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Abstract	The medical device industry is one of the fastest growing industries. Medical devices cover a wide range of products for medical use, ranging from the simplest to the most sophisticated medical equipment. Thanks to today's rapid development in both medicine and technology, the development of medical devices has been intensified. Given the multidisciplinary characteristics of such devices and their environment, the process of developing medical devices involves some special characteristics. Due to their potentially harmful effects in the interaction with tissues and organs, compliance with the various directives is of particular importance. For these reasons, it is necessary to carefully follow all steps in the design and manufacture of medical devices in order to obtain regulatory approval and licensing of the products, so that their implementation is safe for users. This paper demonstrates that medical device design is a unique and complex process which requires an organized development strategy that ensures that the product meets design and user goals, is technically reliable, and can be produced safely and efficiently.

Keywords (separated by '-')	Medical device - Design process - Design methodology - Product development - Directives

Design and Development of Medical Devices

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Abstract. The medical device industry is one of the fastest growing industries. Medical devices cover a wide range of products for medical use, ranging from the simplest to the most sophisticated medical equipment. Thanks to today's rapid development in both medicine and technology, the development of medical devices has been intensified. Given the multidisciplinary characteristics of such devices and their environment, the process of developing medical devices involves some special characteristics. Due to their potentially harmful effects in the interaction with tissues and organs, compliance with the various directives is of particular importance. For these reasons, it is necessary to carefully follow all steps in the design and manufacture of medical devices in order to obtain regulatory approval and licensing of the products, so that their implementation is safe for users. This paper demonstrates that medical device design is a unique and complex process which requires an organized development strategy that ensures that the product meets design and user goals, is technically reliable, and can be produced safely and efficiently.

Keywords: Medical device · Design process · Design methodology · Product development · Directives

1 Introduction

Thanks to today's rapid development in both medicine and technology, the development of medical devices has been intensified. The medical device is a term used for a large variety of products for medical application, going from the simplest to the most sophisticated medical equipment. As the functionality of the device becomes more complicated, problems related to reliability, efficiency and safety appear [1]. Given the multidisciplinary characteristics of such devices, as well as their potentially harmful effects in the interaction with tissues and organs, it is of great importance to harmonize their development process with various directives. Many studies have shown that the application of design methods in the design of medical devices and their development can achieve significant improvements [1–3]. Pietzsch et al. presented the linear stage-gate model that gave a comprehensive description of various activities and decisions related to the development of medical devices [2].

B. Lalic et al. (Eds.): IS 2020, LNMUINEN, pp. 1–8, 2022.
http://doi.org/10.1007/978-3-030-97947-8_6

Medical devices are important parts to improve patient overall safety, so it is necessary to know the way they are designed and developed. Tamsin et al. analyzed important factors such as: product development, tissue modelling, training, and FDA regulations, which must be considered during the design process [3].

Scientific and technological development has made it possible to achieve the design of medical devices that will not be only functional, but also modern and advanced. Barrios-Muriel et al. gave an overview of various rapid prototyping applied in the orthoprosthetic industry and pointed out that the choice of material in the design of an orthotic device is crucial for its success [4]. High-tech development has enabled the research of substances at the molecular level, which has encouraged the design and development of nanostructured materials that offer outstanding properties for use in medicine [5], prostheses and bone replacement implants. The application of these new nanomaterials in bio-medicine has led to the emergence of a hybrid science called nanobiotechnology [6]. Ramos et al. gave an overview of the use of new materials (nanoparticles) for specific medical applications in [7].

2 Regulatory Framework for Medical Devices

In recent decades, medicine and technology have been strongly linked. Nowadays, one of the most important tasks is the development and improvement of devices used in medicine, not only for better medical practice, but also for better understanding of human bodies. For these reasons, it is necessary to carefully and thoroughly perform all steps in the design and manufacture of medical devices in order to obtain regulatory approvals and licensing of products so that their application is safe for users.

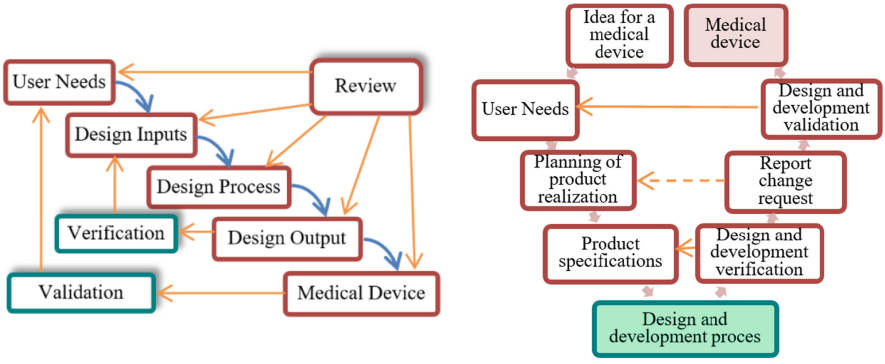
There are many different organizations around the world that are responsible for regulating the activities of companies that manufacture medical devices. In the European Union, the Medical Devices Directives are in force, while in the USA, they follow the regulations of the Food and Drug Administration [8]. There is a common regulation for the members of The Global Harmonization Task Force (GHTF), whose members are: Australia, Canada, the European Union, Japan and the United States. In Serbia, the Medicines and Medical Devices Agency is responsible for regulatory affairs. According to The Global Harmonization Task Force, a medical device is any instrument, apparatus, machine, appliance, implant, etc. intended by the manufacturer to be used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or other condition [9].

3 Medical Device Product Design and Development

Product development refers to the realization of market demands or a new idea into a new product [10]. Within the product development, a creative phase takes place which is related to product design. The design includes the selection and analysis of relevant data and factors in order to innovate the product, optimize its functions and improve quality. When it comes to the design and development of medical devices, the main goal is to provide a more efficient solution for products for medical use in order to improve and save human lives. In order to meet the requirements for good design, it is necessary

to apply a methodology that systematizes research and directs the process towards the right solution [11].

As indicated in the previous chapter, to be compliant to regulations medical devices, must go through rigorous testing, validation and verification processes, which is specific to medical industrial design and production quality control standards. Verification and validation are checks in the design process that identify flaws and deviations in the design before the medical device is produced. Verification is a detailed review of design aspects at different stages of medical device development and provides an answer to the question of whether a product is correctly designed. Validation ensures that the correct product is designed to meet the needs of users [12].



(a) (b)

Fig. 1. Product design and development models: (a) Waterfall model and (b) V-model.

Verification and validation prove that the medical device is safe, effective and meets the needs of end-users and patients. The importance of these activities in the design process of medical devices is illustrated by the example of the traditional waterfall model, shown in Fig. 1a [8]. The design inputs phase involves developing an idea and collecting data to define conditions that the product should satisfy. These conditions (requirements and wishes) are the result of the current needs of the market, users and production capabilities. During the creative phase, requirements are developed and a device is designed that will meet these demands. The design is then tested and evaluated to produce a device that meets customer and market requirements and is optimized for production.

In addition to the waterfall model, validation is also presented in the literature as a product development V-model [13]. V-shaped model, shown in Fig. 1b is an expansion of classic waterfall model and it's based on associated test stage (the right side of the V) for the every development stage (the left side of the V). This model due to the equal number of testing and development is referred to as the verification and validation model. This is a very strict model and the next stage is started only after the previous one is completed.

The main difference between the waterfall model and the V-model is that in the waterfall model the activity tests are performed after the completion of the development activities, while in the V-model, the testing starts from the first phase. While the tests are just one of the steps in the waterfall, it seems to be practically half the process in the V-model. Basically, both models follow the same steps only they are presented in different ways.

4 Design Factors of Medical Devices

In the process of product development in order to achieve high quality, the designer must consider a large number of different influencing factors such as function, purpose, material, colour, texture, etc. In order to design a product that will fully meet the requirements of users and be competitive in the market, it is necessary to define in more detail which functions are vital for the successful operation of the device, and which are the secondary functions. Also, designers must be acquainted in detail not only with what the product should do, but also where it will probably be used (e.g. in a home, hospital, or operating room) and who will use it (e.g. children or adults). The realization of the function and purpose includes many variations of appearance, design and materials used. One of the most effective methods for improving the performance of medical devices is to replace the metal with ceramic or plastic, as shown in Fig. 2. By applying high-performance biocompatible polymers, with simple design modifications, cost savings, improved aesthetics and ergonomic improvements are achieved. One of the advantages of using plastic is the possibility of painting products of different sizes (colour coding), which can be easily and quickly recognized in the operating room.

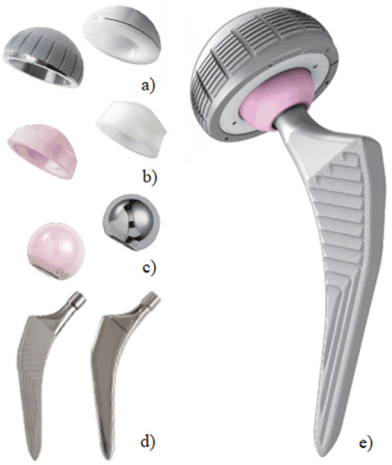


Fig. 2. Material as a medical design factor: (a) cup – metal or polyethylene, (b) liner – ceramic or polyethylene, (c) head – ceramic or metal, (d) femoral stem – cement less or cement and (e) hip prosthesis (adapted from [14]).

Colour is a very important element in the design of both industrial and medical devices because the use of colours can achieve very different effects. In addition to improving the aesthetic appearance of the product and emotional - psychological effects, colour can draw users' attention to certain elements of the product and provide them with information about their functions and characteristics, as well as the possible danger. Also, the parts that are threatened by some danger should be specially painted with colours that are easily noticeable and that excite the human psyche and have a strong effect on it (red, orange, yellow, etc.). One of the most important applications of colour in the design of medical devices is colour coding [15].

When choosing a colour, surface treatment should be taken into account, which can significantly affect the perception of colour. The texture may occur as a result of processing or are deliberately formed as a functional or in order to improve the aesthetic appearance of the product. When designing products for use in the operating room and other environments with high lighting, one should keep in mind the fact that white reflects the most light, causing glare and eye fatigue. Giving white surfaces a matte finish will alleviate these problems to some extent. In addition to visual perception, tactile texture sensation is important in medical devices.

(a) (b)

Fig. 3. The texture of medical devices: (a) trigger for open-surgery device and (b) trigger for laparoscopic-surgery device [16].

For example, while the trigger of an open surgery device is rubberized and textured on the inner edge and part of the outer edge for flexible control, the lower outer edge has become extremely smooth without the use of rubber, as shown on Fig. 3a. This design was chosen after confirming that the rubberized trigger surface can inadvertently catch the surgical curtains and interfere with the operation. For a laparoscopic surgery device, the entire outer edge of the trigger is non-rubberized, as shown on Fig. 3b, because of the greater possibility of it coming into contact with surgical drapes in such operations [16].

The texture of medical devices can affect how easily the product can be cleaned and disinfected. Fingerprints and stains are easily seen on shiny surfaces, but too rough a texture allows for easier surface contamination.

5 The Example of the Designs of Custom Made Hip Prosthesis

Using the artificial hip joint instead of natural hip joint and establishment of the patient's lower limb function become very often procedures in orthopaedic surgery. According to research, more than 500,000 procedures of this type are performed every year in the US and UK alone [17]. There is a significant increase in the number of diseases whose treatment needs replacement of the hip joint with an artificial.

The improvements in the hip endoprostheses' characteristics can be obtained by using a personalised design approach, computer-supported analyses in order to optimise the characteristics and production. Recent research shows that the custom-made endoprostheses allow significantly improved implants fittings to the bone [18] and biomechanical characteristics [19] as well as significantly lower failure occurrences [20].

Researches from the University of Novi Sad [21] presented the original methodology of designing the hip joint prosthesis according to the patient's measurements. It is based on the assumptions that it is suitable to apply a general geometric model based on the mathematical description of the outer surface of the endoprosthesis.

The development of hip joint endoprostheses using computer support in methodology way includes a systematic access to defining geometric parameters which are classified according to the importance regarding the prosthesis shape and its function. The methodology of custom design of hip joint is based on the application of three groups of parameters for the geometry of the endoprosthesis body. According to the purpose and stage in which they are used, the parameters can be classified by their effect on the location, overall dimensions, orientation and the endoprosthesis shape (Fig. 4).

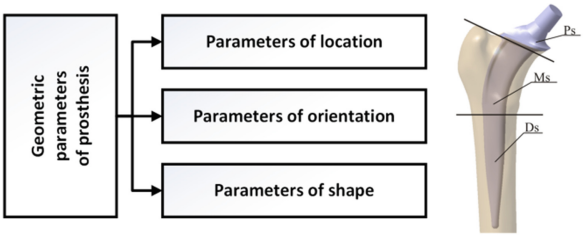
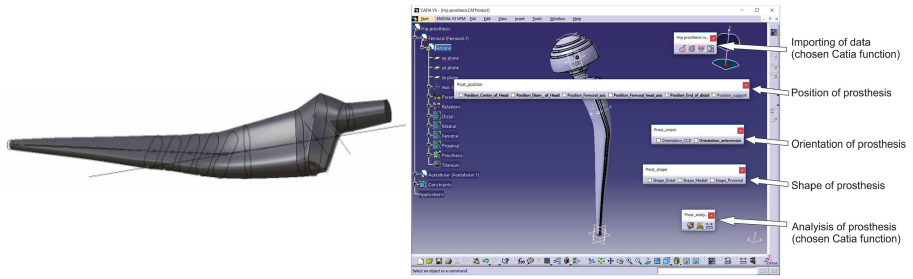


Fig. 4. Parameters of the endoprosthesis [21].

Developed software was used for designing of the hip joint endoprosthesis body. It allows the design of the endoprosthesis body and the selection of the acetabular component. The entire femoral part of the endoprosthesis was obtained by forming a common multi-sections surface containing the said profiles guided by the resulting curve attained by the integration of the partial guiding curves. The surface thus obtained is added to the proximal part of the femur model which is defined by the surface forms, determined by the standard of the bond between the artificial head of the femur and the body of endoprosthesis, as well as additional shapes conditioned by the requirements of the technology of manufacturing and assembly into the body (Fig. 5).



(a) (b)

Fig. 5. Design software implementation: (a) graphical definition of endoprosthesis body and (b) graphical interface of the developed software [21].

6 Conclusion

The development of medical devices is a complex activity based on market demands, where compromises must be made regarding factors such as product innovation, regulatory risk, application of new technologies and production opportunities. Therefore, it is essential that medical device manufacturers consider all influencing factors and apply the most efficient methodology. This paper presents some of the models that are applicable for improving the design and development of a medical product. The need for verification and validation in the medical device design process in order to obtain device approval was emphasized. From the presented review it can be concluded that user requirements must be entered correctly at the beginning of the product development process. Also, consideration of all regulatory aspects should be included in the early design phase. This study highlighted the main factors to consider when designing medical devices.

The process of designing and fabrication of medical devices has been a very interesting research area which still attracts considerable engineering activities. The main reasons for such interest are the complexity of biomechanical conditions, the influencing factors on the operation success and medical devices lifetime, as well as the cost-effectiveness of their production.

The basic advantage of the described methodology of custom made endoprostheses is the formalisation of all stages of the development and production of custom made implants. Additionally, defining the parameters of the endoprosthesis geometry and their association with bone morphology creates possibilities for partial or complete application of the methodology, depending on the available methods of the diseased femur imaging technique. There is a significant area left for its expansion with new parameters and criteria. Also, despite significantly higher prices, research indicates an increase in the need for patient-specific endoprostheses, primarily in the revision and reconstructive procedures. The number of such procedures indicates the market existence, whose growth prospects may influence primary endoprosthesis market as well.

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