S.P.B. REVISTA

SOCIEDADE PORTUGUESA DE BIOMECÂNICA

NÚMERO . 02 — 2022

SOCIEDADE PORTUGUESA BIOMECÂNICA

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Revista da Sociedade Portuguesa de Biomecânica

SOCIEDADE PORTUGUESA BIOMECÂNICA

Revista da Sociedade Portuguesa de Biomecânica

Nº 2, 2022

Conteúdos

Editorial

Caros Colegas,
Caros Membros da Sociedade Portuguesa de Biomecânica,

O primeiro número da Revista da Sociedade Portuguesa de Biomecânica foi disponibilizado em 1 de fevereiro de 2020. Mais de dois anos depois temos disponível o segundo número. Infelizmente, é uma evidência que urge corrigir tão rapidamente quanto possível, pois dificilmente poderemos desenvolver um projeto editorial cientificamente sustentável e que possa, como era referido no Editorial da primeira revista, honrar a tradição científica e formativa na área de conhecimento da Biomecânica, assim como consolidá-la. É, certamente, imperioso, que todos nós tenhamos a consciência de que é necessário contribuir com os nossos trabalhos, os nossos artigos, para que se possa fazer, anualmente, pelo menos, duas edições da Revista.

Este segundo número é composto por seis artigos, todos abordando temáticas de investigação diferentes, sendo um deles em parceria com colegas investigadores brasileiros, o que é salutar e de estimular que próximos contributos possam incluir mais artigos em colaboração com investigadores estrangeiros.

Assim, no primeiro artigo, os autores, de diversas instituições de ensino superior, apresentam a utilização da simulação numérica no desporto numa perspetiva do passado, presente e futuro. O segundo artigo aborda o desenvolvimento de um punho ergonómico para sistemas de laparoscopia e resulta de uma parceria que conta com a colaboração de colegas investigadores da Universidade Tecnolóliga Federal do Paraná do Brasil. Um grupo de investigadores do Instituto Politécnico de Leiria realizaram um estudo e projetam para o horizonte 2030 a utilização de tecnologias aditivas em diversos domínios da medicina. O quarto artigo teve como objetivo estudar as alterações na marcha induzidas por exaustão através de saltos verticais, tendo a participação, no estudo, de vinte e quatro estudantes universitários de desporto. Finalmente, colegas investigadores da Universidade de Aveiro desenvolveram um protótipo de uma aplicação web que permite monitorizar uma rede de sensores capacitivos em co-superfície, que juntamente com um sistema de sensorização, apresenta elevado potencial para a monitorização contínua de implantes instrumentados baseados numa rede de condensadores através de um sistema de comunicação sem fios.

Finalizo este editorial solicitando aos investigadores, membros e não membros da SPB, portugueses e não portugueses, para enviarem-nos artigos de investigação científica, ou outros de interesse, pois é a única maneira de manter “viva esta chama” e a vontade de fazer com que a biomecânica portuguesa cumpra a sua nobre e importante missão: contribuir para a resolução de problemas de sáude das pessoas e seu bem-estar.

Aveiro, 8 de novembro de 2022

José António Simões (Editor Convidado)

Integration of Design Failure Mode and Effects Analysis (DFMEA) and Design Science Research (DSR) to ergonomic design of a laparoscopic handle

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Resumo

The problems associated with laparoscopic surgery and the surgeon's musculoskeletal health have been studied since the beginning of the century. The fatigue, pain, static and forced body postures, and pressure areas are some of the problems that can be caused by the handles lack of ergonomics. For this reason, this work has the objective to develop an ergonomic handle for laparoscopic surgery applying the Design Science Research (DSR) method integrated with the Engineering Design approach of Pahl & Beitz, using Design Failure Mode and Effects Analysis (DFMEA) technique. The main result of this work was the prototype of a laparoscopic handle that follows the several guidelines presented in the literature for a correct ergonomic handle.

Keywords: DFMEA, Biomechanics, Laparoscopy Handle, DSR, Product's design, Ergonomics

1. Introduction

Laparoscopy has been used as a surgical procedure since the past decade and has a large number of advantages for the patients, however it presents many issues for the surgeons as loss of freedom during the surgery, an increased incidence of static postures and risk of developing several injuries due to the persistently forced body postures for a large period of time [1–4].

Beyond the musculoskeletal consequences for the surgeons, another critical consequence of the Minimally Invasive Surgery (MIS) instruments ergonomic issue is reported. The surgeon suffers from muscle fatigue or pain during surgery, which puts patient safety at high risk during surgical intervention [5]. Some studies reported by Alleblas *et al*. [6] described that some surgeons believe that their performance was directly affected by their fatigue or pain and this implicates that in some cases the patients may not receive the best clinical care available due to the surgeon's physical condition.

A survey conducted at the Annual Conference of the German Society of Surgery shows that 83.4% of the surgeons have problems with the MIS instruments, most of them caused by the ringed-handle. The report shows that 36,4% feels pressure areas and 56,9% work with an uncomfortable hand or arm positions [7]. Wood *et al*. [4] also affirms that over 70% of the surgeons who perform MIS surgery suffer from neuromusculoskeletal pain and fatigue.

When the MIS instruments were developed, the ergonomic aspects of its design were not taken into account. In the most common types of laparoscopy instruments the handles were attached to the shaft at a 90° angle [8], today we know by ergonomics researches that this angle should be 135° [9,10].

The handle's design determines the degree of the wrist flexion, ulnar nerve deviation, and forearm supination required to the surgeon to make the different movements during the surgery. The most common ringed-handle design forces the surgeon's wrist into flexion when inserting the thumb in the ring [11]. Unfortunately, this type of handle is not only uncomfortable and causes fatigue, but it also produces different musculoskeletal injuries in the short, medium, and long-term [2].

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Recent studies show that the traditional handle cited by Berguer *et al*. [11] is still used and confirms that the ringed-handle makes the wrist flexion exceeds the acceptable limits even in the rest position [2,3,12,13]. One fact that confirms it is that experienced surgeons do not use the ring for the thumb, manipulating the handle in a position that the handle was not designed [2].
Several studies evaluate the ergonomic aspects of the laparoscopic handles and almost all of them are mechanic and not electronic [2,9,12,13]. The electronic handles have their advantages but in a lot of healthcare systems situations they are too expensive and far from its reality, this is why cheap solutions must be found to improve the ergonomics of these instruments.
For all these reasons is necessary that doctors, mechanical engineers, ergonomic specialists, and surgeons cooperate to improve the design of the MIS handles, to minimize the effects on the surgeons health and consequently increase their performance during a surgical intervention [14,15].
In this sense, this study has the purpose to present a methodology to develop a virtual prototype of a MIS handle design based on ergonomic guidelines found in the literature. The development of the clinical studies to validate the prototype's design will be presented in a future work.

2. Materials and Methods

In the scientific area, it's important to use a research method to build scientific knowledge in a way to give more rigor in its development. In this sense, this work will use the Design Science Research (DSR) method, which is a structure well-accepted by the academic community specially in the engineering field [16,17].
The DSR method is built of 6 phases: (1) Identification of the problem and motivation; (2) definition of the objectives for a solution; (3) design and development; (4) demonstration; (5) evaluation and (6) communication [18].

2.1 Identification of the problem and motivation

This phase consists in collect information about the current problem of the laparoscopic instruments design, also known as bibliometric review, that motivates, and directs the realization of this research.

2.2 Definition of the objectives for a solution

In this work, the objectives for the solution were also collected through the use of bibliometrics. Therefore, the main goal of this work is to develop a new MIS handle design based on ergonomic guidelines.

2.3 Design and development

In this phase due to the responsibility of designers for the technical and economic properties of a product, is important to have a design procedure that offers a consolidated protocol to achieve the main objective [19].
In this sense, Pahl & Beitz [19] developed the Systematic Approach to Engineering Design (SAED) that nowadays it has a significant importance in engineering [20–26], for this reason this approach will be used in this study to develop the MIS instrument handle.
The SAED has 4 stages: (1) Clarification of the tasks; (2) Conceptual design; (3) Embodiment design; and (4) Detail design. Therefore, in the phase 3 of DSR, (Design and development), the stages 1 and 2 of the SAED will be applied, and stages 3 and 4 of the SAED will be used in the next phase of the DSR. A simplified explanation of each SAED stage is presented in Figure 1.

2.3.1 Clarification of the task

Part of this stage consists in the research about the problem and similar products available on the market, this has already been done in the introduction of this research.
At this stage, product requirements must also be listed, with the minimum exigency to create a satisfactory design. For this step some requirements and dimensional restrictions were collected in literature as guidelines to build a functional, comfortable and ergonomically satisfactory handle [28,29]. This list will be presented in the next section.

2.3.2 Conceptual design

In the conceptual design the product's function structures will be created. The function structure represents the intended overall relationship between the inputs and the outputs of a machine [19].
Another great tool that helps the designer in this phase is the project tree. This tool divides the product in its systems, subsystems and components, this divisions helps the designer to make an analysis of all the components that must be aborded in the project [30].

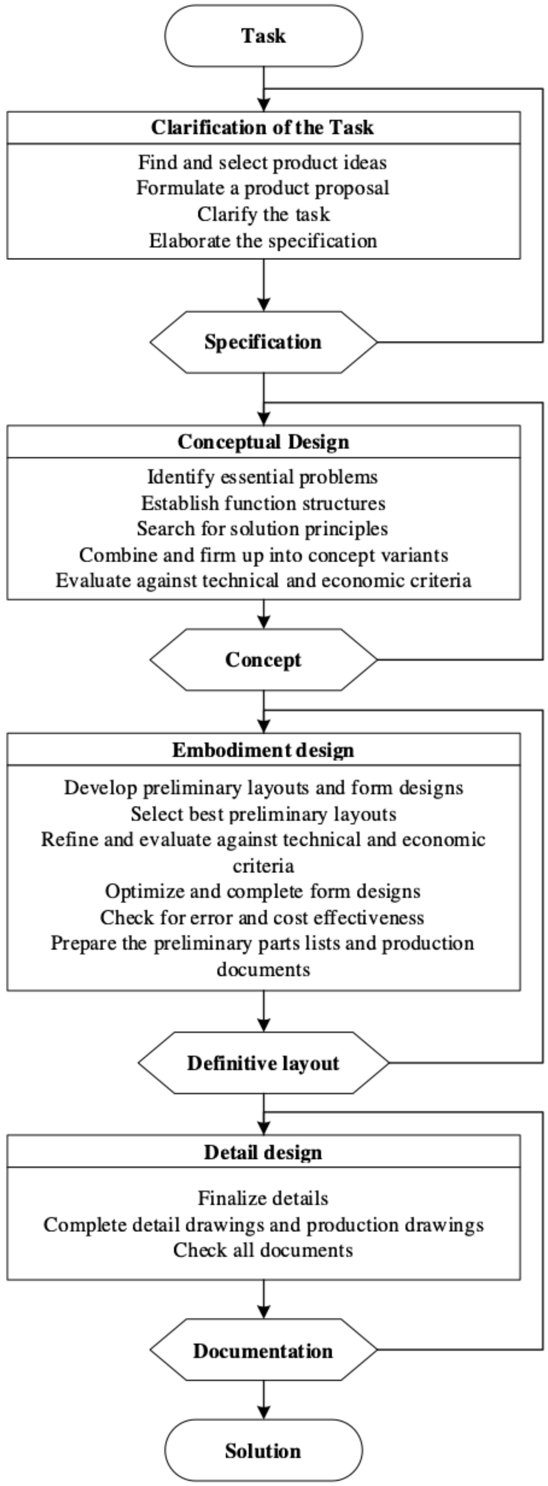

Figure 1. Simplified explanation of each phase of the systematic approach to engineering design Adapted from [27] and [19].

In this stage, Pahl & Beitz [19] also includes the analysis of the failure modes of the project, so that the designer can prevent the most common failures that may occur with the product. For this analysis the Design Failure Mode and Effect Analysis (DFMEA) will be used to help the detection and the determination of the best ways to deal with the design failure when it occurs or even how to prevent it [31,32].

The correct use of the DFMEA provides many benefits: [1] Improved product, process quality, reliability and safety, [2] reduced development time, [3] fewer late changes, [4] increased customer satisfaction, [5] shorter time to manufacturing, [6] early identification and elimination of potential product failure modes, [7] improved validation process, among others [33].

2.4 Demonstration

In this phase will be applied the stages 3 and 4 of the SAED [19], this includes the development of a prototype for the evaluation and validation of the product to be manufactured, that can be made by simulations, analytical calculations, tests or experimental methods.

2.4.1 Embodiment Design

In this stage of the process the design will be developed in accordance to the technical and economic criteria. The designers must determine in this phase the overall layout design (general arrangement and spatial compatibility), the preliminary form designs (component shapes and materials) and if applicable the production processes [19].

2.4.2 Detail design

In this stage all the documentation referent to the project will be presented. The technical drawings, materials selection, manufacturing procedures, operation and manufacturing recommendations, among other that may be convenient to this project. In this paper a preview of these documents will be presented, although the version presented here will not be the definitive design.
The first digital prototype of the project will be presented in this paper. According to Pahl & Beitz [19] the design must be developed with the help of scale drawing and critically reviewed by a technical and economic evaluation. In the most of the cases several prototypes must be reviewed until achieve a definitive design appropriate to the needed solution.

2.5 Evaluation

This phase consists in to evaluate all that has been done in the previous steps and offer consideration about the work that has been made, it's also the last step of Pahl & Beitz [19] methodology and when simulation tests and analytical calculus will be made. This will be presented in the conclusions of this paper.

2.6 Communication. Finished all the previous phases the work must be divulged to the scientific community. This will be done by the publication of this paper and the Master's thesis.

3. Results

3.1 Clarification of the task

After a critical review of the literature the requirements list was elaborated, as shown in Table 1. This list was categorized as demands and wishes, the wishes should be satisfied whenever is possible unless their most demands or important requirements are compromised [27].

Table 1 – List of the requirements gathered in the literature divided by Demands (Obligatory) and Wishes (non-Obligatory)

Demands	Wishes
The instrument must have two independent control components	The control must be done only by one hand, but the design must be symmetrical to be possible to use with both of the hands
The fingers, hands and wrists movements must be between the limits allowed by ergonomics guidelines. This implies that the angle between the handle and the shaft has to be between 15 and 50°	Must allow use for various hand sizes
The components manipulation must be done with the finger and/or the thumb	The handle must de adaptable to one or more applications
If the design has a grasper, its opening can't be over 80 mm and if the handle has a ring, it's diameter must have at least 130 mm	Cross section shape can be rectangular or cylindrical, the rectangular allows a better grip, but the cylindrical is more comfortable
The handle must have a professional trustworthy appearance, according to the users and the work environment	The handle can be in the shape of a pistol grip, which is more comfortable and can be used as the holder for the electronic components

If the handle has a lever, it's contact area must have at least 120 mm²	The handle must have a 135° between the shaft and the handle, to allow the hand to stay in neutral position
The control methods must be intuitive and self-explanatory	The handle must allow the grip to be held with the hand's palm
The handle must be stable when operated with latex gloves	
The maximum instrument's weight must be similar to that of current arthroscopic cutters (40 grams). If it's necessary to have a greater weight, the mass distribution must be concentrated on the hand's palm	
The handle must be comfortable and convenient to use	

3.2 Conceptual Design

In this phase the project tree was designed to help the designer to analyze the complete system and determine its mainly functions. In the project tree the product's systems, subsystems, and components were divided and classified. The project tree is shown in Figure 2.

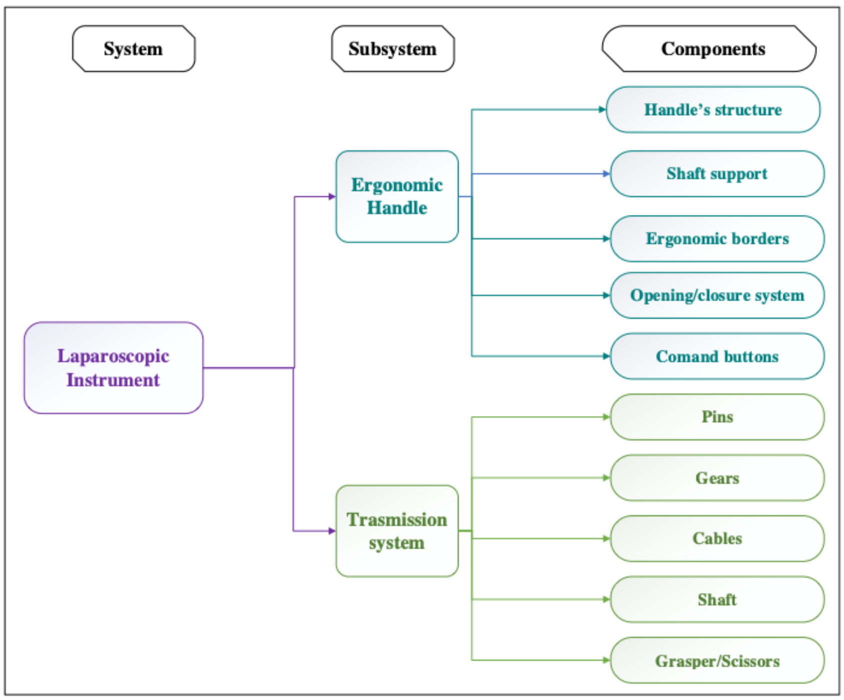

Figure 2. Project tree of the laparoscopic instrument presenting the main components of the product.

The global function structures were also defined in this phase, as seen in Figure 3. With the global structures the designer was able to detail the main function and determine the function structures, see Figure 4.

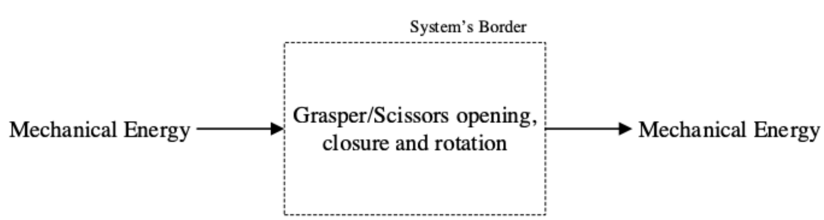

Figure 3. Global Function Structure, presenting the energy transmission that occurs in the laparoscopic instrument

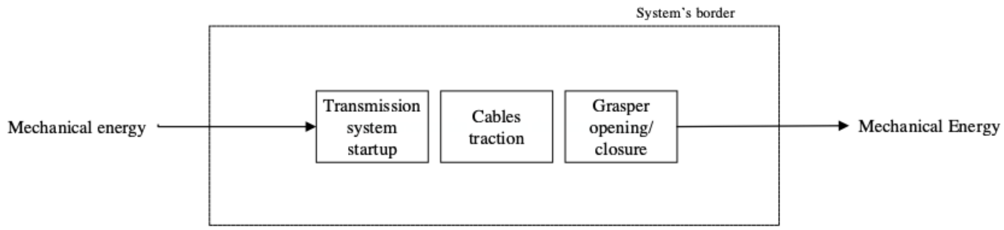

Figure 4. Function Structure presenting the main steps to get the transmission of force in the instrument

After these steps it is important to evaluate the design failure and the possible defects of the laparoscopic handle. For this phase the DFMEA tool was applied. The Top-down approach was used at first to evaluate each subsystem of the laparoscopic instrument, shown in Annex A. The evaluation was made only by the severity (S), and the classification was made by the author based on the information acquired after the scientific research about the product**.** With this first formulary was possible to identify which is the most important component of the system. The severity's (S) average from each subsystem were compared to obtain which is the most critical, according to Table 2.

Table 2 – Resume of the System's DFMEA, presenting the Severity's average.

	Severity (S)	
Subsystem	**Sum**	**Average**
Ergonomic Handle	75	8,33
Transmission system	141	8,29

The subsystem that has the higher severity is the Ergonomic Handle, due to its crypticity during a surgery, where any failure can become fatal for the patient, so the ergonomic handle will be the focus of the next DFMEA evaluation.
The bottom-up approach was used to value the crypticity of the handle's components. In this case all the DFMEA's variables were used Severity (S), Occurrence (O) and Detection (D) to calculate the risk priority number (RPN), see annex B. The RPN results on the DFMEA lead the designer to focus on product improvements and modifications in the most critical components of the handle. Table 3 shows a resumed version of the results presented on Annex B.

Table 3 – Resume of the Subsystem's DFMEA, presenting the RPN average.

	RPN	
Subsystem	**Sum**	**Average**
Ergonomic edges	1512	378
Handle with fingers support	1460	365
Shaft's support	840	280
Joint for the opening and closure of the handle	1764	250

Based on the results of Table 3, the ergonomic edges and the handle with the fingers support were the components with priority during the product's design. The focus was to reduce the risk of failure, because of its higher RPN when compared to the other components.

3.3 Embodiment Design

This will be the last phase presented in this paper, since this is the first prototype and the next step (detail design) will be done only after the author reaches a satisfactory result in the embodiment design. The first model was constructed using the computer aided design (CAD) software, SolidWorks, from SolidWorks Corporation [34] and all the information collected in the previous phases were applied, the model is presented in Figure 5 and following some guidelines presented in the literature the pistol grip shape was chosen [3,14,33]. Other important characteristics are presented in Figure 6.

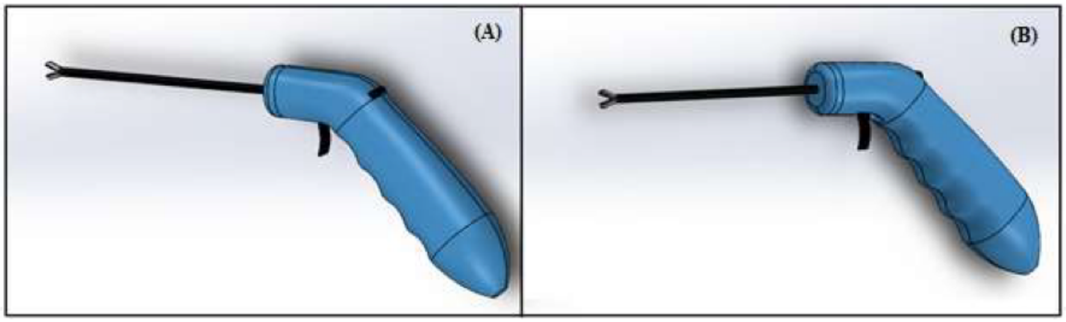

Figure 5. Handle's Prototype. (A) and (B) shows the prototype in different angles.

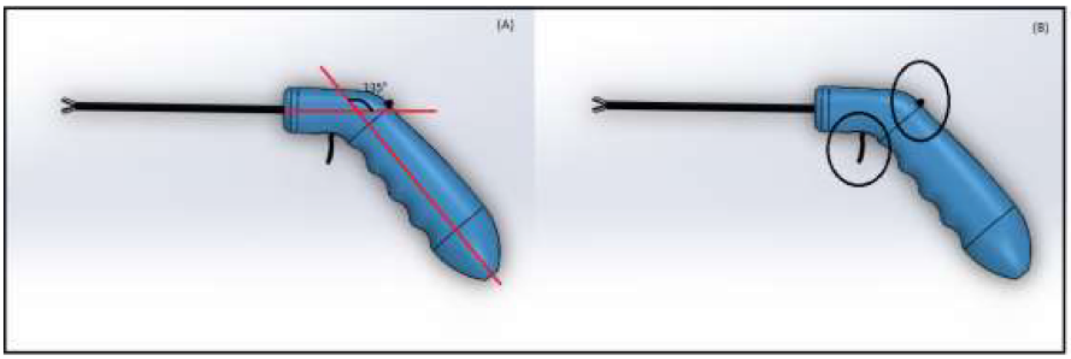

Figure 6. Handle's details. (A) Shows the 135° angle between the shaft and the grip; (B) Presents the command buttons.

In **Erro! A origem da referência não foi encontrada.** (A) is showed that the angle between the shaft and the handle is 135° and it respects the guidelines given by Gonzalez et al. [9] and Van Veelen & Meijer [35]. In Figure 6 (B) it is possible to see both of the control components that were also required in the research. In Figure 7 it's possible to see the 3D printed model of the handle with the hand positioned, to verify the ergonomics of the pistol grip model as it allows the hand to be in the neutral position.

Figure 7. 3D printed prototype. In the Figure it's possible verity the ergonomics of the pistol grip model.

The handle has a right placement for the fingers and it respects the guideline that the grip must be made with the hand's palm. The cross-section selected was the cylindrical, and its diameter respects the guidelines (30-50 mm). The main dimensions of this handle are shown in Figure 8, therefore future tests must be done to evaluate the preferences of the surgeons about having multiples handles sizes available on the market.

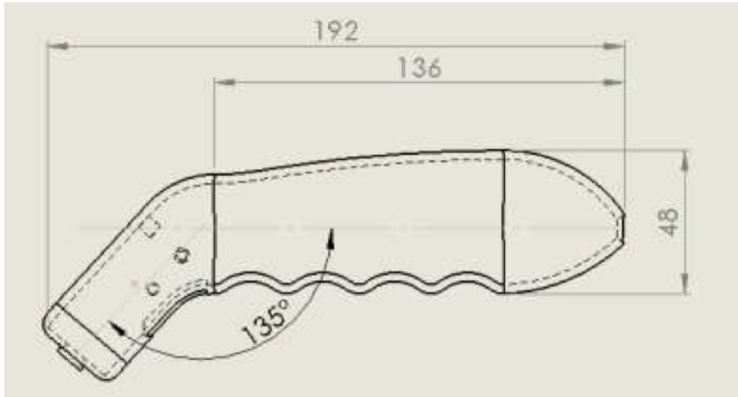

Figure 8. Handle's prototype dimensions that complies with the requirements list

This is the first prototype that will be submitted to tests, evaluations and modifications, until the author reaches a satisfactory solution, this is an important part of Pahl & Beitz [19] method. After that, all the project's documents will be done and the final design will be achieved.

4. Conclusions and future perspectives

The ergonomics studies in laparoscopic surgery still shows that the handle's design is still a big problem in surgeon's musculoskeletal health. For this reason, new designs must be proposed and submitted to tests to improve the achievements in this area, surgeon's ergonomics specialists and engineers must collaborate to develop new devices that may help to solve this problem.

A new handle's model was presented in this article. The integration of the Design Science Research and the DFMEA allowed the designers to structure a product focusing in the improvement of the areas that are the most critical and may present failures. During the development of the list of requisites was possible to determine the main obligatory and non-obligatory product's characteristics based on the recommendations of the literature. The author believes that this compilation of ergonomic requirements may help designers to also achieve satisfactory results in their work.

The prototype was built based on the list of requirements, but it still needs to be evaluated in a physical prototype until the final design is achieved. The model presented in this article is currently in phase of analysis and evaluation of the mechanical transmission system and in the future will be presented in a Master's thesis.

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ANNEX A – SYSTEM'S DFMEA

System: Laparoscopic Instrument	Responsible: Fernanda Virtuozo
Type: System's DFMEA	Approach: TOP-DOWN

Subsystem	Required Function	Possible failure modes	Possible failure causes	Possible failure effects	S
Ergonomic handle	Allow the user to manipulate the instrument in a safe and ergonomic way	The user must stay for a long time in a position that can injure his musculoskeletal structure	Bad use of the equipment, design failures	Chronic musculoskeletal injuries	7
		Cracks on the surface	Bad use of the equipment, design failures	Increased time of surgery	7
				Surgery interruption	8
				Tear of the gloves	8
				Hurt its users	
				Surgical complications or interruptions	9
	Used as a holder and a protector for the electronic and transmission system	Break of supports	Bad use of the equipment, time of use, manufacturing failures	The required function is not performed	9
				Loss of the instrument's control	9
				Vibration	9
				Accuracy loss	9
				Surgical complications or interruptions	10

				The required function is not performed	10
		Gears failure	Time of use, overstrain	Loss of the instrument's control	10
				Surgical complications or interruptions	7
				The required function is not performed	7
				Loss of the instrument's control	7
				Vibration	7
Transmission system	Transmit torque for the engines to give movement to the scissor or to the grasper	Failure in the communication with the electronic components		Accuracy loss	7
			Cables problems, Manufacturing problems	Surgical complications or interruptions	8
				The required function is not performed	8
				Surgical complications or interruptions	8
		Engines Failure	Time of use, overstrain	The required function is not performed	8
				Loss of the instrument's control	8
				Vibration	8
				Accuracy loss	8

ANNEX B – SUBSYSTEM'S DFMEA

System: Laparoscopic Instrument	**Subsystem**: Handle	**Responsible**: Fernanda Virtuozo
Type: System's DFMEA	**Approach**: Botton Up	**Version**: 01

Element	Required Function	Possible failure mode	Possible failure effect	S	Possible failure causes	O	Preventive actions	Detective Actions	D	RPN
Handle with fingers support	Allow the user to hold the equipment in a comfortable and efficient way	Cracks in the surface	Tear the gloves	10	Bad use of the equipment/ time of use	5	Use a resistant material specific for medical use	Visual Inspection	5	250
			Injure the surgeon's hand	10	Bad use of the equipment/ time of use	5	Use a resistant material specific for medical use	Visual Inspection	5	250
		Don't be comfortable to some hand's sizes	Chronic injuries in the long term	10	Manufacturing or design problems	6	Tests before the product's launch	Tests	8	480

		Don't allow the arms and hands to stay in neutral position		10	Manufacturing or design problems	6	Tests before the product's launch	Tests	8	480
Shaft's support	Holds the shaft	Support break	Loos of the gasper control	10	Manufacturing problems, time of use, bad use of the equipment	7	Tests and reinforcement of the shaft's support structure	Visual inspection, manual tests	4	280
		Support break	Shaft detachment	10	Manufacturing problems, time of use, bad use of the equipment	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	4	280
			Complications during surgery	10	Manufacturing problems, time of use, bad use of the equipment	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	4	280

Ergonomic edges	Prevent the gloves from tearing, protect the surgeon's hands	The edge be in a shape that can cause problems	Tear the gloves		Design or manufacturing problems	7	Tests and simulations, design modifications	Visual inspection, manual tests	6	252
			Injure the surgeon's hands		Design or manufacturing problems	7	Tests and simulations, design modifications	Visual inspection, manual tests	6	420
	Prevent the gloves from tearing, protect the surgeon's hands	Design has sharped edges	Tear the gloves		Design or manufacturing problems	7	Tests and simulations, design modifications	Visual inspection, manual tests	6	420
			Injure the surgeon's hands		Design or manufacturing problems	7	Tests and simulations, design modifications	Visual inspection, manual tests	6	420
		Joints break	Handle doesn't close anymore	10	Bad use of the equipment, weak structure, time of use	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	7	490

Joint for the opening and closure of the handle	Open and close the handle in an easy way		Handle doesn't close in the correct way	8	Bad use of the equipment, weak structure, time of use	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	7	392
			Handle doesn't close anymore	6	Bad use of the equipment, weak structure, time of use	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	7	294
			Handle doesn't close in the correct way	8	Bad use of the equipment, weak structure, time of use	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	7	392
			Handle closes but the user can feel its non-conformity	4	Bad use of the equipment, weak structure, time of use	7	Tests and simulations, reinforcement of the shaft's support structure	Visual inspection, manual tests	7	196

Command buttons	Grasper/Scissors activation and control	Mechanical problems	The grasper doesn’t work correctly	10	Bad use of the equipment, weak structure, time of use	5	Tests and simulations	Exchange of the structures when they reach their lifetime, periodic tests.	5	250
		Broken components	The grasper doesn’t work correctly	10	Bad use of the equipment, weak structure, time of use	5	Tests and simulations	Exchange of the structures when they reach their lifetime, periodic tests.	5	250