FEM used in improvement of quality of medical devices

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Analysis and modelling

ABSTRACT

Purpose: The fundamental aim of this research was to determine the biomechanical characteristics of the medical bed made of carbon steel and an assessment of its stability. To define the biomechanical characteristics of the bed design, the finite element method (FEM) was applied. Additionally, the risk analysis was conducted according to the directives of ISO 14971 standard.

Design/methodology/approach: The research was carried out on the typical rehabilitation bed. To define the biomechanical characteristics of this equipment, the finite element method was applied. Geometric model of medical bed, was discretized by means of SOLID 95 element. Appropriate boundary conditions imitating phenomena in the real system with appropriate accuracy were established. The aim of biomechanical analysis was calculation of displacements and stresses in the bed's construction elements in a function of the applied loading. In order to carry out calculations, 3 models of diverse variants of loading were selected – safe working load - model 1, transverse stability - model 2 and longitudinal stability - model 3.

Findings: The analyses showed the difference in displacements, strains and stresses in the characteristic points depending on the selected loading. That also helped to determine maximal loading causing the exceeding of the yield stress of the bed's components.

Research limitations/implications: The limitations were connected with simplification of numerical model of femur as well as with the selected boundary conditions.

Practical implications: The obtained results can be useful in the designing process (modification of requirements regarding design and construction, as well as materials used in the production of the device, and reduction of risk as far as possible to the patient). They prove that 3D geometrical analysis works quite well for assistive medical devices design.

Originality/value: Stress-strain-displacement characteristics of the medical bed's elements, obtained from the numerical analysis were presented in the work.

Keywords: Numerical techniques; Biomechanical analysis; Medical device

1. Introduction

The term "quality" is defined in ISO 8402 [1] as: *the totality of features or characteristics of a product or service that bear on its ability to satisfy stated or implied needs.* Whereas a "medical device" under The Medical Device Directive (MDD) is defined as any instrument, apparatus, appliance, software, material or other article. Its proper application intended by the manufacturer to be used - alone or in combination with necessary software - for human beings in the purpose of: diagnosis, prevention, treatment, alleviation of disease, replacement, modification of the anatomy, supporting or sustaining life, etc. [2]. This MDD is intended to harmonize the laws relating to medical devices within the European Union and also consists the general requirements specification that the medical devices must:

- be safe - any risk must be acceptable in relation to the benefits offered by the device
- be designed and manufactured in such a manner that risk is eliminated or protected against
- perform in accordance with manufacturer's specification
- the safety and performance must be maintained throughout the indicated lifetime of the device
- the safety and performance of the device must not be affected by normal conditions of transport and storage.
- the particular specifications concern e.g. construction and environmental properties - Fig. 1 [3, 4].

Compliance with the requirements of the MDD is declared by placing the CE Marking on the product. The regulatory authorities recognize different classes of medical devices, based on their design complexity, their use characteristics, and their potential for harm if misused. The classification of medical devices in the European Union includes four classes, ranging from low risk (Class I) to high risk (Class III). This classification depends on rules that involve the medical device's duration of body contact, its invasive character, its use of an energy source, its effect on the central circulation or nervous system, its diagnostic impact or its incorporation of a medicinal product. Class I devices present minimal potential for harm to the user and are often simpler in design than Class IIa and IIb or Class III devices. These devices are subject only to general controls. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and additional existing methods are available to provide such assurances. High risk devices (Class III) are life supports, critical monitoring, energy emitting and other devices whose failure or misuse is reasonably likely to seriously injure patient or staff.

Medical devices only cause harm if a sequence of events occurs, which results in a hazardous situation and which then could cause or lead to harm. A sequence of events includes both a single event and combinations of events [3-6].

That's why the manufacturer makes judgments relating to safety of a medical device, including the acceptability of risks, taking into account the generally accepted state of the art, in order to determine the suitability of a medical device to be placed on the market for its intended use. The acceptability of a risk and its perception can vary greatly depending upon many factors - Fig. 2.
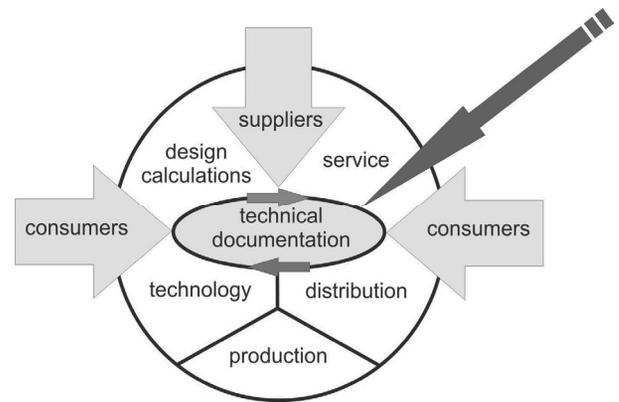
Fig. 1. Environment of organizations connected with technical documentation [3-5]

Fig. 2. Risk ranges in medicine [5]

The quality and risk management regarding the topic for regulatory purposes is convened by:
- ISO standard series
- Directive 2007/47/EC of the European Parliament and of the council of 5 September [2]
- ISO 13485 [6] and ISO 14971 [7].

Assurance of high level quality in relation to medical devices requires many aspects - Fig. 3.

The requirements of standards listed above are applicable to all stages of the life-cycle of a medical device. The standard provides manufacturers with a framework within which experience, insight and judgment are applied systematically to manage the risks associated with the use of medical devices. Particularly ISO 14971 deals with the processes for managing risks to the patient, the operator and other people, to other equipment and to the environment. It was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in

other healthcare industries, this standard could be used as informative guidance in developing and maintaining a risk management system and process. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity [8-11].
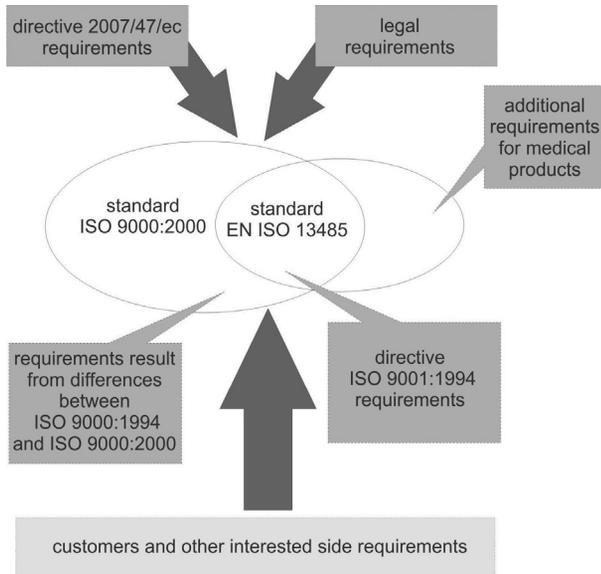
Fig. 3. Requirements for manufacturers assuring high quality of devices [8]

2. Material and methods

Hospital bed is designed for laying of adult patients at hospitals during their diagnosing, monitoring and treatments. Bed construction is made of carbon steel sections, coated with polyester-epoxy varnish. Movement of the back rest segment is performed manually.

The risk analysis resulting from the application of this equipment was applied. Additionally, the numerical analysis was carried out to identify the most hazardous locations of this device and its safety in operational use.

2.1. Risk analysis

To be confident that safety of a medical device will be assured – the systematic use of available information to identify potential source of harm and to estimate the risk should be done. For the rehabilitation bed, belonging to the I class of the medical devices, particular attention was paid to the probability of occurrence of harm and the severity of that harm [14]. The way a risk was perceived also into account, for example:
- whether exposure to the hazard seems to be involuntary
- avoidable
- from a man-made source
- due to negligence.

One of the available techniques for risk analysis is Failure Mode and Effects Analysis (FMEA). It is a technique by which an effect or consequences of individual components are systematically identified and estimated (is more appropriate as the design matures). It is an inductive technique using the question "What happens if ... ?". Components were analyzed one at a time - this is done in a "bottom-up" mode, i.e., estimating priority numbers: LPZ (meaning); LPW (occurring) and LPO (finding) that contain values within the range from 1 to 10. Whereas LPR (priority risk number) determine general risk level. It is enumerated according to a dependence (1):

$$LPR = LPZ \times LPW \times LPO \qquad (1)$$

LPR values are contained within the range from 1 to 100 and are depending on value of the estimated risk, then it is qualified to the one of the risk levels of probability:
- Low risk   LPR < 50
- Medium risk   LPR = (50 to 100)
- High risk   LPR >150.

2.2. FEM analysis

Geometrical model of the hospital bed was carried out in ANSYS software - Fig. 4.
The following material properties were set:
- Young modulus E = 200000 MPa
- Poisson's ratio ν = 0.3
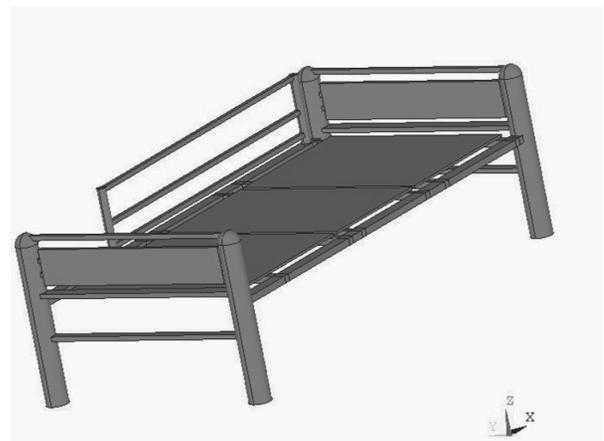
Fig. 4. Geometrical model of hospital bed chosen for numerical analysis

On the basis of the geometrical models a finite element mesh was generated - Fig. 5. The meshing was realized with the use of the SOLID45 element. This type of element is used for the three-dimensional modeling of solid structures. The element is defined by 8 nodes having three degrees of freedom at each node: translations in the nodal x, y, and z directions.

In the course of the work, displacements, strains and stresses, depending on the variants of the loading (closely connected with EN 60601-2-38 [9]) were calculated.

In order to carry out the calculations, appropriate initial and boundary conditions reflecting phenomena in real system were determined - Fig. 6.

The following assumptions were set:

- lower part - all legs of the bed frame were immobilized (all degrees of freedom of nodes on external surfaces of condyles were taken away)
- construction was loaded according to the schemes presented in Fig. 7. There were perform three stages of solution: 1 - safe working load, 2 - transverse stability and 3 - longitudinal stability.
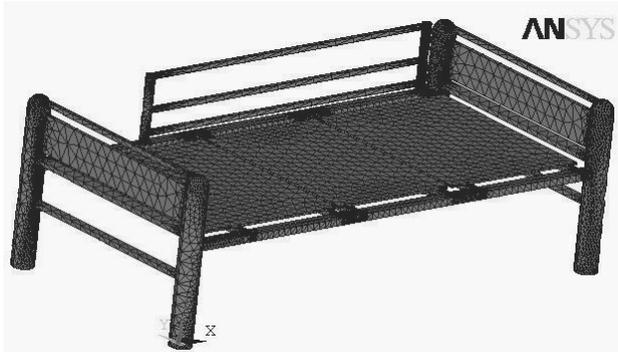
Fig. 5. Discrete model of the bed frame
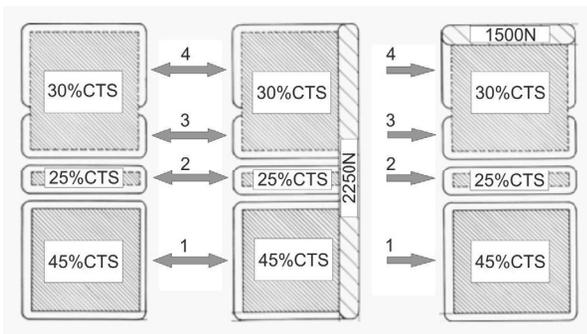
Fig. 6. Variants of loading [9]

The range of analysis consisted of determination of displacements, strains and stresses in elements of the construction of the hospital bed made of carbon steel.

3. Results

3.1. Risk analysis

On the basis of the performed analyses, it can be stated that 21 identified hazards connected with hospital bed is qualified to the low risk [12]. It was demonstrated that medical bed is safe medical equipment oriented to the adults (lying) and to the rehabilitation of the convalescents regaining physical fitness.

a)

b)

c)
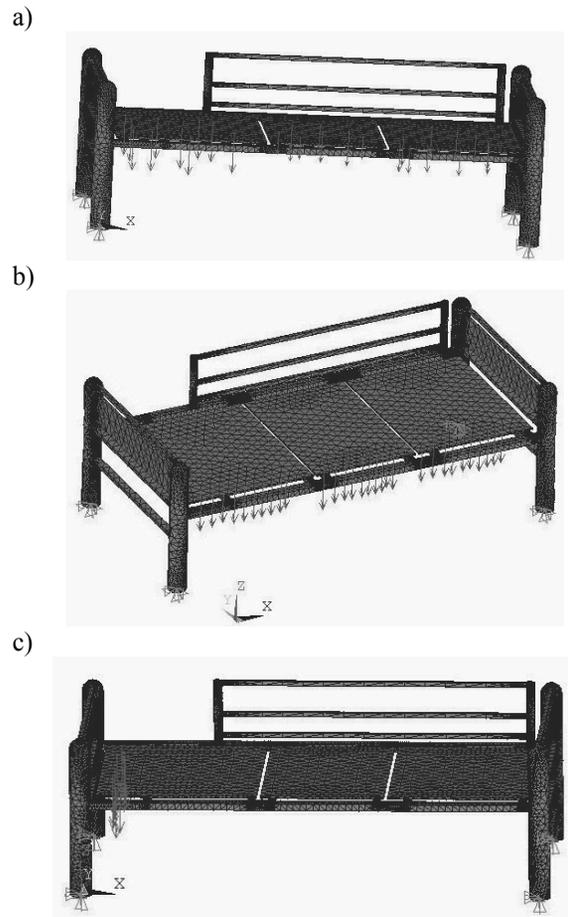
Fig. 7. Loading scheme of model: a) safe working, b) transverse stability, c) longitudinal stability

3.2. FEM analysis

The obtained maximal displacements, strains and stresses for the bed frame for three load steps are the reduced values according to the Huber-Mises-Henck hypothesis. The obtained results were presented in table as well as in the graphic form.

The results for the given boundary conditions were presented in Table 1 and Figures 8 to 16.

On the basis of the analysis it was concluded that displacements depending on the applied boundary conditions were very small. Every displacements were minimal and weren't menace to bed construction and safety of a patient.

Maximum equivalent stresses were localized in the point of the applied loading. Lower values of both displacements and stresses were presented in the model loaded with the force of 1700 N - Fig. 10.

Maximum stresses in the frame construction were localized in the zone of the elements connection. For the transverse stability, maximum stresses on the whole surface did not exceed 24 MPa – Fig. 13.

Table 1.
Results of the FEM analysis of the bed frame

	Variants of loading	Loading value	Displacement D, mm	Total Mechanical Strain ε, %	von Misses Stress σ, MPa
1	safe working load	1700N	0.21	0.087	17
2	transverse stability	1500N	0.35	0.123	24
3	longitudinal stability	2250N	0.14	0.101	19

FEM analysis of the bed frame – safe working load
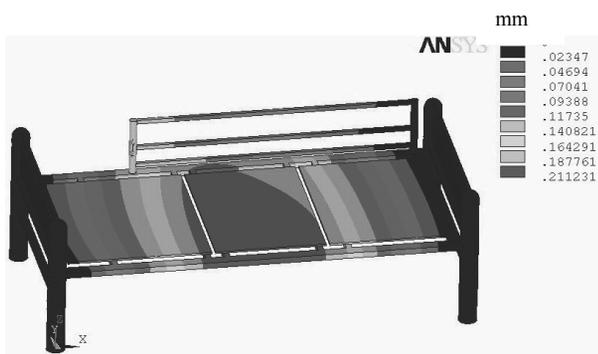
Fig. 8. Displacement distribution in bed frame, safe working load
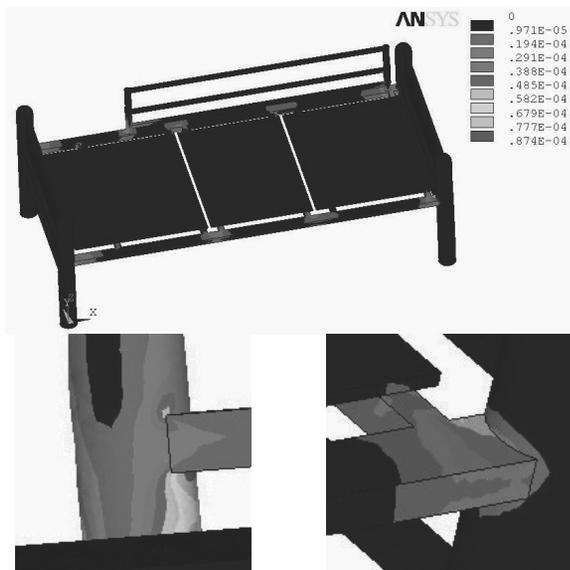
Fig. 9. Strain distribution in bed frame, safe working load
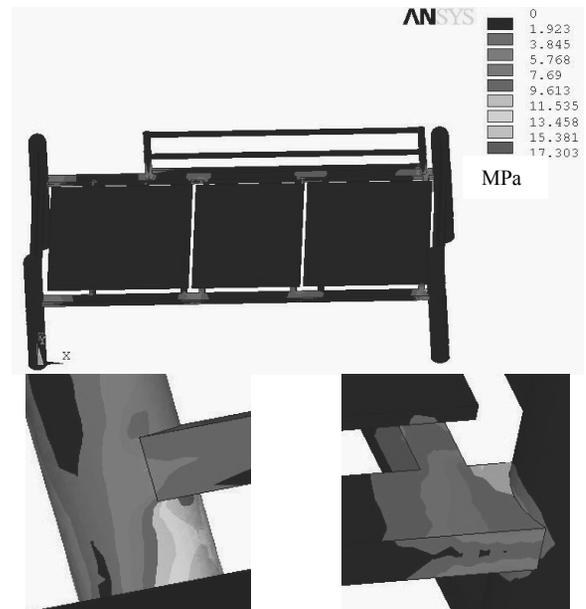
Fig. 10. Stress distribution in bed frame, safe working load

FEM analysis of the bed frame – transverse stability

Fig. 11. Displacement distribution in bed frame, transverse stability

B. Ziębowicz, A. Ziębowicz, J. Szkodny
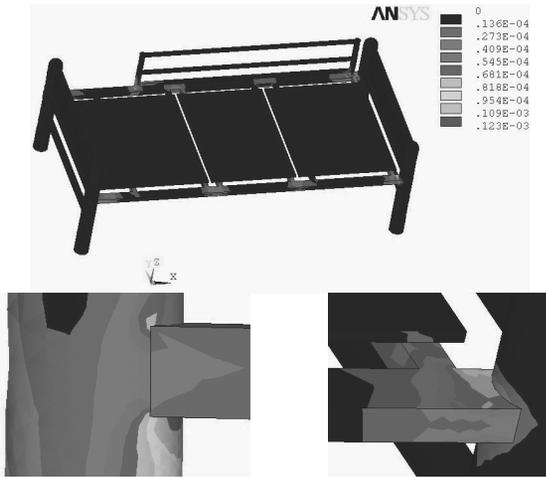
Fig. 12. Strain distribution in bed construction, transverse stability
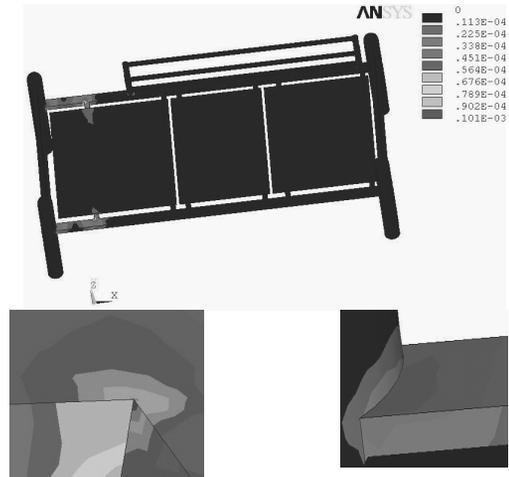
Fig. 13. Stress distribution bed frame, transverse stability
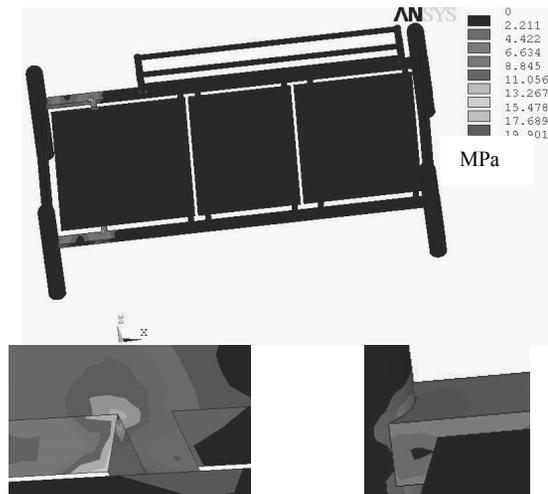
FEM analysis of the bed frame – longitudinal stability

Fig. 14. Displacement distribution in bed construction, longitudinal stability

Fig. 15. Strain distribution in bed construction, longitudinal stability
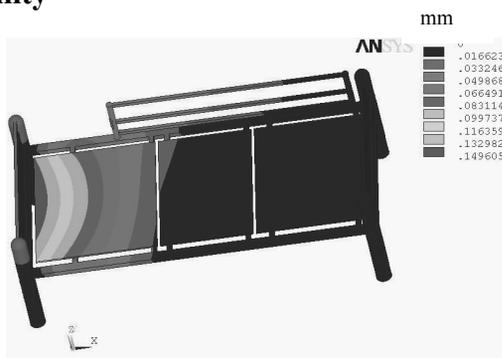
Fig. 16. Stress distribution in bed construction, longitudinal stability

On the basis of the performed analyses, it can be stated that the bed construction is stable and safety because of occurring very small values of strains.

The obtained results of stress analyses for particular variants of loading allowed to reveal critical value of stress [12].

Additionally ascertained, that during examinations both transverse and longitudinal stability – bed frame didn't lose its balance, as well didn't reveal damage of its construction.

4. Conclusions

Medical technology continues to advance rapidly, as physicians and engineers move closer and understand better each other's needs. Nowhere is there more evidence for this than in the development of advanced medical implants. Traditionally, new

products were developed by prototyping and evaluation; however, this process is very time-consuming and often does not fully reveal any potential failures [14-16].

The company producing specialized medical equipment surely wants to increase its speed and flexibility, and looks for a design solution that could support these goals. Then they can choose finite element modeling (FEM) [17-34], because it is instrumental in reducing system failures, improving system reliability, maximizing system uptime, reducing system maintenance and warranty costs, and increasing customer satisfaction (easy to modify existing designs to fulfill client order requests and specification, and in new product design). It is major savings in prototyping and manufacturing because the design is then the first prototype (allowing the designer to computer-test his new product). FEM is also one of the basic research methods oriented toward risk management of the medical devices. Mentioned method consists a computer model of a material or design that is stressed and analyzed for specific results. In case of any failure, finite element analysis may be used to help determine the design modifications to meet the new condition.

The preliminary numerical analysis of the medical bed for the applied different variants of loading allowed to indicate dangerous areas of the construction and it is starting point for the geometry optimization. The analysis of the obtained results showed that for the given way of loading, the damage of the bed frame is highly probable in the most vulnerable area e.g. welding components. The research carried out on the simplified model, taking into consideration only the bed frame.

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