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CUSTOMIZATION OF ELEMENTS FOR ORTHOPEDIC EXTERNAL AND INTERNAL FIXATION

S. Randjelovic, D. Misic, M. Trajanovic, N. Vitkovic, M. Veselinovic
University of Niš, Faculty of Mechanical Engineering, Republic of Serbia

Abstract: *Modern lifestyle and pace of today's man activities carries great dangers and risks for human osteoarticular system. In emergencies that occur in everyday clinical practice, expert teams usually have to react very fast, while maintaining the high quality of intervention. Despite the need to urgently carry out interventions, it is expected to embed to patient fixators that fit his body.*
Therefore, customization and adjustment of medical devices and elements for external and internal fixation, as well as implants, is a major challenge in modern orthopedic surgery. In this paper we present the methods available for the design and manufacture of customized fixators and the standards that should be met.
Key Words: *Orthopedic fixators, production, orthopedic material, FEM analysis*

1. INTRODUCTION

Type of injury or disease stage directly determines the medical diagnosis and therefore the medical procedure to be undertaken. In real conditions, in addition to the usual procedures, medical equipment and supplies, sometimes is not enough to use standard components of the fixators because of unusual anatomy or potential risk of postoperative complications [1], such as aseptic weakening. The usual reason for aseptic weakening is the uneven distribution of mechanical stress to the bone volume and the irregular 3D surfaces of bones. This problem can be solved using tailor made fixators customization implant design, customized to the specific characteristics of the patient's anatomy.

2. DESIGN AND MANUFACTURE OF FIXATORS

Research and development for customization production of orthopedic fixators is typically related to direct manufacturing technologies [2]. New equipment for the rapid prototyping production of prototypes (rapid-manufacturing) allows much greater efficiency in small series or individual production.

The latest methods used for the direct production of high strength materials such as titanium, is the melting of the electron beam (electron-beam melting - EBM).

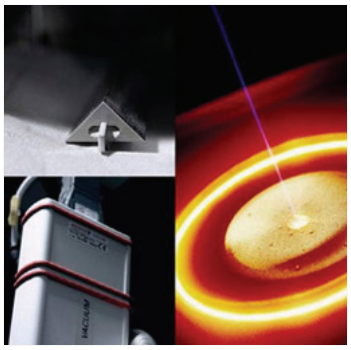

Fig.1. EBM process

The application of conventional technologies allows larger series of products, while still enable small adjustment of fixators shape for a given concrete conditions. Processes of metal forming, both cold and hot, offer technology solutions which are still suitable for the majority of patients. These technologies covered most medical cases in the external and internal fixation. This result in greater savings but these fixators are not customized.

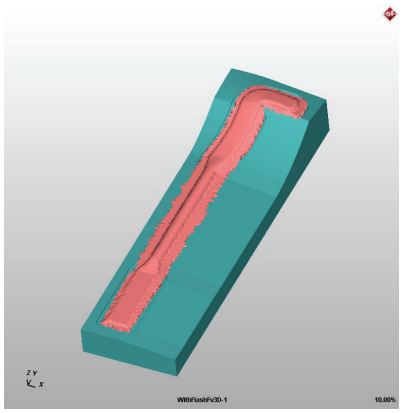

Fig 2. Lower tool for hot forging technology for orthopedic fixatior

Orthopedic fixators can be very complex, customized products to be produced based on the above information, as soon as posible [3]. Key factors of production for customized orthopedic fixators are the level of customization of the final product and delivery time. A higher level of customization reduces the duration of the

operation and increases the reliability of future implants. It, also, reduces the present risks from possible complications.

The general approach in developing the technology of manufacturing companies is to optimize the design of their products according to criteria of simplicity and cost, while adapting their processes mainly for large series production. This is the main reason why they are not able to produce small batches or individual products in an efficient manner. In the traditional sense, the processes for the production of customized implants include a large number of analysis and decision making, such as interpretation and analysis of CT (Computed Tomography) scans, analysis of wax prototypes, mechanical analysis, information gathering, certifications, etc. Lack of efficiency to adapt their traditional workflows to these activities becomes even more critical when companies have to hire suppliers of various parts, components or services.

The fact is that this process involves intensive communication, a number of consultations between the various experts which discuss of the functional (medical), mechanical, organizational, and other perspectives on the process of customized production.

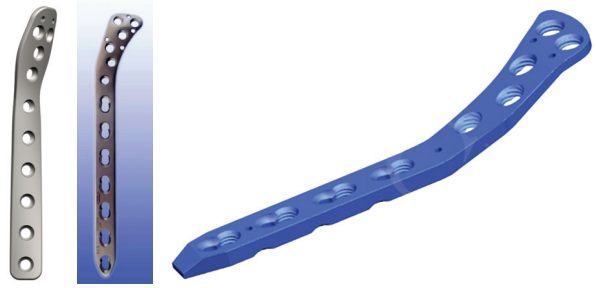

Fig.3. Distal-lateral, proksimal-lateral and lateral plate

By such process models different information which describes orthopedic implants could be represented. They aim to provide relevant knowledge representation and reasoning in decision making process regarding treatment, preoperative planning, configuration of the virtual enterprise, planning technology and business process management. For example, a generic 3D parametric model of selected human bone can be generated by the available tools and features in one of the 3D modeler. Although, a lot of complex surfaces and volumes require a combination of very powerful software options, it is a good way to make fully functional a multi-purpose model. This will be fully covered by the technical documentation and important details, model development, model analysis and simulation of stress and many other sensitive issues. Attempt to represent irregular and complex surface and volume by the parametric mathematical functions and relationships only slightly speeds up the design. Using this procedure it is possible to get models, which probably will not provide an opportunity for a complete analysis.

Fig. 4. Front and medial plate for lowerleg fixation

Typical example of complexity of multi-purpose model of fixators is mechanical simulation model. Simulation models allow the prediction and optimization of mechanical behavior of implants under realistic load conditions, using FEM methods (Finite Element Analysis - FEA). Often, it is not possible to create FEM model without human intervention.

Fig.5. Distal-periarticular plate

3. SELECTION OF MATERIALS FOR ORTHOPEDIC FIXATORS

Modern medical fixators are products which have to satisfy strict standard requirements regarding materials, machining technologies and their functionality. They could be used for almost every part of osteoarticular system. Ideally, they should have biomechanical properties comparable to those of autogenous tissues without any adverse effects. The principal requirements of all medical orthopedic fixators are corrosion resistance, biocompatibility, bioadhesion, biofunctionality, machinability and availability. To fulfill these requirements most of the researches are directed into the study of material selection, genotoxicity, carcinogenicity, reproductive toxicity, cytotoxicity, irritation, sensitivity and sterilization agent residues [4].

Fig.6. T- plate, proximal

Modern medical implants are regulated and classified in order to ensure safety and effectiveness to the patient. One of the most used biomaterial for biomedical applications is titanium alloy Ti6Al4V due to combination of the most desirable characteristics including immunity to corrosion, biocompatibility, shear strength, density and osteointegration. The excellent chemical and corrosion resistance of titanium is caused by the chemical stability of its solid oxide surface layer to a depth of 10 nm [8]. Under *in-vivo* conditions the titanium oxide (TiO_2) is the only stable reaction product whose surface acts as catalyst for a number of chemical reactions [5].

The biggest risk is transfer of load from fixator to the bone surface, which largely depends on the type of fixator's materials [6].

Fig. 7. Contact stress analysis, bone vs. ceramic, bone vs. polyethylene and bone vs. pyrocarbon

In the case of ceramics with extremely high elastic modulus (407 GPa), there is almost no distortion, and it is a solid contact with the implant that does not respond to the effect of mechanical stress or mechanical force causes a large increase in internal stresses in the bone itself. Polyethylene in contact with the bone mass has completely different characteristics. Its much lower elastic modulus (1 GPa) suggests that the entire burden is transferred to the established contact implant and the bone implant produced a disproportionate strain which is not permissible. It is clear that pure pirokarbon, when such an analysis, show the best mechanical properties, that is closest to the behavior of human bone mass [5,6,7].

Table 1. Biocompatibility and Bioelasticity Facts

	Silicone	Bone	Pure Pyrocarbon	Titanium (TA6V)	Cobalt Chrome (CrCo)	Ceramic (Alumina)
E (GPa)	0.0004	15 – 20	20 – 25	110	200 - 240	407
Density ($g.cm^{-3}$)	1.1	2.0	1.7 – 2.0	4.5	8.3 – 9.2	3.5

The basic idea in the development of new alloys for medical applications, therefore, is to replace aluminum and vanadium with niobium, tantalum and zirconium. In order to thus avoid the negative features are now widely applied to the Ti-6Al-4V alloy, as shown that the toxicity of these elements is extremely low.

The alloy Ti-13Nb-13Zr, developed in the United States, shows remarkable properties. This is the type of β titanium alloys and is characterized by low values of elastic modulus and strength significantly improved in comparison to commercial Ti-6Al-4V alloy, which is extremely interesting for applications in biomedical engineering [7].

The relatively low hardness of titanium alloys, however, affect their poor wear resistance and these alloys without additional surface treatment such as ion implementation, can not be used for the preparation of joint surfaces.

4. THE LEVEL OF CUSTOMIZATION AND COMPLIANCE WITH STANDARDS

Experience shows that any impromptu or untested solutions very quickly cause unwanted effects and consequences that are difficult or impossible to correct. For these reasons, the entire field of medicine and orthopedic and reconstructive surgery requires the application of certain standards and guidelines will be a limit to customization and extensions.

The ISO-13485 is an international quality management system (QMS) standard defined for the medical device industry. It is therefore important for manufacturers of equipment, apparatus (accessories) and semiconductor devices used in medical electronics to get certified to the ISO-13485 in order to secure and maintain global business. Created by the International Organization for Standardization (ISO), the ISO-13485:2003 borrowed the structure of the ISO-9001:2000.

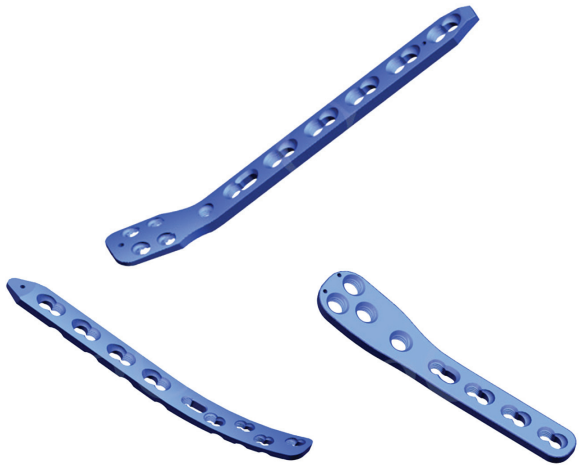

Fig. 8. Distal, distal medial and proxsimal-medial plate

The benefits of registration to ISO-13485 include: 1) international recognition of compliance with the FDA Quality System Regulations and unique medical industry standards, facilitating global business; 2) a more efficient, cost-effective, and stable organization; 3) improved process, product, and service quality; and 4) better documentation of existing processes.

ISO-13485:2003 basically consists of: 1) certain ISO-9001 requirements and 2) newly defined requirements catering specifically to the medical device industry. As such, ISO-13485 differs from ISO-9001 in certain ways, modifying or even excluding some of the latest requirements. For instance, the ISO-13485 excludes the ISO-9001's requirements related to continual improvement because most medical device regulations require organizations to maintain their quality management systems, and not to improve them. Thus, while ISO-9001 emphasizes the importance of improving quality systems, ISO-13485 emphasizes the importance of maintaining them. ISO-9001 customer satisfaction requirements were also excluded because some of the committee members who worked on ISO-13485 found them to be too subjective.

Some key points adopted by the ISO-13485 include: 1) focus on meeting regulatory requirements; 2) focus on meeting customer requirements; 3) use of a 'process' approach; 4) maintenance of the effectiveness of quality management systems; and 5) maintenance of procedural documentation.

As mentioned, the ISO-13485 has special requirements that are not covered by ISO-9001:2000. These special requirements include both documentation and system/process requirements that cater to the medical device industry.

Aside from regulation-required documents, additional documentations required by ISO-13485 include those pertaining to: 1) responsibilities and authorities; 2) training procedures; 3) health, cleanliness, and clothing;

6) environmental conditions; 7) control of contaminated products; 8) risk management; 9) customer requirements; 10) design and development; 11) purchasing control, including purchase traceability and verification; 12) reference materials; 13) labeling and packaging; 14) installation and verification; 15) sterilization process validation; 16) preservation of product (including shelf life); and 17) measurement and monitoring.
Special system / process requirements of the ISO-13485 include: 1) risk management systems; 2) clinical evaluations and trials; 3) product cleanliness and contamination controls; 4) requirements for implantable devices; 5) proper communication of advisory notices; and 6) additional research and development requirements.

5. CONCLUSION

Extensively investigations and the facts point to the possibilities and advantages of new technologies in the field of orthopedic surgery and in other medical disciplines. If the problem considered multidisciplinary, using new technologies and higher degree of customization with good knowledge of the properties of new materials and alloys, patients get a much better chance in their fight for a healthy and normal life. It is certain that medicine retains a leading and crucial role in such a complex process, along with the fact that it must always be ready to accept the latest developments in related disciplines that offer its latest solutions and results**.**

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CORRESPONDENCE

Saša RANĐELOVIĆ, Assoc. prof. D.Sc. Eng.
University of Niš
Faculty of Mechanical Engineering
Aleksandra Medvedeva 14
18000 Niš, Serbia
sassa@masfak.ni.ac.rs

Dragan MIŠIĆ, Asst. Prof. D.Sc.Eng
University of Niš
Faculty of Mechanical Engineering
Aleksandra Medvedeva 14
18000 Niš, Serbia
draganm@masfak.ni.ac.rs

Miroslav TRAJANOVIĆ, Prof. D.Sc. Eng
University of Niš
Faculty of Mechanical Engineering
Aleksandra Medvedeva 14
18000 Niš, Serbia
traja@masfak.ni.ac.rs

Nikola VITKOVIĆ, Ass.
University of Niš
Faculty of Mechanical Engineering
Aleksandra Medvedeva 14
18000 Niš, Serbia
vitko@masfak.ni.ac.rs

Marko VESELINOVIĆ, PhD student
University of Niš
Faculty of Mechanical Engineering
Aleksandra Medvedeva 14
18000 Niš, Serbia
marko.veselinovic@masfak.ni.ac.rs