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Pre-clinical validation and risk management of autonomous tumor prosthesis using FMEA approach

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ABSTRACT

Since prostheses are biomedical devices implanted directly on the patient's body, they carry a higher risk compared to other engineering products. In the development process, it is a critical issue to identify potential errors and malfunctions that may arise during the clinical use of prostheses and to take precautions against them. Autonomous tumor prostheses have a higher risk than any other prosthesis due to its extension capacity of approximately 100 mm, having a large battery in its structure and performing non-clinical extension without physician control. In this study, the risk analysis of the autonomous tumor prosthesis previously developed by the authors was performed using the failure mode and effects analysis (FMEA) method. In order to determine potential failure risks, a literature review was performed on clinical errors of tumor prostheses. In addition, malfunctions caused by each component of the prosthesis have been identified. Risk Priority Number (RPN) values are calculated for each risk determined. The design of the prosthesis was changed by taking the necessary precautions for the risks with high RPN values. After taking the necessary precautions, the RPN values of the risks that the prosthesis still carries have been recalculated and discussed. As a result of the measures taken, the RPN values of all risks were reduced to below the threshold value that was generally accepted.

Keywords: FMEA, Autonomous tumor prosthesis, Risk analysis, Risk management, RPN

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1. Introduction

Bone cancer usually occurs in the ages of growth of individuals and is most commonly seen in long bones. In cases that occur in the distal part of the femur, where cancer is most common, the cancerous part of the bone is removed from the body by surgery and a prosthesis is replaced. The limb, which has lost its growing feature along with the bone piece taken, should be extended as the other femoral grows. For this purpose, extendable tumor prostheses are used for bone cancer patients whose growth process is incomplete.

Patients using the extendable tumor prosthesis often go to the clinic to determine the need for extension and, if necessary, to perform an extension procedure. These clinical visits cause a decrease in life quality of the patients and also increase the workload of healthcare professionals. In addition, the patient is exposed to radiation at each limb length measurement. Autonomous extendable tumor prostheses that are being developed to prevent these problems are systems suitable for making failures with their complex structure and function [1]. COVID-19 demonstrated the importance of performing these and similar medical processes at home. Since tumor prostheses are active devices used directly in the human body, there is a risk of fatal errors to occur.

The life cycle of a medical device consists of performing patient needs analysis, designing the product, manufacturing the product, testing the product function, entering the market and using the device by the patient [2]. Risk management is defined as a management process that focuses on reducing the risk level as much as possible by identifying, analyzing and controlling risk [3]. In medical devices, it is necessary to apply risk management to maximize the benefit of the patient, minimize potential harm, and predict and evaluate risk

events such as death, disability, abnormal physical organization caused by defects or misuse during healthcare. Risk management is a dynamic process and should be applied at different stages throughout the product's life cycle [4]. At these stages, the product constantly changes due to patient requirements, probability of errors, lifetimes of the components that make up the device, worldwide regulations and laws and regulations in the country of manufacture. For this reason, risk analysis should be carried out at each stage of the development of a biomedical device (Fig. 1). It is important to observe and eliminate all possible risks in the stages before the clinical use.

Risk management has been used successfully in many areas such as medical device, medical software, healthcare and infection control [2-7]. With the development of technology in the field of medicine, people's expectations regarding the quality of the medical device are gradually increasing and potential uncertainties in the risk management process are becoming more and more unpredictable [8].

In recent years, error analysis methods have been used extensively in product and process designs. Thus, the errors that may arise during the use of the developed product or process are determined in advance and necessary precautions are taken while the product is still under development. The most common failure prediction approaches are:

- Failure Mode and Effect Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Failure Mode, Effects and Critically Analysis (FMECA)

FMEA is a research method that aims to provide information to make risk management decisions, to determine how a product, process or system can fail and what are the possible effects of failure modes [9]. A product, machine, or structure may physically fail due to the use of an incorrect part in the manufacturing process or user error. A product or business may fail due to insufficient personnel training, incorrect control, incorrect design, or incorrect equipment. In these cases, FMEA can be used to evaluate possible ways of failure, to assess the magnitude of the effects of failure, and to understand what can be done to prevent failures. Detailed procedures on how to achieve FMEA and its various applications in different industries are explained by Stamatis [10].

FTA is an applicable and useful analysis tool; it is an analytical technique used for identifying and classifying hazards, and calculating system reliability for both simple and complex engineering systems. The analyst defines a top event, which is a failure or accident, and then builds the sequence of faults leading to this top event. FMCEA analysis is the combination of FMEA analysis and criticality analysis (CA). In other words, while doing this analysis, FMEA is done first. A critical factor is then determined. As the criticality factor, RPN can be used as in FMEA or new coefficients to be determined by the analysis team.

FMEA aims to quantitatively predict the probability of certain types of system failures. Being able to build an FMEA requires detailed knowledge of the statistical distribution of component failures. It also requires dominating the statistical distribution of faults that can occur during the interoperability of the components that make up the system. FMEA can also be used as part of qualitative analysis. It tries to identify critical components that can lead to failure, accident, injury and / or loss of property. Implemented by the US army for the first time in the 1940s, FMEA is today an analytical tool widely used in quality approaches such as ISO 9000, ISO / TS 16949, Six Sigma and Six Sigma Design (DFSS). Persons who undertake the FMEA of an existing product or transaction must have data from trace systems that show possible failure modes and their most important causes. However, in most cases, a valid measuring system does not exist and there is no historical data for new products or processes. In such cases, the FMEA team should make a subjective decision based on their knowledge and experience, possible forms of failure, practical consequences of failure, and possible causes of failure.

FMEA proposes a three-step approach to identify potential failure types and their effects, allowing them to be identified before the error occurs. FMEA is used in many areas such as health management, product development, gas refinery installation, information management and auto parts production [11-18].

Figure 1. Development stages and risks of a medical device

There are a limited number of FMEA samples made for the biomedical device in the literature. Studies are especially focused on artificial organs. Köll et al. conducted risk analysis of the artificial pancreatic control system they developed using FMEA. The reason for the FMEA application of the authors here is to identify the failures that the system, which operates completely autonomously and which is located in the human body, can make in advance and take precautions. They determined the RPN value by detecting the errors that the system can make and their frequencies with the literature review, and took measures to prevent failures [19]. The largest number of FMEA samples in the biomedical field are available in systems for the prevention of heart conditions. Warsito et al. performed FMEA to determine the electrical, mechanical and electromagnetic risks that Transesophageal Echocardiography Tele-manipulator may cause. As a result of the analysis, they found that the new system with tele-manipulators was less risky than the conventional system [20]. Kitano et al. developed a smaller controller than their current controller to increase the safety of the implantable blood pump they have developed for patients with heart disease. They conducted a risk analysis with FMEA to determine the failures of the new system caused by user errors. It is determined that the device which is suitable for home use and has an external control unit does not has a critical risk. [21]. Similarly, Patel et al. also performed FMEA to prove the reliability of the heart pump they developed, and took the necessary precautions after determining and scoring individual components for each component of the device [22]. Bramstedt examined the importance of FMEA in the biomedical field and provided an example of FMEA for a ventricular device [23]. Muraleedharan and Bhuvaneshwar listed FMEA for an artificial heart valve, listing possible errors and effects [24].
Chou et al. made FMEA for a mobile ECG holter design. They tried to determine the harm that the holter could cause to the patient by calculating RPN for each risk. Depending on the risks identified, they developed and integrated two protection circuits into the system, thereby increasing the safety of the holter [25]. Kazanzides et al. performed FMEA for a surgical robot. They detected two important errors that may occur and took the necessary precautions [26]. Zapanta et al. made a life prediction for the artificial heart they developed. After 2 years of in vitro tests, they determined the errors that the system may encounter, and calculated quantitatively with FMEA and FMCEA [27]. Fischer et al. applied FMEA during the clinical tests of the current-controlled defibrillator they developed. As a result of their analysis for each part of the device, they determined that the level of security is high [28]. Based on FMEA, Inoue and Yamada measured the risks of screening / profiling in vivo during the drug discovery process [29]. Manrique-Rodríguez et al. was used FMEA technique to analyze possible malfunctions in the use of smart infusion pumps in the pediatric intensive care unit to identify possible risks [30]. Frosini et al. made FMEA to increase the reliability of the robotic system in urology and general surgery [31]. Mila et al. evaluated potential failures associated with monoclonal antibody production for hepatitis B vaccine with FMEA and found that in vitro technology should be chosen [32]. Sofronia et al. designed a virtual reality-based training simulator for bilateral sagittal split osteotomy using FMEA [33]. Sadeghi et al. was used FMEA technique to improve reliability in medical gas outlet that connects oxygen, vacuum, air and nitroxide from hospital gas lines to specific equipment [34].
In this study, risk analysis was carried out during the design, development and testing phase of an autonomous tumor prosthesis using the FMEA method. As a result of the analysis, the risk value was determined using RPN, necessary precautions were taken for all risks exceeding the determined limit value and the design was changed. RPN values were recalculated for each risk and it was found to be below the limit value. This study is the first study in the literature where risk analysis is made for the development of a tumor prosthesis. Within the scope of the study, with the detailed study of each failure mode, the problems that may arise during the clinical use of the tumor prosthesis have been identified and measures have been taken.
This paper is organized as follows. In Section 2, FMEA's implementation steps are explained by creating tables. In Section 3, the risks are determined, the RPN values are calculated and the measures taken are explained. In Section 4, the new RPN values after the measures taken are determined and the risks of the new design are discussed. In Section 5, important conclusion is drawn.

2. Materials and methods

The block diagram of the system, in which risk analysis is performed within the scope of the study, is given in Fig. 2. The internal control unit in the knee joint of the prosthesis, collects the data from the sensors included in the prosthesis and extends the prosthesis when necessary by enabling the motor. The internal control unit communicates with the external control unit that enables the patient to communicate with the system using the XBee module in its structure. The energy requirement of the prosthesis is provided by the Li-Ion battery in its structure. The battery charge level is monitored by the internal control unit and a warning is sent to the external control unit when necessary. The battery is charged by wrapping the wireless charging unit to the patient's knee.

The patient connects the wearable sensor unit to his healthy leg in periods determined by the physician and it is determined whether the healthy femur bone is growing. In case of elongation, the necessary commands are sent to the patient through the external control unit and provided to lie on his back. Whether the patient is lying or not is classified by machine learning using the Attitude and Heading Reference System (AHRS) sensor information in the prosthetic structure and the extension process is performed not to exceed 1 mm per day [1]. Detailed information about the system is available at http://ytubiomechatronics.com/portfolio-item/tumor-prost/.

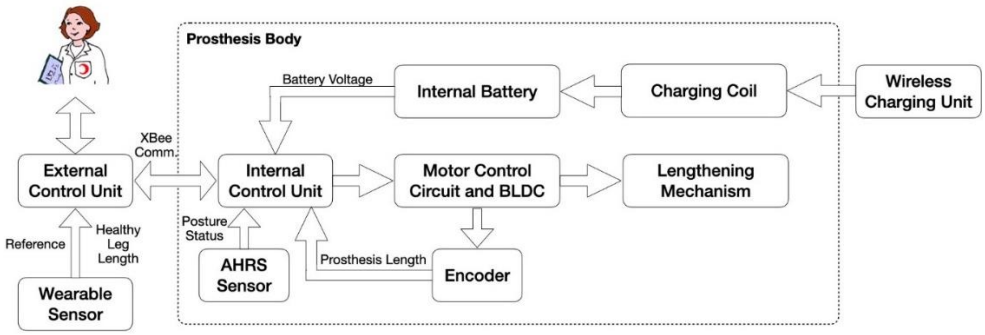


Figure 2. Autonomous tumor prosthesis components and their functioning

The RPN value is calculated using occurrence (O), severity (S) and detectability (D) values for each risk factor. Risk factors with a high RPN value are considered to be high risk and necessary precautions should be taken.
While conducting FMEA, firstly occurrence, severity and detectability values of possible failures are determined. In FMEA, 1-10 scale is used. In severity scale 10 means a situation that causes great damage, while in detectability scale 10 indicates that it is impossible to predict the failure in advance. On the occurrence scale, 10 means that the fault will occur with a very high probability.
As a result of the literature review on clinical studies of tumor prosthesis, potential failures, probabilities and effects were determined. Occurrence ratings are presented in Table 1, severity ratings are in Table 2, and detectability ratings are presented in Table 3.

Table 1. Occurrence values (O)

Possibility	Rate	Value
Very unlikely	<1/20000	1
	<1/10000	2
Unlikely	<1/2000	3
	<1/1000	4
Likely	<1/200	5
	<1/100	6
Possible	<1/20	7
	<1/10	8
Highly possible	<1/2	9
	>1/2	10

Table 2. Severity values (S)

Severity	Results (in terms of patient)	Results (in terms of prosthesis)	Value
Very Low	It does not affect the patient	Prosthesis becomes unstable	1
	The patient does not feel	Prosthesis works minimally incorrectly	2
Low	The patient feels very little	Prosthesis overheats	3
	Short term discomfort	Prosthesis works incorrectly	4
Medium	Long term discomfort	Prosthesis becomes inoperative	5
	Infection	Prosthesis becomes inoperative	6
High	Causes injury	Prosthetic leaks chemical	7
	Distorts joint anatomy	Prosthetic mechanism is broken	8
Very high	Leads to amputation	Prosthesis fractures	9
	Leads to death	Battery explodes	10

Table 3. Detectability values (D)

Possibility	Rate	Value
Very Low	<%20	10
	>%20	9
Low	>%30	8
	>%40	7
Medium	>%50	6
	>%60	5
High	>%70	4
	>%80	3
Very high	>%90	2
	%100	1

The RPN value is found by multiplying the values in Table 1, Table 2 and Table 3. RPN value calculation is given with (1).

$$RPN=O \times S \times D \quad (1)$$

If the RPN value that emerges as a result of FMEA is below 40, it is not necessary to take action for this risk. It is recommended to take measures for risks with RPN values between 40 and 100, and risks with RPN values over 100 should definitely be taken below 100 by taking precautions.

3. Risks (R) and Precautions (P)

In Table 4, the failures, occurrence values, severity values and detectability values that the prosthesis can encounter during its life cycle are given. The risks that must be taken precaution are indicated in red and the risks that may be beneficial to take precaution are indicated in yellow. Within the scope of the study, precautions were taken against these failure risks and RPN values were tried to be reduced below 40.

Table 4. Failures that may occur in autonomous tumor prosthesis

No	Risk	O	S	D	RPN
R1	Overloading the prosthesis during daily activities	5	8	2	80
R2	Overloading the prosthesis during lengthening	6	2	10	120
R3	The extension signal sent by unauthorized persons	2	4	10	80
R4	Charging coil affected by external electrical field	3	3	10	90
R5	Uncontrolled entry in an intensive MR-like magnetic field	4	1	10	40
R6	Incorrect measurement of reference leg length	5	4	2	40
R7	Software update requirement	3	3	8	72
R8	Malfunction of the internal control unit	2	3	8	48
R9	Malfunction of the external control unit	1	1	8	8
R10	The lengthening need of the patient's healthy limb is greater than the maximum length of the prosthesis	1	2	4	8
R11	Drastically low battery capacity	7	5	4	140
R12	Failure of the battery charging circuit	1	6	6	36

R1-Overloading the prosthesis during daily activities

A large number of cases have been reported in the literature where tumor prostheses are overloaded and broken [35-37]. Fig. 3 shows a tumor prosthesis that has broken due to overloading.

After the implantation of the prosthesis, it was determined that the patient will take approximately 108 steps during the total life time and during the daily activities, the prosthesis will be exposed to a maximum bending moment of 40 Nm and a torsion moment of 15 Nm, and a maximum load of 2 kN will be applied on the prosthesis at an angle of 5° [38].

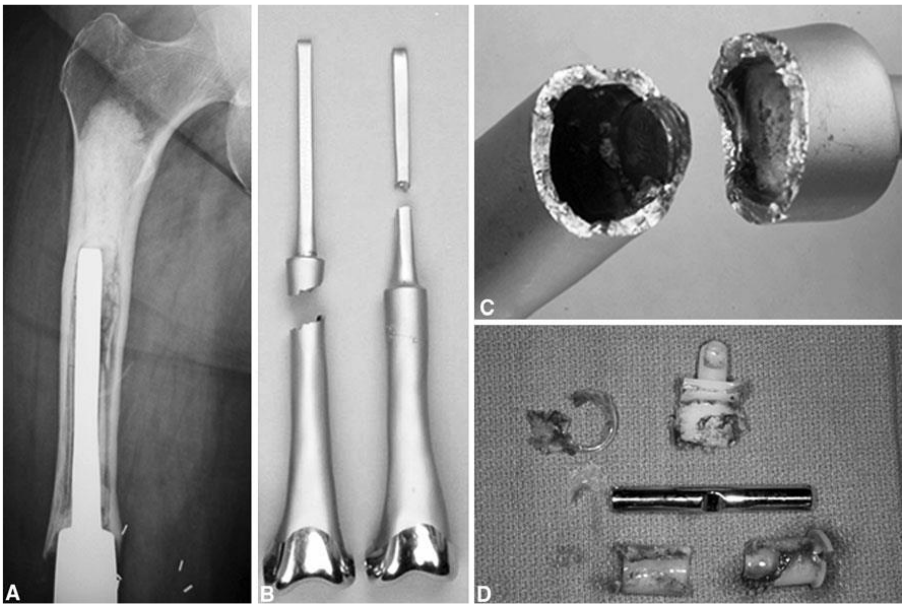


Figure 3. A tumor prosthesis that has broken due to overloading [35]

P1- Bending and Buckling Analysis

Taking into consideration the mechanical structure of the prosthesis, it was determined that bending and buckling analyzes should be performed. In order to measure the resistance of the mechanism, bending and buckling analyzes were done by using finite element analysis method in the modeling environment. By fixing the prosthesis from the femoral attachment point, axial force (load) at the value of 2kN (modeling of approximately 80 kg body weight) was applied on femur stem. This force acts on the knee joint at an angle of 5° due to the structure of the prosthesis. The material was chosen as titanium alloy in Ti6-Al-4V implant norm. Finite Element Analysis (FEA) was applied to the unexpended and maximum extended state of the mechanism. In addition, FEA was performed separately for each component of the mechanism. For the unexpended state of the mechanism, the minimum safety coefficient (FOS) of the system was 29 in the bending analysis and the minimum load factor 459.21 in the buckling analysis (Fig. 4).

R2- Overloading the prosthesis during lengthening

The patient is asked to lie on his back so that the body weight does not create an extra load on the prosthesis during the extension of the extendable prosthesis. Since the extension of non-autonomous tumor prostheses is performed in the clinic, the patient can be provided to be in lying position by the physician. However, since autonomous tumor prostheses are extended outside the clinic and without physician control, it is necessary to ensure that the patient is in lying position by a different way before extending.

P2- Posture recognition by using machine learning

In this study, patient posture status was determined by machine learning using a GY-953 AHRS sensor placed inside the prosthesis and communicating wirelessly with the external control unit. A classifier model has been developed by processing data from the 3-axis accelerometer and 3-axis gyroscope in the AHRS sensor structure. Data are classified in MATLAB using popular classification methods. The most successful classification was obtained with the Support Vector Machine (SVM) algorithm. Using the model created on the implanted microcontroller, a high accuracy posture classification was made, the posture status information was transferred to the control unit located outside the body with the RF communication module XBee. The applied test results carried out with the experimental setup at the end of the classification are given in Fig. 5. According to these results, the posture status is determined accurately at 88 % and more importantly, when there is a load on the prosthesis true classification of the posture (recall), is carried out at 97.1 %. Thus, when there is a load on the prosthesis, the probability of accidentally detecting no load and allowing extension is less than 3%. The precision parameter, serves to determine reliability of the system by checking whether a load really exist when the system reports that a load is present on the prosthesis. Real success rate of the system is obtained with the F-score to be obtained from the two parameters; recall and precision. Precision value of 86.3% indicates that the probability of false alarms preventing extension is less than 14% and is sufficient. The F-score of 91.7% confirms the overall classification success of the system.

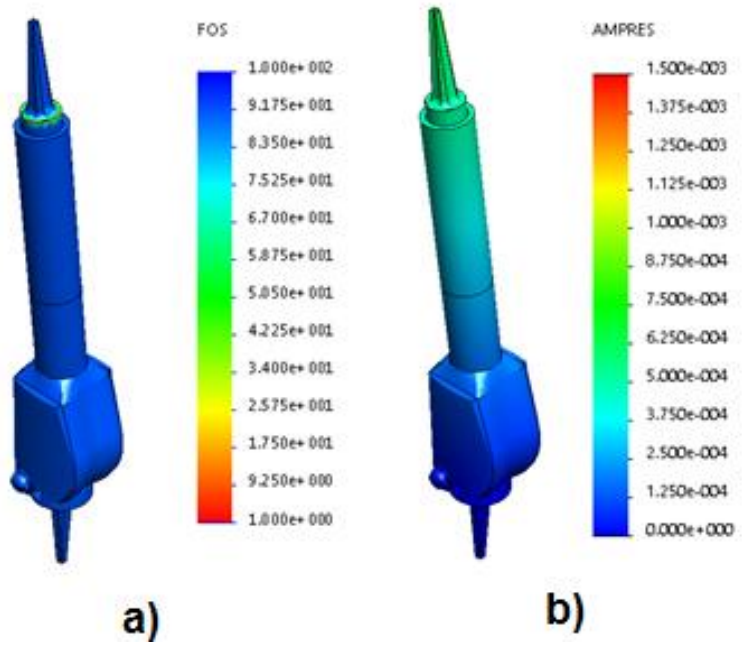


Figure 4. a) Bending Analysis Safety Factor Map b) Buckling Analysis Result Amplitude Map

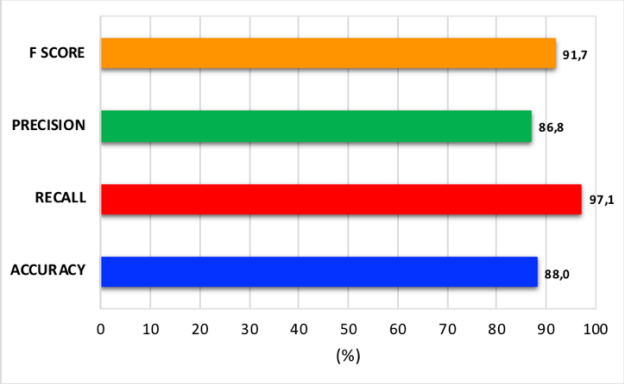


Figure 5. Patient posture status classification applied test results

R3- The extension signal sent by unauthorized persons

The lengthening of the autonomous tumor prosthesis developed within the scope of the study can be performed both automatically after the length of the limb length is determined by the system and by sending a signal when requested by the physician. This poses the risk of involuntary extension as a result of a malfunction or the extension signal being sent by unauthorized / malicious persons. In the literature, it is observed that especially involuntary elongation problems are encountered in electromagnetically extended prostheses [35-39].

P3- Protection with Xbee VID number and current limitation

System communication and sending of elongation command takes place wirelessly. As a wireless communication module, XBee modules that use point to point communication using IEEE 802.15.4 network protocols, inside one external control unit and one internal control unit, were used. With 128-bit encryption, it is only possible to exchange information between modules previously paired (Fig. 6a).

Elongation in the developed prosthesis is made as a maximum of 1 mm per day. One of the reasons for this is the mechanical resistance of soft tissue to the larger amount of elongation. This mechanical resistance will lead to excessive current draw in the motor, even if the patient is lying at the time of failure. The Digital Electronic Controller (Maxon DEC module) shown in Fig. 6b, used as a motor driver in the developed system has adjustable current protection feature [40]. In this application, the current limit is determined as 1 A. In currents exceeding this value, the extension process is terminated by the motor driver. In extensions over 1 mm, the current value drawn by the motor will increase rapidly and the motor drive will terminate the extension process. Thus, even if an error occurs in the internal control unit or an extension signal is sent by malicious people, the amount of unwanted elongation will not exceed several mm.

R4- Charging coil affected by external electrical field

The energy of the prosthesis is provided by the Li-Ion battery placed inside the artificial knee joint. Battery charge is continuously measured by the internal control unit. An alert is sent to the external control unit when it falls below 3V per cell, determined for charging. In this case, the battery is charged with RF method by using the wireless charging module (Fig. 7a) that the patient will wrap around the knee joint. The wireless charging unit has a transmitter charging coil. The receiver charging coil is located on the back of the artificial knee joint within the internal control unit. Uncontrolled entry of the patient into an external electric field may result in unintentional charging of the battery.

P4- Using battery charge protection module

Battery charging and protection unit was used to ensure safety in the system and to protect the battery (Fig. 7b). Thus, the discharge process is terminated if the battery voltage drops below the limit value, and if the battery goes above the limit value, the charging process is terminated. Thus, even if the user continues to keep the wireless charging module connected to the body after the battery is fully charged or enters an external electric field, charging does not occur.

a)

b)

Figure 6. a) XBee Module b) DEC Module

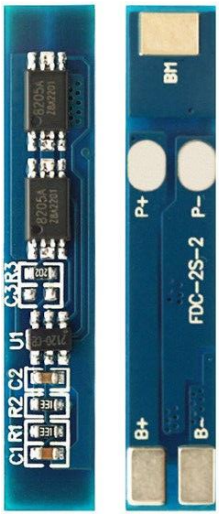
a)  b) 

Figure 7. a) Wireless Charging Module (red circle) b) Charge Protection Module

R5- Uncontrolled entry in an intensive MR-like magnetic field

Imaging techniques such as MR, which create a very high magnetic field in patients with metal prostheses or implants on their bodies, cannot be used. The extensible tumor prosthesis is in the class of large prostheses used in the body, and if they are made of metal material to be affected by the magnetic field, entering an MR or similar magnetic field poses a fatal risk.

P5- Using titanium material on prosthesis body

Titanium is a kind of metal that is not affected by magnetic field. To prevent possible accidents, titanium (Ti6-Al4-Va) was used in the implant norm in the prosthesis developed in this study.

R6- Incorrect measurement of reference leg length

The developed autonomous prosthesis makes the decision to lengthen by measuring the length of the healthy limb. A wearable sensor unit has been developed for this purpose (Fig. 8a). The patient connects the wearable sensor externally to the healthy limb at regular intervals, and the system measures whether the patient's healthy limb femoral bone is extended. If elongation is determined, the prosthesis is also extended. In this case, as a result of the erroneous measurement of the reference leg length, limb length difference (LLD) may occur with the incorrect prolongation of the prosthesis.

P6- Extension is done minimally, if necessary, prosthesis is shortened

As explained in Precaution 3, limb lengthening is limited to 1 mm per day. In this way, the extensions caused by incorrect measurement can be maximum 1 mm. LLD up to 20 mm in the human body can be tolerated. For this reason, 1 mm incorrect extension will not cause any problems. It also has the feature of making a shortening of 1 mm as a result of the fact that the situation is noticed by the system in the next measurement (Fig. 8b).

R11- Drastically low battery capacity

The energy of the prosthesis is provided by the Li-Ion battery placed inside the artificial knee joint. Battery manufacturer companies produce special Li-Ion batteries for use in medical implants [41, 42]. These batteries are airtightly sealed and biocompatible. The battery used in the prosthesis developed in this study is a biocompatible Li-Ion battery. The battery is charged wirelessly via RF. For this purpose, the receiver charging coil is placed at the back of the artificial knee joint. When the battery is to be charged, the patient wraps the wireless charging unit in the knee. The energy transfer begins with the mutual positioning of the transmitter charging coil placed under the skin and the receiver charging coil located in this unit. The capacity of the batteries decreases over time and become unusable.

P11- Battery charge and protection module is used

Battery charge information is continuously measured by the internal control unit. An alert is sent to the external control unit when it falls below 3V per cell, determined for charging. In this case, the battery is charged with RF method by using the wireless charging module that the patient will wrap around the knee joint. Li-Ion

batteries developed with today's technology can maintain approximately 70% of their capacity at the end of 8 years if used in accordance with the recommended cut-off value, as in this study.

a) b)

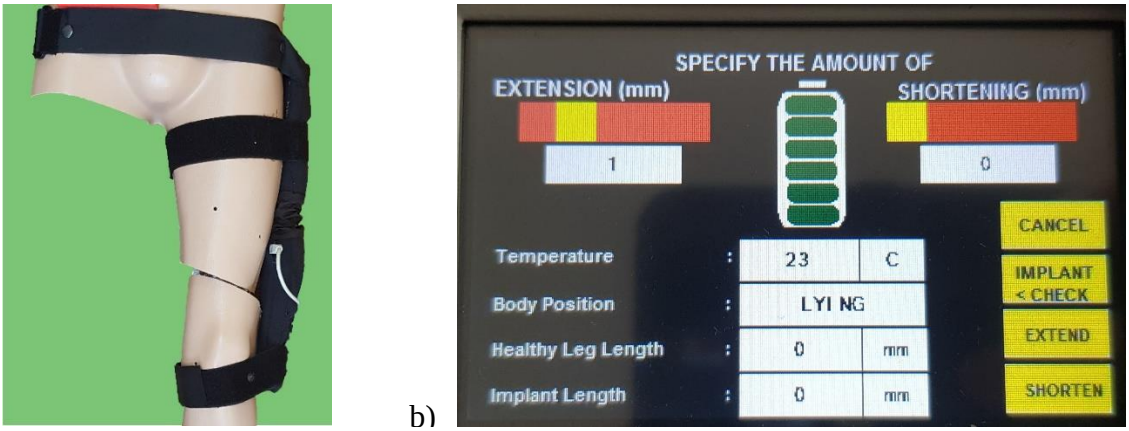


Figure 8. a) Wearable Sensor Unit b) External Control Unit Extension / Shortening Screen

4. Results and discussion

RPN values that are recalculated as a result of the measures taken for the risks that the system may be exposed to are given in Table 5. With the measures taken, the RPN values of all risks were reduced to less than 80. RPN values of 3 of 12 common risks remained in the 40-80 range. If any of these errors are encountered during clinical use, the surgical prosthesis will need to be removed and replaced. The initial RPN value of R1 is 80. As a result of the mechanical analysis performed, the decreased occurrence value decreased the RPN value to 32 with the improvement of the prosthesis mechanism and the increase in the safety coefficients. Thus, R1 entered the acceptable risk group. R2's RPN value was initially determined to be 120. By confirming that the patient is in a supine position using the sensor data, the probability of detectability increases and the number of D decreases, thus reducing the RPN value to 12. For the risk of R3, the wireless communication module was selected as a module with a high coefficient of safety, and the RPN value decreased from 80 to 4. The wireless charge control and protection module used to reduce the risks of R4 and R11 drastically reduced both risks. Thus, with a single protective module used, both the battery capacity was maintained for at least 8 years and the battery was protected against the risk of explosion due to overcharging. The risk of R5 indicates physiological damage that may occur as a result of the patient carrying the prosthesis uncontrolledly entering the magnetic field. It is known that the titanium material used to prevent this is not affected by the magnetic field. Thus, the risk is completely eliminated. The risk of R6 is to make a wrong measurement especially with a mistake caused by the user during the measurement of a healthy limb length using a wearable sensor and as a result, the prosthesis is extended too much. This risk was also eliminated with the 1 mm extension limitation per day and the shortening feature added by the physician if necessary. R7 and R8 risks are in the group of risks that are in the range of 40-80 and are not compulsory to take action. Considering that the negative side effects of the measures to be taken for these risks will be more negative than the effects of these risks, it was decided that it would be appropriate not to take measures for the related risks in this process. RPN values of R9, R10 and R12 are below 40. It will not be necessary to take action against these risks.

Table 5. Calculation of RPN values and precautions

No	Risk	RPN	Precaution	O	S	D	RPN
R1	Overloading the prosthesis during daily activities	80	The prosthesis is subjected to bending and buckling analysis	2	8	2	32
R2	Overloading the prosthesis during lengthening	120	Posture is determined by AHRS sensor	6	2	1	12
R3	The extension signal sent by unauthorized persons	80	Protection with Xbee VID number	1	4	1	4
R4	Charging coil affected by external electrical field	90	Using battery charge protection module	1	3	10	30
R5	Uncontrolled entry of an intensive MR-like magnetic field	40	Using titanium material on prosthesis body	4	1	1	4

No	Risk	RPN	Precaution	O	S	D	RPN
R6	Incorrect measurement of reference leg length	40	Extension is done minimally, if necessary, prosthesis is shortened.	5	1	2	10
R7	Software update requirement	72	If the patient's growth phase is not completed, the prosthesis is renewed by surgical intervention.	3	3	8	72
R8	Malfunction of the internal control unit	48	If the patient's growth phase is not completed, the prosthesis is renewed by surgical intervention.	2	6	8	48
R9	Malfunction of the external control unit	8	No action is required	1	1	8	8
R10	The lengthening need of the patient's limb is greater than the maximum length of the implant.	8	No action is required	1	2	4	8
R11	Drastically low battery capacity	140	Using battery charge protection module	2	5	4	40
R12	Failure of the battery charging circuit	36	No action is required	1	6	6	36

5. Conclusions and future works

In this paper, risk management of autonomous tumor prosthesis was done using FMEA method. The RPN value was calculated for each identified risk, and the malfunctions that may occur during the use of the product were determined. Precautions were taken against identified malfunctions and the possibility of their occurrence or negative effects on the product when they appeared was tried to be reduced. After the precautions the recent RPN values calculated and demonstrate that the autonomous tumor prosthesis is completely safe. Since the risk analysis is a dynamic process, it will be necessary to repeat the risk analysis in the next steps (clinical tests, animal experiments and use on the patient), when necessary.

Development stages of autonomous tumor prosthesis have been completed and the prosthesis is ready for clinical tests. In future studies, it is planned to review the new findings that will emerge as a result of clinical tests, to repeat the FMEA analysis and to identify and eliminate all the important risks before the product meets the patient. The main aim of the study is to develop an autonomously functioning tumor prosthesis, unlike existing tumor prostheses. Because of the mechanic production is not the main concern of the study, a 3D-printed prototype of the prosthesis is used, and titanium-made original mechanism has not been produced. In future studies, it is planned to produce using titanium and perform the necessary mechanical tests.

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