

Product Development and Cost Analysis of Fabricating the Prototype of Roller Clamp in Intravenous (I.V) Tubing Medical Devices using Fused Deposition Modeling (FDM) Technology

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Abstract. The main aim of this research is to develop a new prototype and to conduct cost analysis of the existing roller clamp which is one of parts attached to Intravenous (I.V) Tubing used in Intravenous therapy medical device. Before proceed with the process to manufacture the final product using Fused Deposition Modeling (FDM) Technology, the data collected from survey were analyzed using Product Design Specifications approach. Selected concept has been proven to have better quality, functions and criteria compared to the existing roller clamp and the cost analysis of fabricating the roller clamp prototype was calculated.

1. Introduction

Rapid Prototyping technology (RP) offers the user the ability to optimize part design in order to meet customer requirements with few manufacturing restrictions. One of the most common RP processes is Fused Deposition Modeling (FDM). The majority of commercial rapid prototyping system build object by adding one layer after another. RP was mainly used for product development in the manufacturing industry. It was used to speed up design process for household products, toys, tools and mechanical components [1]. The mechanism of rapid prototyping technology basically just same as the mechanism of normal printer that we use to print images. The different is on the product where the product produced from rapid prototyping machines is in 3D form as well as solid physical model while the product produced from normal printer is in 2D form [2]. As shown in Figure 1, FDM machine was developed by StratasysInc. FDM creates 3D models out of heated thermoplastic material, extruded through a nozzle positioned over a computer controlled X-Y table. The table is moved to accept the material until a single thin slice is formed. The next slice is built on top of it until the object is completed. FDM utilizes a variety of build materials, such as polycarbonate, polypropylene and various polyesters which are more robust than the SLA models [3].





Figure 1. FDM machine

Previous works conducted by Petzold et.al [4] and Ed [5] in medical sector mentioned that rapid prototyping can be used as an important tool to improve sub-sectors in medical such are orthopedics, surgery and implant. Compare to other traditional making process of prototype, rapid prototyping is better because it can speed up the process and manufacture the prototype in minutes. Besides, the complex parts of human anatomy are not considered as problem anymore because rapid prototyping can easily manufacture complex fracture without any obstacles. In traditional making process such as foundry, the complexity of product becomes one of the disadvantages of the process Sanghera et.al [6]. FDM models can also be made in wax, enabling custom-made implants to be investment cast for individual patients. Gibson et al. [3], Sanghera et.al [6] and Ed [5] agreed that recent improvements in technology are leading to the increased use of rapid prototyping to make implant human body parts. Jarnieson et al. [7] suggested that the implant human body parts must be customized for each patient for instant nearly all hearing-aids today are made using either Stereolithography or Selective Laser Sintering.

According to Webb [8] and Aspden et.al [9], intravenous therapy is a treatment that experienced by mostly people in the world. It is because the therapy is the most efficient way to solve or operate several common problems such are maintain imbalance electrolyte in our body, blood transfusion, deliver fluids and medications. Even for blood donation process, the treatment used is intravenous therapy. Matthew [10] defines the word 'intravenous' simply means 'within a vein'. I.V. therapy is the infusion of liquid substances into vein. The term vein is taken from Latin phrase which is 'vena' which means blood vessels. Blood vessels are considered as the route for I.V. therapy. Indications for I.V. therapy include achieving or maintaining fluid and electrolyte balance, replacing or supplementing needed blood components, providing nutrients, and administering medications. Jarnieson et al. [7] compared with other routes of administration, the intravenous route is the fastest way to deliver fluids and medications throughout the body. Because of this situation, it is very important to maintain the safety of the I.V. therapy. Aspden et.al [9] noted that medication errors were among the most common medical mistakes, it is among the top 10 leading causes of death in the U.S harming at least 1.5 million people each year and costing more than \$3.5 billion annually for preventable drug-related injuries in hospitals alone.

. One of the popular treatments in medical sector is intravenous (I.V.) therapy. It use the device known as Intravenous (I.V) Tubing which is a combination of several parts as shown in Figure 2. Barbara [11] found that the idea Intravenous (I.V) Tubing may be a macrodrip solution administration set that delivers 10 or 15 drops/ml, or a microdrip set of the burette type that delivers 60 drops/ml. Macrodrip sets are used for routine infusions. Microdrip sets are used in pediatric and neonatal care and when relatively small amounts of fluids are to be administered over a long period of time. The infusion tubing drip chamber will achieve maximum flow rate when suspended approximately three feet

above the site of injection due to the force of gravity. The higher of the roller clamp height, the greater force flow due to the weight of the fluid column.

Among these parts, roller clamp is one of the parts that have led to many problems as well as medication errors. Roller clamp has an important and critical function for the intravenous therapy which is to control the flow rate of the medication supplied. By referring to the previous research by Barbara [11]; Aspden et.al [9], Webb [8] reported the possibilities for medication errors to occur still are very high. Given the uprising number of medications error and medical mistakes, there will be high risk for the cost of losses to increase and at the same time harming more patients Jarnieson et.al [7]; Matthew [10]. This situation also can lead to dropping of the reputation of medical institutes because the duty of medical institutes is to provide medications or treatments, not to harm their patients.

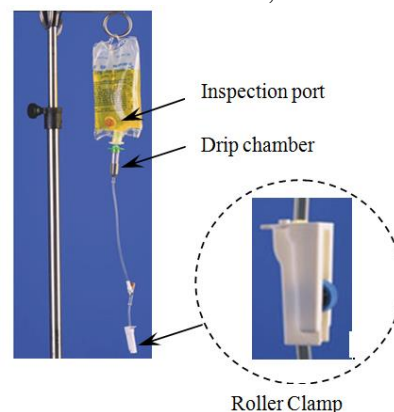


Figure 2. Basic Intravenous IV tubing Setup

In response to this predicted possible national concern, this research was set up in order to improve medical sector by redesign roller clamp to be used in Intravenous therapy. The existing roller clamp still has some weaknesses at the design and need to be improved to avoid medication errors and increase the effectiveness of the treatment. The purpose of the research is to redesign and to the optimum the effectiveness and its functions by considering several factors such as ergonomics, dimension, features and functionality while at the same time reduce the fabrication cost.

2. Methodology

In order to understand the current problem of Roller Clamp in Intravenous (I.V) tubing a survey has been conducted. The purpose of this survey is to identify the common problem of the Roller Clamp in Intravenous (I.V) tubing and to gain some ideas for redesigning task of new Roller Clamp in Intravenous (I.V) tubing. In addition, several interviews have been done with medical assistants thoroughly. The target participant for this survey and the interview were medical students, medical assistants, nurse, surgeons and also experienced physicians in local hospitals. After problems of the current designs of Roller Clamp in Intravenous (I.V) tubing have been obtained, and the customers' voices and needs about the ETT have been known, the basic specifications of the new design of Roller Clamp in Intravenous (I.V) tubing parts were determined. The new features of Roller Clamp in Intravenous (I.V) tubing that has been proposed by participants were analyzed and instilled together into the new design. Several design concepts were generated, which will include all the basic specifications and semi-finished designs of the new product. These visible design concepts were analyzed before the final product is selected. This final product has been tested to ensure that it is conform to the basic specifications, which are already determined at the early stage of the product development and process. The test ensures the new product met the customers' needs. If the test result is negative, the whole process will be redone until the right and most suitable final product is chosen. Then, the specifications of the final design concept will be revised if necessary in order to merge all the positive features that might be good to be added together with the final product.

3. Results and Discussion

Table 1 shows the major problems faced by the existing design of roller clamp that is used as a reference concept to be compared with each of the generated concept. Analysis has been carried out on the existing design of roller clamp. It is found that, the linear bottom part of existing roller clamp should be modified to non-linear to improve the flow rate. Figure 3 shows the selection of criteria of existing roller clamp in Intravenous (I.V) tubing. It shows the selection of criteria demanded by respondents it also provides rough information regarding the customer needs but not specifically and accurately. It is found that only four criterion above clearly rated as important by the respondents. Therefore, to get better analysis and accurate result, the data was analyzed using Product Design Specifications (PDS) by constructing a table of customer need at the beginning of process. From the previous analysis on the data gathered from questionnaire and PDS, the research procedure is preceded and 5 concept designs have been successfully created. Basically, the design of roller clamp consists of two parts, roller and body. These parts will be combined to form roller clamp and below is the table of 5 concept designs that have been successfully produced. Each of the design has its own special features and differences.

As shown in Table 2, the metrics listed are the technical data that roller clamp must have and the metrics will be matched to each of the metrics. This comparison is very important to find marginal value and ideal value that will be used to generate five concept designs Table 3 shows how the analysis conducted, it is found design E obtained highest final score compare to other designs. It is found that concept design E has been successfully chosen as the best design and will be developed. Figure 4 shows the engineering drawing and its main components. The final prototype of roller clamp in Intravenous (I.V) tubing fabricated using FDM machine is shown in Figure 5.

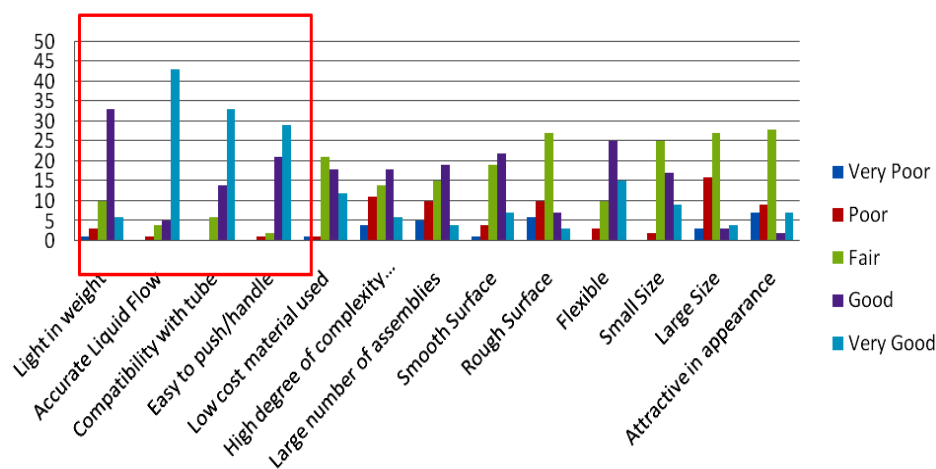


Figure 3. Criteria selection of roller clamp

Table 1. Problems faced by the existing design of roller clamp

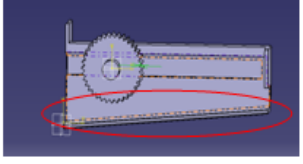
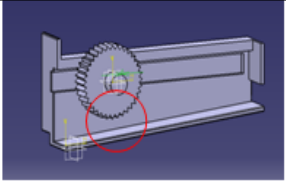
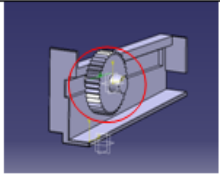
No	Problem	Causes	Parts involve
1	Lack of accuracy of the flow rate.	Linear shape of the bottom part of roller clamp.	
2	Pressure or movement from patient disturb the roller clamp and modify the location of the roller.	Lack of gripping force from the roller to the IV tube.	
3	Lack of gripping force at the finger to push the roller.	Smooth surface of roller.	

Table 2. Target specification

Need #'s	Metric	Imp.	Units	Marginal Value	Ideal Value
1	Weight	4	kg	>0.010	>0.010
2	Flow rate	5	drops/mL	>20	>30
5	Cost	4	RM	5-50	<20
11,12	Width	4	mm	20-30	<20
11,12	Length	4	mm	30-100	>40
8,9	Surface roughness	4	subj	Good	Good
7	Number of assemblies	4	integer	2	2
5	Biocompatible material for roller clamp	4	list	ABS/PP	ABS
5	Thermal resistance temperature	4	'C	100-110	>110
4,7	Ergonomic	5	Subj	Good	Good
7	Manufacturing time per each	4	min	10-50	<20
13	Color	3	Subj	Black/White	Black/White
3,6,10	Part complexity	3	Subj	Reduce	Reduce

Medical sector is one of the best platforms for rapid prototyping to develop. One of the popular treatments in medical sector is intravenous (I.V.) therapy. In rapid prototyping technology, there are two most popular materials used in the fabrication process. The first one is ABS and the second one is Polypropylene (PP). There are pro and contras between these two materials in term of price, strength, and resistivity and so on. In the fabrication of roller clamp, it is clearly stated that ABS is used as the fabrication material. There is not much different about the price between these two materials and of course ABS material has higher price compared to PP, however both prices are affordable for any fabrication process [2]. In addition, ABS has been proven to have better quality and characteristics compared to PP material. Below is the calculation of the total fabrication cost of the roller clamp [1].

Table 3. Selection matrix for concept screening

Selection Criteria	For the following criteria, please indicate for each of the design concept below.				
	<div> 1 – poor 2 – fair 3 – good 4 – very good 5 – excellent </div>				
	A	B	C	D	E
1.Functionability					
Compatible with tube	0	0	+	0	+
Able to control flow rate of fluid	+	+	+	+	+
2.Convenience					
Easy/comfortable to grip	0	0	+	-	+
Convenience to hold/place tube	0	0	+	0	+
3.Ergonomic					
Easy to push	0	0	0	-	+
Easy to hold with one hand	0	-	-	+	+
4.Appearance					
Attractive	-	-	0	0	+
Non-complicated	+	+	0	0	0
5.Surface texture					
Smooth surface	0	0	0	+	0
Rough surface	-	-	+	-	+
Gripping surface area	0	0	+	-	+
6.Manufacturing ease					
Low number of assembly steps	+	+	0	0	0
Low cost of design complexity	+	+	-	0	-
Low complexity of parts	+	+	0	0	0
7.Size/dimension					
Small	-	-	-	-	-
Medium	+	+	0	+	0
Large	0	0	+	0	+
TOTAL '+'	6	6	7	4	10
TOTAL '0'	8	7	7	8	5
TOTAL '-'	3	3	3	5	2
NET SCORE	3	3	4	-1	8
RANK	3	3	2	4	1
Continue?	Combine	Combine	Yes	No	Yes

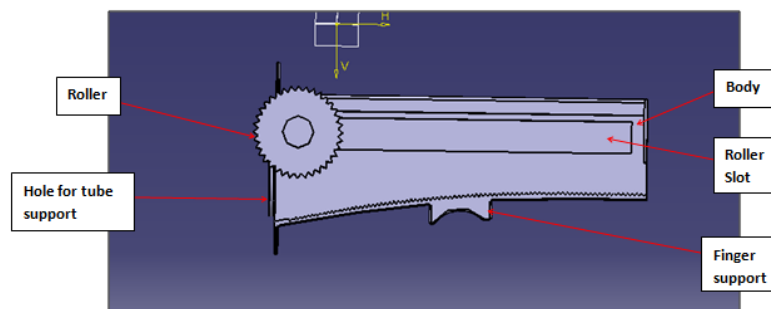


Figure 4. Best design selected (Design E)



Figure 5. Prototype of roller clamp in Intravenous (I.V) tubing

Below is the calculation of the total fabrication cost of the roller clamp.

Cost per cartridge: RM3300

Volume per cartridge: 1700

Total cost = $\frac{\text{Model Material (cm}^3\text{)} + \text{Support Material (cm}^3\text{)} \times \text{Cost per cartridge}}{\text{Volume per cartridge (cm}^3\text{)}}$

$$= \frac{1.467 \text{ cm}^3 + 1.615 \text{ cm}^3 \times \text{RM3300}}{1700 \text{ cm}^3}$$

$$= \text{RM5.98} \approx \text{RM6.00 per roller clamp}$$

$$\text{Total of roller clamp can be produced per cartridge} = \frac{1700 \text{ cm}^3}{1.467 \text{ cm}^3 + 1.615 \text{ cm}^3}$$

$$= 551 \text{ units}$$

$$\text{Total of roller clamp can be produced per hour} = \frac{60 \text{ minutes}}{\text{Estimated build time per roller clamp}}$$

$$= \frac{60}{19}$$

$$= 3.15 \approx 3 \text{ units of roller clamp per hour}$$

Some improvements that have been to design E compared to reference concept especially on the non-linear bottom part of body, surface made rougher to increase gripping force, hole is created to support tube and finger rest part created at the bottom to support the finger while pushing the roller.

4. Conclusion

The overall findings in this study showed that the respondents which taken among medical students, doctors and nurses give positive feedback and good supports to the research and most of them clearly want the existing design to be improved. It can be clearly seen that the existing design still do not satisfy the users which are among nurses, doctors and medical trainers. In other words, the existing roller clamp still have some weaknesses and this is the purpose of this research to be done which is to complete the weaknesses and then improves the process to deliver blood and medications through Intravenous Therapy. Moreover, the selected concept has been proven to have better quality, functions and criteria compared to the existing roller clamp and this research successfully achieved the mission. As the prototype of improved design has been fabricated, it will be introduced to doctors and medical officers for some advises regarding the steps should be taken to develop the prototype further.

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