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An Ergonomic Customized-Tool Handle Design for Precision Tools using Additive Manufacturing: A Case Study

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Abstract: A study was carried out with 135 surgeons to obtain a surgical laparoscopic grasper handle design that adapts to the size of each surgeon's hand, in a functionally appropriate way, and has the sufficient ergonomics to avoid generating the problems detected nowadays. The main conclusion of the work is the practical 3D parametric design obtained for a laparoscopic surgical graspers handle that is scalable to fit each particular surgeon's hand size. In addition, it has been possible to determine that the anthropometric measure of the surgeon's hand defined as Palm Length Measured (PLM) allows the design of the 3D parametric model of the surgical handle to be conveniently scaled. The results show that both additive manufacturing and the application of ergonomics criterion provide an efficient method for the custom design and manufacture of this type of specialised tool, with potential application in other sectors.

Keywords: parametric design; anthropometric; custom handle design; rapid prototyping; 3D CAD

1. Introduction

Universal object designs try to fit all users using the criterion known as "design for all" [1]. This criterion is included in the "Universal Design" guide, which in turn lists the "7 principles of universal design" [2]. One of these principles is to facilitate "flexibility in use". The proposal by Mace et al. [2] was further developed by Story et al. [3], in order to make the use of products designed for the greatest number of people, accessible [4]. To comply with this principle, hand tools in particular should satisfy a number of guidelines in their design. These include overcoming such obstacles as age, sex, dexterity, motor skills, etc., and whether the user is right- or left-handed, so that the handles can be adapted to different hand sizes and shapes.

One of the fundamental problems in hand tool design is in trying to optimize the dimensions of the tool relative to the hand anthropometry. Another fundamental challenge is faced when trying to make sure that the shape and dimensions of the design are consistent with the type and specific functionality of each instrument type [5]. For the instruments used in laparoscopic surgery, Alleblas et al. [6] notes the need to assess expert opinions regarding the current designs of their handles. This is done in order to determine surgeons' needs and expectations with respect to the laparoscopic instruments they currently use and the possibility of the future implementation of haptic feedback in their design. Other studies, such as that of Stoklasek et al. [7] on tools used for the assembly of electric motors, show that while requirements for the functional parts of the tool (duration, making it impossible to damage the motor's installation, etc.) were taken into account in the design, ergonomic requirements for the gripping area of the tool were not. Prolonged use of tools with poor ergonomic design was shown to cause discomfort resulting in numbness or paraesthesia ("pins and needles") in the workers' fingers.

Hand size is a determining factor in how precision tools, in particular laparoscopic graspers, are used [8]. Small-handed surgeons experience more grip problems than those with large hands, and are forced to hold the handle differently from what was originally considered in its design phase [8]. Current surgical laparoscopic tools usually come in a standard size, and the surgeon must adapt accordingly by holding and gripping them in certain ways, which a priori depend on the size of his or her hand.

The conventional laparoscopic surgery graspers shown in Figure 1 incorporate a pistol grip mechanism with finger rings, and a mechanism that allows full rotation of the tip of the shaft (upper part of the graspers). The three images in the figure show different forms of gripping the instrument depending on the size of the user's hand. In the case of Figure 1a, a surgeon with a small hand holds the handle without being able to encompass all of the instrument's grasping elements. In Figure 1b, the opposite case is revealed: A surgeon with a large hand is unable to make simultaneous use of most of those elements, and grips the handle in a completely different way. The ideal grip would be that shown in Figure 1c, in which all the grasping elements fit the size of the hand perfectly. It is important to note that the grips represented in Figure 1 are not arbitrary, but rather reflect real situations brought about when the size of the hand and the dimensions of the handle do not correspond. These different grips were observed in the Centro de Cirugía de Mínima Invasión Jesús Usón (CCMIJU) which collaborated in the development of the present study.

(**a**) (**b**) (**c**)

Figure 1. Different forms of gripping the surgical laparoscopic tool according to the surgeon's hand size. The most irregular ones for this grip are the first two (**a**,**b**). These usually appear when the size of the tool is not adapted to the size of the surgeon's hand. The third (**c**) is the most common, and the information provided directly by the surgeons indicate that it caused the least injuries.

At present, as various recent studies have observed [9–12], the instruments used in laparoscopic surgery are characterized by being of a single size (as mentioned above) and with little ergonomy in their design. The single size of minimally invasive surgery (MIS) instruments means that surgeons have to adapt to the instruments, and different surgeons show different patterns of adaptation depending on their hand size. In spite of this adaptation, neither small- nor large-handed surgeons can find a comfortable zone to grip and manipulate laparoscopic grasping tools. This is especially true for actioning the opening and closing mechanism of the grasper. This problem has been brought to light in various studies such as that of Berguer and Hreljac [5], who surveyed users of these instruments, finding that both those with large hands and those with small hands found them hard to use.

Given this situation, several research papers have been published in recent years analysing the correspondence that must exist between a user's anthropometric characteristics and the precision instruments they use, which need to be ergonomically adapted to the user's hand. Sancho-Bru et al. [13] used a biomechanical model of the hand to study the appropriate diameter of a handle with cylindrical grip for men and women. Other studies indicate that the shape of the handle should be designed to optimize the performance of the tasks in which the tool is to be used [9], maximize the ease of use and contact area between the hand and the handle [10,14], and to distribute pressure so as to minimize discomfort [11,12]. Other anthropometric studies have had the aim of determining laparoscopic surgery instrument dimensions that adapt to different hand sizes [8,15–18]. However, it should be noted that these last works defined three or four sizes for the handle, but listed no criterion for the design of a handle customized for each surgeon.

There are many ergonomic directives and guides in the literature for the design of everyday products. Examples include "Ergonomics and Design. A Reference Guide" [19] for the development of products to improve workplace environments and the "Office Ergonomics. Guidelines for Preventing Musculoskeletal Injuries" [20] which gives a series of guidelines to make working with computers more comfortable. A few even appear in the healthcare sector, such as "Ergonomics Guidelines" [21] for surgical instruments, although none specifically discuss laparoscopic graspers. Most of these ergonomic design guides are too generic for specific applications, and there is a clear need to develop more specific guidelines for the ergonomic design of precision MIS tools [6,22–25].

The ever more widespread application of MIS has brought to the forefront the problem of specific injuries related to the use of laparoscopic tools. Although the techniques of MIS have already attained a relatively high level of development, the ergonomic characteristics of the tools it uses are still deficient [17,26–31]. Surgeons frequently complain of pressure, pain, and fatigue in their hands while using these instruments, which frequently result in lesions [26,28,29,32–37]. According to Trejo et al. [36], these lesions can be attributed to the repetitive and prolonged use of unergonomic instruments. Park et al. [37] found that 87% of surgeons who regularly perform laparoscopic surgery suffer lesions, and that the main cause is this lack of ergonomy.

Therefore several firms in the medical sector, such as Dimeda-Surgical Instruments and WISAP Medical Technology GmbH in Germany, Medtronic in the US, and Endomexico in Mexico, have been working to overcome the problems with the design of MIS tools.

In the circumstances, the main purpose of this paper was to design an ergonomic handle for laparoscopic surgery tools that adapted to each surgeon based on the anthropometry of their hands. The basis would be a parametric design of the handle that includes all the specifications needed for it to be more ergonomic and functional than current handles. The work involved the participation of a total of 135 surgeons, and most of it was carried out in coordination with the CCMIJU.

2. Methods

2.1. Introduction

The experimental phase of this work was conducted with surgeons in the CCMIJU. The basic shape of the handle that was worked with to determine an ergonomic and customized design for laparoscopic surgery graspers is shown in Figure 2. It was the result of the ERGOLAP project [38], and is patented (Patent Number EP2471473A1). The ERGOLAP project was carried out by the authors of the present work in coordination with the CCMIJU and with the Institute of Biomechanics of Valencia (IBV).

2.2. Participants

The study population comprised 135 surgeons. Their ages ranged from 20 to 70 years (mean age = 39.7 years; SD = 9.78 years), and the distribution of the sample population by sex was 69 female and 66 male. The main anthropometric data of the participants are presented in Table 1.

Table 1. Anthropometric data of the study's participants (n = 135).

Characteristics	Mean (SD)	Range
Age (years)	39.7 (9.78)	20–70
Hand length (mm)	178.9 (13.08)	159.3–194.4
Palm length measured (mm)	96.5 (8.79)	87.6–111.6
Hand breadth digitized (mm)	79.9 (6,98)	71.1–86.5

2.3. Experimental Task and the Parametric Prototype Handle

The design and development of the handle shown in Figure 2 was based on a study of the ergonomic preferences of 135 surgeons during their period of training in laparoscopic techniques in the CCMIJU. Two of the handle design criteria were a large palmar grip surface and the combination of precision and turning ability. These criteria eliminated the possibility of a handle design with rings.

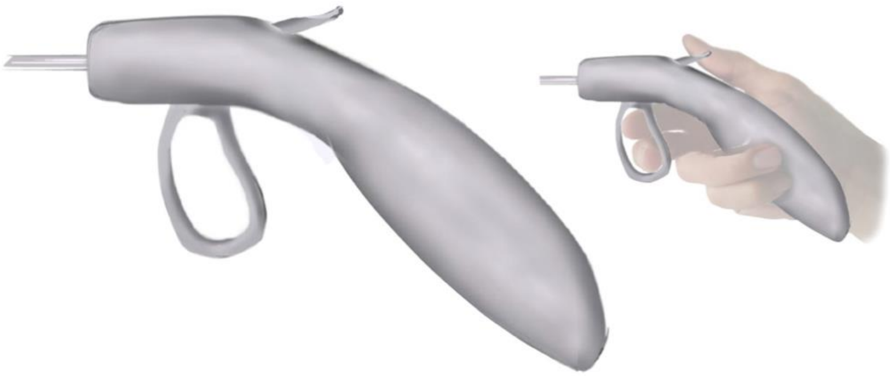


Figure 2. The laparoscopic tool handle developed in the ERGOLAP project.

The resulting handle design has been studied and further analyzed in the work of González et al. [18]. In that study, a first approach was to define a grasper handle size that would best suit the surgeon's hand size, but without attempting to customize the design as this is the purpose of the paper at hand, considering designs based on four hand sizes (XS, S, M, and L). The results of that work are summarized in Table 2. It should be noted that, in addition to this study of González et al. [18], other workers have proposed different sizes for surgical handles and hand tools, specifically by defining three sizes [5,16,39–41]. Nonetheless, given the precision required in surgery and the many hours that some operations last [36], together with the technological means available today such as additive manufacturing and the development of 3D parametric design software [42], a personalized solution would seem to be called for, with the handle being designed to have the size ergonomically best suited to the anthropometric dimensions of each surgeon's hand. Recent studies, such as that of Zanetti et al. [43], show that the use of 3D printing can bring substantial benefits, such as customization, optimization and the manufacture of very complex geometries.

Table 2. Optimal for each of the hand size categories.

Hand Size	%	Sex	Mean Diameter (mm)
XS	26%	Both sexes	29.4
S	11.1%	M	32.9
	18.5%	F	31.7
M	24.4%	M	36.4
	6.7%	F	33.1
L	13.3%	Both sexes	37.9

The final design of the handle used in this study (Figure 2) allowed us to resolve a series of ergonomic problems that existed with other types of MIS handles which did not meet the design criteria obtained in ERGOLAP. In this sense, it should be noted that, since the entire palm of the hand is now involved in gripping the handle, it is easier to achieve a neutral position of the wrist. This reduces fatigue and the risk of thenar lesions. Hence, the grip was designed in such a way that the pressure is distributed evenly between the palm and the fingers. Allowing greater contact of the handle with the whole hand avoids flexing the wrist, stretching tendons, distending the elbow, and limiting shoulder movement. The length of the handle and its diameter were increased relative to the handles traditionally used in MIS, as this provides a better fit for different hand sizes, and the fingers have a larger contact surface thus reducing the pressure on localized areas, especially the thumb.

Regarding the geometry of the handle design developed in the ERGOLAP project (Figure 3a), there are three significant parameters. These are identified as the "inferior diameter" (D_I), "median diameter" (D_M), and "superior diameter" (D_S). The median diameter (D_M) coincides with the diameter defined at the point of inflection of the curvature of the handle (Figure 3a). It also defines the position of the hand relative to the handle during grasping, since for all the surgeons this diameter coincides with the line defined between the third and fourth (Figure 3b). Similarly, D_S and D_I correspond to the narrowest and the broadest parts of the handle design, respectively. These diameters, as shown in Figure 3b, in turn coincide with the lines defined between the second and third phalanges in the case of D_I and the fourth and fifth phalanges in the case of D_S.

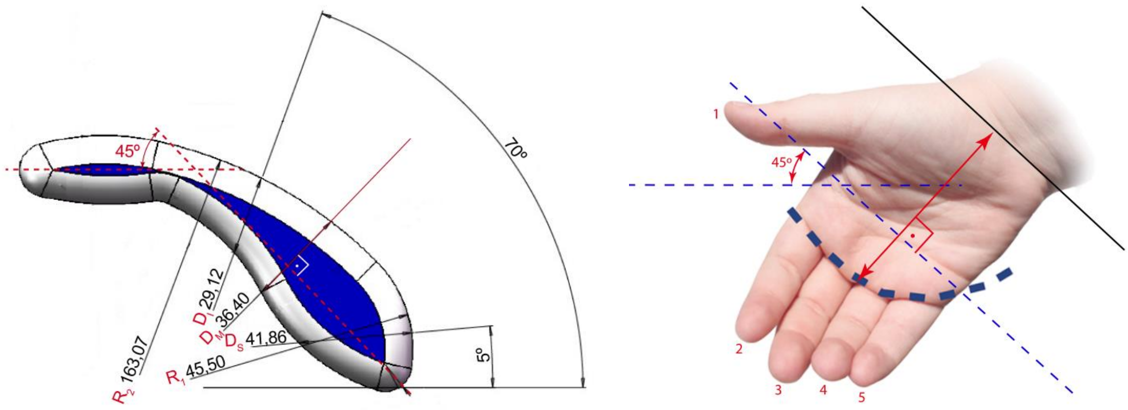


Figure 3. (**a**) Parameters used in the study; (**b**) directives for determining the handle position.

Other features of this handle are that the angle of the handle with the shaft is 45° (Figure 3b). This is a design constraint that must remain unchanged, regardless of the size of the handle or size of the surgeon's hand since it is the value recommended by previous studies [23] and was approved by all the surgeons who participated in the ERGOLAP project.

To define a 3D parametric model of the handle, we chose as the scaling parameter the median diameter (D_M), since this is the most characteristic diameter of the design. It is defined as the line of the hand between the third and fourth phalanges, and which must pass through the point of inflexion of the curvature of the handle during grasping. The other parameters that have to be modified to properly adapt the handle to the surgeon's hand size are D_S, D_I, R_1, and R_2 (Figure 3b). The other parameters are kept invariant, affecting neither the scalability of the model nor the functionality of the design, as we explain below. We reached this result by modifying in various ways the physical model generated by additive manufacturing [42,44], and testing it on a large number of surgeons. Physical models were manufactured for each subject using rapid prototyping technology for their subsequent evaluation. All the handles were manufactured with a 3D printer using white ABS plastic and a smooth surface finish.

For simplicity of the 3D parametric CAD handle model, we found it possible to relate the values of D_S, D_I, R_1, and R_2, to the value of D_M. The ratios between D_M and the other parameters are listed in Table 3.

Table 3. Constants which relate the parameters of the handle to D_M.

Parameter (mm)	Parametric Ratio
D_M	1
D_I	0.80
D_S	1.15
R_1	1.25
R_2	4.48

2.4. Anthropometric Relationship between the Surgeon's Hand and the Size of the Handle

In this subsection, we shall describe the study that we carried out to relate the anthropometry of the hand to the size of the handle. The aim was to determine which hand measurements are related to the size of the surgical handle developed in this paper to scale the parametric model of the handle to the size most appropriate for each surgeon's hand.

To this end, we started from the base of previous studies of anthropometric dimensions of the hand for the optimal design of everyday utensils. In this sense, one of the most thorough-going works is entitled "Hand Anthropometry of U.S. Army Personnel" [45]. This reports the statistical results of data collected in an anthropometric study of the hands of US Army personnel in 1987 and 1988. The population of that study consisted of 1003 men and 1304 women. The 86 hand dimensions analyzed in the report consisted of 64 measurements obtained photometrically, and 22 direct measurements. Figure 4 shows some of these dimensions which have been widely used in anthropometric and ergonomic studies of the hand [5,16,41,46,47].

Greiner's study is of great importance given the sparsity of the literature that includes any analyses of such a large number of anthropometric parameters of the hand. Such is the case for the design of hand tools whose design can make use of a large number of anthropometric parameters such as the finger length, the width of the hand, and the length of the hand [5,16,41,46–48]. As a complement to this anthropometric study, we also analyzed papers that studied the relationship of the dimensions of the hand with the ergonomic use of hand tools. For example, Matern and Waller [49] presented a detailed analysis of the concave surface of the hand with respect to its longitudinal and lateral dimensions which has a correspondence with the generatrix used in the present work (Figure 3b). Using data from the work of Greiner [45], DiMartino et al. [16] defined three categories of hand tools (small, medium, and large) in accordance with hand length. To reduce the number of anthropometric data that we needed to employ in this study, we carried out a comparative study of the different lengths studied by Greiner [45] and those studied by González et al. [18].

In accordance with the aspects indicated above in Section 2.3 that the handle design must meet, the following two criteria were established to determine the most appropriate hand measurements to be analyzed:

- Measurements related to the palm support of the handle—these correspond to the importance of having greater contact between hand and handle, and are therefore related to the breadth of the hand.
- Measurements related to the diameter of the handle—these correspond to the handle appropriately fitting the different types of hand, allowing the fingers to have a greater contact surface, and are therefore related to the total length of the hand and the length of the palm.

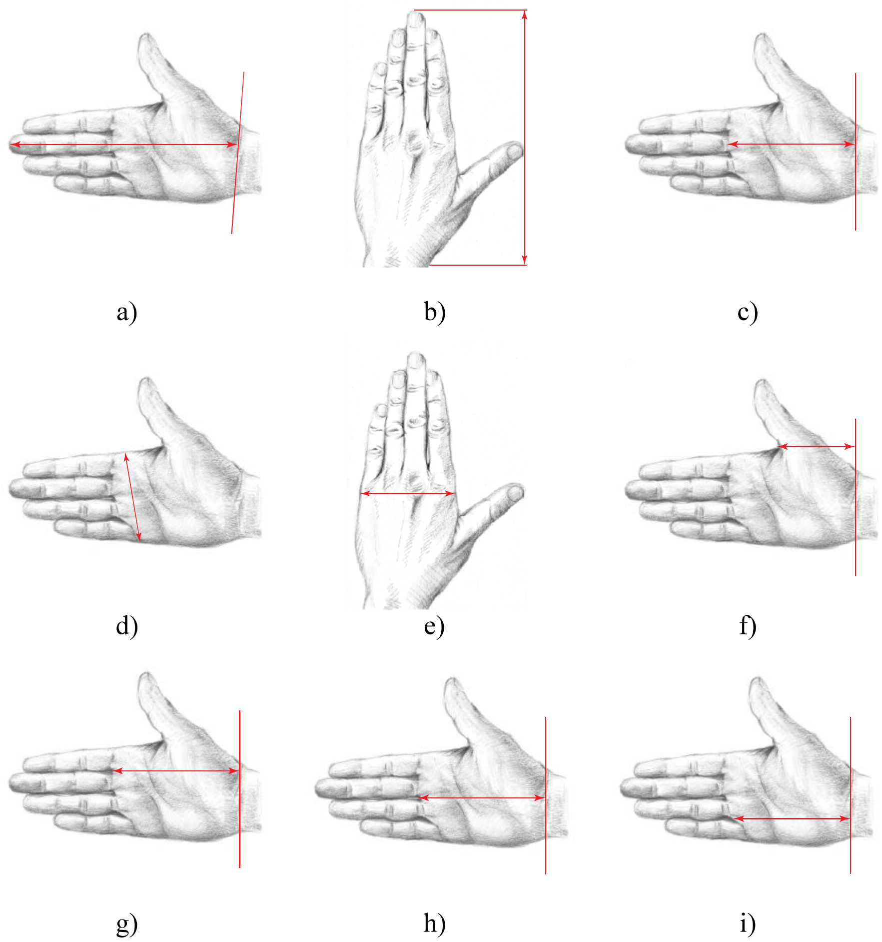


Figure 4. (**a**) Hand Length Digitized (58); (**b**) Hand Length Measured (59); (**c**) Palm Length Measured (61); (**d**) Hand Breadth from Digitizer (62); (**e**) Hand Breadth Measured (63); (**f**) Crotch 1 Height (69); (**g**) Crotch 2 Height (70); (**h**) Crotch 3 Height (71); (**i**) Crotch 4 Height (72).

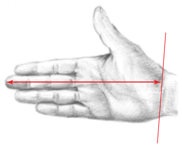
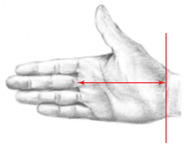
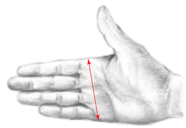
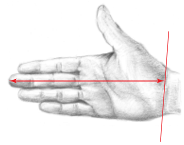
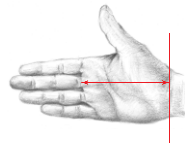
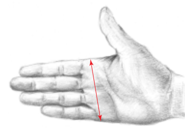
Based on the above and on the anthropometric measurements of the hand that have already been analyzed in other works on ergonomics, in the present work we analyzed the following three anthropometric parameters of the hand:

- Hand Length from Digitizer (HLD) (Figure 4a).
- Palm Length Measured (PLM) (Figure 4c).
- Hand Breadth from Digitizer (HBD) (Figure 4d).

To investigate the correspondence between hand size and handle size, we analyzed the anthropometric data for the 135 surgeons who participated in this study, as summarized in Table 1. From the values obtained, we first calculated HLD, PLM, and HBD (Table 4, columns 3 to 5) for each sex and each hand type as defined in González et al. [18], and then, in order to have parameters that are very similar in value for any hand size, calculated the ratios between these three sets of anthropometric values and the optimal median diameter of the handle (Table 4, last three columns).

The last two rows of Table 4 give the mean values and standard deviations of these ratios weighted according to the population of each sex and hand type (see Table 2). One observes that, of the three anthropometric ratios, that of PLM (a measure of the inner length of the palm) has the smallest standard deviation (0.0113021). We therefore concluded that this ratio would be the most appropriate to use to relate a surgeon's hand size with the best handle size of a laparoscopic grasper, and hence ultimately the best custom handle design.

Table 4. Relationships between the Hand Length from Digitizer (HLD), Palm Length Measured (PLM), and Hand Breadth from Digitizer (HBD) dimensions and the optimal median diameters of a laparoscopic surgery handle.

HSC	Sex	Hand Length from Digitizer (HLD)	Palm Length Measured (PLM)	Hand Breadth from Digitizer (HBD)	Ø Optimum Diameter of handle D_M	Anthropometric Relationship Factor		
		Units in mm				$\frac{HLD}{D_M}$	$\frac{PLM}{D_M}$	$\frac{HBD}{D_M}$
								
XS	Both sexes	159.3	87.6	71.1	29.4	5.418	2.980	2.418
S	Male	174.1	97.6	79.1	32.9	5.292	2.967	2.404
	Female	170.2	94.3	72.5	31.7	5.369	2.975	2.287
M	Male	188.8	107.8	86.5	36.4	5.187	2.962	2.376
	Female	182.1	98.2	78.9	33.1	5.502	2.967	2.384
L	Both sexes	194.9	111.6	86.5	37.9	5.142	2.945	2.282
					$\overline{x}$	5.308	2.967	2.362
					$\overline{s}$	0.1173040	0.0113021	0.0549504

3. Results and Discussion

The main result of this work has been to obtain the 3D parametric design of a handle for the graspers used in laparoscopic surgery, in which the parameter D_M allows the design to be scaled to adapt the size of the handle to each surgeon's hand size. In particular, it was found that the anthropometric measurement of the hand that is most appropriate to relate the handle size to the surgeon's hand size is that defined by PLM. To obtain a 3D design, first the surgeon's PLM value is taken. This value is then divided by the coefficient 2.967 (see Table 4) to give the most appropriate value of the median diameter of the handle (D_M). With this value, the 3D parametric model of the handle is scaled to the surgeon's hand size. Figure 5 shows some examples of 3D CAD models scaled to different surgeons among the participants in this study. The curve drawn in a dashed line on the different customized models is in this way adapted to the surgeon's hand as shown by the equivalent dashed line in Figure 3b.

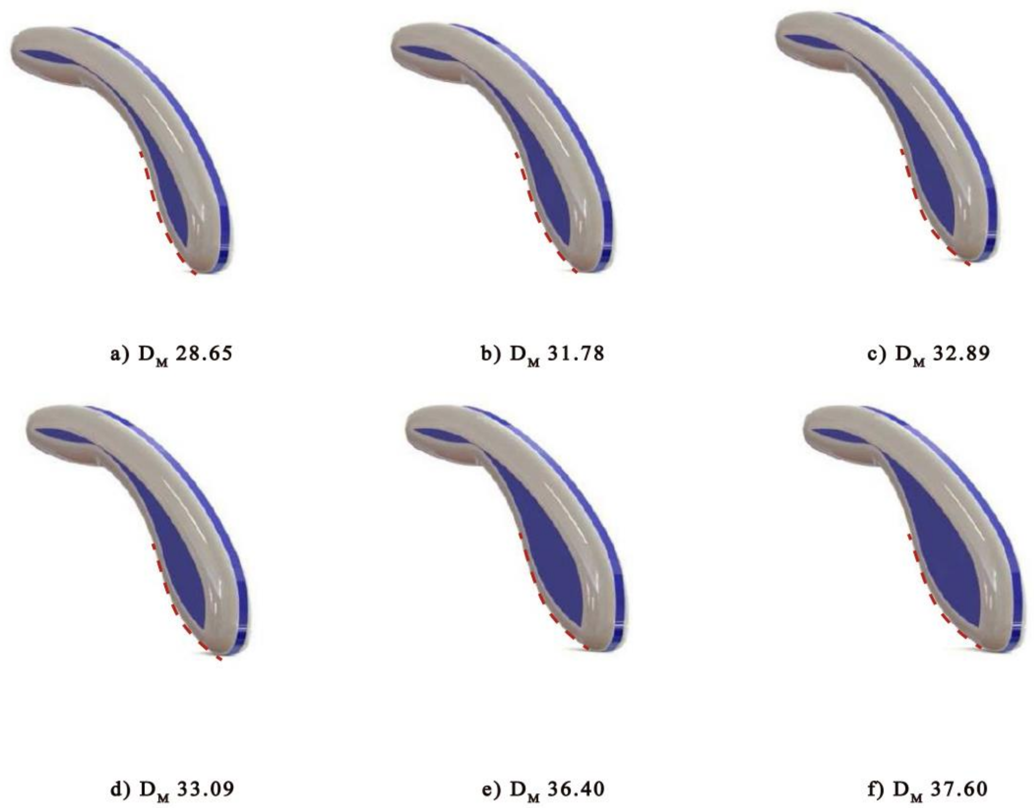
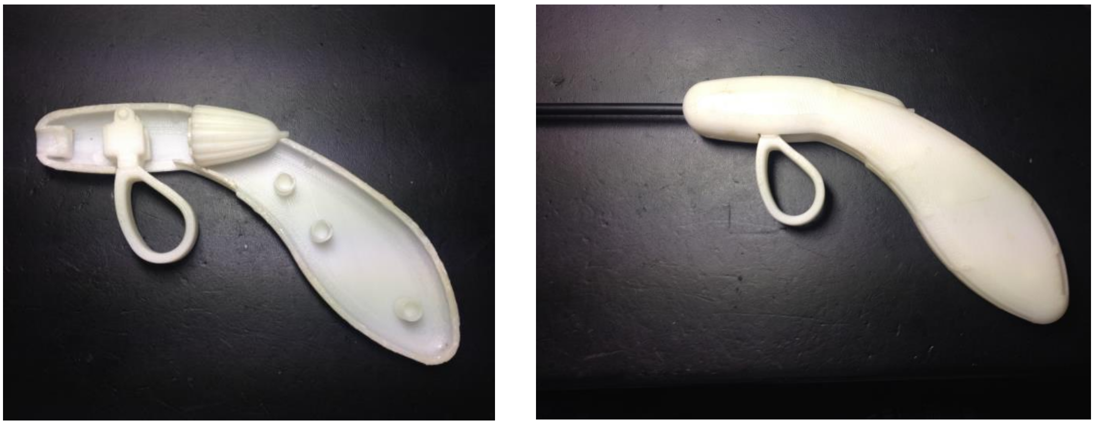


Figure 5. Custom 3D Computer Architectural Drawings (CAD) models of the surgical handle depending on each surgeon's PLM measurement.

To check the results, several 3D CAD parametric designs for different surgeons were fabricated by additive manufacturing (for different sexes and hand sizes). Figure 6 shows one of these handles made for a particular value of PLM, and therefore with a characteristic value of D_M (a value that determines the complete design of the handle). For this, first the surgeon's hand was scanned, to then obtain the palm length (PLM), in this case giving a value of 96.55 mm. The optimal diameter was calculated from the anthropometric ratio PLM/D_M resulting in a custom value of D_M = 32.54 mm, which was used to generate the parametric model of the handle (Figure 6).

To be fully functional for the validation tests, the 3D CAD model was designed with a hollow interior. This allowed the shaft (the metallic clip) to be inserted together with the opening and closing mechanisms of the grasper and the shaft's rotation mechanism (Figure 6).



(a) (b)

Figure 6. Prototype custom handle. (**a**) Details of the pieces; (**b**) assembled prototype.

Figure 7 shows a surgeon using the prototype (D_M = 32.54 mm) during the validation test. At the conclusion of the test, the surgeon confirmed that their experience using the handle was completely satisfactory [18]. Identical results were obtained with the surgeons whose handles corresponded to those illustrated in Figure 5.

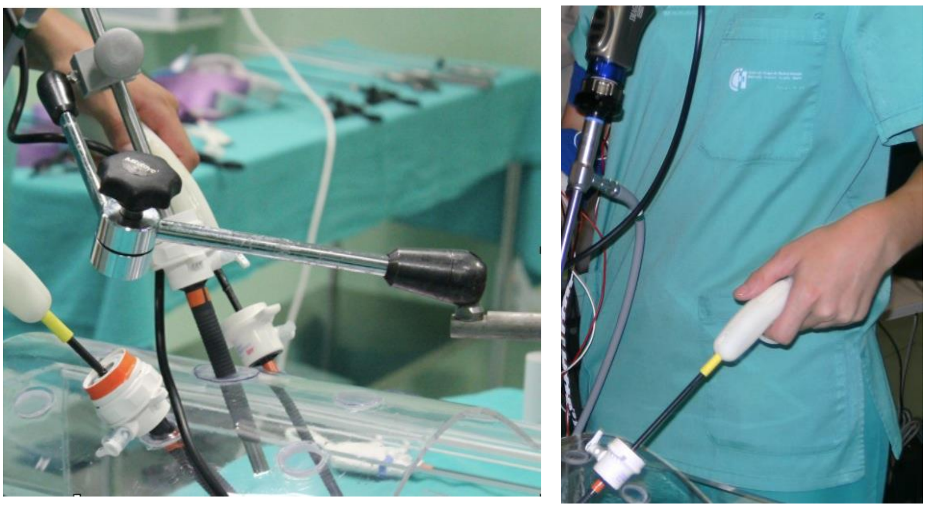


Figure 7. Prototype custom handle used in a simulation test.

4. Conclusions

The main finding of this work was confirmation that it is possible to obtain 3D parametric designs of a handle for laparoscopic graspers that are scalable to fit each surgeon's hand size. Furthermore, it was found that a single anthropometric factor—the "Palm Length Measured"—can be used to relate any surgeon's hand size to the optimal diameter of the handle. Functional tests carried out in the CCMIJU confirmed that the parametric design developed for the handles adapts ergonomically to different surgeon's hand sizes.

Thus, the specific contributions of this work include the following:

- A 3D parametric CAD design has been obtained for the handle of laparoscopic surgery graspers that is scalable for different hand sizes. All of the resulting models personally customized for each surgeon complied with the ergonomic criteria for their use.

- The results show that additive manufacturing and the application of ergonomics criterion provide an efficient method for the customized design and manufacture of this type of specialized tools, being possible to be applicable to other sectors.
- The relationship between the anthropometry of the surgeon's hand and the most suitable size of the handle was determined, with the most suitable anthropometric parameter to measure being the "Palm Length Measured" (PLM).

Finally, the authors consider that the customization of the geometry of a surgical tool can serve as a reference for future research that addresses the optimal material and tools for their subsequent production through additive manufacturing techniques.

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Conflicts of Interest: The authors declare no conflicts of interest.

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