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RISK MANAGEMENT DURING A PROCESS OF DESIGNING A TECHNICAL PRODUCT

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Abstract

This paper focuses on an application of risk management in a process of creating technical solutions on a specific case study. The case study will deal with manufacturing of a medical equipment made of unconventional materials, specifically a tibia protector. Basic theoretical starting points for managing risks will be described in the introduction of this article, these starting points will be used to determine the key risks which will be later described and evaluated on a base of their probability and impact. Defined risks will be then included into the designing phase in order to fully unlock the potential of risk management even for prevention purposes.

Keywords: Risk management; Tibia protector; Technical solution; Unconventional material.

1. Introduction

The number of authors studying risk management is increasing lately because companies have to reduce their error rate and make themselves as efficient as possible due to still raising competition on the market. [1;2] If organizations do not wish to suffer a loss in business, they can follow the methods of business risk management where various risks can be found. Such as manufacturing, technical, economic and investment risk and more. [3;4] The problem starts when the organizations are supposed to begin control risks in new products in early development, here it is up to the designer to take into account certain risks when creating a design. They also have to be familiar with the concepts of risks and acknowledge benefits from timely implementing it. Because there is an idea at the very beginning of designing a new product. An idea which the designer will transfer into the final product, the methods of risk management have to be in this case sufficiently easy to follow. [5]

We can find many different motives for such developments but if we focus solely on medical industry, these new concept designs should be united with only one goal in mind which is helping others, making their lives easier and being as useful as possible. In order to achieve this, it is necessary to also focus on risks which could endanger our efforts from the very beginning of the project. There are several questions that have to be answered before any advanced stage of a project. Which risks can we expect to occur, how grave the risks are and their impacts and consequences? What should be done with these risks? How the negative impacts and economical results should be approached? How the possibility of a risk occurring can be reduced and how to evaluate the experience obtained while dealing with a dangerously situation? [6] This paper follows up on managing risks during a process of designing a technical application.

2. Risk management

A risk is defined by ISO 9000:2015 norm as an effect of uncertainty where the effect is a deviation from what was expected, it can be either positive or negative and the uncertainty is a state caused by a lack of information. [7] From risk control point of view the risk will be viewed as a possible event which differs from expected state of development. Nevertheless, the risks should not be reduced to mere possibility because it includes both possibility itself and a quantitative range of the event. [8] If a risk occurs it does not immediately mean it will cause a negative effect with consequences. It is beneficial to have some corrective measures prepared in case the risk has to be mitigated.

Division of risks
- Expectable – easier to control and to work with, these risks are repeatable in many cases.
- Unexpectable – harder to control, impossible to predict and their repeatability is improbable. [9]

Risk management is no longer optional but it is rather established by norm requirements, legislation or by customers personal requests.

2.1 Risk management process

No matter the reason an organisation has for risk management, these logical steps have to be always followed.
- Risk analysis (finding out what are the threats and if there are any) – it is necessary to locate risks that can endanger the project, mark them and describe them in the most detailed manner possible. Only the risks that are a significant threat to the project should be chosen for monitoring because it is impossible to create a list of all possible threats.
- Evaluate risks (determine a level of risk and its acceptability) – qualitative and quantitative methods are used for risk analysis both of these methods are sorted according to the mean of expression of given values in the risks analysis. It is possible to use either one or combination of both methods.
- Secure risks (supervise the risks and set corrective measures in case some risks occur) – most often used applied methods of reducing and securing the risk are mainly preventive actions, risk retention, transferring the risks to other entrepreneurial subjects, insurance, avoiding risks (avoiding the activity during which the risks could occur), creating reserves. [10]

The risk management is not only beneficial to organizations and their owners for whom the knowledge of risk is important for its financial reasons but also project managers and end customers. (Customers get products they need for a fair price, in agreed time period with no extra expenses). [11]

Hard benefits	**Soft benefits**
More trustworthy plans with better information, time schedules, budgets	Gaining experience and improving communications
Objective comparison of alternative suggestions	Development of employees' ability to evaluate risks
Identification of responsibility for specific risks	Focusing on important issues
Realistic evaluation of possible risks	Responsible approach to customers

Table 1. Hard and soft benefits of risk management process

3. Case study

Case study was performed on the process of making a medical device made of unconventional materials in this case a custom-made shinbone protector designed for a leg of specific patient. The main purpose of this protector is spreading the pressure on the spot where the bone had been broken which is caused by the edge of skiing boot during manoeuvring.

3.1 Current status

The patient has recovered from fractures of his shin bone and calf bone of his left leg. Two surgical bolts were used for fixation of the shin bone during the surgery. The bone later outgrew the bolts making them impossible to take out, see Tab. 1.

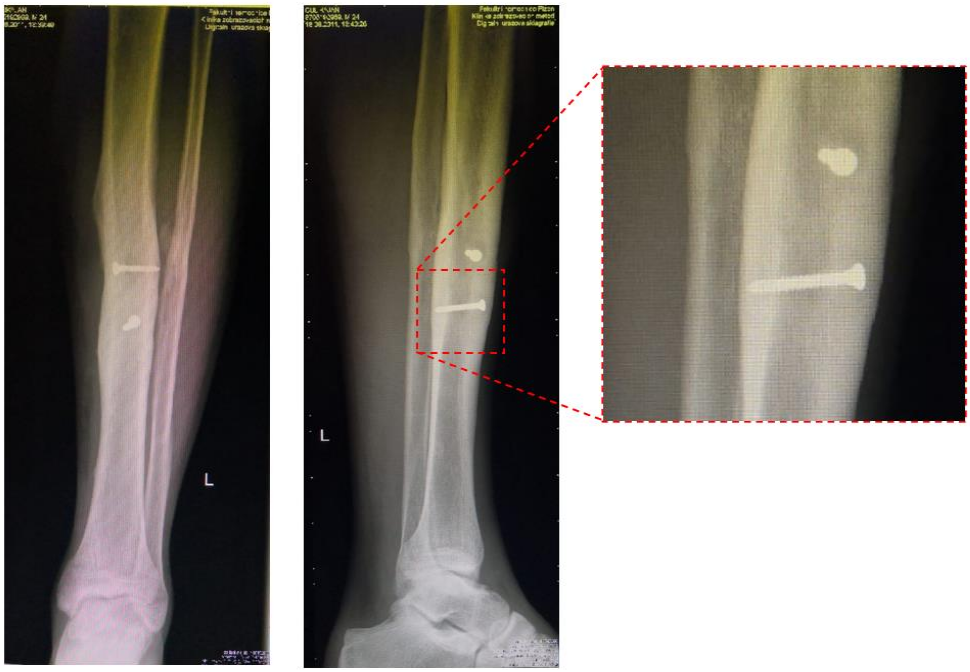

Fig. 1. Current state of the fractures of shin bone and calf bone. Side view on the left, front view on the right

The patient is restricted by pain only in certain activities, skiing being one of them. The pain is inflicted by increasing pressure on the contact point of the edge of the skiing boot and the leg itself when a skier performs a downhill stance (see Fig. 1.) and it basically prevents the patient from downhill ski. Numerous commercial shin bone protectors were tested for their ability of reducing pressure thus reducing the pain but none of them was found adequate. The most common causes of failure were following: a) the protector did not fit precisely. b) the protector was too thick and thus did not fit between the leg and the boot (in some cases inflicting pain to other areas of the leg). c) the protector lacked needed rigidity making it unable to effectively spread pressure in the stricken area.

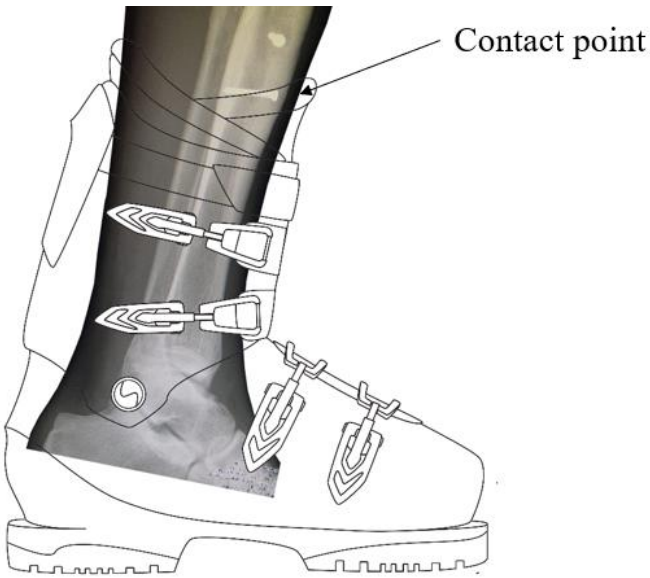

Fig. 2. A depiction of the pressure sensitive area of the leg shown in a skiing boot.

Based on the available pieces information these preliminary requirements for the design of the protector were set.

- Low thickness <=1,5 mm
- Sufficient bending stiffness
- Low weight <= 200 g
- Shape accuracy according to the patient's leg

3.2 Risk management

In order create a product as beneficial as possible a thorough risk analysis had been processed before the product designing began. Analysing the risks in a timely manner helped to understand the issue and to uncover further design requirements. Table 2. shows some of the key risks which can have negative effect on the quality of finished product.

Requirement	Risk occurrece criterium	Risk	Probability	Impact	Value
Safety/Compliance with legislation	Possible defect formation, which would make the product unsafe for use with no warning sings or incompliant with legislation.	**R1**-Structure failure and loss of stability when the product is being used	2	4	8
	Possible defect formation, which would make the product unsafe for use despite obvious warnings or incompliant with legislation.	**R2**- the product is being used by a person for whom it was not designed	2	3	6
Accomplishing primary function	Loss of primary function (the product no longer serves its purpose, safety not compromised)	**R3**-The product is not rigid enough in required direction, but does not crack when used.	2	2	4
	Loss of effectiveness of the primary fiúnction (the product serves its purpose in a limited extent)	**R4**- Rigidity of the product allows it to be used for what it was designed but does not provide desired support in borderline situations.	3	2	6
Accomplishing secondary function	Loss of secondary function (the product serves its purpose, but comfort securing features are not working)	**R5-** The product servers its purpose, provides needed rigidity in required direction. Extremity injury will occur when use. (formation of scrapes, blisters)	1	4	4
	Loss of effectiveness of the secondary function (the product serves its purpose, but comfort securing features are limited)	**R6**-The product servers its purpose, provides needed rigidity in required direction, it was used in complience with given instructions, but leg proportions changed (e.g. change of muscle conditions). **R7-** The product was used in complience with given instructions, but when used for a longer period of time edges of the product damage the sock .	1	2	2
Amenity	Appearance, weight, the product serves its purpose, but it does not match all the amenity expectations of a common user	**R8**-The surface of the product is wrinkled because of used hand-handled process and used mold. **R9**- Total weight is over 200g.	3	1	3
	Appearance, weight, the product serves its purpose, but it does not match all the amenity expectations of a demanding user	**R10**-The manual laying of carbon fibers caused minimal distortion of the fabric. **R11**-Total weight is over150g.	4	1	4

Table 2. The key risks which can have negative effect on the quality of finished product

Based on evaluation of the impacts and probability each risk is assigned with numerical values, the resulting value is then set. This value is calculated as product of impact and probability. Final evaluation of the risk is then shown in the impact and probability matrix (see table below).

		Impact			
		1 - Insignificant	2 - Minor	3 - Medium	4 - High
Probability	1 (0-10%)		R6		R5
	2 (11-35%)	R10	R3, R9	R2, R4	R1
	3 (36-65%)	R7, R11			
	4 (66-100%)	R8			

Table 3. Risks matrix

3.3 The connection between risk and design process

- R1 – Due to high demands on rigidity, low weight and small thickness a carbon fibre reinforced polymer was used for manufacturing because it has the required properties. In order to avoid a structure failure and a loss of stability during use three variants with different rigidity and thickness were made. The products were then tested in operating conditions and based on results of the tests the most suitable variant was chosen.
- R2 – The formation of risk cannot be influenced during designing or manufacturing process, the risk was reduced with instructing the user about correct use of the equipment.
- R3 - The risk corresponds with R1. Each product variant was evaluated during testing.
- R4 - The risk corresponds with R1. Each product variant was evaluated during testing.
- R5 – This protective equipment was designed and manufactured in such way that when using it, there is always a functional ski sock 2-3mm thick between the leg and the protective equipment. The user was introduced to the method of use.
- R6 – The formation of risk cannot be influenced during designing or manufacturing. The risk was reduced with the user being sufficiently trained in using the product (e.g. if the user feels any discomfort or the product does not fit well it is necessary to produce a new piece).
- R7 – All sharp edges were sanded during manufacturing
- R8 – Due to a fact that the product is made by hand it was impossible to fully eliminated the wrinkle. Great emphasis was placed on laying the separation foil on the top and bottom of the product. The foil directly influences the quality of finished product.
- R9 – The weight is affected by the number of layers in relation to the R1 risk and matrix to fabric ratio. The ratio of the matrix cannot be greatly influenced in wet lamination without the infusion method. Production was carried out using a minimum amount of matrix during lamination.
- R10 – Because of the hand-made process and shape complexity it was not possible to fully eliminate the fabric distortion. Great emphasis was placed on laying each layer especially the top layer which then forms the view part of the product
- R11 – The weight is affected by the number of layers in relation to the R1 risk and matrix to fabric ratio. The ratio of the matrix cannot be greatly influenced in wet lamination without the infusion method. Production was carried out using a minimum amount of matrix during lamination.

3.4 Design

Material: Due to the required values of weight, thickness and stiffness, it was chosen as the basic construction material carbon fibre reinforced polymer. Composite orthotropic materials such as carbon fabric laminates are characterized by 9 material constants to determine the mechanical properties in all three directions. [12] Material CC200 carbon fabric twill with Toray T300 3K fibres with density of 1690 kg.m-3 was used for manufacturing tibia protection. The thickness of one layer is 0.26 mm. The material properties given by (Table 4) were taken from the article. [13] These values are for the production of laminate in an autoclave at a specific pressure and temperature.

Material properties		**Value**
Young's modulus	E_1	52.3 (GPa)
	E_2	48.7 (GPa)
	E_3	5 (GPa)
Shear modulus	G_{12}	2.32(GPa)
	G_{13}	2 (GPa)
	G_{23}	2 (GPa)
Poisson's ratio	μ_{12}	0.11 (-)
	μ_{13}	0.35 (-)
	μ_{23}	0.35 (-)

Table 4. Material properties of Twill CC200 – Toray T300 3K

Load: The tibia protection is loaded by bending stress. This bending moment is created by a torque moment with the axis of rotation in the ankle. This torque moment during the normal carving curve for 50th percentile of European male adult weight (85kg) is M_b=195 (Nm) according to the publication. [14] This torque produces a force F_c= 750 which is given by equation 1 and which is at a distance l=0.260 (m) from the ankle to contact point (see Fig. 3.)

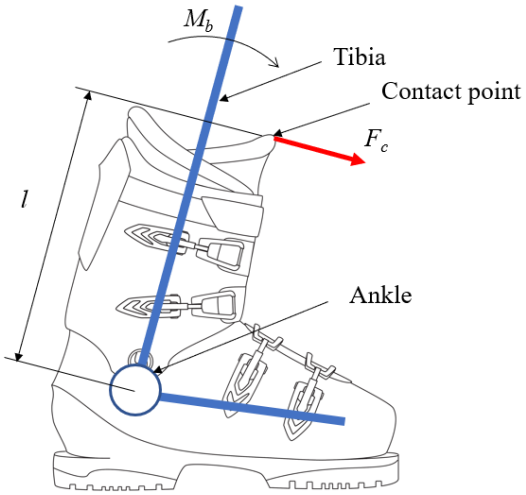

Fig. 3. Schematic action of forces at the contact point of the leg and ski boot

$$F_C = \frac{Mb}{l} = \frac{195}{0.26} = 750N \quad (1)$$

where F_c is force in the contact point (N), M_b is torque moment to ankle point (Nm), l is distance from ankle to contact point (m).

Shape: One of the requirements was the exact shape of the tibia bone protection in relation to the shape of the leg. The method of direct production on the patient's leg was chosen, because in this case it was a prototype intended for just one patient. This method of production ensures the shape accuracy of the produced parts.

Manufacturing: The product was manufactured using a method of wet lamination directly on patient's leg. To ensure the product will keep its ergonomic shape during the whole process a skiing sock was put on the leg. This also reduced a possibility of the risk R5 occurrence. An Unperforated Release Film was applied to the sock for preventing the resin from getting into contact with patient's skin while making separating the sock from the product significantly easier. Layers of CC200 carbon fabric twill with Toray T300 3K fibres were applied onto the release film. Direction of the threads is parallel to the axis of tibia which enriched the product with the highest possible level of bending stiffness in required direction. Polyester resin, the material chosen for manufacturing, is processable for 30 minutes. That provides enough time for the lamination process and at the same time it was not necessary to keep patient's leg fixed for hours. The release film was then applied to the saturated fabric layers again. The whole kit was fixed with a stretch foil in order to tighten the layers together around patient's leg (see Fig. 4. For cross section and Fig. 5 for real manufacturing final status).

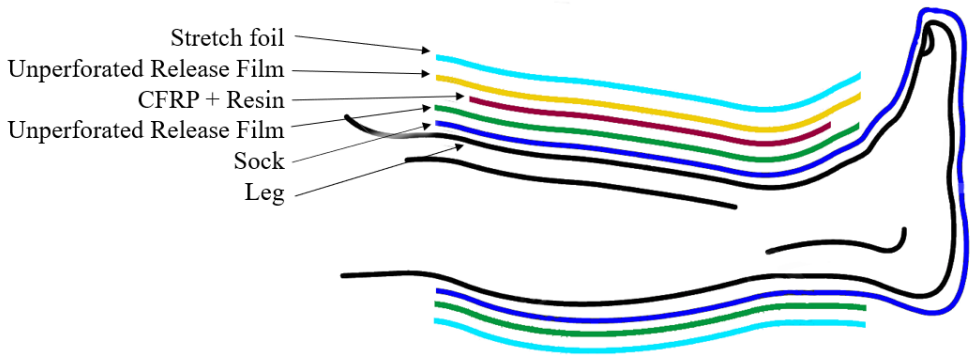

Fig. 4. A cross-section view of lamination layers

Fig. 5. Manufacturing of leg protection (final status with all layers)

The unfinished protector was removed from patient's leg after 30 minutes and then left in room temperature for 24 hours which allowed the resin to harden completely. Then the resin excesses were cut off and the surface was sanded smooth into a round shape as shown in the Fig. 6 in an effort of minimizing the risk of formation of scrapes, blisters and bruises, and keeping the sock from being damaged. This reduced a probability for risks R5 and R7.

Fig. 6. Left - Raw product with sharp edges, right – final product round shape

Three samples were produced using this technique, they differ from each other only in the number of layers of the fabric. The samples were tested in common and extreme conditions of downhill skiing, the results were recorded in the table 5.

The sample No. 1 with four layers of fabric was found unsatisfactory because its rigidity was not sufficient in both tested cases. The samples No. 2 & 3 with six and eight layers of fabric provided sufficient rigidity in both common and extreme skiing conditions and the shape was not causing any discomfort to the user. After evaluation of the results the sample No. 2 was chosen as the best fit because its weight was lower than the set goal of 150 g.

Sample No.	Layer count	Thickness (mm)	Weight (g)	Test results		
				Rigidity during common conditions	Rigidity during extreme conditions	Shape
1	4	1.5	105	Insufficient	Insufficient	Satisfactory
2	6	1.8	140	Sufficient	Sufficient	Satisfactory
3	8	2.5	182	Sufficient	Sufficient	Satisfactory

Table 5. The properties of each variant and test result

4. Conclusion

We can find a plethora of methods of risk evaluation on the market which are being used in various modifications. Unfortunately, utilising this tool usually comes later during the process instead of in the very beginning and that often brings lower effectiveness and some unnecessary efforts into the project. Theoretical starting points were set in the introduction of this paper which focused on an application of risk management in a process of creating technical solutions on a specific case study. Specifically, it described the said issue during a designing and manufacturing process of protective medical equipment for tibia.

At first, based on user's needs and other important factors, basic requirements for product structure were set. A table with chosen key risks was created. The risks marked as the most influential were risks R1, R2 & R4. During designing process, the risks R1 and R4 were reduced by choosing a suitable material, producing multiple variants and consequential testing. The risk R2 can be eliminated completely by sufficient introduction of the product to the user.

The risk R5, which had a great impact, influenced the technological procedure with using a functional ski sock during manufacturing. This procedure modification led to reducing the impact of risk. This case study showed that risk management in the design of medical equipment is applicable and very useful even in case of prevention. For future research will be focus on the use of risk management methods and tools for more complex medical protective equipment.

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