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Design and Development of a Customized Laparoscopic Forceps Handle Using Fused Deposition Modeling

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Key words: Customization; Ergonomics; Anthropometry; Additive Manufacturing; Comfort

ABSTRACT

Laparoscopic surgeries are predominant in present day healthcare services due to its reduced hospital stay. However, complex procedure usually increases the discomfort of surgeons. Customized surgical instruments incorporating hand anthropometric measurements and ergonomic factors can solve this issue. The paper addresses this problem by developing prototype of a customized laparoscopic forceps handle using hand anthropometric dimensions. Ergonomic factors included are mass of the tool handle, grip, contact area of the tool with the hand, and wrist posture. The evaluation is completed by collecting subjective ratings and subjects confirmed an enhanced comfort with modified prototype of the handle when compared to existing design of laparoscopic forceps handle.

INTRODUCTION

Number of laparoscopic surgical procedure is increasing day by day across the globe as it reduces hospital stay and healing time compared to open surgical procedure (Richardson et al. 2000; Raymond et al. 2008). However, in laparoscopic surgery, surgeons go through more rigorous procedure and experience more pain, which results in discomfort of the surgeons (Hemal et al. 2001). Laparoscopic surgeons experience pain usually on body segments like back, neck, shoulder, hand, and thumb (Doné et al. 2004; Soueid et al. 2010; Davis et al. 2013).

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One of the main causes of increased pain during or after laparoscopic surgery is due to improper size of tool handles and lack of implementing ergonomic criteria for the design of surgical tools (Veelen et al. 1999; Berguer and Hreljac 2004; Adams et al. 2008). Ergonomics can be considered as one of the important factors in customisation and in successful product development (Yang et al. 2004).

Focusing further, hand size can be considered as an important factor in the laparoscopic surgical tool design (Berguer and Hreljac 2004; De 2005). A study among 120 laparoscopic surgeons indicates the imperative idea of implementing surgical tools with modified design, which address surgeons with small hand size (Adams et al. 2008). In a study, most of the surgeons reported about physical pain during or after laparoscopic surgeries, and claimed this is due to deprived ergonomics of handle design (Sari et al. 2010). Another study reported that main causes of discomfort for surgeons in laparoscopic surgery are increased technical complexity and poorly adapted equipments (Supe et al. 2010).

Comfort is a term which is difficult to describe as it varies between individuals and at the same time incorporating customisation and ergonomic in the design of equipments can improve the comfort of users and ultimately increase their efficiency (Dumur et al. 2004; Harih and Dolšak 2013; Bhuse and Vyavahare 2014). Back and shoulder strain suffered by laparoscopic surgeons can be reduced by developing new hand surgical instruments or modifying existing ones ergonomically (Hanna et al. 2001).

Additionally, prototype of an ergonomically designed laparoscopic surgical grasper and surgeons responded that it reduces discomfort than the conventional or existing one (Doné et al. 2004). In addition to this, ergonomic design alteration of surgical scissor handle and endoscopic dissector handle increases the contact area and decreses the muscle strain than the exisitng designs (Shimomura et al. 2015; Shimomura et al. 2016). Another study confirms the supremacy of ergonomically designed laparoscopic handle prototype fabricated using addtive manuafcturing incorporating a pistol handle arrangement to ensure increased contact area and neutral position of wrist during surgery over exisitng handles in terms of comfort (Sancibrian et al. 2014; Sancibrian et al. 2016).

Apart from ergonomic design of surgical tools, DiMartino and team proposed that present setback of laparoscopic surgical tools including discomfort can possibly solve by collecting anthropometric data of target population (DiMartino et al. 2004). Science of collecting various body dimensions, including hand measurements for different purposes is known as anthropometry, and it is a branch of ergonomics (Krishan 2007; Zhang and Molenbroek 2004).

A research by DiMartino and fellow researchers on ergonomic design of laparoscopic hand tools based anthropometric data of targeted population, concluded that diameter of the handle may be between 4.8 cm to 5.7 cm to enhance the comfort of users (DiMartino et al. 2004). Customized spring and pivot forceps surgical instruments were modeled using SolidWorks 2012 and fabricated using uPrint fused deposition modeling (FDM) additive manufacturing machine for a clinician and successfully completed a surgical procedure on a realistic human simulator with the aid of these instruments (Kondor et al. 2013).

The research reported above indicates that, considering hand size with ergonomics as a complementary factor when designing hand surgical tools to reduce discomfort of surgeons in the neck, shoulder and upper extremity. Some of the research employed additive manufacturing as a potential technology to build custom products that have a promising future in healthcare engineering to benefit surgeons and patients. Pistol type handles can increase the contact area and anthropometric dimensions can effectively incorporate in the handle design to develop customized products.

Accordingly, aim of this research is to design and develop a customized laparoscopic surgical tool handle using hand anthropometric data of targeted population and incorporating ergonomic factors to enhance comfort of the surgeons. The main objective of the modified laparoscopic handle design is to include pistol type grip without changing the existing ring type handle. This will in turn increase the contact area, bring wrist in a neutral position during surgery and ultimately increase the comfort of surgeons. Also objective of the modified design is to decrease the mass of the handle by fabricating the handle through additive manufacturing technology.

METHODOLOGY

The research comprises three phases such as collecting hand anthropometric data, modeling, and additive manufacturing of the model. The detail of various stages for procuring new, customized, and ergonomically designed laparoscopic surgical instrument handle is discussed in subsequent sections.

Hand Anthropometric Data

Hand anthropometric data of 120 subjects collected from south India using tracer method, which is adopted for reducing time spend by subjects for collecting hand measurements. A pen and paper are used for recording hand anthropometric dimensions. The hand profile of each subject is traced to a paper using pen and measurements are taken by the researcher later. Tracing the hand profile took five to ten minutes. So, it may not affect the day to day responsibilities of the subject.

Selected hand anthropometric data is shown in figure 1. Table 1 explains about the terminology used in figure 1. Table 2 details the minimum, maximum, mean, standard deviation and 5th, 50th, and 95th percentiles of collected hand anthropometric dimensions. These dimensions can be utilized for designing various hand tools. Here it is employed for procuring customized laparoscopic surgical tool handle.

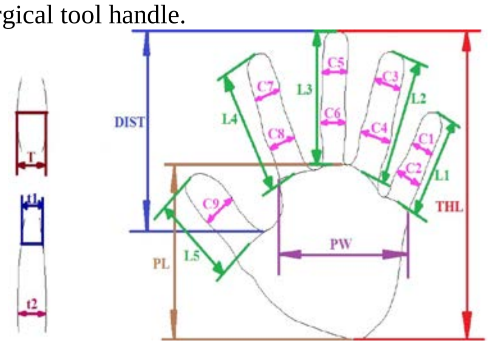

Figure 1. Selected hand anthropometric data

Modeling

Modeling of the laparoscopic surgical forceps handle is carried out using SolidWorks 2013 3D CAD software. Figure 2 shows the existing laparoscopic forceps with ring type handle in assembled and disassembled form. By analyzing the existing design, some of the problems identified are grip is not sufficient to take up the whole load, contact area between hand and tool is less, awkward wrist posture, and mass of the tool. Integrating pistol type grip, increased contact area, and reduced mass will enhance ease of handling the forceps. Revealing which, it will lead to more comfort. Free from awkward posture of the hand also augment the comfort of surgeons. Modification of the existing laparoscopic forceps handle is done by keeping these factors in mind, also keeping the basic ring type handle.

The research aims to impart modification without having major change in the existing ring type handle of forceps. The new forceps is modeled in such a way that the components like Cannulas, locking collar, rotatable appliers, and dissecting grasper from the existing design can be utilised in the modified design. In the new design little, ring and middle finger will be inside finger holes of the handle whereas in the existing one, only ring finger will go through the finger hole. Index finger set to keep outside for operating rotatable appliers to rotate dissecting grasper to make easy grasping of organs.

Table 1 Terminology of hand anthropometric data

S. No.	Terminology	Definition of hand dimensions
1	C1	Circumference of little finger in between distal and intermediate phalanges
2	C2	Circumference of little finger in between intermediate and proximal phalanges
3	C3	Circumference of ring finger in between distal and intermediate phalanges
4	C4	Circumference of ring finger in between intermediate and proximal phalanges
5	C5	Circumference of middle finger in between distal and intermediate phalanges
6	C6	Circumference of middle finger in between intermediate and proximal phalanges
7	C7	Circumference of index finger in between distal and intermediate phalanges
8	C8	Circumference of index finger in between intermediate and proximal phalanges
9	C9	Circumference of thumb in between distal and proximal phalanges
10	L1	Length of little finger
11	L2	Length of ring finger
12	L3	Length of middle finger
13	L4	Length of index finger
14	L5	Length of thumb
15	THL	Total hand length
16	DIST	Distance between bottom of thumb to tip of middle finger
17	PL	Length of palm
18	PW	Width of Palm
T – Thickness of Thumb t_1 – Thickness of other fingers in between distal and intermediate phalanges t_2 – Thickness of other fingers in between intermediate and proximal phalanges		
T, t_1 and t_2 are used to measure the circumference of (C1 etc) respective fingers		
		All Dimensions are in mm

Table 2 Hand Anthropometric Data (n = 120)

Anthropometric Data	Minimum	Maximum	Mean	SD	Percentile		
					5th	50th	95th
Age	18	31	20.42	1.973	18	20	23
Height (cm)	138	186	169.86	9.038	155	172	182.85
Weight (kg)	40	106	64.84	12.595	45.05	62	86.95
BMI (kg/m^2)	12.346	35.156	22.479	4.038	16.467	21.618	29.352
Shirt Size	38	44	38.63	1.316	38	38	42
C1 (mm)	42	74	56.3	8.103	46	54	70
C2 (mm)	46	86	64.43	9.291	52	63	80
C3 (mm)	46	76	58.83	8.148	48	58	72
C4 (mm)	52	86	67.02	9.171	54	66	83.9
C5 (mm)	48	80	60.68	8.791	50	58	76
C6 (mm)	54	90	69.2	9.782	56	68	86
C7 (mm)	46	80	60.03	8.922	48	58	76
C8 (mm)	52	90	68.33	9.929	56	66	84
C9 (mm)	52	94	70.76	9.71	54.1	70	86
L1 (mm)	54	88	64.11	4.892	57.05	64	71.95
L2 (mm)	64	94	78.06	5.063	71	78	88.9
L3 (mm)	72	100	84.15	4.708	77.05	84	92.95
L4 (mm)	68	95	77.9	4.799	70.05	78	86.9
L5 (mm)	47	80	56.97	5.096	50	56	65
THL (mm)	170	223	191.12	9.314	176.1	191	205.95
DIST (mm)	110	160	129.98	8.721	115.05	129.5	145.95
PL (mm)	90	126	107.1	6.309	97.05	107	117.95
PW (mm)	72	108	86.39	6.534	77	85.5	97

Figure 2. Existing Laparoscopic Forceps (Courtesy: Hospiinz International)

Position of the thumb finger hole is shifted upward to make the wrist in a straighter position. The thumb finger hole and other finger hole are set in a same plane in the existing design. In the modified design of part for inserting thumb is made an offset. An attachment which has a shape similar to hammer is another important modification to include pistol type grip in the laparoscopic forceps handle and it will rest on the palm when performing surgery. Customisation is fulfilled by adopting mean values of hand anthropometric dimensions. The critical dimensions for modeling the handle identified are the mean values of the circumference of fingers, length of the middle finger, and distance between the bottom of thumb to tip of middle finger.

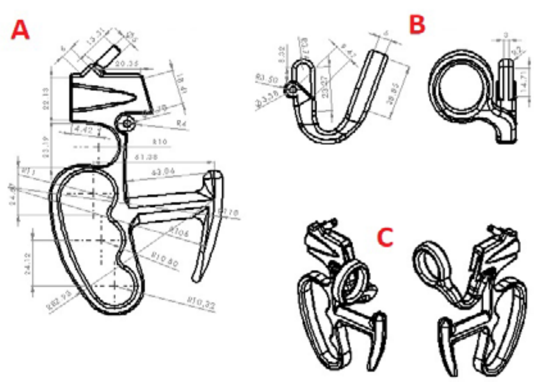

Figure 3. CAD model of part for inserting other fingers (A) thumb (B) and isometric view (C)

Figure 3 exemplifies the modified design of laparoscopic forceps handle (part for inserting thumb and other fingers) along with isometric view. Diameters of holes for inserting little, ring, middle, and index fingers are 21mm, 22mm, 25mm, and 24mm respectively. Diameter of thumb hole is fixed to 29mm. Length of the palm rest region is 43mm and it is set based on distance between the bottom of thumb to tip of middle finger and length of middle finger.

Additive Manufacturing

CAD model of ergonomically designed, customized laparoscopic forceps handle exported to STL file format. STL stands for STereoLithography or Standard Tessellation Language widely used as a file format which is recognized by most of the additive manufacturing machines (Ciobota 2012). The machine used for fabrication is uPrint (Stratasys) works on Fused Deposition Modeling (FDM) technology with a build size of 203 x 152 x 152 mm. The build or model material is ABS P430 in ivory and support material is SR-30 which is soluble in a mix of hot water and sodium hydroxide.

Consumption of build or model and support material, number of layers, and time taken to complete the build process is tabulated in table 3. After the building process, support material is removed using a post processing process. Water temperature usually will be between 75 to 80ºC for better removal of support. The forceps handle after the removal of support and assembled with cannulas, and other parts are shown in figure 4.

Table 3 Details of build and support material consumption

Parameter	Consumption
Build or Model Material	1.77 in^3
Support Material	1.23 in^3
Time	5:05 hour
Number of Layers	184 Nos.

Figure 4. Modified laparoscopic froceps handle

RESULTS AND DISCUSSION

In this section, the ergonomic factors of the customized laparoscopic forceps handle are discussed in terms of pistol grip, mass of the tool handle, contact area, and wrist posture. As there are no measures to measure certain data, subjective evaluation to compare existing and modified laparoscopic forceps in terms of grip, usability, comfort, and wrist posture had also been completed.

These factors are discussed in detail in the subsequent sections.

Ergonomic factors

Pistol grips are beneficial for handles with bent or angled part (CCOHS 2015). Scissor type or ring type handle’s grip is not sufficient to take up the whole load as compared to power and pistol type grips. Here to add pistol type grip in the existing laparoscopic forceps handle, a small attachment similar to the shape with a hammer is included as shown in figure 5. This feature can enhance the grip strength and also the load carrying capacity of the hand. It also straightens the forearm and wrist which led to more comfort for surgeons.

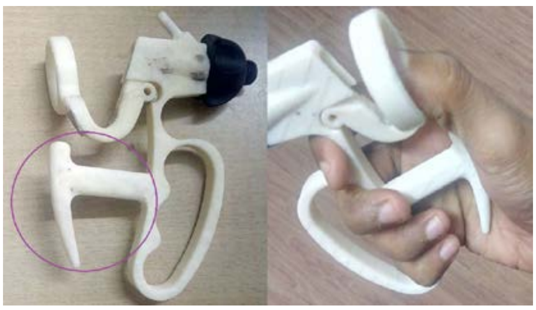

Figure 5. Attachment for changing to pistol type grip

Mass or weight of the tool is a key consideration in ergonomic design and evaluation. Reduction in mass of the tool eventually made handling effortless for the user. Mass of the existing and modified laparoscopic forceps handles is presented in table 4. By using ABS plastic and additive manufacturing technology, there is a reduction in mass about 33.33%.

Table 4 Mass of existing and laparoscopic forceps handles

Tool	Mass (g)
Existing Laparoscopic Forceps handle	39
Modified Laparoscopic Forceps handle	26

The hammer like attachment also increased the surface area of contact between the hand and the tool in the customized and ergonomically modified laparoscopic forcep handles. Increment in contact area is also helpful for uniform pressure distribution among the palm and fingers. The increased area of contact with the hand is shown in figure 6 for both existing and modified laparoscopic forceps handles for comparison.

Posture analysis plays a key role in ergonomic evaluation while interacting with tools and machines. One of the important objectives of this research is to make wrist straight while using the laparoscopic forceps handle. Figure 7 illustrates the wrist position when using existing and modified laparoscopic forceps handles. A slight modification on thumb finger hole and initiation of pistol type grip made wrist in a straight or neutral position when compared to the existing design of laparoscopic forceps handle. This will lead the surgeons to a more comfortable zone and reduce pain on upper extremity.

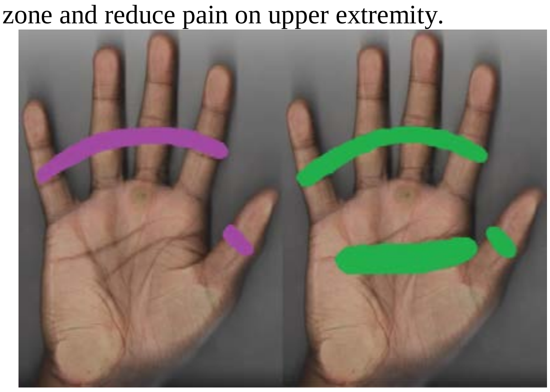

Figure 6. Contact area of exisitng (left) and modified (right) laparoscopic forceps handles

Figure 7. Wrist posture when using existing (left) and modified (right) laparoscopic forceps handles

Stress Analysis

Stress analysis of the modified forceps handle is undergone using SolidWorks 2015 simulation software. Von Mises stress and deformation determined from finite element analysis are compared with experimental data. Stratasys reported that experimental analysis indicated that yield strength of ABS P430 is 31MPa (Stratasys 2014). Value of grip strength of Indian males with right hand dominance obtained was 291.4 N (Koley and Melton 2010). Normally human strength capability should not go beyond one third of their isometric or maximum strengths in task performances (Putz-Anderson 1994; Das and Wang 2004). In this regard, one third of 291.4 N, which is equivalent of 97.13 N is used in this analysis. Deformation and von Mises stress are displayed in the figure 8 (A & B).

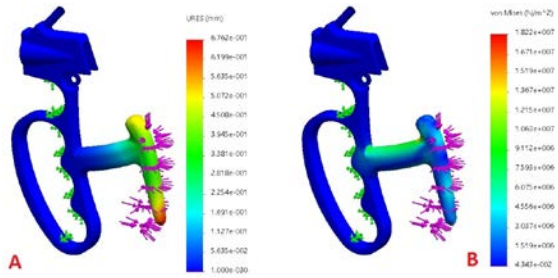

Figure 8. Deformation (A) and von Mises Stress (B)

Von Mises stress criterion of failure in ductile materials is used for stress analysis of modified laparoscopic forceps handle, which states that the von Mises stress obtained from analysis should be less than the yield stress of the material (Chandrupatla and Belegundu 2002). Here maximum value of von Mises stress obtained is 18.22 MPa (Figure 8-B), less than experimental value of yield stress of 31MPa. Hence the analysis indicates that the design is safe. In addition to this, Hernandez and his team of researchers reported that maximum deformation of ABS P430 is 7.62mm (Hernandez et al. 2016). Based on the finite element analysis conducted in this research, maximum deformation obtained is 0.6762mm (Figure 8-A). This reconfirms that the design is within the limit.

Subjective Evaluation

Evaluation of modified laparoscopic forceps has also been done by conducting a face-to-face interaction with 52 subjects with an average experience of 9.4 years in laparoscopic and general surgical procedure and an average age of 38.3 years. The subjective evaluation parameters selected are grip, usability, comfort, and wrist posture. Subjects were asked to evaluate the existing and modified laparoscopic forceps handle and rate the modified laparoscopic forceps on a 5-point ordinal scale over the existing design. The values assigned for scale are 1 for “very poor”, 2 for “poor”, 3 for “fair”, 4 for “good”, and 5 for “very good”.

Figure 9 demonstrate the average rating given by the subjects for the newly developed customized and ergonomically designed laparoscopic forceps handle over existing one. X axis for parameters and y axis for subjective rating. From the subject ratings the highest average rating obtained is for wrist posture which is equal to 4.3. For grip and comfort, average ratings obtained are 4.06 and 4.2 respectively. Usability attained the lowest value of average rating equals 3.9. The subjective rating indicates the ascendancy of modified laparoscopic forceps over existing design of laparoscopic forceps in all the selected parameters such as grip, usability, comfort, and wrist posture.

Ergonomic evaluation in terms of pistol grip, mass of the tool handle, contact area, and wrist posture point out that these features can enhance the comfort. Introducing pistol-type grip to the existing ring type handle improves the holding capacity. Mass of the tool is reduced by 33.33% when compared to the existing design, and it leads to easier handling. Increased area of contact between tool and hand can distribute the pressure uniformly. Modification of the tool by initializing pistol grip and changing position of the thumb finger hole made wrist in a neutral position. These all factors, in one way or the other, improve the comfort. Subjective evaluation also confirms that comfort is enhanced by modified laparoscopic forceps.

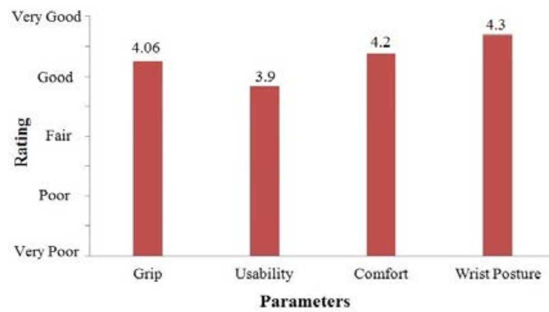

Figure 9. Average subjective ratings of new forceps handle

LIMITATIONS

The hand anthropometric data collected can be increased to get more accurate dimensions of targeting population. It will be appreciable to analyses the muscle activity using electromyography (EMG) in the future when using the modified laparoscopic forceps handle.

CONCLUSION

This research attempted to make a customized and ergonomically modified laparoscopic forceps handle to augment surgeon’s comfort. 33.33% of mass reduction is found in modified design when compared to the existing design. The modified laparoscopic forceps handle prototyped using FDM technology consumed 1.77 in^3 of build material and 1.23 in^3 of support material. Total time taken to build the tool is just 5 hours and 5 minutes. Subjects gave highest average rating for wrist posture and comfort with 4.3 and 4.2 respectively. This is pointed toward the conclusion that developed prototype of the laparoscopic forceps handle is comfortable.

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