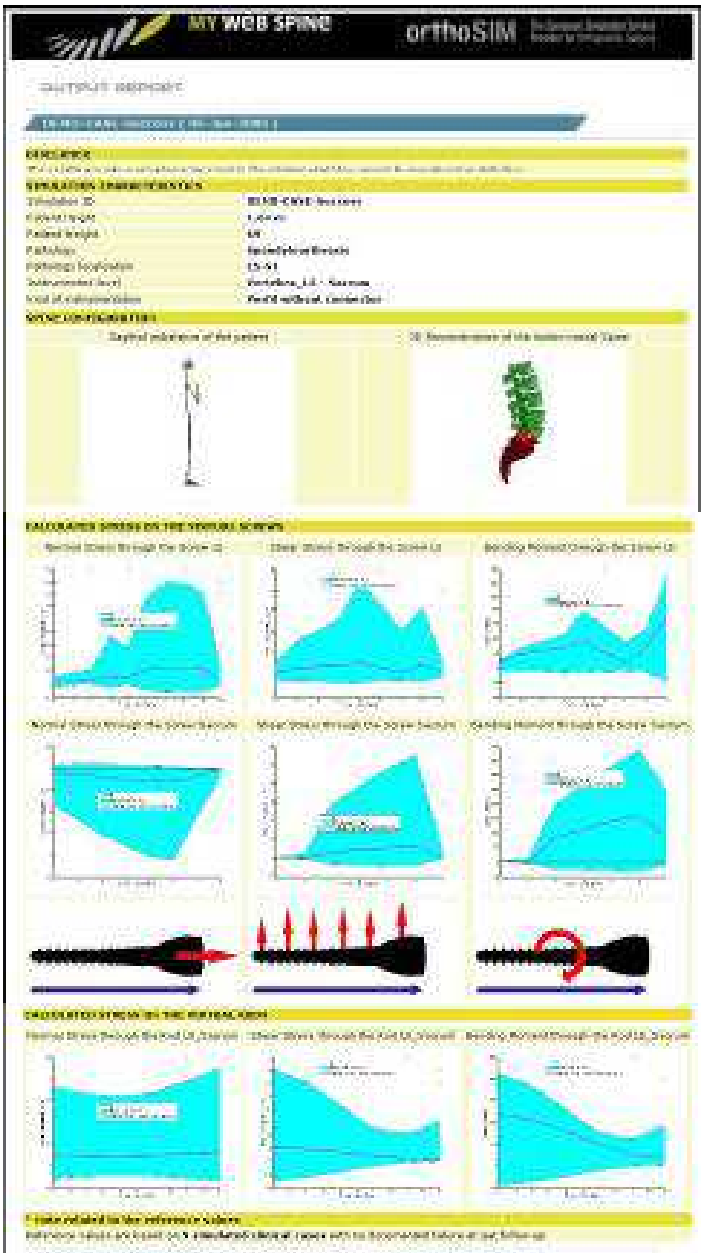

Figure 3. Simulation results.

For each of the graphs (Figure 3), it can be observed a blue zone belonging to the reference values obtained from the simulation of those clinical cases with a successful evolution at last follow-up. These reference values are continuously recalculated as new cases are provided to the model owners, which assure the precision of the tool.

4. Business Benefits

The ORTHOSIM service will partner with implant manufacturers and resellers, in order to perform a biomechanical model of their product catalogue and a technical setup of the portal prior to enabling these products for simulation.

The advantages of delivering “simulation” as a type of “application service provider” (ASP) approach are the same of a typical ASP, which are:

- The centralization of functional resources, databases and know-how.
- The scale effect, which permits to deliver quality services to a broader audience.

- The simplicity of utilization and access for users (without the need of acquiring licences or maintaining software).
- The pay-per-use approach, which gives the users the option to pay only for what they "consume" as a service.
- The modularity of this approach, which enables the ASP to offer new service packages, without changing the way of interfacing with the application.

The income model for sustaining the service is based on three major sources:

1. The simulation service, aimed at two markets (surgeons and implant designers)
2. The inclusion of new products, which requires biomechanical modelling and inclusion of technical data into the portal's catalogue.
3. Information services, aimed at exploiting the valuable database, and marketing services, such as promotion of products, banners, recommendations, etc.

For payment, the service will be based on a credit system. Credits can be bought on-line by any user or "sponsored" into a user's account by a registered company ("point injection"). So any user will have a credit account where all credit transfers are registered.

Therefore, credits can be either bought, or obtained by asking a sponsor to provide them. Sponsors will have their own administration panel, in which all credit transfers and reports of activity will be displayed. In this respect, two alternatives are possible for clinical simulation:

1. The surgeon can only choose products of one and the same sponsor.
2. The surgeon is free to compare implants from different manufacturers.

A last option can be devised:

The surgeon is free to compare implants from different manufacturers if s/he (or his/her hospital) has paid the points for it and doesn't use sponsored points.

After this process, the partners of ORTHOSIM will receive a specific amount of sponsoring credits that can be employed by them to sponsor some users or to provide an added value to their customers.

Furthermore, partner companies will obtain a special password to manage the products displayed at the simulation portal and make them available for simulation. These companies will have access to a sponsor credit administration, in order to distribute their credits among their customers.

5. Conclusions

There are some research teams in the EU and worldwide that have validated and customised models of different parts of the body. Nevertheless, presently they are only used for scientific purposes. This is a clear example of the European Paradox, which ORTHOSIM wants to reduce: excellence in research that is not used for economic or social helpful purposes.

ORTHOSIM service is now under market validation. The success of this endeavour is based on the possibility to measure and certify the effectiveness of simulations in reducing uncertainty and improving the quality of surgery interventions. By determining the extent of such gains for each of the available models, both savings for the health administrations

(public and private), as well as advantages for the patient treatment will be demonstrated. In fact, continuous scientific validation of each model together with adequate dissemination of these results to professional associations, private hospital consortia and public health authorities are key success factors of the ORTHOSIM service. The underlined criteria will be used to rate the success of the services. Other criteria of success of this service are related to the consortium's ability to cope with the following issues:

- Inclination / barriers of identified purchasers to pay for the services.
- Barriers for the users to use the services at a routine basis.
- Inclination/ barriers of owners of new models to comply with and admit the certification process of ORTHOSIM.
- Diversity in the relationships between market stakeholders in the different countries where market validation is to be conducted.

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