

Risk Assessment of Individualized 3D Printed Prostheses using Failure Mode and Effect Analysis

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ABSTRACT

Risk analysis of personalized medical devices, such as prostheses, is challenging due to the complexity of technological and geometrical issues. The paper undertakes a process of risk analysis for upper limb prostheses for adult patients, individualized by 3D scanning and produced by additive manufacturing. The analysis was performed to systematize the process and its steps and diagnose specific problems to achieve future devices with correct fit and function, produced in as few iterations as possible. The Failure Mode and Effect Analysis of Process (PFMEA) method was used. The results identified main process risks: the problems are primarily caused in stages, where the operator's decision or activity is to be performed, regarding socket length, offset, and suitable lining. The primary prevention activities were determined – human involvement in the decision process should be minimal, and the intelligent models should be adjustable to as many patient cases as possible. Consequently, future steps for process optimization were determined – a more extensive base of patient cases is necessary to acquire and study, to gather data for model and process improvement.

Keywords: PFMEA, 3D printing, Risk assessment, prosthetics

INTRODUCTION

The present level of technological advancement allows the manufacturing of prostheses for upper limbs, which can replace the missing limb to a certain degree. Their functions may be purely visual (cosmetic prostheses), but they can also be fully operational – controlled mechanically or electronically. An adequately designed prosthesis should maximize the extent of movement, ensure a balance of weight and stability of the prosthesis, and guarantee the comfort of prolonged use [1]. A prosthesis, as an artificial replacement of a missing body part, is usually manufactured in several steps, involving manual shaping of a prosthetic socket based on measurements of the patient's stump. The production should be considered as single piece production, of engineering-to-order type. The total manufacturing time can take, depending on the particular prosthesis type, anywhere between one

week and several months [2]. As certain studies indicate, there is often a problem in mutual communication between a patient and a prosthetic technician, which can negatively affect the final satisfaction of using a given prosthesis [3].

For a typical patient, however, a problem in accessing these devices is their price, which is proportional to technological advancement and the production quality of a given prosthesis. The time of obtaining a prosthesis is also an essential factor, especially in cases of severe injuries and small children, where several weeks or even months can be much too long for the patient's therapeutic and psychic comfort. The problem of accessibility of limb prostheses for children is even greater than in the case of adults. This is due to the fact that human anatomy rapidly changes during adolescence, while the design of prostheses does not allow for their smooth adjustment as their users grow. This means a much more frequent need to change prostheses that, on the one

hand, are not yet worn out and, on the other hand, cannot be used by another patient to a full extent due to the individual nature of the product. However, using individualized prostheses is extremely important for children's participation in sports and everyday activities [4].

More and more often, 3D scanning and 3D printing (additive manufacturing) technologies are used to fabricate cheaper, more widely available prosthetic and orthotic devices [5–7]. Additively manufactured prostheses usually have a cosmetic function or are just plain mechanical devices. However, their proper fitting and correct usage depend on many factors, as developing such a personalized device requires various hardware and software (a 3D scanner, a Computer Aided Design system, a 3D printer). One of the enormous problems is the requirement for specialized engineering knowledge of various domains. Firstly, the patient anthropometric data must be gathered and processed, usually manually. This can generate a lot of inaccuracies [8]. Obtaining a shape requires techniques of advanced surface modeling in CAD systems.

Additionally, 3D printing of thermoplastic products with satisfying values of accuracy and strength is complex, as process parameters significantly influence the properties of obtained parts [9–10]. That is why the traditional process of making prostheses, especially prosthetic sockets, has still not been replaced with 3D printing in everyday use. There are ongoing studies on making data gathering, processing, and manufacturing more accessible and available in general medical practice. Automation of specific engineering tasks seems a promising direction [11].

The use of the FDM (Fused Deposition Modeling) 3D printing technology in the production of upper limb prostheses, in combination with three-dimensional scanning, can potentially eliminate the disadvantages of traditional manufacturing methods [12]. The main advantages of modern prostheses can therefore be described as follows:

- digital documentation of patient's limb allows limiting their presence in the product design and production to a minimum [13]; the measurement could be completely remote [14].
- anatomical individualization (i.e., holistic geometrical differences between each consecutive product) is not a problem using 3D printing technology [15]. It also takes less time and is cheaper, increasing availability [16],

- production process itself does not require high engineering nor technical skills from the worker, apart from basic computer usage skills [17].

Despite the advantages of using the 3D scanning and 3D printing method in prosthetics indicated in the available literature, the implementation of this modern manufacturing method in medical practice progresses slower than expected [18], in the authors' opinion. If an appropriate material is used, the strength of additively manufactured prosthetics was found to be not far from what is required [19]. However, studies on this matter are relatively scarce and on a minimal number of patients, so it is difficult to make significant progress [20].

This paper aims to introduce a well-known industrial tool for diagnosing reasons behind defects of manufactured products into the branch of 3D printed prosthetics to find out the most extensive problems preventing supplying patients with properly fit and functionally correct prostheses. This tool is FMEA – Failure Mode and Effects Analysis. In literature, this method is rarely used for medical purposes – its primary use is in machine part production, especially in the automotive branch [21, 22]. However, the authors decided to investigate if it is possible to describe the process of manufacturing a 3D printed personalized prosthesis using P-FMEA (P for the process) and what problems could be diagnosed using this approach. The paper presents the results of these endeavors.

MATERIALS AND METHODS

AutoMedPrint system and research context

The AutoMedPrint system was created in response to the problems associated with obtaining personalized medical treatment for more widespread use. The mission of the AutoMedPrint project is to develop the technology that will provide orthoses and prostheses with a low purchase cost and the shortest possible patient waiting time (a matter of hours or few days, instead of current weeks or months) and make this technology widely available. Using the system, it is already possible to automatically or semi-automatically realize the contactless measurement of human limbs, perform the digital design of specific orthopedic

or prosthetic devices, and prepare and realize additive manufacturing processes. Automation introduced at various levels and stages of work enable the reduction of the workload of preparing orthopedic products to mere hours or minutes instead of usual days or weeks [23].

The system and more technical studies related to different phases of its use have been described in numerous previous publications [23, 24]. Its initial prototype (hardware layer shown in Fig. 1) is described on the website of the AutoMedPrint project [25]. The current stage of studies focuses on the possibilities and risks of clinical and commercial use of the technology, and this paper describes one of the experiments. The final aim of these studies is to elevate the technology to the final, ninth level of technological readiness (TRL) from the currently achieved level of 8. Risk analysis and management are vital to this work, as recognized in available standards and regulations [26].

Case and problem analysis

The case analyzed in this paper is focused on a specific product – a modular, mechanical upper limb prosthesis intended for personal operating means of transportation, such as bicycles, scooters, etc. This type of prosthesis has been successfully made before for several child patients (Fig. 2a) using the AutoMedPrint system, partially described in earlier studies [24]. However, translating this prosthesis to fulfill the needs and requirements of adult patients (more formally stated, among other sources, in [27]) is a more

challenging process. As a model patient for the case analysis presented in this paper, a 40-year-old male patient was selected (Fig. 2b).

The main problem with low-cost 3D printed prostheses for adult patients encountered by the authors is that the prosthesis should stay firmly on the patient's arm during all the activities, with or without a given transportation device. This was not a problem in child prostheses, which meant easy removal in case of an accident. In the case of adult patients, however, the main problem found by the authors is the looseness of the prosthetic socket.

The prosthesis itself is a modular device (Fig. 2c), consisting of three main parts: a prosthetic socket (in direct contact with the patient's stump), an end effector (for realizing the primary purpose – gripping and operating the handlebar), and a forearm connecting the two. All parts are semi-automatically designed (human operators can modify specific parameters) based on 3D scan data obtained by direct contact with the patient. Then, a prosthesis for a given patient is 3D printed, manually processed and assembled, and later tried out for fit and functionality.

Currently, it is an accepted routine that the procedure consists of two, three, or more iterations – the prosthesis is rarely fit and functional on the first try, and adjustments are needed. This is not a critical issue (in traditional processes, adjustments are also a regular occurrence). However, it would be necessary to reduce the number of iterations to two (first and then final). The main problem found in the case of this particular prosthesis – made for adult patients – is the looseness

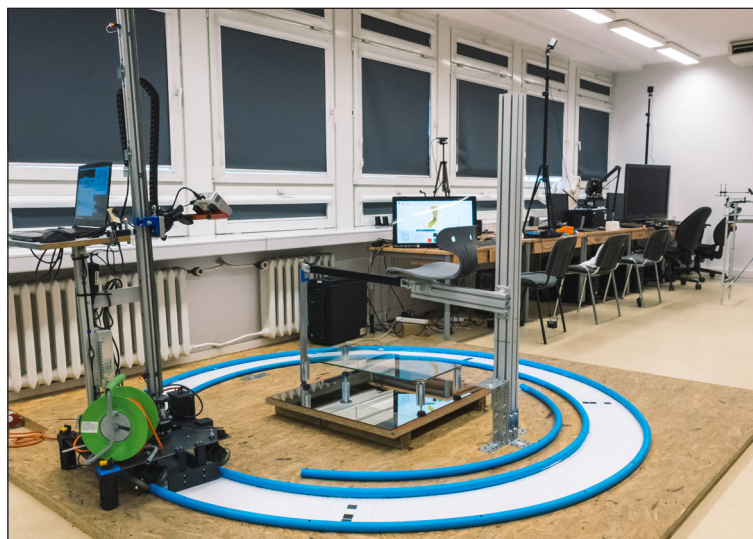


Figure 1. Prototype of the AutoMedPrint system

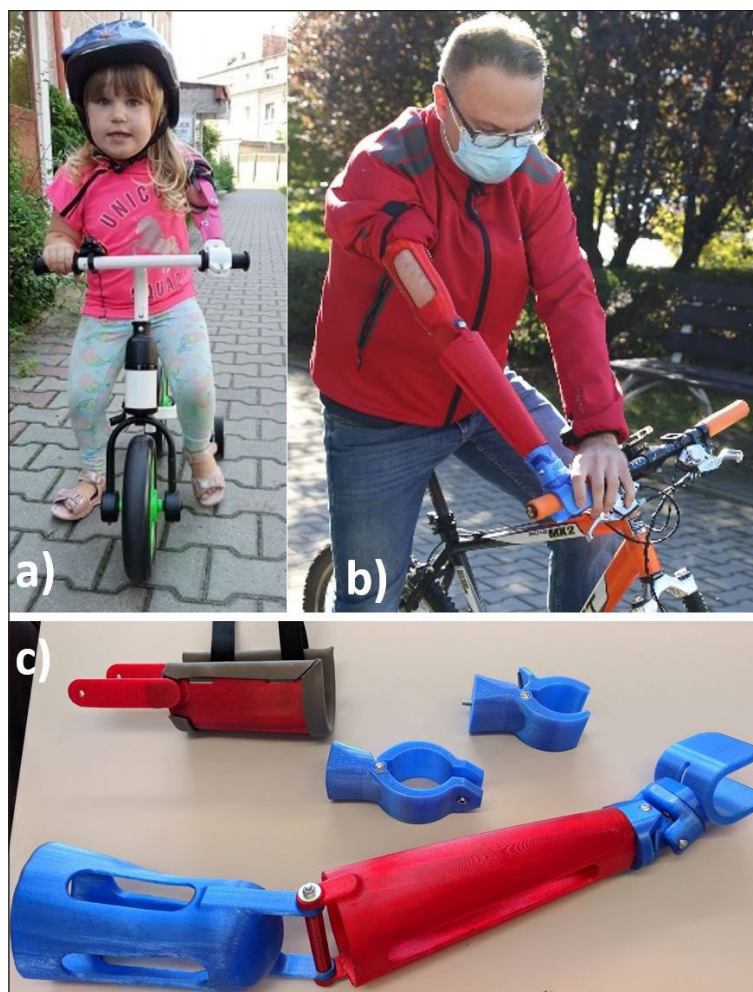


Figure 2. The bicycle prosthesis produced by AutoMedPrint system, used by a child patient (a) and an adult patient (b); modularity and parts of the prosthesis (c)

of the socket. In previous tests, the manufactured prosthesis was usually too loose on the first and frequently on the second try (despite various approaches and parameters applied), forcing counterintuitive measures to prevent that (among others, applying a negative offset value to the stump geometry).

In order to fully assess the sources, possible causes, and risks related to the main problem of looseness, it was decided to try out the tools known in quality management, which are rarely applied to personalized medical devices, such as prosthetics. The subsequent chapters of this paper describe all the steps taken to perform the PFMEA analysis for the aforementioned problem.

FMEA methodology

Qualitative analysis of the process's failure mode and effect analysis (PFMEA/FMEA) was applied as a tool to diagnose the main problem

throughout work with the AutoMedPrint system. The PFMEA is a cooperative, systematic, analytical quality method for assessing potential technical risks of process errors, analyzing their causes and effects, and identifying prevention and detection behavior. There are seven steps: project planning and preparation, structure analysis, function analysis, failure analysis, risk analysis, optimization, and documentation of results. For the scope of this article, the first five steps were performed and described, with the remaining two staying in progress. The risk analysis and optimization steps were combined as the performance monitoring step. The PFMEA method was based on the method standardized in the AIAG & VDA FMEA handbook for the automotive industry [21]. It was adapted to the requirements of the medical industry – orthopedic products – by the authors, a leading innovation shown in this paper. FMEA is rarely, if never, used for personalized medical devices, no previous record of using it

for 3D printed low-cost hand prostheses has been found in the available literature to date.

As a preparation for the analysis, first, a single case (i.e., one patient) and a single, most crucial problem were selected (already described in the previous section). The PFMEA was applied to a selected, most important part of the AutoMed-Print system, i.e., the process of production of a mechanical prosthesis for the upper limb. There are three sub-processes: data acquisition, process preparation, and preparation of the product for the patient. Each sub-process consists of three steps. As such, nine distinct steps were determined. These nine steps were considered the lowest level of the process flow. Each step has one or more categories, which are analyzed together as interdependent in the given stages.

As input for further analysis, an Ishikawa diagram was prepared considering the 5M categories, where M stands for: measurement, material, method, man, and machine. The causes of the main problem – slipping of the prosthesis from the prosthesis patient’s stump – were sought within the categories. The diagram is shown in Figure 3. For clarity, the last level of detail was omitted in the Figure. It contains possible detailed errors, which were later taken into consideration in the FMEA. The main problem was too loose / too tight prosthesis (prosthetic socket). These are not two opposite problems – the prosthesis could be loose in a way preventing from proper use, and still too tight at specific places, causing discomfort or even leading to more serious problems (e.g. with blood circulation, skin irritation, even tissue necrosis in an extreme worst-case scenario).

Defining the causes for a specific problem is a basis for identifying the actual causes of the process errors. For each phase, a single causal

element was defined, i.e., what is needed to complete a particular phase of the process. In the process elements, the causal elements interdependent for the operation of the individual process steps are noticeable – these are man, machine, and to a small extent, measurement and method. The realized product case is so specific that it requires a unique solution. For this purpose, there is no clear separation of man and machine in the following analysis; the causes of failure result from comparing these two or more categories. Two key customers are included in the FMEA analysis: the end user, i.e., the patient who uses the device, and the facility where the manufacturing operations occur. A block diagram in the form of steps was used to visualize the structure of the prosthesis manufacturing system, each of which considers the next phase of the process considered in the analysis. The block diagram is shown in Figure 4.

The process phase that precedes all steps, the patient interview (“phase 0”), in which the patient’s requirements for the prosthesis and the medical case are determined, was not considered for the analysis. It was assumed that technical risk in the case of the patient interview is not involved, as this phase is a purely medical event. No medical consultation is required in the case of a prosthetic patient whose stump is healed (a prevailing majority of considered possible use cases). Moreover, in the case selected for analysis, i.e., the cycling prosthesis, the operator selects the process parameters so that the prosthesis performs the required function.

As a result of these considerations, three subprocesses of three steps each (data acquisition, data processing, product preparation) were put through the analysis. Its primary purpose was a diagnosis of sources of the main problem

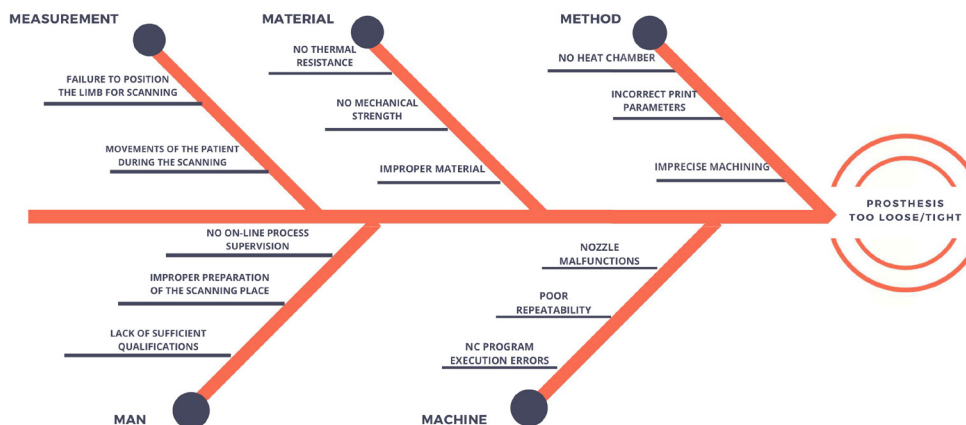


Figure 3. Ishikawa diagram of the analyzed main problem

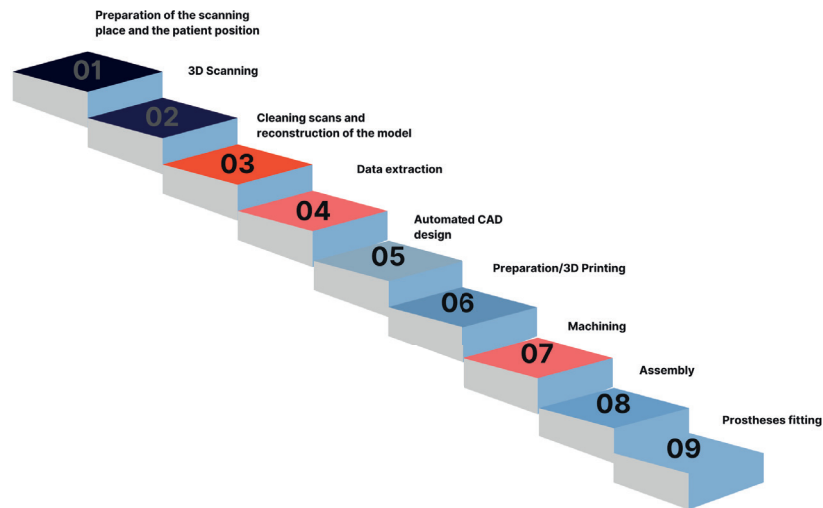


Figure 4. Process block diagram including 9 process phases

and to set proper action priorities for optimization and improvement, which will be a second stage of the studies (not a part of this paper). According to the FMEA methodology, structure (name of the step, relation to 4M) and functions were analyzed and described. Then, a group of experts performed error and risk analysis, performing a numerical assessment in a standard SOD (severity, occurrence, detection). Evaluation criteria were prepared anew for the severity, occurrence, and detection based on available criteria for the automotive industry (AIAG & VDA FMEA Handbook [21]). The criteria are shown in Tables 1–3.

To properly assess the results, AP (Action Priority) criteria were also set. These are presented in Table 4. Three levels of AP are indicated (according to standardized FMEA methodology) – low, medium and high. These are dependent on specific combinations of SOD values. Table 4 presents a map of these combinations, leading to a final result of setting appropriate APs for all the stages of the process.

After setting up the criteria, the FMEA tables were filled for each step and subprocess, within a group of experts, consisting of three technical and one clinical specialist. The results and discussion of this process are presented in the subsequent chapters.

Table 1. Product evaluation criteria according to the severity (S) of the error effect, own work based on [21]

Potential consequences of the error assessed in accordance with the assumed criteria			
S	Effect	Impact on the manufacturer	Impact on the end user (patient)
10	Severe	A mistake may endanger the health or safety of the production worker	The error affects the safe operation of the product, it may result in a disability (e.g. breakage of the prosthesis during use while riding a bicycle)
9		Failure to do so may result in non-compliance with internal regulations	An error may affect the safe operation of the device, it may over-compress the tissues and even cause their necrosis.
8	Moderately significant	It may be necessary to repeat the entire process and dispose of the products	Loss of basic function, no possibility of further use resulting from the occurrence of a pain syndrome, e.g. stump injuries
7		It may be necessary to recycle the product	Deterioration of the basic function, discomfort of use caused by the removal of the prosthesis from the patient's stump
6	Moderately slight	It may be necessary to repeat the operation, reworking the product and re-approval	Moderate discomfort in using a device that does not match the patient's anatomy
5		Part of the process may need to be redone	Moderately slight discomfort in using the prosthesis related to very undesirable tactile sensations, not interfering with further use
4		The product requires modification at the position	It may result in an extension of the waiting time for the finished product
3	Slight	The product may require modification	Moderately undesirable appearance or feel
2		Slight inconvenience to the process / operation / operator	Slightly undesirable appearance or feel
1		Very slight	No noticeable effect

Table 2. Product evaluation criteria according to the occurrence (O) of the error cause, own work based on [21]

Potential causes of error assessed according to the criteria			
O	Predicting error cause	Type of inspections	Preventive inspections
10	Extremely high	No inspection	No preventive inspections
9	Very high	Behavioral	Preventive inspections will have little effect in preventing the cause of the error
8			
7	High	Behavioral or technical	Preventive inspections are partially effective in preventing the cause of the error
6			
5			
4	Moderate	Best practices: Behavioral or technical	Preventive inspections are effective in preventing the cause of the error
3			
2	Very low		Preventive inspections highly effective in preventing the cause of the error (ongoing control of the process results)
1	Extremely low	Technical	The inspections are extremely effective in preventing the cause of the error. It is not physically possible to produce the error due to the cause of the error

RESULTS

The principal results of the FMEA analysis are presented in Tables 5–7. The results have been split into three separate tables, representing three subprocesses mentioned in the previous chapter. This is due to clarity, and the subprocesses are mainly independent of each other, related only to data and results. For example, data acquisition could be performed using entirely different hardware and approach, and it

would not affect the data processing, as long as accurate data would be obtained at the end of acquisition.

Tables 5–7 contain numerical values of SOD parameters. For the occurrence and detection, there are more than one value for a single process step, as related to specific aspects of the step. For the severity, always the worst case was taken into consideration, hence only a single value was assigned to a single step. Designations in the tables mean MP-manufacturing plant, U-end-user.

Table 3. Product evaluation criteria according to the detection (D) of the cause of the error of its type, own work based on [21]

Detection controls assessed according to the maturity of the method and the detectability			
D	Detection capability	Maturity of the detection method	Detectable
10	Very low	No method of detection is established or known	The type of error will not be detected
9			The type of error is practically undetectable / cannot be detected
8	Short	The detection method has not been proven to be effective and reliable and the establishment has little experience in using it	The nature of the error is not easily detected by occasional checks
7			Type of the error or its cause can be detected by the operator
6	Moderate	A detection method that is proven to be effective, the establishment is experienced in carrying out the method	Detection based on the operator’s visual control in the context of numerical data against the pattern, detection of anomalies and manual completion of missing data
5			Visual inspection carried out by a trained operator consisting in process supervision and patient observation during measurements (including ergonomic inspection) and manual inspection of products against standards
4	High	The control method is proven to be effective and reliable, the establishment is experienced in carrying out this method	Visual and manual control related to the comprehension of visual and tactile sensations, verification carried out by a qualified operator
3			Based on manual or visual detection of the type of error, including model structure and parameters
2			Based on a visual inspection carried out by a highly qualified operator or inspection based on specialized measuring instruments, such as a profilometer, 3D scanner, no possibility of leaving the product from the plant
1	Very high	The error type cannot be physically produced	

Table 4. Action priority selection criteria related to SOD values, own work on the basis of [21]

S	O	D	AP	S	O	D	AP		
9-10	8-10	7-10	H	4-6	8-10	7-10	H		
		5-6	H			5-6	H		
		2-4	H			2-4	M		
		1	H			1	M		
	6-7	7-10	H		6-7	7-10	M		
		5-6	H			5-6	M		
		2-4	H			2-4	M		
		1	H			1	L		
	4-5	7-10	H		4-5	7-10	M		
		5-6	H			5-6	L		
		2-4	H			2-4	L		
		1	M			1	L		
	2-3	7-10	H		2-3	7-10	L		
		5-6	M			5-6	L		
		2-4	L			2-4	L		
		1	L			1	L		
	1	1-10	L		1	1-10	L		
	7-8	8-10	7-10		H	2-3	8-10	7-10	M
			5-6		H			5-6	M
			2-4		H			2-4	L
1			H	1	L				
6-7		7-10	H	6-7	7-10		L		
		5-6	H		5-6		L		
		2-4	H		2-4		L		
		1	M		1		L		
4-5		7-10	H	4-5	7-10		L		
		5-6	M		5-6		L		
		2-4	M		2-4		L		
		1	M		1		L		
2-3		7-10	M	2-3	7-10		L		
		5-6	M		5-6		L		
		2-4	L		2-4		L		
		1	L		1		L		
1		1-10	L	1	1-10		L		
					1		1-10	1-10	L

DISCUSSION

As a final result of the performed risk analysis, Action Priorities (AP) were set for the whole process (last column in Tables 5–7). These are summarized in the diagram in Figure 5. In the diagram, successive infographics denote: 1-preparing the scanning station, 2–3D scanning, 3-cleaning the scans and reconstructing the model, 4-data extraction, 5-automatic CAD design, 6–3D printing, 7-machining, 8-assembly, 9-fitting the prosthesis.

Step number one (preparation of the workplace) and step number 6 (preparation and realization of the 3D printing process) are the ones

where actions are not immediately required. Risks are easily mitigated, and consequences are not severe for the final product and its end user.

The first of highest APs was indicated for stage 5, where the risk was assessed to be the highest. The design phase (5) is crucial, as some decisions are made by a human operator and can influence the proper adjustment of the prosthesis. The current problem, as identified by FMEA, seems to be the offset value of the prosthetic socket (nominal distance between the stump scan and inner surface of the socket). Its selection depends on operator expertise, but this is difficult even at high levels of expertise. Even at values of nominal 0, the experts have confirmed occurrences of

Table 5. FMEA results – data acquisition process (stages 1–3)

Acquiring anthropometric data											
Structure analysis		Function analysis	Error analysis				Risk analysis				
Process step	Element 4 M	Process step function	Effect of error	S	The nature of the error	The cause of the error	O	Prevention available	Detection available	D	AP
1. Preparation of the scanning place	Man: checking the position, positioning the patient's limb	Support for the limb, darkening the room, checking the scanner calibration	MP: Stopping the development process (5)	6	Scanner discalibration	Scanner unchecked	2	Scanner Calibration (instructions)	Ergonomic Control: Providing the patient with a comfortable and stable scanning position	5	L.
			U: Socket tight / loose (pinching pressure) (6)			Room not blacked out	4	Employee training (scanning)			L.
						Limb unsupported	4	Patient training (AutoMedPrint Scan Helper)			L.
2. 3D scanning	Man: performing a manual scan, Measurement: automatic scanning	Stump geometry mapping: 6 scans for the stump and for a healthy limb, stable scan bed	MP: Product disposal (7)	7	Incorrect mapping of the stump geometry	Patient Lack of Cooperation (movement)	5	Removal of distractions	Visual inspection: supervising the process and the patient	5	M.
			U: Socket tight / loose (pinching pressure) (6)			Lack of process and patient supervision	4	Instructions for supervising the process and the patient	Ergonomic control: observing the patient during measurements	5	M.
						Wrong order of scanning	3	Providing the operator with reference scans	Ongoing checks of the process results	3	L.
						Collecting too few data needed to reconstruct the model					
3. Cleaning and reconstruction	Machine: obtaining an image of the reconstruction Man: cleaning scans, selecting planes (start and end of the funnel), entering dimensions into the sheet	Model reconstruction, CAD design data	MP: Suspension of the process and the need to repeat the measurements (5)	5	Wrong reconstruction (containing artifacts)	Collection of data of too low quality	6	Carrying out measurements from the stump and normal limb (collection of more data)	Visual inspection of the reconstruction of scans	2	M.
			U: Extension of the waiting time for the product (4)								

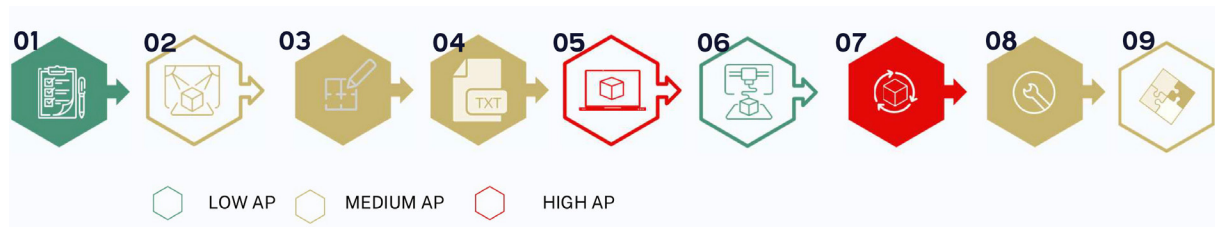


Figure 5 Action Priorities at specific stages of the prosthesis manufacturing process

possible looseness of prosthesis. In the authors’ opinion, the problem lies in an improperly prepared CAD model of the socket, with unintuitively working values of offset, not allowing negative values, and 0 not being a close fit under any circumstances. A solution to this problem is experimenting on a larger group of diversified patients to find out the relation between offset values and looseness and implementing the results into the CAD model. However, it is also worth considering that increasing the variance (diversity) of the group does not always produce adequate results, particularly in medicine. A second parallel solution would be to enhance the prosthetic model’s

parameterization to adjust the socket at a more complex level, not just by editing a single value (offset). Both solutions are currently being pursued in separate studies.

The second highest AP (high assessed risk level) lies in the post-processing, which is the only technical stage done entirely manually by the operators (without relying on computer systems, mechanization, or automation), thus being the most similar to the traditional process. Based on their experience, the operators’ decisions at this stage can further influence the prosthesis’s fit, comfort, and function. The solution would be to leave fewer decisions to the operators and

Table 6. FMEA results – data processing (stages 4–6)

Data processing														
Structure analysis		Function analysis	Error analysis				Risk analysis							
Process step	Element 4 M	Process step function	Effect of error	S	The nature of the error	The cause of the error	O	Prevention available	Detection available	D	AP			
4. Data extraction – design	Man / Machine: generating data to power the generative model	Generation of 2 planes for the socket	MP: Need to repeat the operation (6)	7	No data useful for the next step	The operator selected the plane too close to the end of the stump	5	Checking the generated sheet with the pattern sheet	Visual inspection of the data sheet	6	M.			
			U: Socket too loose (falls off) (7)		Socket too short									
			U: Socket tight / loose (rubbing, chafing) (6)		Socket too long									
5. CAD design	Man: selection of the offset dimension, verification of the stump model with a generated socket, corrective actions Machine: Generating a socket using an intelligent model	Selecting the value of the offset in the range <0,4> [mm]	MP: Need to repeat the process (8)	9	Too much offset 4 [mm]	The operator incorrectly verified the model for offset value	7	Analysis of previous cases and inclusion in the model	Visual inspection: subjecting the model to verification, checking the structure and parameters of the model	3	H.			
			U: Socket tight / loose (rubbing, chafing) (6)		Too little offset value 0 [mm]									
			U: Socket too tight (tissue necrosis) (9)		Checking the planes				4			H.		
6. Preparation of print / 3D printing	Man: starting AutoMedPrintCAM, selecting the right filament, setting the print parameters Machine: printing the product	The material is not brittle, not damp, with low roughness	MP: Need to repeat the operation (6)	6	Poor surface quality	The operator did not check the material before printing	3	Card with the requirements for the preparation of material for printing	Visual inspection	4	L.			
			U: Moderately undesirable appearance and tactile sensation (3)		Low accuracy of the product				Manual inspection			5	L.	
			U: Socket abrasions / tears (6)		High surface roughness				Providing the operator with model products			3D scanning	2	L.
					Profilometer tests				2			L.		

create a set of straight selection criteria, e.g., the type, thickness, and location of foam lining inside the socket.

The other stages of the process have been evaluated as being of medium priority. The 3D scanning itself, as well as trying out the prosthesis, are processes realized in contact with the patient. It is therefore essential to minimize the human factor that could influence this, but on the other hand, this might be difficult to control entirely. The data processing stage, as well as the assembly stage, could be improved in terms of possible errors. One of the problems for improvement should be a better selection of representative points extracted from the raw scan for a better fit socket. The process is now partially automated – the human operator indicates specific section planes at the stump scan. More examined cases would allow building a simple AI algorithm, doing this completely automatically.

While summarizing the results, what is important to mention here is that according to the FMEA results, the riskiest stages involve human experts, and their decisions are based almost solely on previous expertise and intuition. If the results could be confirmed for other cases, this

would mean that scanning and design automation is a promising direction, eliminating possible error causes, and should be pursued until the need for human expertise and intuition is minimized. In the authors’ opinion, this is possible and viable but would require experiments involving a much higher amount of patients (i.e., hundreds of cases) to build a knowledge base and a complete expert system, allowing for better decision-making at the design stage.

CONCLUSIONS

The FMEA has been successfully applied to a modern production process of an individualized prosthetic device. As of the authors’ knowledge, this is the first case in the available literature. The proposed approach is experimental, and the proposed criteria were discussed with a small number of experts. As such, the FMEA way of conduct for personalized medical devices presented in the paper could be potentially improved before applying this approach to a broader range of medical applications. Still, the obtained results are beneficial, as they indicate what could be improved in

Table 7. FMEA results – product preparation (stages 7–9)

Product preparation																	
Structure analysis		Function analysis	Error analysis				Risk analysis										
Process step	Element 4 M	Process step function	Effect of error	S	The nature of the error	The cause of the error	O	Prevention available	Detection available	D	AP						
7. Machining	Man: Performing basic post-processing	Surface smoothness, dimensional accuracy, shape accuracy, layering	MP: Need to repeat the operation or reprint (6)	7	Lack of proper Socket padding	The operator did not select the appropriate thickness of the foam	6	Checking prepared sockets with model sockets	Visual inspection	4	H.						
			U: Socket sliding off, falling off (7)			Inadequate foam lining											
			U: Slightly undesirable appearance / tactile sensation (2)						The operator inaccurately removed surface irregularities								
			U: Irritations, abrasions (6)			Unevenness, burrs on the surface of the prosthesis											
8. Assembly	Man: Connecting the prosthesis parts with screws, hiding the screws	Bolt protection	MP: -	8	The protruding screws that connect the parts of the prosthesis	No operator securing the bolts	4	Checking the socket before dispensing it for try-on	Visual inspection on the phantom	5	M.						
			U: Cut stump (8)						Visual inspection of the prosthesis	4	M.						
									Manual socket inspection	5	M.						
9. Socket fitting	Man: performing prosthetic fittings with the patient	Adjusting to the patient's limb, carried out at the same times of the day, friendly biomet,	MP: The need to repeat the entire process and dispose of the defective products (8)	8	The prosthesis does not fit the patient's limb	The operator placed the prosthesis incorrectly (vice versa)	2	Consultation with a specialist doctor in the presence of the patient	Visual and tactile control through an interview with the patient	4	L.						
			MP: Need to repeat the operation (6)									Failure to take into account changes in the patient's physique	5	Carrying out subsequent fittings at the same time of the day	Static and dynamic tests on the bike		
			U: Pain syndrome (8)													4	Carrying out more fittings at different times of the day
			U: Longer waiting time for the product (4)														

the production process and where the corrective and preventive action priorities lie. These predictions have been consulted and confirmed with the experts as valid. A number of slight improvements were made in the AutoMedPrint system, but more studies are required to obtain a significant reduction in the occurrence of the main indicated problem.

Future studies will focus on gathering more patient cases to perform quantitative analysis and confirm the initial observations made in the presented experiments. A greater number of cases would also help to build a knowledge base, allowing to reduce the number of high-responsibility decisions made by human operators. Also, the FMEA methodology for personalized medical devices will be applied to other cases to determine if it is a suitable and viable tool for assessing these processes.

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