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TOWARD AN INTEGRATED INFORMATION SYSTEM FOR THE DESIGN, MANUFACTURING AND APPLICATION OF CUSTOMIZED IMPLANTS

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Abstract. *The adjustment of products to the needs of customers has been present in various industries for many years. Personalized medicine is a field that has been rapidly developing recently. This kind of medical help mainly implies the use of medications which are adjusted to each patient individually. In this paper, we describe an information system which manages the process of designing and manufacturing personalized products in the area of orthopaedics. The system output comprises patient-adjusted orthopaedic implants. In addition to the process management, the information system ought to enable the process to be adjusted to unexpected situations which may occur in different stages of designing and manufacturing. The information system should also assist doctors and engineers in the decision making process. This aid is realized in the form of the expert system which provides doctors and engineers with advice about defining an appropriate treatment for the patient.*

Key Words: WfMS, Exceptions, Expert System, Personalized Medicine

1. INTRODUCTION

Modern products and services currently on the market must develop in accordance with the ubiquitous globalization. Nowadays, a company cannot expect the customers to buy their products only because there is no alternative. In order to keep the customers, the company must establish a close relationship with them, whereby they cannot rely solely on the price lower than that of the competition. The use of the Internet technologies and online business leads to the possibility of easily comparing prices, and the customer may thus choose to buy a product from some other company, if he finds the price or some other characteristic more fit to his needs.

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One of the possible reactions to such environment is to attempt to establish a closer relationship with the customers, which would contribute to customer satisfaction and their loyalty. In this context one can speak of personalization as a business model. In [1] the author defines personalization in the following manner: "personalization is about building customer loyalty by building meaningful one-to-one relationship; by understanding the needs of each individual and helping satisfy a goal that efficiently and knowledgeably addresses each individual need in a given context".

In the domain of industrial products and services, the personalization falls under marketing, but it must also be connected to the production which must be able to respond to the customers' needs.

In comparison with the personalization in industry, personalization in medicine has just recently begun to gain importance. Personalized medicine derives from the belief that the same illnesses that afflict different patients cannot be treated in the same manner [2]. The assumption is that every individual responds differently to specific medications in accordance with his unique genome.

Introducing personalized medicine into practice has brought up different problems which should be regarded not only from the medical point of view, but from the technical and, also, legal aspect [3, 4].

The term 'personalization' in medicine mainly refers to the use of medications and treatments which are adjusted to a specific patient, and thus there are not many examples of applying this principle when manufacturing orthopaedic implants. In this paper, we describe the system which enables the designing and manufacturing of the orthopaedic implants which are adjusted to specific patient (customized implants).

Another aspect of this paper which has not been well researched is the connection between medical institutions and production organizations which produce for these institutions. In our paper, we discussed the connection between an orthopaedic clinic and an implant manufacturer. Usually, the clinic purchases a certain number of implants via public procurement process and then uses them for all patients for a period of time. The only contact between the company and the clinic is tender by which the clinic makes a purchase.

Instead of this usual way of working, we propose the integration of the processes in clinics and production organizations by using the information system which would manage the whole process, starting from the doctor's diagnosis, and ending with the manufacturing of the implant which is adjusted to a specific patient, if the adjustment is required.

When talking about use of information systems in medicine, it is mainly referred to Health IS. The Health Information System (HIS) is dealing with processing of data, information and knowledge in health care environments [5]. These systems deal with information flow in medical facilities; however, they are rarely connected to information systems of companies that make equipment used in hospitals.

In [6], for example, is described integration in medicine manufacturing enterprises. They recommend use of SOA and RFID integration technologies.

Some authors are trying to apply the Supply chain management technologies to health care [7]. Those authors emphasize the fact that the supply chain management in a health care setting is characterized by some unique features, which makes it difficult to transfer knowledge from the industrial sector to the health care one in a direct way.

We propose the integration of information systems of clinics and companies via the Workflow Management System (WfMS). The role of this system is to manage the process which is carried out in two different organizations, namely, the orthopaedic clinic, on one hand, and the enterprise which designs and manufactures implants, on the other. The idea behind the use of such system is to enable flexibility when selecting and embedding implants. This flexibility is achieved through a process which deals with the manufacturing of customized implants, on one side, and through the possibility to respond to exceptions which may occur during the process, on the other.

Exception handling in workflow systems is a problem which does not have a real solution yet. Nowadays, there a lot of different approaches connected to it [8, 9, 10, 11]. In this paper, we use an expert system for problem solving. This expert system is integrated with the basic process management system and is in charge of dealing with unexpected situations and possible modifications of the process according to the new conditions [12]. The knowledge base of the expert system is created by purchasers (in this case, doctors) as well as the implant manufacturers.

Besides being used for dealing with exceptions, the expert system also provides support for doctors and engineers in decision making process. In orthopaedics, one of the most important decisions which the doctor makes is the choice of appropriate osteofixation material. Choosing the right treatment requires a certain amount of experience and knowledge which experienced doctors possess. This knowledge is heuristic, so the easiest way to present it in computer form is in the form of rules which are part of some expert system. During the expert system exploitation, less experienced doctors may use knowledge and experience of their colleagues to help them with making decisions related to the patient treatment.

Some research projects [13] show that, even in the environments where there are developed Clinical Decision Support systems (CDS), the implementation faces various problems. Probably the most important one is that these systems are not integrated with the clinic workflows. In this paper, we propose integration of CDS systems with the workflow management systems. The integration is performed by automatically calling the CDS system when executing certain activities, which then offers to doctors and engineers intelligent advice related to the choice of right treatment. The system is capable of doing so due to all the data that exist within the workflow and the data which it collects through a series of questions that the users give answers to.

The rest of this paper is organized as follows: In section 2 we show the process of designing and manufacturing osteofixation material and its application. In third section we describe the manner of handling exceptions which may occur during the execution of this process. The fourth section explains the expert system which is used as a support for choosing osteofixation material. The paper is concluded in section 5.

2. MANAGING THE PROCESS OF CREATING OSTEOFIXATION MATERIAL

Within the project VIHOS (Virtual human osteoarticular system and its application in preclinical and clinical practice) [14] which is carried out at the Faculty of Mechanical Engineering and the Faculty of Medicine at the University of Niš, the 3D parameterized geometrical and bone models for FEA (Finite Element Analysis) are being developed. Also, a method for design of patient specific internal and external fixators and scaffolds is

developed. The mentioned models are developed by the use of the Method of Anatomical Features which is presented in [15]. The MAF consists of several procedures which enable the creation of geometrically precise and anatomically correct geometrical models of the human bones. Based on such bone models, additional models of fixators, scaffolds and other elements can be constructed. In general, the MAF is a reverse engineering (modeling) method and its main procedures are:

- CT scanning of the human bone data, importing the data into CAD and adequate filtering of the input point cloud.
- Creation of Anatomical model [15] - Morphologically and anatomically defined descriptive model of human bone.
- Definition and creation of Referential Geometrical Entities (RGEs) [15] - Geometrical entities which are created on polygonal model of the human bone in relation to anatomical features. They can be: planes, views, lines, points, curves, etc.
- Definition and creation of the basic geometrical elements - In this procedure, the basic geometrical elements are created, namely, spline curves, planes, surface patches, lines, etc. These elements can be used for the creation of different types of geometrical models like surface, volume or parametric.
- Creation of parametric models - This procedure enables creation of the parametric model which consists of anatomical points whose coordinates are defined as parametric functions. Arguments of these functions are morphometric parameters defined in medicine literature, as described in [9]. This model enables the construction of complete bone models in the cases of incomplete data about bone geometry. This can be the case when part of the bone is missing because of some bone disease (e.g. osteoporosis), or for example, when only one X-ray image is available.

On the basis of the obtained models it is possible to achieve another goal of the project, and that is to develop osteofixation material which could be adapted to a specific patient. Osteofixation material is a term that usually refers to implants for bone fixation and support, and they can be: fixator, scaffold and/or the graft, etc.

In order to make appropriate osteofixation material models, which will be used in surgery that a given patient will later undergo, the cooperation between doctors and engineers is required. Within the proposed system, this cooperation is carried out by information system, The work of doctors and engineers is considered to be a unity and a part of a common process, The process begins in orthopaedic clinic, continues in the company which designs and produces customized osteofixation material, and it ends also in clinic, where the planning of the surgery and the surgery itself are being conducted.

Since the work on designing and implementing of osteofixation material is considered a process, it is only natural that this process is managed via computer, i.e. via appropriate software - Workflow Management System.

Since the said process is carried out partly in hospital, partly in company, the best option is to implant everything by using two different processes which communicate via messages. Due to the lack of the tool which is used here (Enhydra Shark), it is not possible to carry out the process in that manner. That is why everything stays within one process which is carried out in both hospital and company.

In order to successfully manage the process, it is necessary to know who the owner of the process is. Since the responsibility is divided in this case, our option is that the owner is neither the company nor the hospital. Instead, a specific interdisciplinary organization

is formed, in order to govern, monitor and execute the overall process. The members of that organization are doctors and hospital staff, on the one hand, and engineers and company staff, on the other.

Depending on the type of the patient's injury, there is a possibility of using standardized osteofixation material (doctor can select only those osteofixation materials that are already in stock). It is also possible that the injury is somehow specific, in which case it is needed to adjust the products to the patient.

Orthopaedic fixators are made in the specific dimension range (sizes), in order to enable the application of fixators to bones of 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 the so-called customized fixators. The geometry and topology of those fixators are adapted 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, it requires additional time for preoperative planning and fixator manufacturing. Therefore, these fixators are used in situations where the application of predefined fixators can lead to complications in the surgical interventions or in the process of recovery. The process of designing and manufacturing of customized implants may be schematically presented, as in Fig. 1 [16].

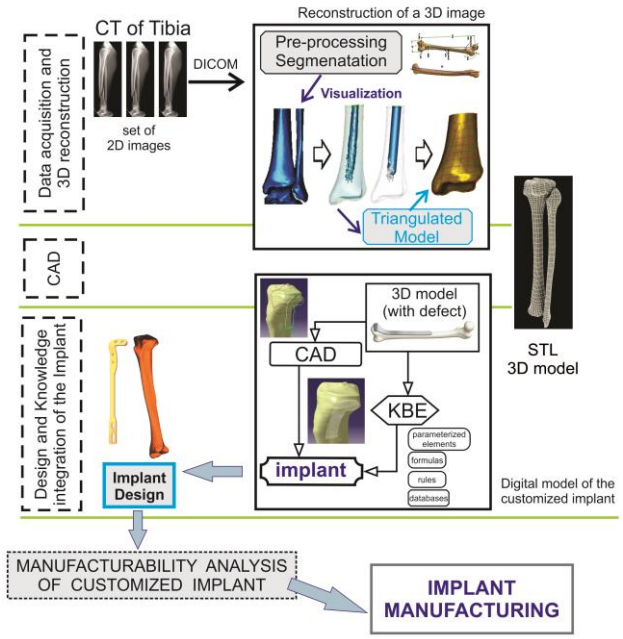

Fig. 1 Automated design process phases and manufacture of customized implants

The process in Fig. 1 may be physically realized by defining activities which would be monitored by WfMS. The process diagram realized in JaWE editor [17] is shown in Fig. 2.

The above mentioned process may be carried out in a few different ways. The first possibility is that the use of customized osteofixation material is not required. In that case, after defining the treatment, the standard material is immediately sterilized and the operation may begin.

In the case when it is recommended to use the customized osteofixation material, the first task is to make appropriate 3D models of fracture and fractured bones. When it comes to the fracture itself, it may be such that all parts of a bone are present, but it may also happen that a part of the bone is missing. If the missing part is small, a scaffold may be used as a support for fracture healing, while in cases when the missing bone part is large, it is required to make the missing part using the methods of reverse engineering.

The four described cases are at the same time the four possible paths which the process may follow. After the activities related to designing and manufacturing of the missing bone part or scaffold comes designing and manufacturing of customized fixator. The complete osteofixation material is sent to sterilization at the end of the process, and later used in surgery.

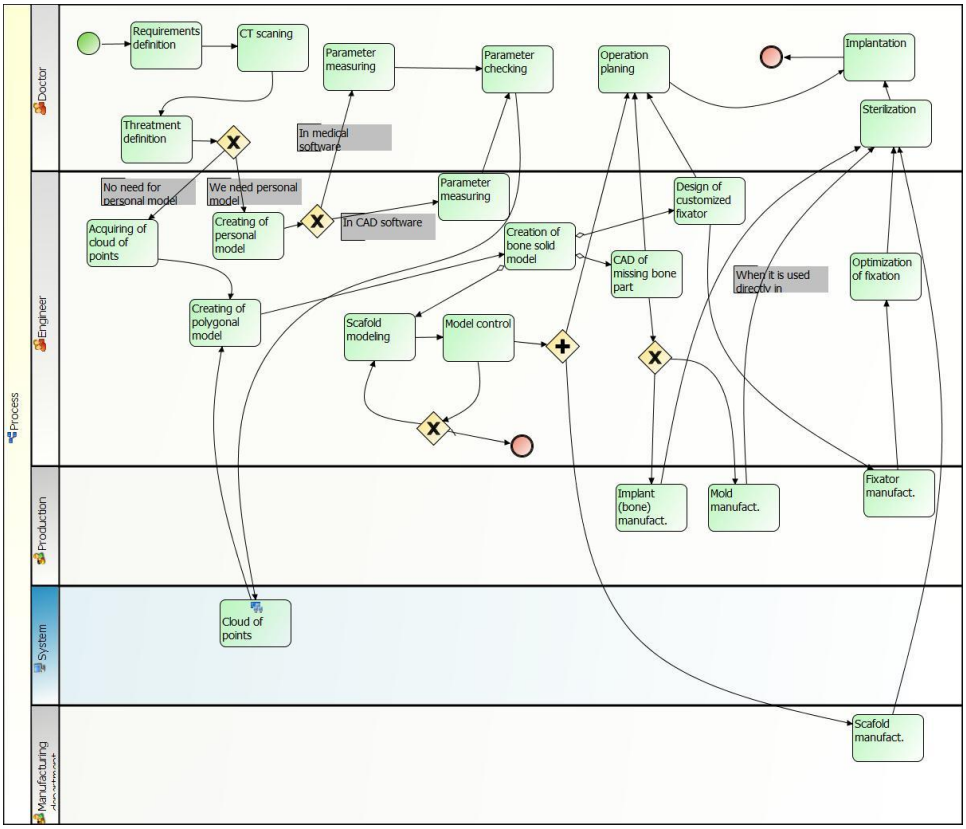

Fig. 2 The process of creating customized osteofixation material

A precondition for execution of branches in which the customized osteofixation material is designed and manufactured is the existence of corresponding models. Bone models may be obtained from radiology images, if the images are of good quality (Fig. 3). Some activities of the process which is monitored are in charge of definition of these models.

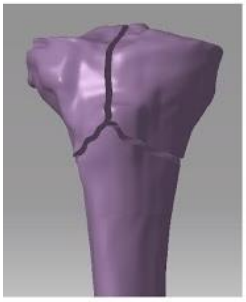

Fig. 3 3D model of bone and fracture

It may happen with some patients that some parts of the bone are missing, or the image quality is not satisfying. In such cases, the required models are obtained by using the methods of reverse engineering, which are described at the beginning of this chapter.

The models of bone and fracture created in the first stages of the monitored process are also used for the manufacturing of customized fixator (Fig. 4). In this case, the models are used for adjusting the shape and the dimensions of fixator.

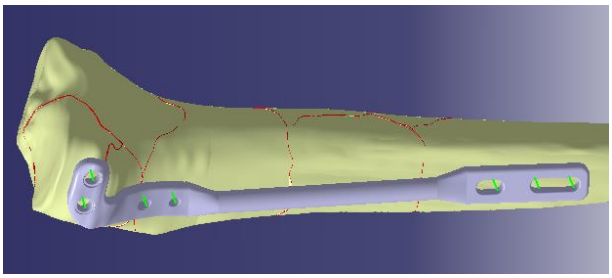

Fig. 4 Fixator adapted to the specific bone model

For the creation of the geometrical models of customized fixators a new design method has been developed and presented in paper [18]. 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.

When the production of all elements of osteofixation material is finished, the process is continued in the hospital which receives these elements. After their sterilization comes the surgery, when the osteofixation material becomes functional.

The process activities which we are describing are shown in Fig. 2. A detailed description of particular activities may be found in [19].

3. EXCEPTION HANDLING IN THE PROCESS OF CREATING OSTEOFIXATION MATERIAL

Business Process Management Systems have proved themselves to work best in environments where the processes are well scheduled, whereby those processes do not change often. The problem occurs in the situations when the process must deviate from predefined scenario. Nowadays, these deviations occur rather frequently. They also occur in production companies, which are forced to quickly react to changes in the environment due to the constant battle with the competition, but they occur in medical facilities as well. The processes in medicine are variable by their nature, since it is difficult to predict everything that will be required for a specific patient treatment.

The process we describe in this paper is carried out partly in a production organization, partly in a hospital, so it is natural to expect that the situation in which it is impossible to bring results should occur during its execution, if the process is not modified.

One of the possibilities is to embed all possible process deviations in the model. This solution is not adequate for two reasons. Firstly, it is difficult to predict all possible scenarios, and secondly, the process model would become more complex, difficult to read and monitor. The process shown in Fig. 4 is complex enough on its own, so it is necessary to avoid its further complexity.

We have attempted to find the solution in integration of the system for process management with the expert system, which is in charge of dealing with problems and possible modifications of the process according to new circumstances. The expert system functions on the basis of rules, which are defined independently of the process model. These rules are activated in the situations when the system or human notice that the regular process execution is not possible. The rules may offer advice or modify the process, thus solving the problem. Since they are independent of the process model, they do not burden it.

The proposed solution is realized by the WfMS MD, developed at the Faculty of Mechanical Engineering in Niš [12]. This system uses open source system Enhydra Shark as a workflow engine, which is modified and adapted to specific needs. For execution of the rules, we use the expert shell JESS [20]. The connection between these systems is shown schematically in Fig. 5.

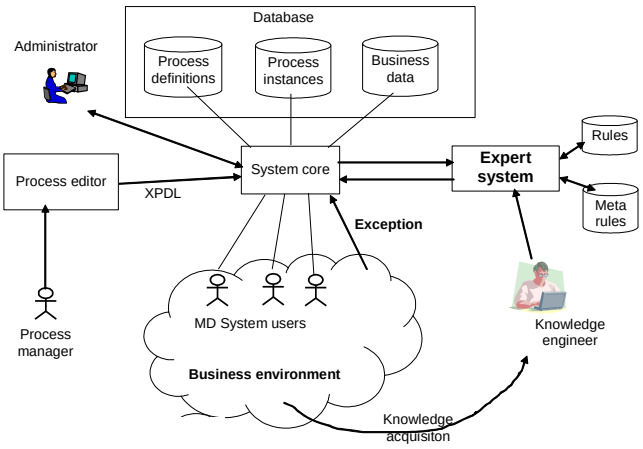

Fig. 5 The connection between WfMS and Expert system

We will provide an example of exception handling, in order to explain it thoroughly. The example is the process of creating fixator for tibia.

One of the activities which are executed in the hospital at the beginning of the process is the preparation of images which will later be used for creation of 3D osteofixation material model. In some cases it is not possible to obtain an adequate image. For example, such situation occurs when there is a part of bone missing, or when it is not allowed to expose the patient to radiation. Without the image, it is impossible to continue the process, because all further activities are based on the existence of those images. The solution may be found in process modification. For example, if the bone whose part is missing is tibia, possible solutions are to scan the other sound leg or to start the process of reverse engineering of tibia based on available data, if it is not possible to scan that other leg, either.

At the moment when such problem occurs, the process is stopped. MD system may be notified of it by entering specific values of parameter which is related to the process continuation, but in some situations the system itself is able to independently reach the conclusion that something is wrong. In this case, after the execution of the activity images acquisition, it checks whether there is an image of the fracture. If the image does not exist, that is a signal that the exception occurred. Another possibility is that the user notifies the system of the exception.

The processes which are defined and monitored via WfMS systems may refer to various areas. For that reason, there are so-called meta rules, which ought to determine whether there is domain knowledge (defined rules) for the problem which has occurred. These meta rules enable modularization and easier management of knowledge.

In particular case, the meta rule which determines whether the system possesses knowledge about ways of solving the problem is not necessary. Its role is overtaken by the rule which checks whether the image exists. If it does not exist, and the process is that of creating the customized implants and the activity is image acquisition, the rules which are related to solving this problem are loaded.

Depending on the manner of detection, and on the specific process which is monitored, it may occur that the expert system requires additional information in order to conduct the concluding procedure. Additional information refers to that which is not in the process itself, because all data from process are transferred to the expert system.

In accordance with the aforementioned, we have developed rules which ask certain questions concerning the given problem to the user. In the expert system, the questions are presented as rules. The user's responses enter the fact base and present additional facts on the basis of which the expert system makes conclusions.

Interface by which the questions are asked to the user is completely coordinated with the whole system, thus the user is not aware that he is actually communicating with the expert system. The questions are usually multiple choice or yes/no questions.

As mentioned before, if there is not an image of damaged bone, it is possible to use the image of the other sound leg, or measure the distance between certain points on the sound leg. The first option is to record the sound leg. The system cannot automatically determine whether it is possible to make image of the sound leg; instead, it asks the user (doctor). The rule which defines asking this question is:

```
(defrule recording
(answer (ident images) (text ?d))
=>
(if (eq ?d yes) then
   (assert (question (type multi) (text "Is it possible to make a CT
scan of a sound leg?") (ident possible_recording) (valid yes no)))
else (assert (answer (ident no-solution) (text no-solution))) ) )
```

If the user responds to the question which is asked based on this rule with yes, the rules which modify the existing process are loaded.

The rule which loads these rules is:

```
(defrule load-image-rules
(answer (ident images) (text yes)) (answer (ident possible_recording)
(text yes))
=>
 (clear)
(batch image_rules.clp)
)
```

In file image_rules.clp, there is only one rule, which ought to modify the process according to new circumstances. That rule is:

```
(defrule recording_sound_leg
  (Exception (id ?id) (type ?t) (currentActivityId
     ?currentActivityId)          (resActivityId    ?resActivityId)
(sourceProcessId ?processDefId))
       (answer (ident possible_recording) (text yes)
       (place before current)
=>
(bind ?packageDefinition (fetch PackageDefinition_1))
       (bind ?process (get-process-from-definition ?processDefId
?packageDefinition )) ;
       (bind ?prevResActivities (call org.enhydra.jawe.MisicProba
findPreviousActivities  ?currentActivityId ?process));
       (bind ?transitions (call ?process get "Transitions")) ;
       (bind ?activities (call ?process get "Activities"));(bind
?currentActivity (call ?process getActivity ?currentActivityId));
       (bind ?prevResActivity (call ?prevResActivities get 0));
       (bind ?nextResActivity (call ?nextResActivities get 0));
       (bind ?b1 (call org.enhydra.jawe.MisicProba createActivity
"recording sound leg" "recording_sound_leg" ?activities ?process
"Description" 1 "" "doctor" 1  1 "" "" "" nil))
       (bind ?tNew1 (call org.enhydra.jawe.MisicProba
createTransition ?transitions ?prevResActivity ?b1 nil))
       (bind ?tNew2 (call org.enhydra.jawe.MisicProba
createTransition ?transitions ?b1 ?nextResActivity nil))
       (call org.enhydra.jawe.MisicProba removeActivity
?currentActivity ?nextResActivity ?transitions) ;
       (bind ?strategy (new org.enhydra.shark.Strategy nil nil
?processDefId nil "CURRENT_INSTANCE_ONLY" nil ?processDefId
?resActivityId "CHANGE" nil "PackageDefinition_1"))
       (bind ?strategies (fetch strategies))
       (?strategies add ?strategy))
```

Within this rule, the process definition is modified by deleting the activity images acquisition, and the activity recording sound leg is inserted instead. The process

modification may generally refer only to the current process instance, but it may also refer to all future instances. In the specific case, the recording of the sound leg is added only for that particular patient, so the modification of definition refers only to current instance (value CURRENT INSTANCE ONLY). This is defined by list "strategies", in which the conclusions of the expert system related to application of the solution are inserted. This is a list because the solutions may be applied in several ways.

For example, if the new process definition ought to be applied to the current instance as well as all future instances, then in addition to the option CURRENT INSTANCE ONLY there would be the option ALL_NEW_INSTANCES in this list.

After the execution of this rule, the new process definition is returned to the WfMS. Further execution of this process instance continues on the basis of the new process definition. Specifically, this means that the activity recording sound leg appears in the doctor's work list.

Rules for other exceptions which may occur during the execution of the process may be defined in a similar manner. The rules are defined independently of the system operation, thus it is not required to modify the process model. By adding a new rule in the rule base, the rule immediately becomes available for execution during the processing of exceptions.

4. DECISION SUPPORT SYSTEM

It is already mentioned that the system which we describe in this paper may function as a decision support system as well. Since the process is carried out partly in clinic, partly in production organization, this system ought to support the work of doctors as well as that of engineers. The advantage of this system over other similar solutions stems from the fact that the system is embedded in the WfMS, and it may thus help to execute the process in the best possible way.

We have also created a decision support system via expert system, i.e. the expert system shell JESS. What distinguishes it from the mechanism for exception handling is the fact that this system is called as a part of activity execution but not in the case when the activity is impossible to execute. This means that the activities are predefined in a manner which enables the expert system to be called during their execution. The expert system offers recommendations to a doctor/engineer about executing the activity in the best possible way.

For making successful conclusions, data and knowledge are required. When it comes to the process of manufacturing osteofixation material, it may be said that data and knowledge are placed within the knowledge model and the topological and geometrical models of product. The topological model describes its position and orientation within the fracture and bone models. The geometrical model contains geometrical data about points and surfaces which it is composed of. It is a surface model which describes the geometrical shape of osteofixation material. Within the knowledge model, there are all necessary data which are related to physical, biological and mechanical characteristics, as well as characteristics of implementation and other things necessary for its manufacturing, ways of sterilization, implementation, removal, disposal, etc.

The knowledge model contains a lot of different information. For example, it contains information about the type of implant whose purpose may be bone reconstruction, soft-tissue reconstruction, augmentation, cosmetic reconstruction. It also contains data about whether the vascularization is necessary, whether the biodegradability is required, etc. The CDS may use all the information in decision making.

We will explain the manner of functioning of clinical decision support system by using the activity selection of fixator material as an example. Within this activity, the appropriate material for fixator manufacturing is being chosen. The right choice depends on many factors which should be taken into account. In addition, there is a variety of materials which are appropriate under some, and less appropriate under other circumstances.

In the literature, there is a large number of different materials which are used for the manufacturing of implants. Thus, in [21] the following materials are mentioned:

- Metals
  - Stainless steel
  - Vitallium (cobalt-chromium)
  - Titanium
  - Gold
- Calcium ceramics
  - Hydroxyapatite
  - Tricalcium phosphate
  - Hydroxyapatite cement
  - Bioactive glass
- Polymers
  - Silicone
  - Polymethylmethacrylate
  - Hard tissue replacement (HTR) polymer
  - Polyesters (Dacron, Mersilene)
  - Biodegradable polyesters (polyglycolic acid,
  - poly-l-lactic acid)
  - Polyamides (Supramid, Nylamid)
  - Polyethylene (Medpor)
  - Polypropylene (Prolene, Marlex)
  - Cyanoacrylates
  - Polytetrafluoroethylene (Teflon, Gore-Text)
- Biologic materials
  - Collagen
  - AlloDerm
- Discontinued materials
  - Polyurethane
  - Proplast

As mentioned before, the choice of materials depends on various conditions. In most cases there is not only one possibility, instead, a number of different materials may be used. We have illustrated the process of choosing materials with a few rules, which give recommendations about the right choice of materials. They can be further developed in the case that the material is not available (but this case is not presented in the paper).

Various factors may have influenced the choice of materials. Some of them are:

- the place where the implant is prepared (whether it should be prepared in the operating room immediately prior to the implementation or not)
- whether the implant is going to be high load-bearing
- what amount of money can be given for the implant
- the complexity of shape
- the required weight of the implant
- the purpose of the implant (cosmetic reconstruction or other)

Based on this information, a few rules which illustrate the process of choosing material are defined. Those rules are shown in Table 1.

Table 1 The rules for choosing material

Conditions		Material
▪ the implant should be prepared in the operating room immediately prior to the implementation	⇨	Calcium ceramics – Hydroxyapatite
▪ load-bearing implant ▪ low price ▪ not compex shape	⇨	Metal – Stainless steel
▪ high load-bearing implant ▪ very complex shape ▪ need low weight	⇨	Metal – Titanium (Additive technology)
▪ implant for cosmetic reconstruction ▪ very complex shape ▪ need low weight	⇨	Biologic materials - Collagen

The system does not have an access to the information which is required for the activation of the rules from Table 1 so that the users must enter them. In this case, a doctor and an engineer should do this together. The system of questions and answers is also used in this case. The questions are defined in the form of rules whose action part enters certain facts in the fact base and enables new questions to be asked or to reach an appropriate conclusion.

The first question which is asked is whether the implant should be prepared in the operating room immediately prior to the implementation. The rule containing this question looks like this:

```
(defrule implant-preparing
       (initial-fact)
=>
       (assert (question (type yes-no) (text "Is the implant
prepared in the operating room?") (ident operating_room) (valid
yes no)))
)
```

If the user confirms this, the rule which recommends Hydroxyapatite as the material type is executed.

```
(defrule def_1 "material is Hydroxyapatite"
       (answer (ident operating_room) (text yes))
=>
       (store material Hydroxyapatite)
)
```

If this question is answered negatively, the system continues with questions, i.e. it continues entering the required data. The questions related to load, price, shape, etc. are asked. There is a defined question for each of the parameters which may affect the decision making process. The system asks questions as long as there are some that the user has not answered yet.

Some of the rules which are used for defining the questions posed to the user are:

```
 (defrule load_question
       (answer (ident  operating_room) (text no))
=>
       (assert (question (type yes-no) (text " Is the implant high
load-bearing?") (ident high-load ) (valid yes no)))
)

(defrule price_question
       (answer (ident operating_room) (text no))
=>
       (assert (question (type multi) (text "The price of implant")
(ident price) (valid low high)))
)

(defrule shape_question
       (answer (ident operating_room (text no))
=>
       (assert (question (type multi) (text " Is the shape of the
implant complex?") (ident shape) (valid complex not_complex)))
)

(defrule weight_question
       (answer (ident operating_room) (text no))
=>
       (assert (question (type multi) (text "Is the implant heavy
or lightweight?") (ident weight) (valid high low)))
)

(defrule reconstruction_question
       (answer (ident sala ) (text no))
=>
       (assert (question (type yes-no) (text "Is it a cosmetic
reconstruction?) (ident cosmetic_reconstruction) (valid yes no)))
)
```

After the user has answered these questions, the expert system should have enough data to reach a conclusion about the type of fixator material which should be used. Some of the rules that do that are:

```
(defrule solution_metal_stainless_steel
       (answer (ident sala) (text no))
       (answer (ident high-load) (text yes))
       (answer (ident price) (text low))
       (answer (ident shape) (text not_complex))
```

```
=>
       (store material stainless_steel)
    (printout t "material is stainless steel" crlf)
)

(defrule solution_metal_titanium
       (answer (ident sala) (text no))
       (answer (ident high-load) (text yes))
       (answer (ident weight) (text low))
       (answer (ident shape) (text complex))
=>
       (store material titanium)
    (printout t "material is titanium" crlf)
)

(defrule solution_biologic_material_collagen
       (answer (ident sala) (text no))
       (answer (ident cosmetic_reconstruction) (text yes))
       (answer (ident weight) (text low))
       (answer (ident shape) (text complex))
=>
       (store material biologic_materials_collagen)
    (printout t "material is collagen" crlf)
)
```

These rules choose the most appropriate fixator material. The chosen material is put in the variable material, which is later accessible from the system for process management. The value of the variable which is read is used for definition of the value of the variable defined at the process level and the activity selection of fixator material. The user can access that variable, defined within the system, in subsequent activities in which the process of making fixators is defined.

If the expert system does not have any solution, the value of variable remains empty. In that case, the user chooses and enters the appropriate value on his own.

Decision support system which is modeled in this manner is open for expansion, since it is not necessary to compile a program code or to change the activity in some other way. In case that some new materials become available, it is enough to enter new rules which are related to this case in the rule base, and the expert system will take that into account when defining its recommendations.

5. CONCLUSIONS

In this paper, we have described the system for management of the process of designing and manufacturing customized osteofixation material.

The process of designing and manufacturing osteofixation material is carried out partly in hospital, partly in production organization which produces this material. In this paper, we discuss customized osteofixation material, and this process is started when the patient needs a specific type of the service. In the cases when the standard osteofixation material can be used, the process is carried out by the usual procedure, which we did not discuss in this paper.

The connection between activities which are carried out in the hospital and those which take place in the production organization is achieved by the workflow management

system. The novelty of this work is that the processes in the hospital and in the production organization are not considered individually. Instead, they are considered to be a unity, managed by one computer system, thus integrating businesses which are carried out in two different environments.

Processes of designing and manufacturing osteofixation material are modified frequently, with the goal to provide a patient with the best treatment possible. Instead of changing process definition and adapting it to the new conditions every time a change occurs, we enhanced the system by connecting it to the expert system which deals with unpredicted situations. The main workflow management system is integrated with the expert system which solves problems on its own, in case that unpredicted problems occur. The conclusions which expert system makes may lead to a change of the process definition, at the level of one or more instances of the process. Those modifications, however, are carried out automatically, thus allowing the user to continue with working on the new process, without having to manually modify the model.

The expert system is used also as a support for making decisions in activities whose execution requires experience. In this paper, we describe this process by using the activity of choosing fixator material as an example. That choice is a result of experience, not estimation. The experience and knowledge of both doctors and engineers are presented by rules, which attempt to recommend the material which is the most appropriate for the conditions given. In this case, the integration with the expert system is realized by embedding the calling of the system in the activity. The user is not aware of the fact that he is communicating with another system. The main advantage of this work is the fact that it is easier to present experiential knowledge by rules, and that it is not necessary to change the process activity in case that the knowledge is upgraded or changed. In such cases it is enough to change the rules, and the expert system (and the activity in which it is embedded) will automatically offer new conclusions. The rules which are used for solving problems are placed in the file which is not related to the system, thus the rules can be easily modified.

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