Model-Based System for the creation and application of modified cloverleaf plate fixator

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***Abstract*— In healthcare systems there is a requirement to provide the best possible medical treatment for the patient, and that involves application of different procedures conducted by various experts in the field of medicine and other connected disciplines (engineers, software developers, managers, etc). For the medical treatment of the bone fractures various types of internal and external fixation techniques are used. The important components of these techniques are the fixators which enable fixation of broken bone parts. In this paper a new method for the customization of the modified cloverleaf plate fixator for the proximal part of the humerus bone is introduced. Furthermore, the application of Model-Based System Engineering (MBSE) for the modeling of the customization process is also presented. The main goal of this and future researches is to develop a complete system for the medical treatment of the humerus bone (and possible other human bones) which can improve patient general health and recovery process, and which will help doctors to improve their diagnostic and treatment skills in the field of orthopedic surgery.**

I. INTRODUCTION

In healthcare systems there is a requirement to provide the best possible medical treatment for the patient, and that involves application of different procedures conducted by various experts in the field of medicine and other connected disciplines (engineers, software developers, managers, etc). In the field of orthopedic surgery, especially in the field of bone trauma (e.g. fractures) this requirement can be achieved by the application of proper fixation technique for the implantation of customized fixator into the patient's body [1]. The important components of this technique are geometrically precise and anatomically accurate models of human bones. With such bone models, it is possible to build customized fixators [1] using rapid prototyping technologies or perform preoperative planning procedures [2,3]. Becides fixators and its design and implantation techniques, it is important to define the whole process of patient treatment from the diagnostic procedures to the full recovery. This process can be considered as System Engineering (SE) process [4] which involves all the management and technical skills in order to achieve patient/doctor requirements. Possible requirements can be: implantation of proper (customized) fixator, fast recovery process, bone function is returned to the state before trauma, etc. The management of the SE implies planning of technical details, risk management, control of the overall process, etc. The technical part of the SE implies specification of the technical data, hardware and software definition, etc [5]. SE applied in orthopedic surgery is a complex process and in order to conduct it in proper way experts from various fields must be included, like: orthopedists, surgeons, engineers, software developers, managers, etc. The application of SE in medicine or healthcare is a special academic field and it is often called Healthcare Systems Engineering (HSE) or Healthcare Engineering (HE), as described in [6,7]. It involves all processes which are needed for the physical and mental impairments of the patients. The modeling tools which are used for the graphical and textual representation of the HSE processes are based on the UML (Unified Modeling Language) which is maintained by the OMG (Object Management Group) [8]. The UML is a modeling language which focus is on modeling software systems and included processes, but there are various modifications which enable application of this language in other fields (e.g. SE). One of these modifications is SysML (Systems Modeling Language) which is a adapted UML language for System Engineers [9], and also maintained by OMG. SysML is a tool which can describe Model-Based System Engineering (MBSE) which is model oriented system engineering architecture [10]. The definition of MBSE from the official OMG site is "the formalized application of modeling to support system requirements, design, analysis, verification and validation activities beginning in the conceptual design phase and continuing throughout development and later life cycle phases."[8]. This means that this systems are model centric and not document centric as it was in previous or traditional approach [10]. It is expected that MBSE becomes an important factor of System modeling in the System Engineering practice in the future and to include various aspects of the systems, like social, economical, environment and other [11].

In this research MBSE is applied for modeling a part of the orthopedic treatment process for the patient with bone fracture. The part of the system which is modeled is fixator customization process. The method for the definition of fixator geometry and topology is newly developed by the authors involved in this research, and it enables creation of customized fixators for the human bones. This is very important process because it directly affects the success of the patient's treatment [1]. The example of this procedure is presented on the creation of the modified internal cloverleaf plate fixator for the humerus bone [12, 13]. The tool for modeling this system is a SysML-Lite sub-language which is not a standard UML language, but it is successfully used for the modeling of simpler systems, or for making a prototype of system (or parts of the system) [5], as is the case in this research. The main goal of this and future researches is to develop a complete system which can improve patient general health and recovery process, and which will help doctors to improve their diagnostic and treatment skills in the field of orthopedic surgery.

II. The Case Study

The bone trauma that is analysis in this research is a fracture of proximal part of a humerus bone. There are various types of bone fractures and they are defined by the adequate classification [14, 15]. The fixator which is used for the treatment of the fractures is a modified cloverleaf plate fixator. The process of patient's treatment for the fixation of the mentioned fracture(s) is presented in Fig. 1. This process can be considered as a framework process, and because of that not all sub-processes are presented, like ones defined in [16].

The four main processes are:

Diagnostic procedure - In this procedure the bone fracture is defined through the verbal communication with the patient and with the medical imaging procedure.

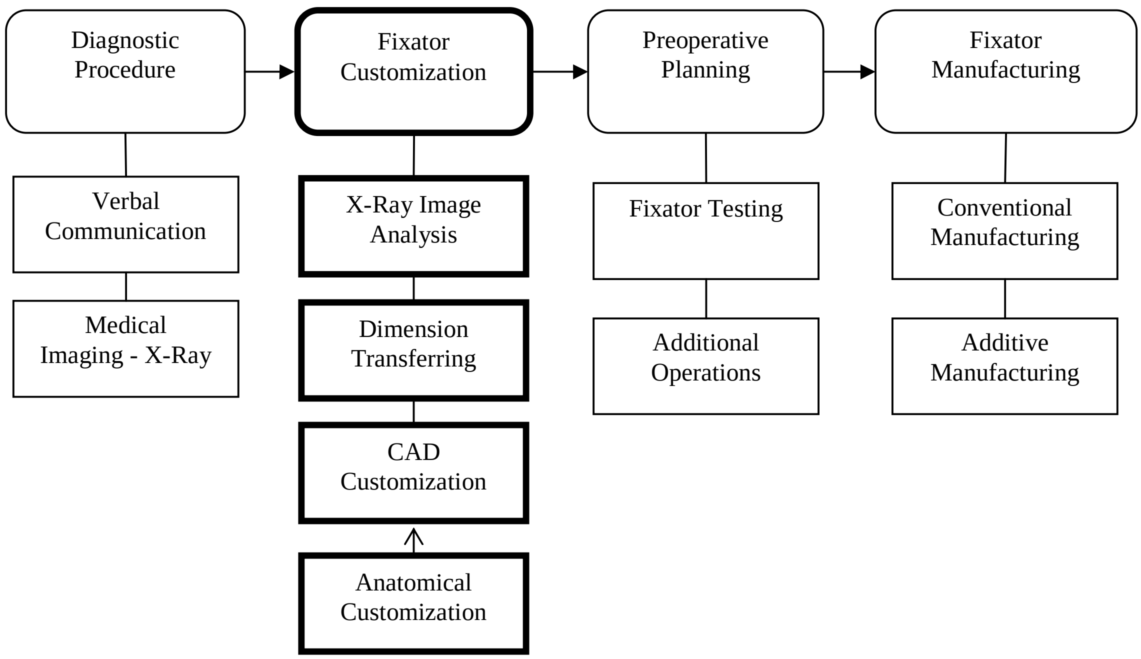


Figure 1. Scheme of the Customized fixator definition and manufacturing processes

In this case the procedure is conducted by the radiography (X-ray) scanning. To conduct a proper scanning it is desirable to scan the patient with some etalon placed near the patient. In this way proper scaling of the dimensions can be done. If etalon is not available, then X-ray scale for the scanning device must be known, which is always the case because it is supplied by the manufacturer of the radiograph.

Customization of the fixator - In this process geometrical model of the customized fixator for the specific patient is created. The input for this process is a digitized X-ray image of the patient's humerus bone. Based on the edge detection algorithm(s) applied in an open source software (e.g. GIMP in this case), it is possible to acquire the edge of the proximal part of the humerus bone and adequate values of dimensions measured in Anterior-Posterior plane of the humerus bone [2]. The dimensions which are measured are presented in the Fig. 2. There are two important dimensions RDmax (distal part of fixator) and RPmax (proximal part of fixator). These dimensions represent maximal distance from the detected edge to the Z axis of humerus body [12]. These dimensions enable creation of the profile curves with for the multisection feature in CATIA. The radius of this curves (part of the circle in this case) are limited by the values of RPmax and RD max respectively. There is another dimension which is important, and that is a rotational angle defined around Z axis of the fixator (angle of fixator rotation). This angle enables additional adjustment of the fixator position. In the dimensions transfer process adequate scaling of values is done, and the scaled values are stored in a textual file - Microsoft Excel. These values are the important input for the next process which is CAD Customization of the fixator's geometry. The acquired values are entered as values in CATIA and geometry of the parametric model of the fixator is adjusted to the patient's bone (dimensions and anatomy), as presented in the Fig. 2. This whole process of fixator customization is presented in the Fig. 3. This process can be improved by the application of the parametric bone model as described in [2]. The geometry of parametric bone model can also be adjusted to the measurements acquired for the specific patient. In that case it would be easier to adjust the fixator's geometry, because the bone geometry would be known. It should be noted that the geometry of fixator adapts to the geometry of the patient's bone based on only one 2D image, and not on the basis of multiple images or 3D volumetric model (acquired by the CT or MRI), which means less radiation exposure. The outcome of this process is a 3D geometrical model of the customized fixator.

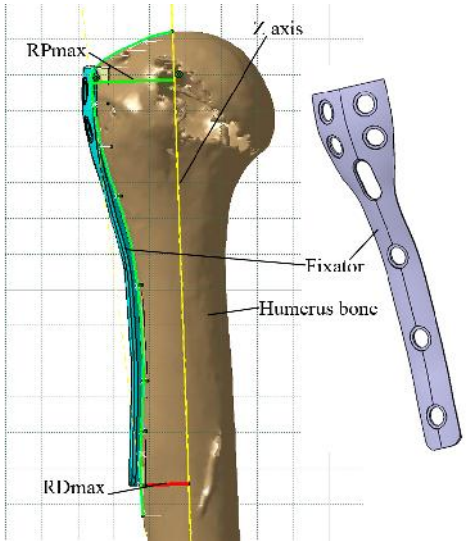


Figure 2. Scheme of the Customized fixator definition and production process

Preoperative planning - Based on the constructed fixator, medical practitioner (surgeon, orthopedist) plans the orthopedic intervention. This can be a very complex process and it involves planning all of the tasks which must be done in order to provide the best possible treatment for the patient. This process can be combined with previous process in order to better adjust the geometry and topology of the 3D model of the fixator.

Manufacturing of the fixator - The geometrical model of the customized fixator can be used in CAM for the conventional manufacturing processes (e.g. CNC machines), or for the manufacturing by the additive technologies, or by the combination of these two. In this case better solution for the manufacturing of the fixator will be additive technologies because of the complexity of the fixator's shape (free-form surface). The outcome of this process is a physical model of the customized fixator which can be implanted in the patient's body.

The main focus of this research is the process of fixator customization and the application of the MBSE for that process is presented in the next section of the paper.

III. MBSE WITH SYSML

The Systems Modeling Language (SysML) is a graphical modeling language for systems engineering applications. SysML is defined as a sub-language of the UML standard, and supports the specification, analysis, design, verification and validation of complex systems. SysML has been adopted by the Object Management Group (OMG) as OMG SysML (shorten SysML) and has evolved into standard for MBSE applications. "Model-Based Systems Engineering (MBSE) is a key enabling technology for Systems Engineers who seek to transition from traditional Systems Engineering processes that are document-based and code-centric to more effective processes that are requirements-driven and architecture-centric", as stated in [8]. These Systems Engineering activities include, but are not limited to, requirements analysis, functional analysis, performance analysis, and system architecture specification [8]. The SysML diagram contains five sub-diagrams and they are: package, requirement, behavior, parametric, and structure. Behavior diagram is represented by activity diagram, sequence diagram, state machine diagram and use case diagram. Structure diagram is defined by block definition diagram and internal block diagram. The detailed description of all of this diagrams is presented in [5, 8], but here only short definition is given.

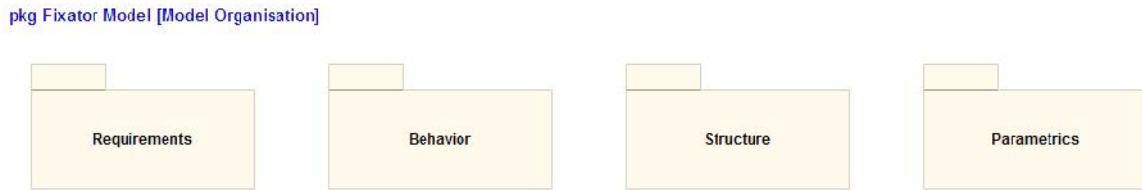
- Package diagram is the same as UML package diagram and it defines model elements organized in packages.
- Requirements diagram defines text based requirements and their relationships.
- Activity diagram is a modification of UML Activity diagram and it represents an activity flow in the order which activities are executed.
- Sequence diagram is the same as UML Sequence diagram and it defines the messages which are exchanged between systems or part of the systems.
- State machine diagram defines states of the entity(ies), which changes in a correspondence to the events - Same as UML State machine diagram.
- Use case diagram is standard UML diagram and it defines actions which are performed by the actors to the system in order to achieve defined goals.
- Block diagrams are the modification of UML class diagrams and they defined relationships between structural elements.
- Internal block diagram represents interconnection between parts of the block(s).
- Parametric diagram represents functional relationships between properties and its values.

In this research modified version of SysML called SysML-Lite is used, because it represents the prototype and not the complete and fully functional system which is tested in practice. The application of the system prototype in real clinical practice would give proper verification of the proposed system. The SysML-Lite diagram contains only six (6) diagrams and they are: package, requirement, activity, block definition, internal block, and parametric diagram. The tool which is used for modeling with SysML is Modelio SysML Architect Module. Modelio is Open Source software based on Eclipse environment [17]. The important diagrams which were created are presented in Fig. 4a - 4d, and they are:

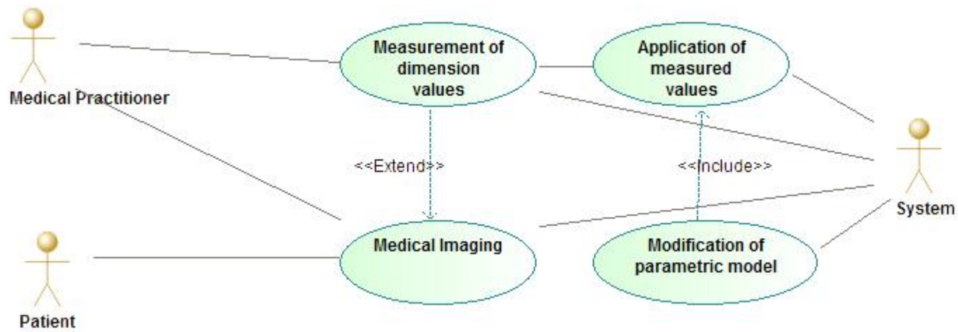
- Package diagram with defined packages for Requirements, Behavior, Structure and Parametrics.
- Use Case diagram for the customization of geometrical model of the fixator.
- Block Diagram for the Fixator Customization Context - All other blocks connected to the context are displayed.
- Internal block diagram for the fixator - In this diagram component of the fixator are presented together with attribute values.
- Parametric diagram for the internal block for the fixator with defined attributes.

- Requirement diagram for this process contains only one requirement and that is a proper adaptation of the fixator, so there is no need for the construction of that diagram for the presented case.

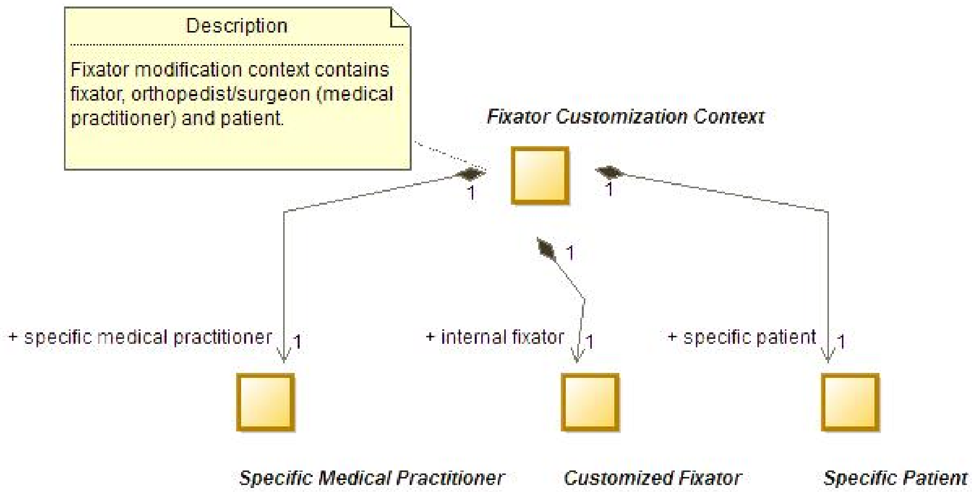
In the future work more diagrams will be created, some diagrams will be modified, and the whole business process (model) will be included.



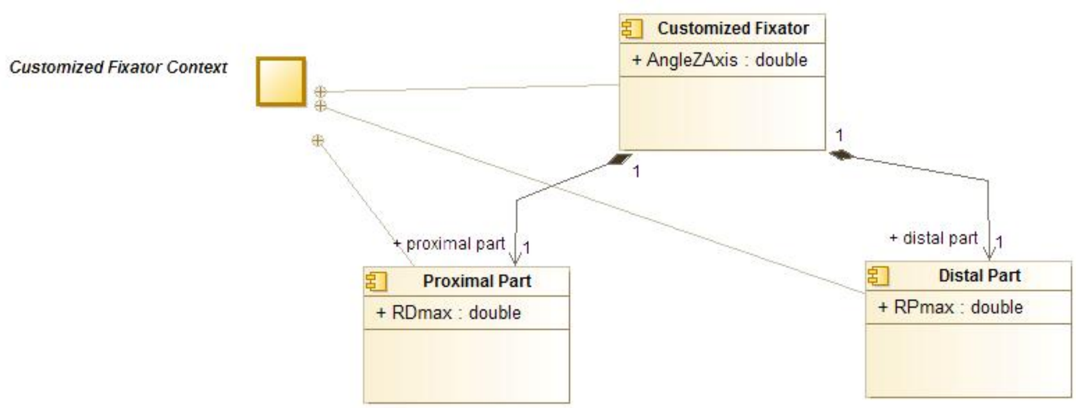
a) Package diagram - SysML-Lite



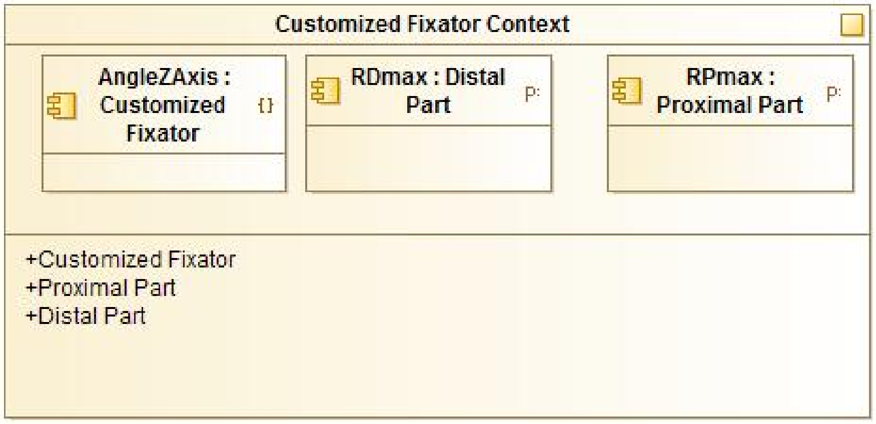
b) Use Case Diagram for Customization of fixator's geometrical model



c) Block Diagram for Fixator Customization Context



d) Internal block diagram for Customized Fixator Context



e) Parametric diagram for Customized Fixator Context block

Figure 3. SysML diagrams for the Customization of the modified cloverleaf plate fixator process

IV. CONCLUSION

In this research application of the MBSE for modeling the customization process of internal cloverleaf fixator for the humerus bone of the specific patient is presented. The process is based on newly developed method for the creation of the geometrical model of the customized fixator. This method is developed in order to enable creation of fixator geometrical model by the use of only one 2D X-ray image of the patient's bone, which means that patient will be exposed to the lesser radiation dose compared to volumetric scanning (e.g. CT).

The presented system is a prototype system, and in the future additional research will be conducted in order to create the complete system for the medical treatment of the patient with the bone trauma.

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