The concept of the information system for managing business processes of designing and manufacturing of osteofixation material

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Abstract— **One of the characteristics of modern production is adapting products to specific customer requirements. This principle is applied in the industry for some time, but this is not the case in medicine. The idea behind the information system described in this paper is to support, improve and accelerate manufacturing of medical supplies, which are adapted to the patients (customers). This IS will be applied in process of design and manufacturing of osteofixation material, in order to obtain high-quality products customized to the individual needs of patients. The MD system for business process management, developed at the Faculty of Mechanical Engineering, will be used as a tool for the implementation and integration of the various activities in this processes.**

I. INTRODUCTION

The project VIHOS (Virtual human osteoarticular system and its application in preclinical and clinical practice) [1] is focused on developing various tools that ought to help doctors and engineers in specific segments of their work. The project deals with the development of geometrical and simulation models of human bones, internal and external fixators and the scaffolds. Also, project addresses development of mathematical parametric models that, based on different types of radiology images which come from doctors, generate the aforementioned models. Developing software which can be used as assistance with planning orthopedic operations is also one of project's goals.

These tools are in fact independent software modules, often developed by using different software packages or in different programming languages.

One part of the project mentioned above refers to creation of the production environment which will enable mentioned services to be used and contribute to improving the quality of services which are offered in orthopedics.

Due to variety of applied techniques and tools, the main problem with defining information system which would try to automate this process is integration of different software solutions.

By analyzing researches related to integration of information systems used in medical facilities and enterprises which manufacture medical equipment, we realized that there are very few papers dealing with this subject.

When talking about use of information systems in medicine, it's mainly referred to Health IS. Health Information System (HIS) are dealing with processing data, information and knowledge in health care environments [2].

These systems deal with information flow in medical facilities, but they are rarely connected to information systems of companies that make equipment used in hospitals.

In [3], for example, is described integration in medicine manufacturing enterprises. They recommend use of SOA and RFID integration technologies.

Some authors are trying to apply Supply chain management technologies in health care [4]. Those authors emphasize the fact that supply chain management in a health care setting is characterized by some unique features, which make it difficult to transfer knowledge from the industrial sector to a health care sector in a direct way. The authors conclude that existing concepts, models and supply chain practices can be extended to supply chain management in health services and existing research underpins the assumption that the health sector can benefit from the lessons learned in the industrial sector.

In this paper, we described integration of parts of information system in hospital (orthopedical clinic) and enterprise(s) that manufacture osteofixation material.

Because of its flexibility, we chose Business Process Management System technology (BPMS) to be the tool for integration [5].

The flexibility which BPMS offer can be noticed in several aspects. These systems provide a very simple way of creating business process model, which is later used to execute particular instances. On that occasion there is no need for any coding, so even the person without any programming experience is able to define and change the model.

The activities which are executed within process instance can be automatic and manual. Automatic activities are those that BPMS automatically executes by calling third-party software modules, while manual activities are executed by people (process participants).

The processes referred to in this particular case use both automatic and manual activities. So far we have automated parts of process for which developed software exists (such as generating geometrical models of human bones based on radiology images coming from hospital), while manual activities will be used for those parts of process that are not yet automated.

BPMS – MD is used for executing and monitoring the activities of this process.

II. BUSINESS PROCESS MANAGEMENT SYSTEM MD

Business Process Management System MD is developed at the Faculty of Mechanical Engineering in Nis. Architecture of this system is shown in figure 1.

In MD WfMS, workflows are defined by a process manager, i.e. the manager who is responsible for planning and managing the process. Workflows are defined by a person who is in charge of them, usually a business process manager i.e. the manager who is responsible for planning and managing the process. According to that definition, the system administrator with the assistance of

an editor enters the process model. If the structure of the organization allows that, it is possible for the process manager to enter the process definitions himself. The definition is entered by means of graphic process editor [6].

This system is not developed from scratch. The existing system Enhydra Shark was used as a system core, and it was later extended with elements related to artificial intelligence. That means that the system is connected to expert system in which is possible to define the rules which will be used for exception handling. We use expert system created via JESS expert system shell [7]. This is the Java rule based system, created in Sandia National Laboratories, from Livermore, California.
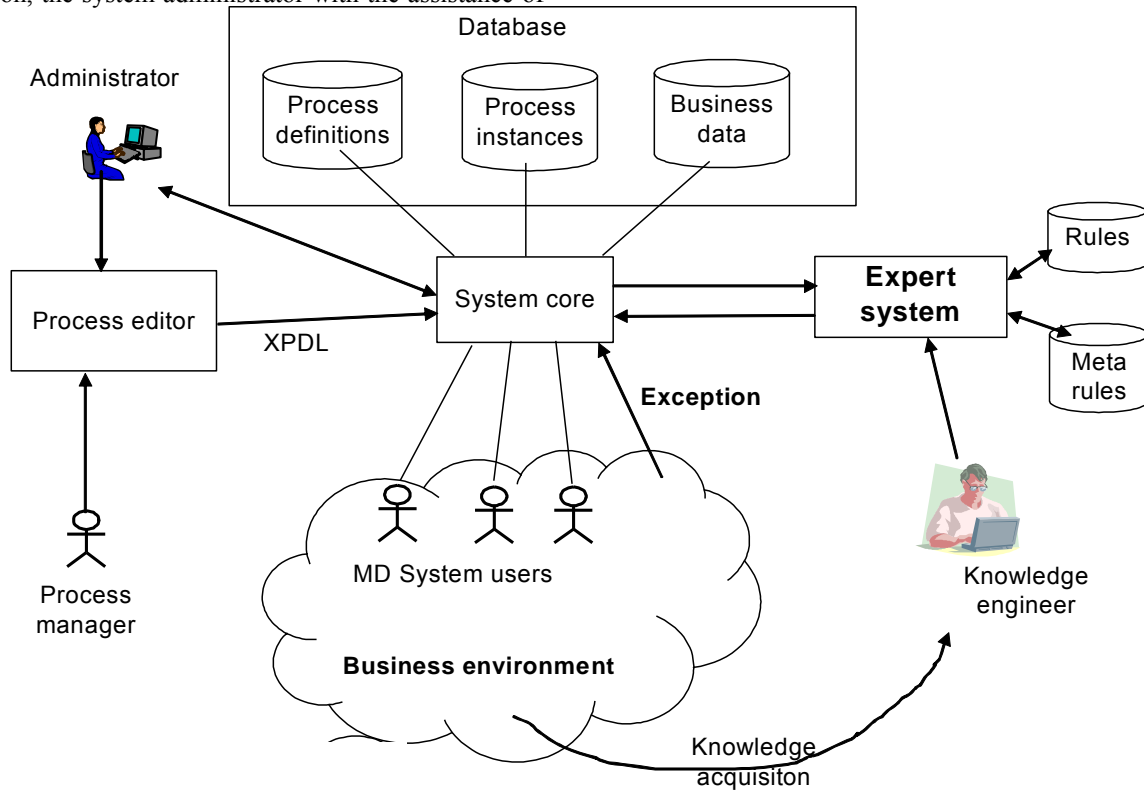

Fig. 1. MD BPMS architecture

III. THE PROCESS OF DESIGNING AND MANUFACTURING OSTEOFIXATION MATERIAL

The information system described here should support creation of osteofixation material and its application to the patient. Osteofixation material is a term that typically refers to an assembly which consists of fixator, scaffold and/or the graft. When the bone suffers less mechanical load, the fixator isn't needed.

In this scenario, the owner of the automating process is a fictional company, whose mission is to deliver the final product (osteofixation material) to the doctors.

Depending on the type of the patient's injury, there is a possibility of using osteofixation material which is standardized (doctor only takes the aids that are already in stock) or it can happen that the injury is somehow specific, in which case is needed to adapt aids to the patient.

In cases when it's necessary to adapt, information system speeds up the whole process of designing and developing tools, and it's also responsible for achieving adequate quality. That can be done by arranging the whole process, automating as many activities as possible and by using knowledge management tools.

Depending on the type of the fracture, doctors and engineers have to deal with many problems. One of the possibilities is that the patient is missing a part of a bone. If the missing part is large, it must be made for the patient by reserve engineering and embedded. If the missing part is smaller, a scaffold is used to enable the bone to regenerate.

In case that it's a fracture at which there are no missing parts, then the goal of this process is to make a fixator which will be adapted to patient's needs (this is the reason for starting the process).

The processes which we plan to define and follow through the information system will consist of the activities shown in figure 2.

As already mentioned, the activities in process can be automatic or manual. Processes that only have automatic activities are very rare and those are mainly cases when the BPMS is used for integration of computer applications, in order to create a new one.

Real processes consist of both manual and automatic activities, and the process described here is like that. Some of the listed activities are realized as manual. These are the activities for which appropriate software doesn't exist yet. There are also automated activities, such as activity Creation of cloud of points, when the corresponding algorithm, that is able to define how the bone looks based on radiology image, is called.

The process that we plan to define and monitor using information system consists of the numerous activities.

After reviewing the patient's condition, consilium of surgeons, based on radiology images, decide which osteofixation material is most appropriate in that particular case. If it is the case for standard osteofixation material, the information system can be used for selection of size and type of aids. If it is a fracture that requires customized approach the process of designing and developing the aids will be lunched. Surgeons select company which can offer they need in this particular case. Based on that, a system administrator of manufacturing company or surgeon, depending on organization of process, starts a new process instance.
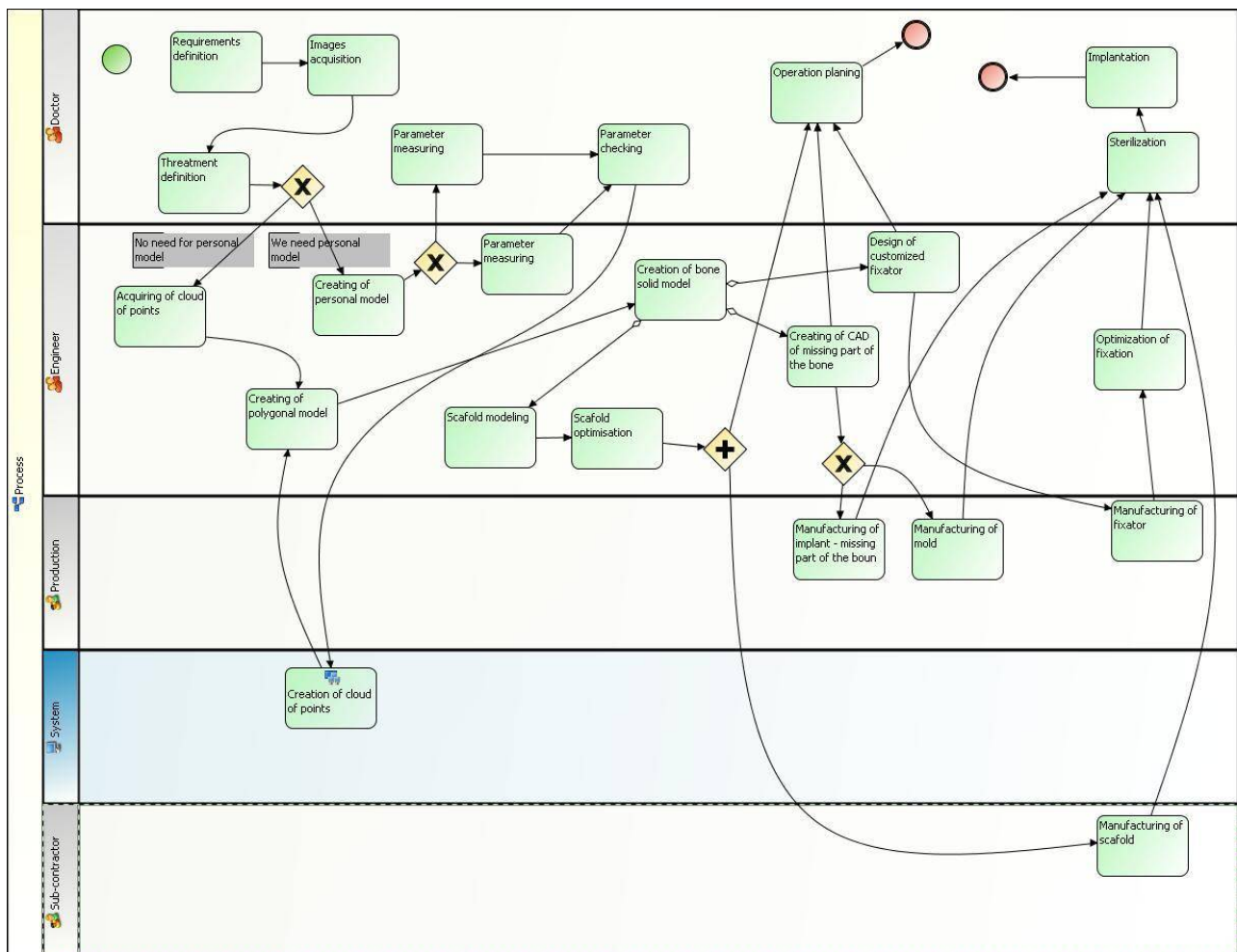

Figure 2: Process model

In the next activity radiology images that are required for work are collected. Those are X-ray images, CT images or MRI images, or a combination of the above. Images mentioned here are in digital form. As such, they enter in the process and become a part of data flowing through the process. That way they will be available in every activity of the process in which they are required.

After collecting the images (which is done in a hospital), surgeons should inform the information system about the chosen treatment. This decision defines which branch of the process will be executed; defines the method

of designing and manufacturing aids. There are several treatments that the information system can monitor. The doctor can decide if it is necessary to make the missing part of the bone (which will be realized by using reverse engineering and in that case the personal model is required) or the scaffold is needed or just the fixator should be customized.

If the part of the bone is missing or the radiology images are not good enough, it is necessary to create personal model of the bone. This model suits to the particular patient. It is obtained on the basis of parametric

bone model developed at the Faculty of Mechanical Engineering. If the radiology images are of good quality and if the bone does not have any missing parts, then the geometric model of the bone is created. In order to create this model, we use reverse modeling.

If the personal model isn't necessary, the next activity is reverse modeling of a bone. Reverse modeling of a human bone's geometry using CAD software means generating digital 3D model of bone's geometry from radiology image (CT, MRI). Importing the raw data into the CAD system results in generating of one or more clouds of points (discrete points of the tissue, which are scanned by some of radiology methods). In the next phases of remodeling, the geometrical features of higher order (curves, surfaces and solids) are being designed. The reverse modeling procedure consists of several steps, which are presented by activities Creation of polygonal model and Creating of CAD model in the model of process. The reverse modeling procedure for the bone geometry is consisted of following steps [8]:

1. Importing and editing (filtering, aligning, etc.) of clouds of points (activity Acquiring of clouds of points),
2. Tessellation of polygonal model (mesh) by creating a huge number of small triangular planar surfaces between the points in the cloud, as well as editing of polygonal model (activity Creation of polygonal model).
3. Identification of RGEs (points, directions, planes and views) (activity Creation of polygonal model),
4. Creating and editing the curves on polygonal model of the bone (activity Creation of polygonal model)

In the next activity solid model is created based on polygonal modal (activity Creation of solid model).

If the surgeons decide that it's necessary to make the missing part of a bone, a model of a specific bone is created based on a parametric model. In that case, there is a software solution, which partially automates the process. Developed software system prototype enables creation of polygonal human femur model based on input data from one or more X-ray images of a certain patient. The system is based on application of the pre-created generic parametrical point model, which is the most important component of the software system. Exchanging the values of parameters, acquired from X-ray images, CT or MRI patient's scans, generic model is transformed into a subject specific bone model. Parameters can be read from medical images manually (by measuring from X-ray images), or through adequate software (e.g. Mimics, Vitrea - DICOM).

The next activity in process is parameter measuring. That can be done by a surgeon (which is recommended), or an engineer.

Whether the entry (measuring) of the parameters was done by a surgeon or an engineer, the next activity is the verification of those parameters, done by a surgeon. The verification is done by comparing with already known and recommended values.

After the verification of the parameters comes the creating of a cloud of points using a developed software. That's an automatic activity, which means that BPMS calls the corresponding application. Parametrical points

model can be treated as cloud of points model, and as such, it can be used in any CAD application. The model is based on anatomical points defined on B-spline curves created over input polygonal femur models. Use of B-spline curve enables creation of geometrical femur models with high geometrical and topological/morphological precision. B-splines curves were defined in CAD software (CATIA) and they are absolutely applicable for the use in the generic shape design of free form surfaces (human bones can be described as such), within this module. This application is defined in software package Mathlab [9].

After creating the cloud of points, which is the output from the previous activity, procedure is the same as in reverse modeling.

After getting CAD model of a bone (whether it was parametrical or realistic) comes designing and manufacturing osteofixation material.

If it was decided in the beginning that the scaffold would be used, the process of designing and manufacturing the scaffold begins. This process has its sub activities, that are not presented individually on a diagram, but as two larger activities: designing and manufacturing the scaffold.

When designing the scaffold its geometry is defined first. This is done based on previously defined orthopedic treatment, in accordance with anatomy of the missing part of a bone, load and other parameters. The next step is defining material from the aspect of biocompatibility and biodegradability. When designing, manufacturing characteristics should be taken into account, because there's a possibility that the wanted design cannot be made. In the end, a method of implantation and fixation of the scaffold also affect the design. The output from this process is CAD model of the scaffold.

After modeling the scaffold, the next activity is its optimization, using different CAE methods.

Manufacturing the scaffold comes after its optimization. It can be done in the company, or by sub-contractor, if the basic company does not have the conditions for manufacturing (such a case is represented on the model of the process).

If it was concluded in the beginning that the large part of the bone is missing, which must be replaced by an implant, then after creating CAD model of a whole bone, the model of a missing part should be extracted.

After processing parametrically obtained model comes whether manufacturing a mold, or manufacturing the missing part of a bone, depending on defined orthopedic treatment.

Another possibility is to manufacture customized fixator, after getting a solid model of the bone. In that case, designing the fixator comes next.

For the treatment of bone fractures orthopedic surgeons use methods of external and internal fixation. External fixation involves fixation of the bone by the use of elements that are positioned at some distance from the site of the injury, that is, outside of the human body. Internal fixation implies surgical implementation of the implant in the human body for the purpose of healing the bone.

For both internal and external fixation standard fixation elements can be used. All mentioned internal (and external) fixators are made in the specific dimension range (sizes), in order to enable the application of fixators to

bones belonging to different patients. Application of predefined internal fixators to the specific patient may be problematic because of the difference in the size and shape of the particular bone and the fixator.

One of the solutions for this problem is the application of so-called customized fixators. The geometry and topology of those fixators are adjusted to the anatomy and morphology of the bone belonging to the specific patient. Application of customized fixators has a positive effect on patients, but on the other hand requires more time for preoperative planning and fixator manufacturing. Therefore, these fixators are used in cases where the application of predefined fixators can led to complications in the surgical interventions or on the recovery of patients. For the creation of the geometrical models of customized fixators new design method has been developed and presented in paper [10]. Geometrical models of internal fixator by Mitkovic for tibia bone created by this method could be applied for the preparation of preliminary models for FEA, for the preoperative planning, for the production of customized internal fixators, etc.

Designing of the fixator is followed by its manufacturing, which can be done in a company or subcontractor. In the example it's represented as done in a company.

After manufacturing of the fixator comes optimization of its implementation. On one hand, location of fixator on the bone is important because of mechanical factors (such as fixator stability and durability) and on the other because of biological factors (such as preservation of underlying bone material and blood supply in surrounding tissue). Experienced orthopedists use a set of empirical rules which help them set the fixator in a position that enables the healing of the fracture without significant damage to the tissue with which it comes into contact. At the same time, the fixator has to be sufficiently strong and durable as well as correctly configured and positioned, in order to stay functional throughout the whole fracture healing process.

Reverse engineering and CAE methods may be used to find an optimal position of the fixator on the bone. Parametric CAD models of the bone (based on medical imaging) and fixator are composed into assembly and their optimal position, with respect to fixator stability and durability as well as to stresses in the bone, is sought. During this process, the constraints that prevent fixator components to damage the bone or block blood supply must be obeyed.

Thus, the input parameters of the process are geometric parameters that define the shape of the bone and the fixator, parameters used in material models representing bone and fixator material and parameters that define the loads and supports on bone-fixator assembly that originate from muscles, joints or tendons. The parameters acting as constraints are allowed distances from bone surfaces or anatomical landmarks, which ensure the prevention of any damage to the bone or eventual blocking of blood supply. Output parameters are optimal dimensions of fixator components (if their allowed to be changed), number and location of fixator screws or clamps. At the moment, this process cannot be performed automatically and it requires that a case study is performed for each individual case.

Manufacturing of all the osteofixation material elements is followed by their sterilization and usage during an operation. That, of course, happens in the clinic.

One of the branches which is not mentioned before is planning the surgery. As part of the project VIHOS, we are developing an application for planning and simulating the surgery. In that application polygonal bone and fixator models are used. The application is based on the use of WebGL and HTML5 technologies and it supports X3D ISO standard. X3D is a standard based on the VRML (Virtual Reality Modeling Language) that allows creation of 3D content which can be displayed in any compatible browser (IE, Mozzila, Chrome are supported). The application allows the transformation of basic models (rotation, translation, scaling), and pairing bone and fixator models in the appropriate assembly. Practitioners have ability to choose adequate fixators models from the models database and to pair it with the specific bone. Currently, models of fixators for the femur and tibia bones are implemented [9].

IV. CONCLUSION

Information systems that support the activities which happen at medical facilities and companies that manufacture the osteofixation material are very rare. This paper presents the proposal of such information system, using fictional company as an example. BPMS technology and MD system developed at the Faculty of Mechanical Engineering are used as integration tools. The system integrates large number of activities that exist in the process of designing, manufacturing and implementing of osteofixation material. Some of the activities in this process are automated, some work with help from computer (there are procedures developed) and some are still manual, but they are monitored via this system.

In the further development of this system we plan to integrate activities related to the use of artificial intelligence methods. System MD can be programmed to react on exceptions, too, and we also plan to use Active Semantic Model in cases when computer should make its own conclusions.

REFERENCES

[1] *http://vihos.masfak.ni.ac.rs/site/*

[2] Health Information Systems, Alfred Winter, Reinhold Haux, Elske Ammenwerth, Birgit Brigl, Nils Hellrung, Franziska Jahn, Springer, 2011

[3] Wu Deng, Huimin Zhao, Li Zou, Yuanyuan Li, Zhengguang Li: Research on Application Information System Integration Platform in Medicine Manufacturing Enterprise, Springer 2011,

[4] Jan de Vries, Robbert Huijsman, Supply chain management in health services: an overview, Supply Chain Management: An International Journal 16/3 (2011) 159–165

[5] Marlon Dumas, Marcello La Rosa, Jan Mendling, Hajo A. Reijers, Fundamentals of Business Process Management, book, Springer 2012.

[6] Mišić D., Domazet D., Trajanović M., Manić M., Zdravković M., Concept of the exception handling system for manufacturing

business processes, Computer Science and Information Systems (ComSIS), 2010, 7(3):489-509

[7]   JESS, the Rule Engine for the JavaTM Platform, Sandia National Laboratories, http://herzberg.ca.sandia.gov/jess/.

[8]   Stojkovic, M., Trajanovic, M., Vitkovic, N., Milovanovic, J., Arsic, S., Mitkovic, M. (2009). Referential Geometrical Entities for Reverse Modeling of Geometry of Femur, Computational Vision and Medical Image Processing – VipIMAGE, Porto, Portugal, CRC Press/Balkema, Taylor & Francis Group. 189-195

[9]   Vitković, N., Milovanović, J., Korunović, N., Trajanović, M., Stojković, M., Mišić, D., Arsić, S.: Software system for creation of human femur customized polygonal models. Computer Science and Information Systems, Vol. 10, No. 3, 1473-1497, 2013

[10] D. Stevanovic, N. Vitkovic, M. Veselinovic, M. Trajanovic, M. Manic, M. Mitkovic, Parametrization of Internal Fixator by Mitkovic, The 7th International Working Conference "Total Quality Management - Advanced and Intelligent Approaches", Belgrade, Serbia, Proceedings, pp 541-544, 3 - 7 June 2013

[11] Trajanović, M., Korunović, N., Milovanović, J., Vitković, N., & Mitković, M. (2010). Primena računarskih modela samodinamizirajućeg unutrašnjeg fiksatora po Mitkoviću u saniranju trauma femura. Facta universitatis - series: Mechanical Engineering, 8(1), 27-38.

[12] Mišić D., Stojkovic M., Domazet D., Trajanović M, Manić M., Trifunovic M., Exception detection in business process management systems, JSIR-Journal of Scientific Industrial Research, Vol.69(03), March 2010, pp 1038-1042

[13] Milos Stojkovic, Jelena Milovanovic, Nikola Vitkovic, Miroslav Trajanovic, Stojanka Arsic, Milorad Mitkovic, Analysis of femoral trochanters morphology based on geometrical model, JSIR-Journal of Scientific Industrial Research, Vol.71(03), March 2012, pp 210-216

[14] Vitković,N., J. Milovanović, M.Trajanović, M.Stojković, N.Korunović, M. Manić, Different Approaches for the Creation of Femur Anatomical Axis and Femur Shaft Geometrical Models

[15] Milan Zdravković, Miroslav Trajanović, Miloš Stojković, Dragan Mišić, Nikola Vitković, A case of using the Semantic Interoperability Framework for custom orthopedic implants manufacturing, Annual Reviews in Control, Volume: 36   Issue: 2   Pages: 318-326

[16] Vidosav Majstorovic, Miroslav Trajanovic, Nikola Vitkovic, Milos Stojkovic, Reverse engineering of human bones by using method of anatomical features, CIRP Annals - Manufacturing Technology 62 (2013) 167–170