

Investigation of the simple mattress suturing technique

by

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ABSTRACT

The research looks into investigating the simple mattress suturing technique with respect to human factors and ergonomics by comparing the conventional method of suturing with the devices developed by the researchers.

The study looks at two aspects of suturing, to improve the learning experience of suturing and redesigning the existing needle holder to improve the speed of suture.

The experiment is a 2 X 2 factorial design, consisting of 2 phases with 32 participants divided into four groups. The first phase is the learning phase, in which 2 groups learn suturing with the learning tool and 2 groups learn without the learning tool. In the second phase, 2 groups of participants, suture with redesigned needle holder and 2 groups with the conventional needle holder.

The study aims at studying the difference in the participant's performance if one learnt without the guide, compared to the one who learnt with the guide, and the performance of the redesigned suture holder as compared to the traditional. The study also looks at if there is a difference in performance if the redesigned holder is used in conjunction with the learning tool, and hence, the four groups. The emphasis is on the speed of suturing and the quality of the suture knot specifically symmetry of the entry and exit points of a knot.

The results show that the time taken by the participants to suture is lesser when learnt with the guide as compared to those who learnt the conventional. There is no effect on the quality of the suture by using the guide. The redesigned suture holder has shown to have better symmetry, without respect to the learning method with or without guide.

CHAPTER I

INTRODUCTION

As defined by Wickens, Gordon and Liu (2004), “the goal of human factors as making the human interaction with systems one that: reduces error, increases productivity, enhances safety and enhances comfort.” In many fields, the safety of the human using the system or dependent on the system is of paramount importance. The same is true in the healthcare sector. Healthcare is one of the crucial fields in which the customer or patient safety is of utmost importance and human errors might lead to irreversible disasters or worse.

In one case, the wrong lymph node of the patient was removed, in another case the patient was operated on the wrong wrist, and in another one the patient had decompressive lumbar disc surgery on the left side instead of the right (Human Factors in Healthcare, A Concordat from the National Quality Board, n.d.). These are examples of only a few of the reported cases. According to studies at Utah and Colorado, it was found that adverse events occurred in 2.9% of the hospitalizations, of which 32.6% in Utah and 27.4% in Colorado are due to negligence (Carayon & Wood, 2010, Thomas et al., 2000). In New York, adverse events occurred in 3.7% of the hospitalizations, of which 27.6% are due to negligence (Carayon & Wood, 2010, Brennan, 2004). These statistics show the importance of incorporating human factors in every aspect of health care to improve the experience of the patient and make it error free for the healthcare professionals.

Suturing is one of the basics of a medical professional’s career and every medical student has to learn in their course (Sweeney, 2012). The way it is taught varies from one educational organization to another (Sweeney, 2012), and time taken to learn suturing varies

from individual to individual. There are many aspects that affect the quality of the suture ranging from the suture thread used to the nature of the wound, therefore many decisions to be made by the operator (Wound closure manual, 2005).

This research deals with development and modification of tools for improving the quality of the suture and the time taken to suture by with investigating a simple mattress suture, the methods use in this experiment can be used in further research with regard to other suturing techniques. The focus of this research is on improving the learning method of suturing which can be used simultaneously with the methods used now and designing & testing a new tool, resulting in an improved quality and efficiency of the suture.

CHAPTER II

INVESTIGATION OF THE SIMPLE MATTRESS SUTURING TECHNIQUE

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Abstract

Objective: The study researches the human factors side of simple mattress suturing technique with an aim towards improving the quality and learning experience.

Background: The method of suturing remains fundamentally the same from when it was first invented, highly variable, painful and moderately predictable. A human factors and ergonomics view of the process can enhance the experience of both the operator and the patient.

Method: 32 participants were divided in four groups, and were evaluated on their suturing skills, using the conventional tools and the tools developed by the researchers. The independent variables are with the learning tool or without the learning tool, with redesigned holder or without the redesigned holder with a 2 X 2 factorial design, and the dependent variables are time, symmetry and discomfort.

Results: There is a significant difference in time taken between few pairs, the participants using the learning guide have taken lesser time as compared to the groups that learnt without the guide, and the redesigned holder has improved the symmetry of the entry and exit of the suture.

Conclusion: The new tool design and the learning tool have a positive effect on the symmetry and time taken to suture respectively.

Application: The research tries to bring into light the importance of human factors in improving the long-standing processes in the healthcare industry. The methods used in the study can be used with the various other suturing techniques and design improvements into the tools.

Keywords: simple mattress suture, human factors, suture, design, learning.

Introduction

Wound closure is the process of approximating the tissue to assist in healing by giving mechanical strength. There are two kinds of wound closures, one being primary wound closure which involves bringing the edges of the skin together for healing and secondary wound closure which involves allowing the wound to heal by leaving it open (Danks,2016).

The various tools that exist for wound closure are staples, clips, skin closure strips, topical adhesives and sutures. Depending on the wound type a specific tool is chosen, since each of them have their own advantages and disadvantages (Wound closure manual, 2005). Suturing is used for primary wound closure by bringing the edges of the skin together by approximating the tissue to assist in healing by giving it mechanical strength until it gains enough strength to withstand the tensile stress (Wound closure manual, 2005, Wiggan, 2016). According to “Pocket guide to suture materials and knots” published by “Serag-Wiessner“, suturing is one of the ancient techniques of wound closure and can be traced back to as early as ancient Egypt, throughout the time many materials including gold was tried for suture material, in 1867 research was done by Dr Lister to eliminate wound suppuration (Pocket

guide to suture materials,n.d.) but there does not exist a single suture material that has all the properties of an ideal suture. The method, tools and material selected for suturing depends on various factors such as depth of cut, location of the wound etc, the surgeon's preference also plays a vital role in choosing the material (Wound closure manual,2005).

The various tools used for suture closure are suture material, needle and needle holder. Suture material is used for bringing the wounded tissue together and it remains in contact with the tissue for extended length of time, which is why, the material should not initiate a tissue reaction, and should possess many qualities such as sterility, plasticity, uniform tensile strength, elasticity etc. (Wiggan, 2016) There is not a single material that has all the qualities necessary for an ideal suture which is why the surgeon/nurse has to choose the material based on the wound. Few important characteristics of needles are high strength, toughness and resistance to corrosion. Stainless steel is one alloy which has these characteristics (Szarmach, Livingston and Edlich, 2003). Needle holder is used for driving the needle, which must be appropriate to the needle size and the depth of the suture.

Suturing is a highly variable, meticulous task which depends on various factors such as needle penetration, suture passage and is riddled with dangers of wound dehiscence and hypertrophic scars (Wiggan, 2016).

According the "Wound closure manual" by Ethicon, there are many principles when it comes to suturing, example surgical principles, principles conducive to wound healing, principles of knot tying, principles for handling the tissue etc (Wound closure manual,2005). Some of the principles specifically for suturing as identified by Wayne W. LaMorte of the Boston University School of Medicine (LaMorte,n.d.) are:

1. Keep bacterial contamination to a minimum/ aseptic technique

2. Remove any foreign bodies from the wound,
3. Hemostasis (or stopping of flow of blood) must be achieved,
4. The tissue must be handled gently (fine toothed forceps are better than smooth forceps, since the smooth ones require a lot of pressure to hold the skin).
5. The wounds should not be strangulated but approximated.

The wounds should not be strangulated but should be approximated could be one of the difficult principles to maintain since the operator should know how much stress he/she can put on the damaged skin so that the suture does not cut through the skin but at the same time holds the skin with just enough strength to aid in bonding and healing the skin, sutures that are too tight can cause ischemia leading to infection (LaMorte,n.d.) .Although there is no absolute evidence to suggest the entry and exit points of a suture, it is suggested that the distance of the entry and exit points from the edge of the wound must be equal (Perret-Gentil,n.d.) For achieving this balance, it is identified that symmetry of the exit and entry points of the suture in a straight cut wound could lead to the highest quality of suture. This is the basis of developing a learning guide by the researchers (Dr Stone and I) which forces the participant to suture symmetrically. It is our hypothesis that learning and practicing using the guide will improve the spatial skills of the operator thereby enhancing the symmetry of suture, consequently the user needs lesser mental resources for achieving symmetry thereby increasing the speed of the suturing.

Suturing is a challenging task to learn and suturing with precision is considered a skill which needs hours of practice. Typically, a medical student spends 4 years of education with the first two years learning the basics and the next 2 years in clinical training

(Sweeney,2012). The experience of learning to suture can be stressful and needs numerous trials of practice and might not still yield a high quality suture. Students generally use suturing kits or fruits to practice sutures. According to Sweeney (2012) the University Of Massachusetts Medical School uses simulation to teach medical students common medical procedures, e.g. intravenous catheter insertion, nasogastric tube insertion etc. Simulation techniques are not yet used for learning to suture, but augmented reality can assist the students in learning to suture in the future.

This study focuses on developing a guide to be used in conjunction with the learning methods used now, which can improve the quality of the suture, and to develop a suturing tool which will increase the speed of suturing. Subsequently, we hypothesize that the suturing tool will increase the speed of suturing, and increased symmetry when used in conjunction with the guide.

Methodology

Participants

A total of 32 participants participated in the experiment, with 8 participants in 4 experimental conditions. The participants were recruited through verbal announcements, fliers and word-of-mouth, and were required to be a minimum of 18 years of age, to be able to read, write and speak in English, do not experience hemophobia, they should have 20/20 vision (with or without corrective lenses), they were screened using a screening questionnaire, followed by a photo identification check. The participants received a t-shirt and/or 5% course credit if they are in IE271.

Technology

The technology used and the reasons behind selecting the apparatus is as follows:

Suturing Pad The skin has three layers the epidermis being the outermost layer, dermis being the middle layer and the hypodermis, the lower fat layer. The SIM-VIVO suturing pad was used to imitate the 2 layers of skin, the upper layer is made of synthetic rubber imitating the epidermis and the lower layer is made of porous sponge like material. Since the technique of the suture chosen does not penetrate the subcutaneous fat tissue the third layer was not imitated by any means.

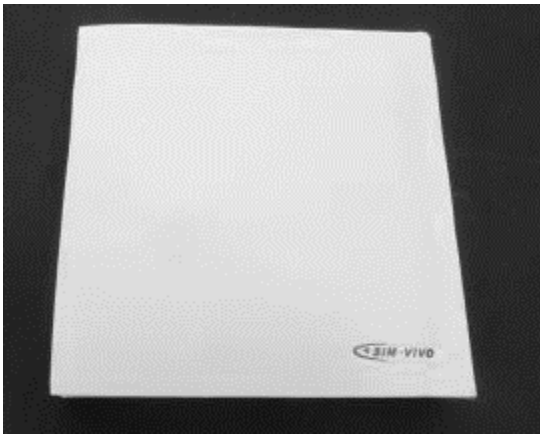


Figure 1: SIM-VIVO suturing pad



Figure 2: Cross section

SIM – VIVO suture pad was used to simulate skin, the pad was attached onto the arm of a mannequin using layers of Flexi-Seal adhesive to imitate the rest of the area of the skin. Straight cuts are made on the pad for the participants to suture.



Figure 3: Suturing pad on the arm of the mannequin with adhesive

Forceps The forceps are used to hold the skin for better access.



Figure 4: Forceps

Needle Holder The needle holder is used for holding and driving the suture, it is one of the tools this research focuses on. Depending on the group the participants used the traditional needle holder or the re-designed needle holder.



Figure 5: Needle Holder

The redesigned needle holder has a knurling on the arms of the holder to hold the suture thread from slipping while wrapping around during the process. The average width of each of the teeth is 1.7mm. Distance between each of the teeth on an average is 1.45 mm.

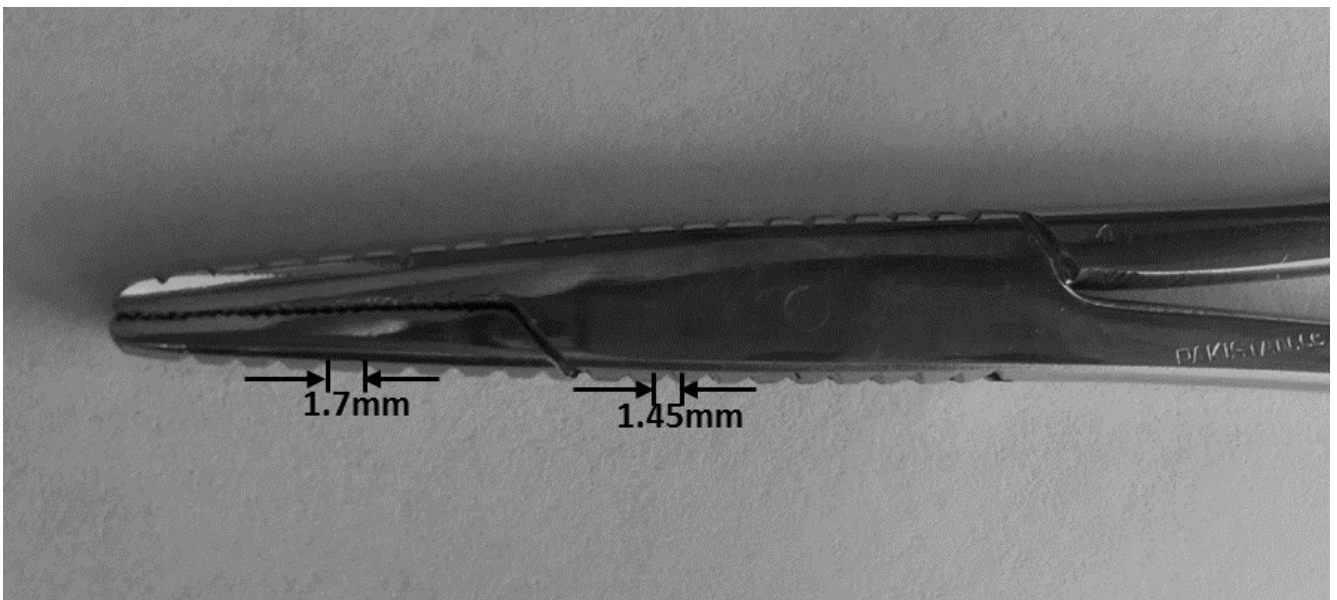


Figure 6: Serrated Needle Holder

Suture There are broadly two types of needles in suturing- curved and straight needles. The straight needles do not use any tools for handling but are not commonly used since they have a higher risk of puncturing fingers, the curved needles use needle holders and the forceps (Semer,2007). The curved needles can be of 2 types, cutting needles which have sharp edges and sharp tips which can cut and pass through the skin, tapered needles have blunt tip and smooth edges, and are usually used for closing soft tissues (Semer,2007). The size of the suture used is directly related to the scar, the bigger the suture more likely it is for scarring to occur (Semer,2007).

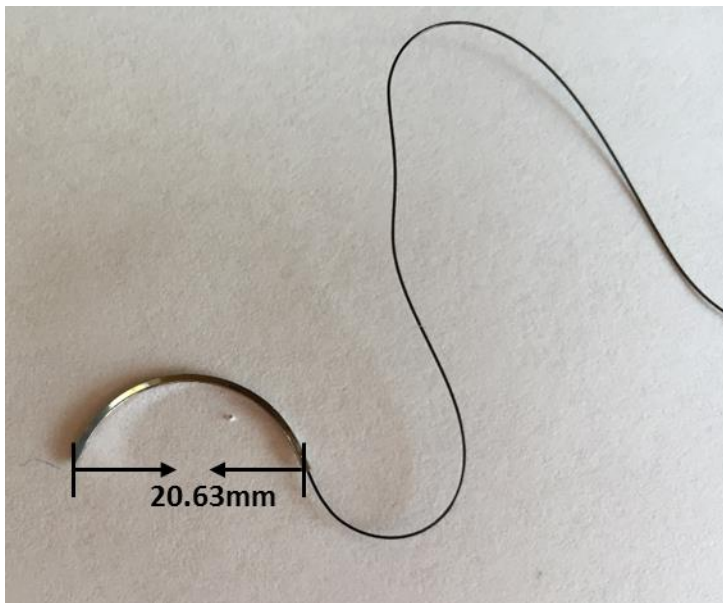


Figure 7: Suture and suture thread

For the purpose of this experiment curved sutures were used since a straight cut skin wound was simulated. The participants used the same type of suturing needle which is a reverse cutting (24mm) nylon monofilament, non-absorbable suture.

Suture Thread The suture comes attached with the suture thread which is made of nylon, and is a monofilament thread.

Many different types of materials like human hair, gold, steel wire, gut strings etc were tested before the catgut became popular as the suture material. (Pocket guide to suture materials,n.d.)

In the earlier days, metal is considered a good contender for suturing since it is stiff but the same stiffness made it difficult to tie the knot, leading to knot breakage easily and caused suppuration of wound edges (Pocket guide to suture materials,n.d.) After the failure of metal as a suture material, silk was considered the best for suturing since it is easily absorbable and can be tied easily.

But after further research and especially Dr Lister's research in 1867, it was found that wound suppuration can be reduced by disinfecting the sutures and the equipment using carbolic acid (Pocket guide to suture materials, n.d.). For the purpose of this experiment, the suture material used was nylon, which has easy handling characteristics.

Learning Guide As discussed earlier, the distance of the entry and exit from the wound margin must be equal. According to Kudur, Pai, Sripathi and Prabhu (2009), the distance of the entry and exit from the wound is 1-3 mm for a vertical mattress suture and 5-10 mm for horizontal mattress suture, for a simple mattress suture there is no suggested distance from the edge of the wound, so an average distance of 4mm is assumed to be the ideal distance. The learning guide as developed by the researchers is made of polyethylene and has entry and exit holes as shown in figure 8, the center of the hole is 4mm away from the straight cut, which is represented by the red line. By trial and error method with various guides with different diameters, a diameter of 3 mm was settled upon.

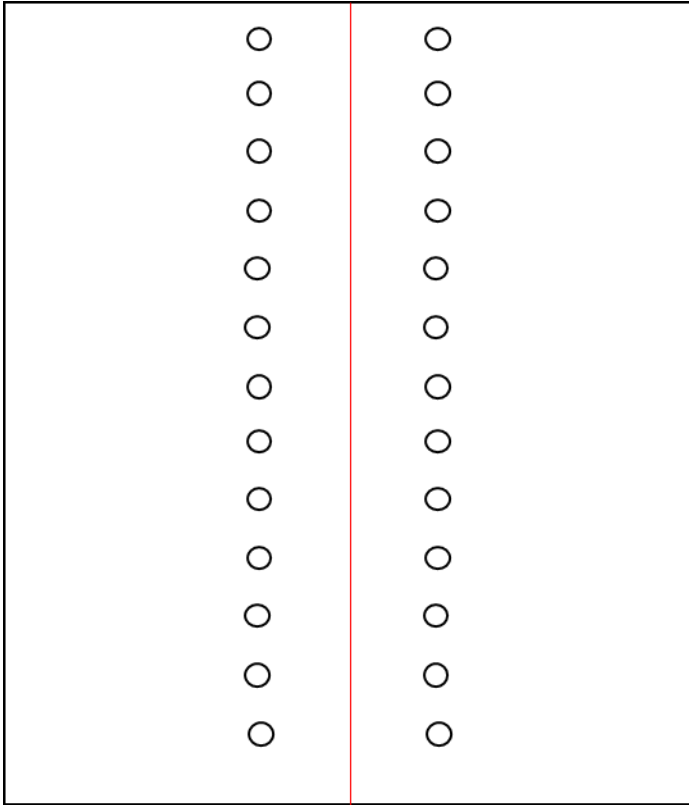


Figure 8: Representation of the learning guide (not drawn to scale)

Nitrile gloves Nitrile gloves are worn by participants for safety.

Procedure

Experimental Design

The experiment is a 2 X 2 factorial design consisting a total of 32 participants, of which 16 participants suture a least of 3 sutures without guide, and 16 suture with guide. The participants are further divided into 2 groups with half suturing with the traditional needle holder and the other half suturing with the redesigned needle holder. Each participant takes an approximate 40 to 60 minutes to complete the experiment. The various independent variables are the conditions of the experiment- with guide or without guide and with

redesigned needle holder or with traditional needle holder, and the dependent variables are time, symmetry and discomfort.

Table 1: Experimental Design

	With Guide	Without Guide
Traditional Suture Holder	8 participants	8 participants
Redesigned Suture Holder	8 participants	8 participants

In further detail, the following were the 4 groups of participants, the experiment is performed in 2 phase the first phase is the learning phase where the participant either learns with the guide or without guide, and second phase is the implementation phase where the participant sutures with the traditional needle holder or the redesigned needle holder:

Group1: with redesigned needle holder, traditional suturing- The participant performs the experiment using the redesigned needle holder for one trial and the traditional holder in another trial, referred later as Traditional Redesigned (TR).

Group 2: with redesigned needle holder, using suture guide- The participant performs the experiment using the redesigned needle holder for one trial and using the suture guide in another trial, referred later as Guide Redesigned (GR).

Group 3: with traditional needle holder, traditional suturing- The participant performs the experiment using the traditional needle holder for one trial and using traditional holder in another trial, referred later as Traditional Traditional (TT).

Group 4: with traditional needle holder, using suture guide- The participant performs the experiment using the traditional needle holder for one trial and using the suturing guide in another trial, referred later as Guide Traditional(GT).

The experiment is two-fold, the first phase is the learning phase and second phase is the implementation phase. In the first stage, the participants either suture with/without guide and in the second stage they suture with redesigned/traditional suture depending on the group.

After the 6 sutures in 2 conditions, the participants are given another pain scale to note down if they are experiencing pain in any part of their arms/hands.

The participants are given a consent form before beginning the experiment, and a safety procedure and information form containing the safe methods to be practiced during the experiment, the procedure they would have to follow and emergency procedure to follow was to be read and signed. The participants were explained the functions and the procedure to use the various tools, and were shown a video of a nurse performing a simple mattress suture. The participants are asked to watch the videos and are prompted to do a trial of suturing to feel comfortable with the procedure. The participants are given a pain scale at this point to jot down any pain they are experiencing before the experiment.

Effort was done to set the experiment in a way which will seem closer to the real life conditions as much as possible in the confines of the laboratory, a mannequin is set on a raised hospital surgery table on to which the SIM-VIVO suturing pad is attached using layers of adhesive.

For the accomplishment of the goals of the study, the suturing technique chosen must be simple and complex at the same time, simple enough to be learnt by the participants easily and complex to fabricate a valid experimental set up, which is why the simple mattress

suturing technique was chosen. Also, the simple mattress suturing technique is one of the most commonly used procedures and leaves less scarring.

The following is the procedure for a simple mattress suture:

1. The suture is grasped at the center or 50-60% from the pointed end and 1 -2 mm from the tip of the needle holder.



Figure 9: Suture grasped at the center

2. Grasp the skin with forceps and slightly evert it.
3. Rotate the right hand and pierce the skin at a 90-degree angle.



Figure 10: Piercing the skin at 90-degree angle

4. Drive the needle through by rotating the needle holder and keeping the shaft of the needle perpendicular to the skin at all times.

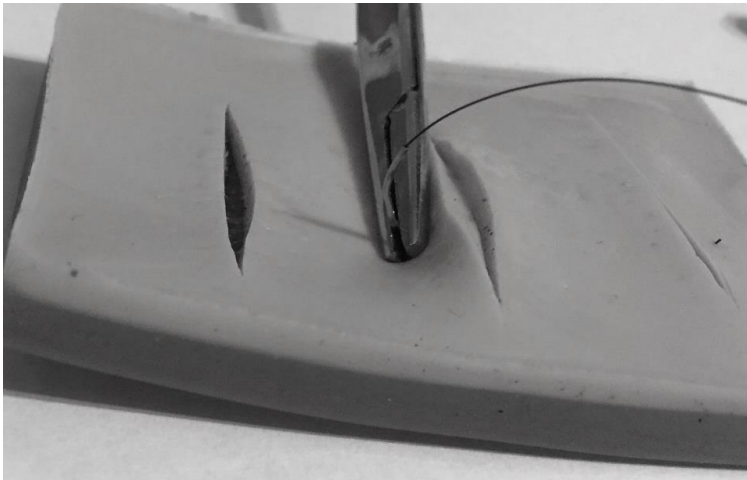


Figure 11: Drive the needle through keeping the shaft perpendicular

5. Once the suture is in the skin, release, pronate your hand and re-grasp the needle holder. Drive the needle through the skin by supinating the hand to rotate.



Figure 12: Drive the needle through skin by supinating

6. Draw the suture through the foam.

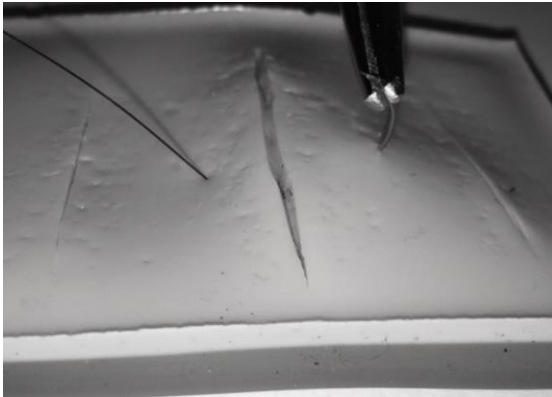


Figure 13: Hold the suture

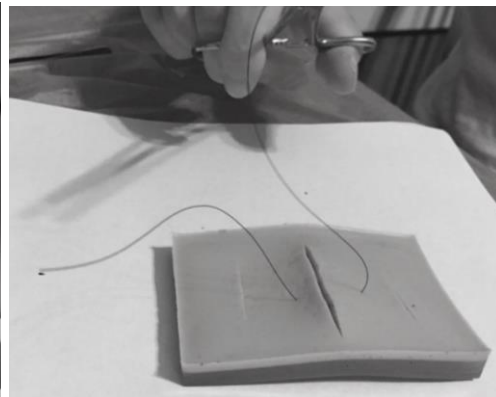


Figure 14: Draw the suture through the foam

7. Drop the forceps and grasp the suture material with a hand.

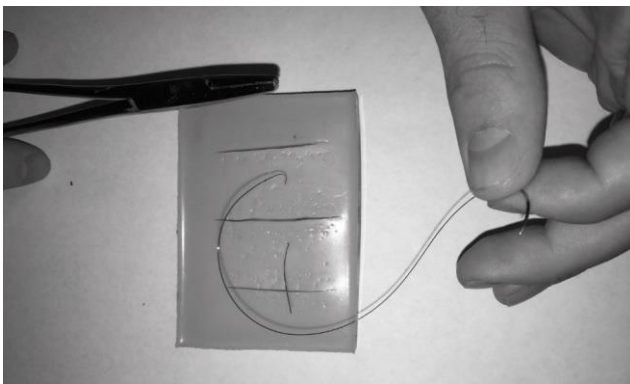


Figure 15: Grasp the material with hand

8. The long strand is wrapped around the needle holder to form a loop.

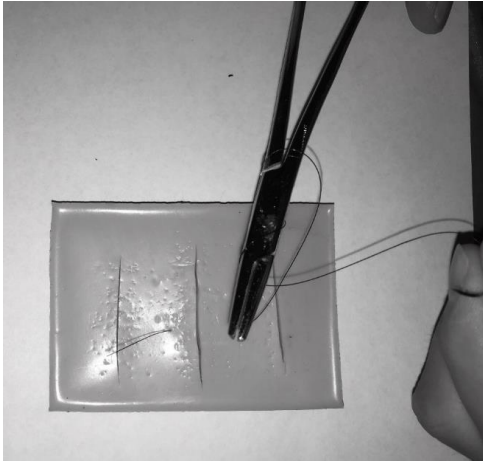


Figure 16: Thread is wrapped around the needle

9. Rotate the needle holder away from yourself, and grasp the short end of the suture.

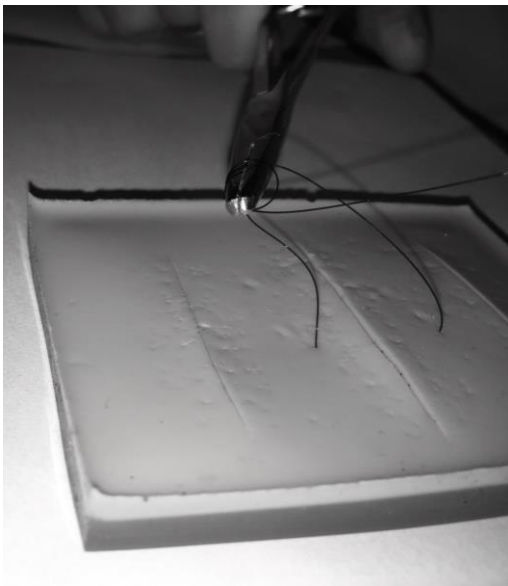


Figure 17: Grasp the short end of the suture

10. Grasp the short end and pull it back through the loop towards yourself.

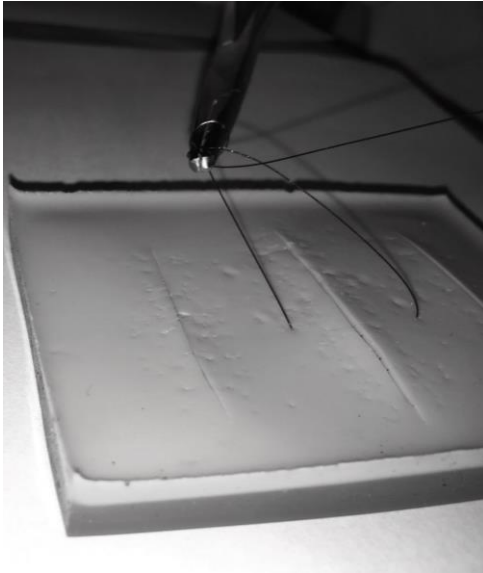


Figure 18: Grasp the short end and pull it back

11. Tighten the loop to approximate the edges of the skin, do not strangulate.

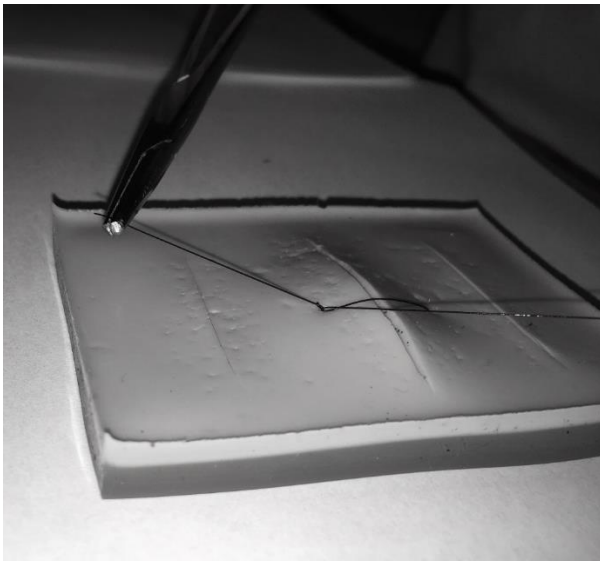


Figure 19: Tighten the loop

12. Tie 6 knots the same way.

13. Cut the suture leaving 3 – 4mm tails.



Figure 20: Simple mattress suture knot

After filling the forms and being assigned a group, the participants are given nitrile gloves which serve as a safety measure against puncturing their skin accidentally.

After the participants feel comfortable about the suturing, they are taken to the experimental set up, and directions are given to perform a total of 6 sutures, the first 3 on the straight cut and are told to stay 4 mm on either side of the straight cut, to not to strangle the suture (do not tie it too tight or leave it too loose), try to maintain symmetry of suture.

The participants filled the following forms in the given order, some before the experiment and some after the experiment,

Pre-experiment forms:

- consent form,
- screening questionnaire,
- safety procedure information,
- Pain scale (pre-experiment).

Post-experiment forms:

- pain scale (post-experiment)

The participants are given the following instructions before starting the experiment:

- a. When the participant is suturing without the guide in the first part of the experiment.
 1. suture 4mm away from the straight cut,
 2. maintain symmetry of suture (exit and entry points of a suture must be equal distance from the straight cut).
 3. Do not strangle the suture (or tie the suture too tight),
 4. You will perform 3 sutures in this way (6 knots on each suture),
 5. Keep the tail of the suture short,
 6. When you are tying the knot do not let the suture dangle, hold it with you for safety concerns.

The following instructions are given in addition to the instructions above when the participant is suturing with guide.

7. Suture through the guide,
8. Remove the guide after the entry and exit punctures are made.

The pain scale consists of the participants indicating pain on various locations of their arms using a NASA TLX scale. Below is the figure of the various locations where the pain is rated.

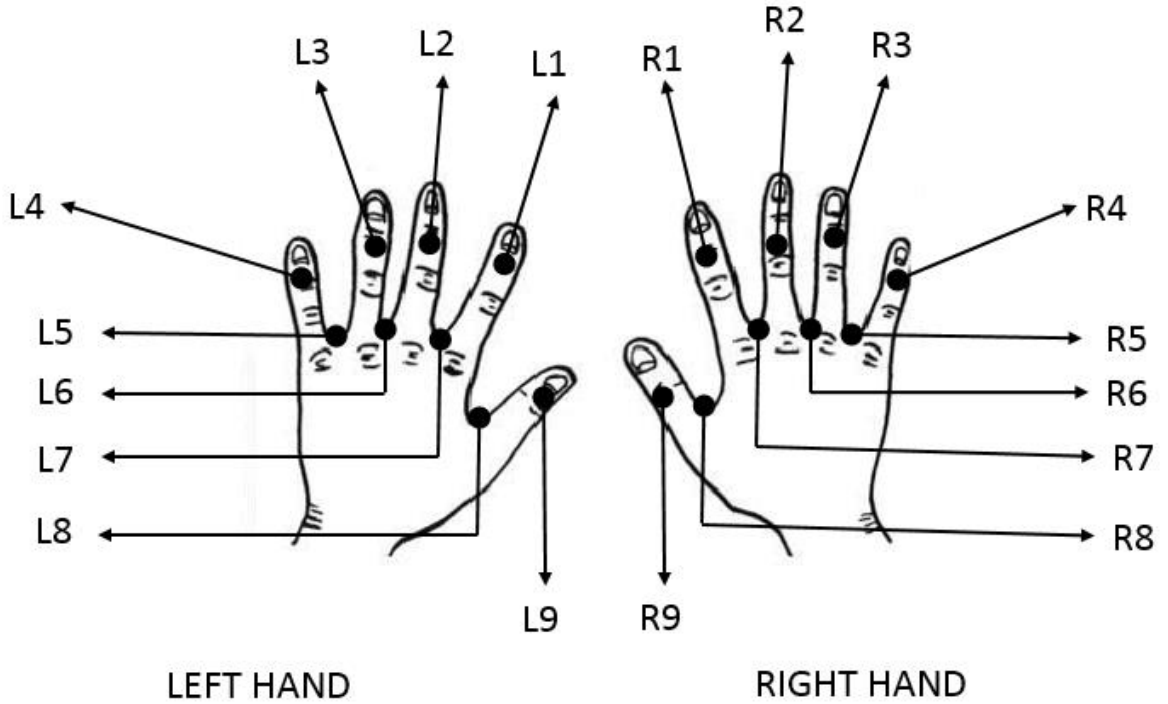


Figure 21: Various locations of the hand where discomfort is rated.

The following is the scale used by the participants to rate pain at the various locations indicated above.

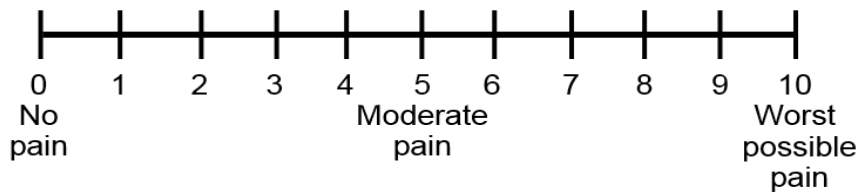


Figure 22: NASA TLX scale for rating pain

The distance of the entry and exit wounds from the straight cut wound are measured. If the participant's entry and exit are 4mm away from the straight cut, it is counted as score of 1 and if it is not, it is counted as 0.

Results

As explained in the methods section, each trial consisted of performing 3 sutures as a learning experience with guide or without guide depending on the group, and 3 more sutures with the redesigned sutures or the traditional sutures depending on the group.

Task analysis was conducted on performing a simple mattress suture, and the tasks are defined as:

1. Holding the suture with needle holder,
2. Put the suture through the skin,
3. Unclamp the suture,
4. Clamp the suture on the other side,
5. Put the suture through the skin,
6. Pull the suture through,
7. Loop the suture around the needle holder,
8. Pull through & tie a knot,
9. Loop the suture around the needle holder,
10. Pull through & tie a knot,
11. Loop the suture around the needle holder,
12. Pull through & tie a knot,
13. Loop the suture around the needle holder,
14. Pull through & tie a knot,
15. Loop the suture around the needle holder,
16. Pull through & tie a knot,
17. Loop the suture around the needle holder,

18. Pull through & tie a knot.

Time Data

The time taken for each of the tasks of suturing are recorded, and following are the data charts with the information showing the trend of the time.

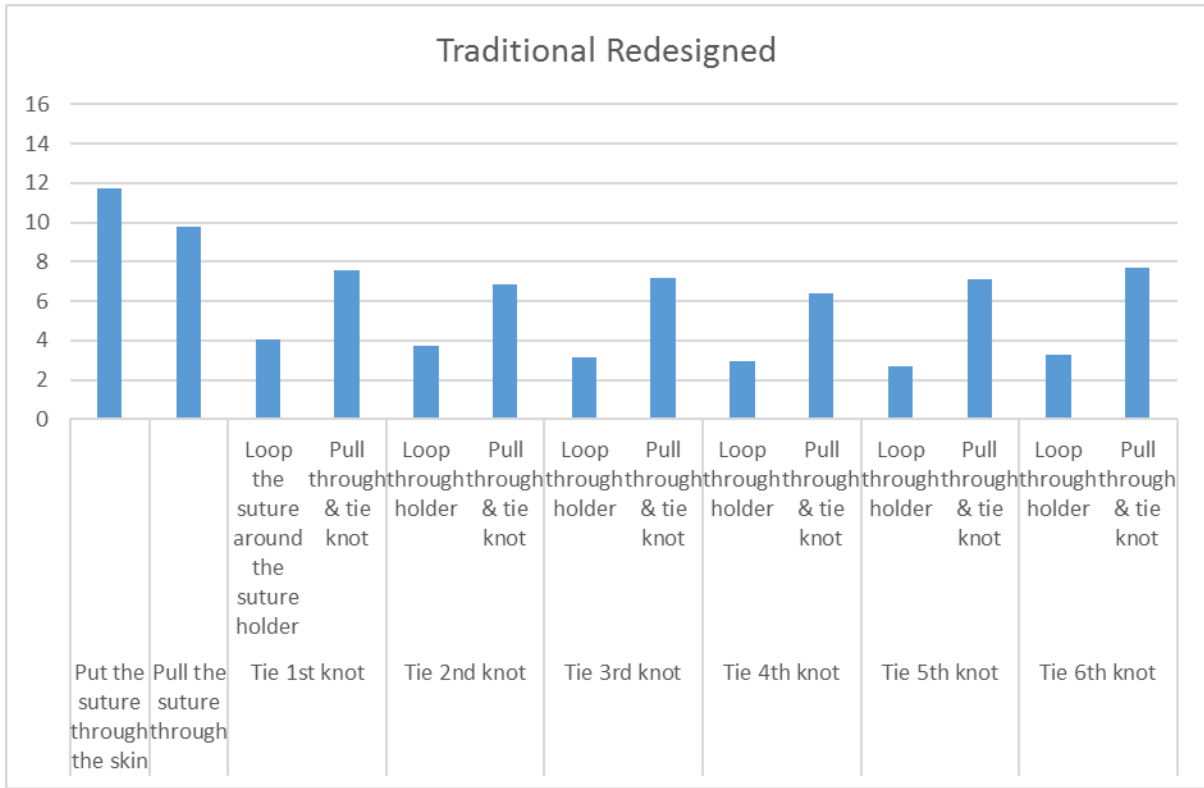


Figure 23: Task Vs Time in seconds for Traditional Redesigned

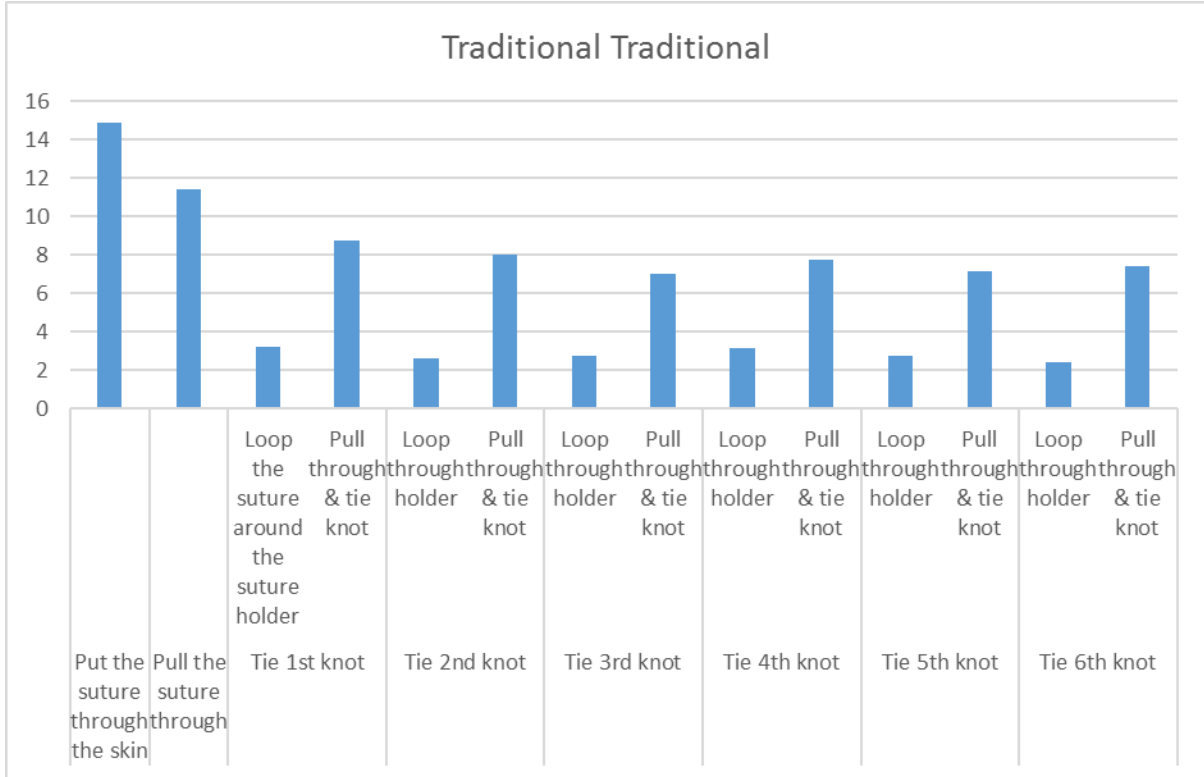


Figure 24: Task Vs Time in seconds for Traditional Traditional

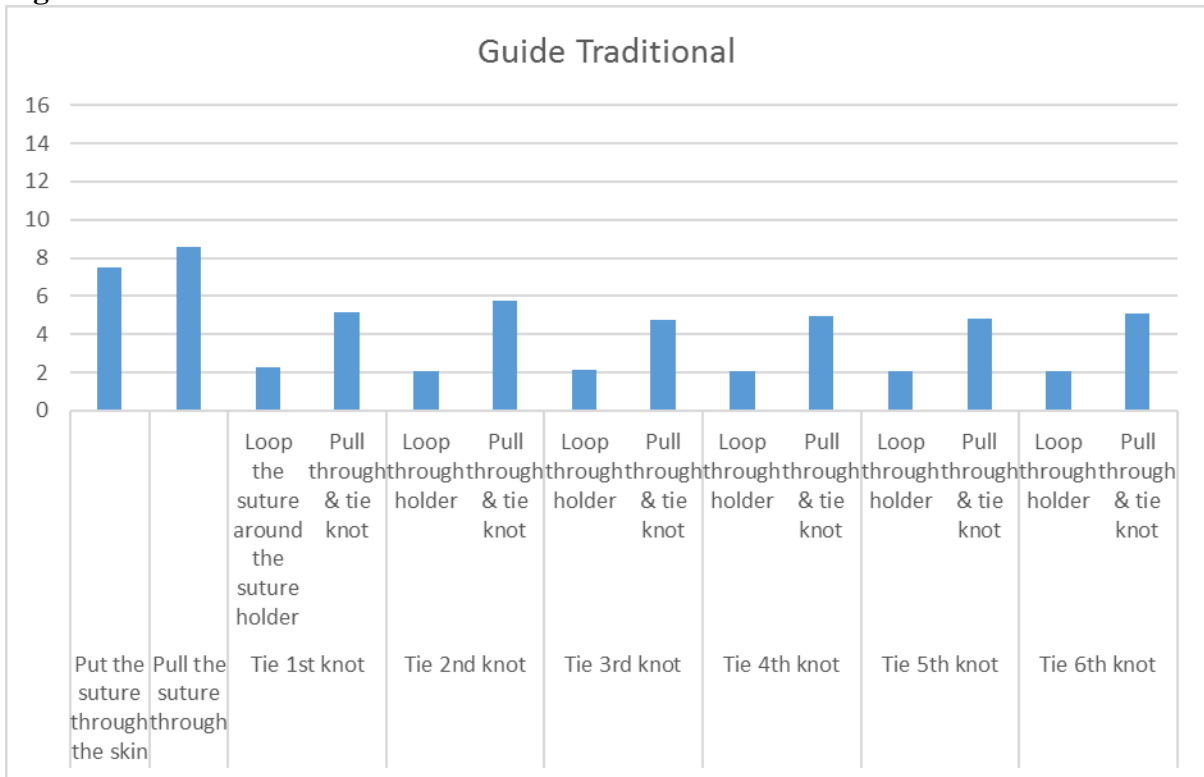


Figure 25: Task Vs Time in seconds for Guide Traditional

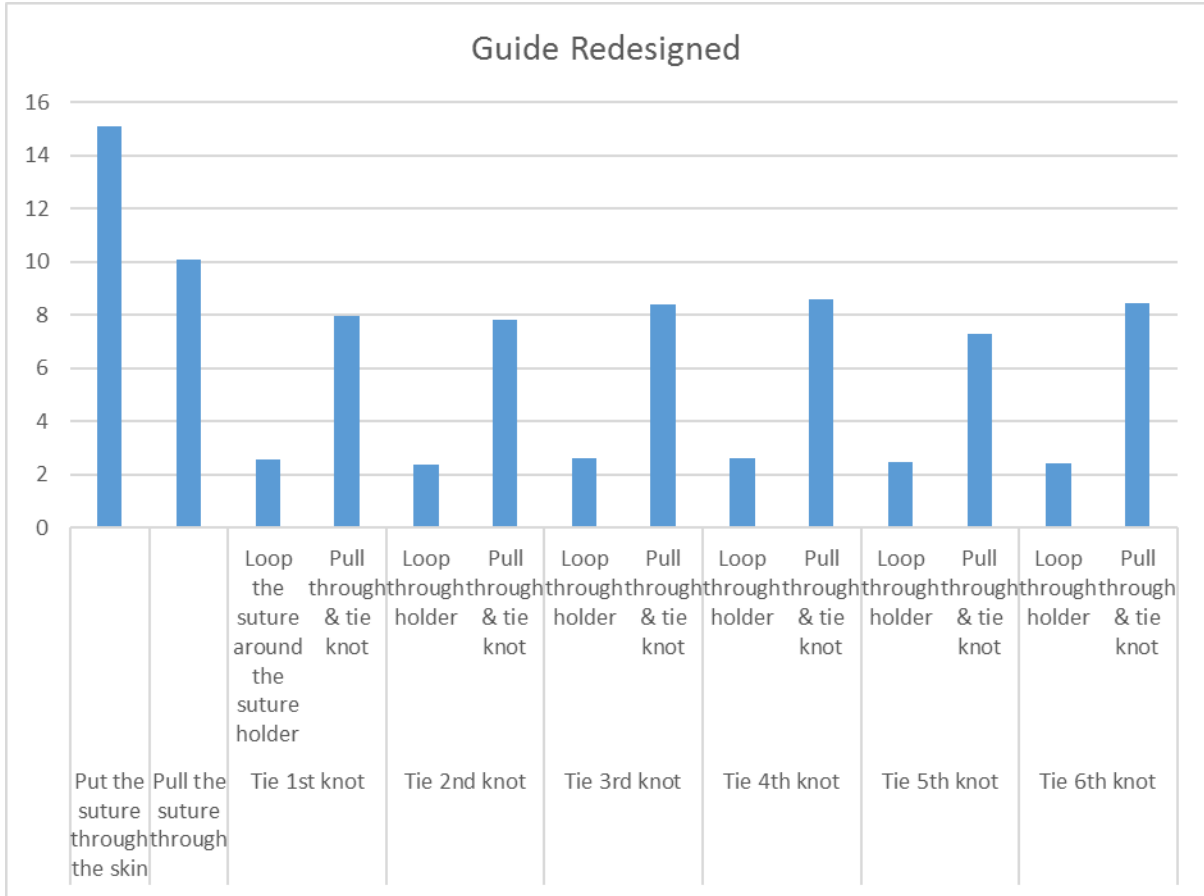


Figure 26: Task Vs Time in seconds for Guide Redesigned

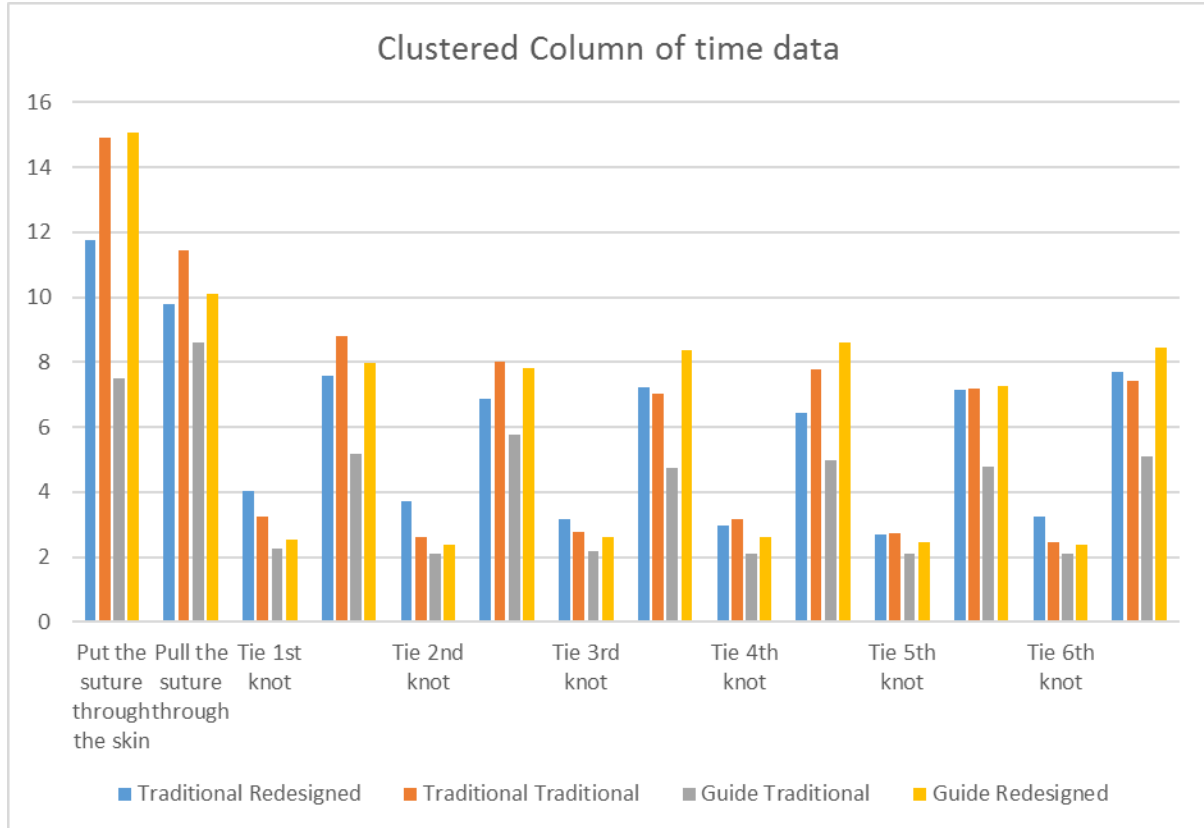


Figure 27: Clustered columns for time data

The trends of the tasks of each of the experimental conditions show that the task of guiding the suture through the skin takes the highest time for each of the conditions, except for the Guide Traditional condition in which the task of pulling the suture through the skin takes more time than guiding the suture through the skin. The following is the average time taken for each of the tasks,

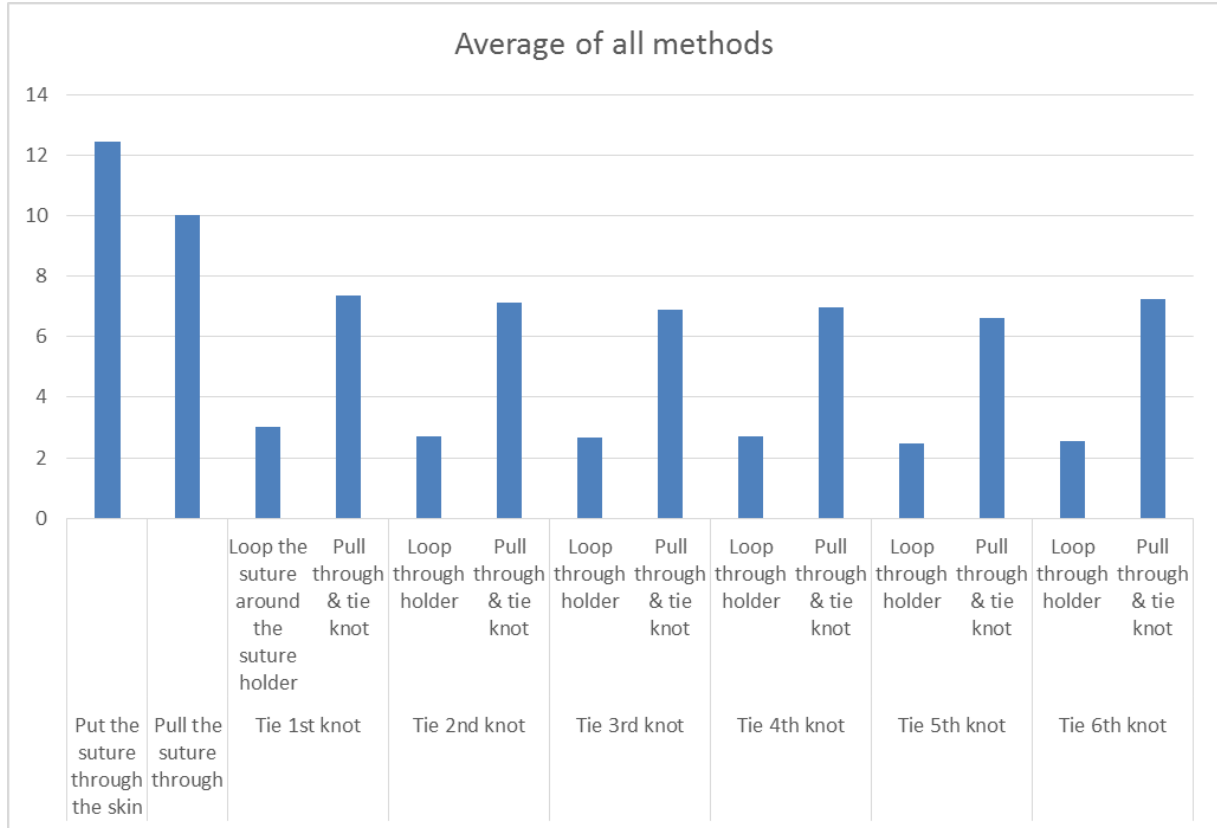


Figure 28: Task Vs Average time in seconds for all the methods

On an average, the task of guiding the suture through the skin takes the highest time.

Table 2: Average time taken by each of the methods

S. No.	Learning Phase	Time Taken (seconds)	Implementation Phase	Time Taken (seconds)
1	Learning without guide	118	Redesigned holder	84.3
2	Learning without guide	118.9	Traditional holder	89.6
3	Learning with guide	81.8	Traditional holder	59.3
4	Learning with guide	126.7	Redesigned holder	88.7

Two tests for normality were done. One is the Shapiro-Wilk test for normality and the Anderson-Darling test. The results of the Shapiro – Wilk test are as follows:

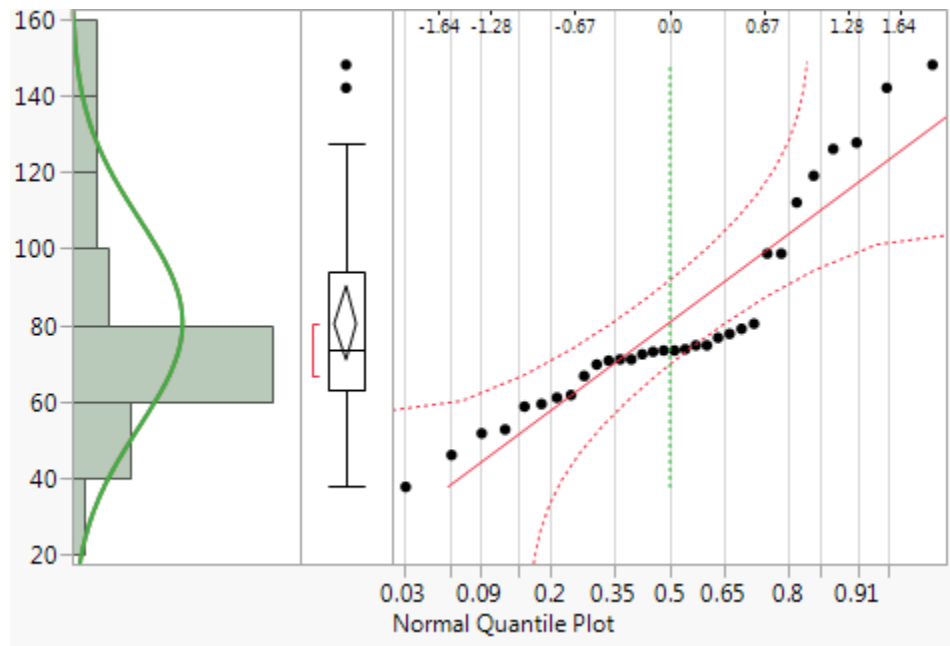


Figure 29: Normal Quantile Plot for Shapiro – Wilk test

Shapiro-Wilk W Test	
W	Prob<W
0.879856	0.0020*

Figure 30: Goodness of Fit test

The p-value for the Shapiro-Wilk test is less than 0.05, which means the data is not normal.

Below is the plot from Anderson-Darling test,

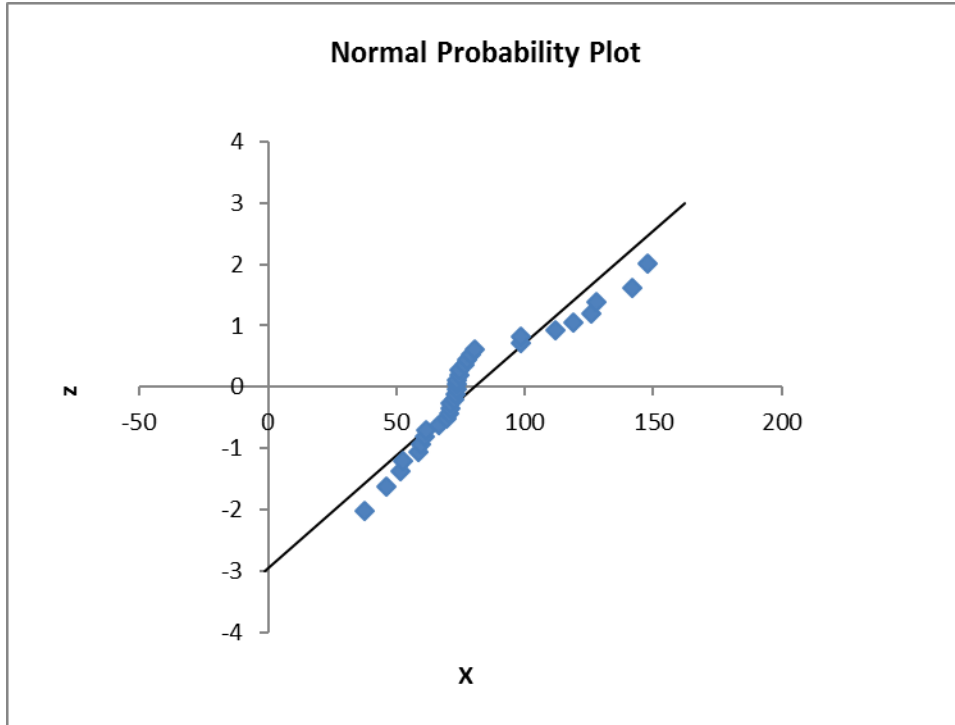


Figure 31: Normal Plot for Anderson Darling test

<i>p Value Calculations</i>	
p	0.000147

Figure 32: P value

As seen in the normal plot the data is not linear, and the p value is less than 0.05, which proves that the data is not normal.

Since the data is not normal, a non-parametric test was chosen to determine the significance. Kruskal-Wallis test determined the p value to be 0.032 which is lower than 0.5, which means the data has a significant difference.

Since the sample size is lesser than 20, U value is used and not the Z value. The results of the post hoc analysis of the data using Mann Whitney U test are as following:

Table 3: Mann Whitney U test

Pair	Sum of Ranks	Mean Rank	Standard Deviation	U - Value	Critical value of U @ $p < .05$	Significance (at $\alpha = .05$)	Comments
TR	59	7.38	9.5219	23	13	Not significant	Mean rank & sum of ranks of TR is lesser than TT, so TR takes lesser time.
TT	77	9.62					
TT	92	11.5	9.5219	8	13	Significant	Mean rank & sum of ranks of GT is lesser than TT, so GT takes lesser time.
GT	44	5.5					
TT	73.5	9.19	9.5219	26.5	13	Not significant	Mean rank & sum of ranks of GR is lesser than TT, so GR takes lesser time.
GR	62.5	7.81					
TR	87	10.88	9.5219	13	13	Significant	Mean rank & sum of ranks of GT is lesser than TR, so GT takes lesser time.
GT	49	6.12					
TR	60.5	7.56	9.5219	24.5	13	Not significant	Mean rank & sum of ranks of TR is lesser than GR, so TR takes lesser time.
GR	75.5	9.44					
GT	46.5	5.81	9.5219	10.5	13	Significant	Mean rank & sum of ranks of GT is lesser than GR, so GT takes lesser time.
GR	89.5	11.19					

Pain Data

The following is the pain data:

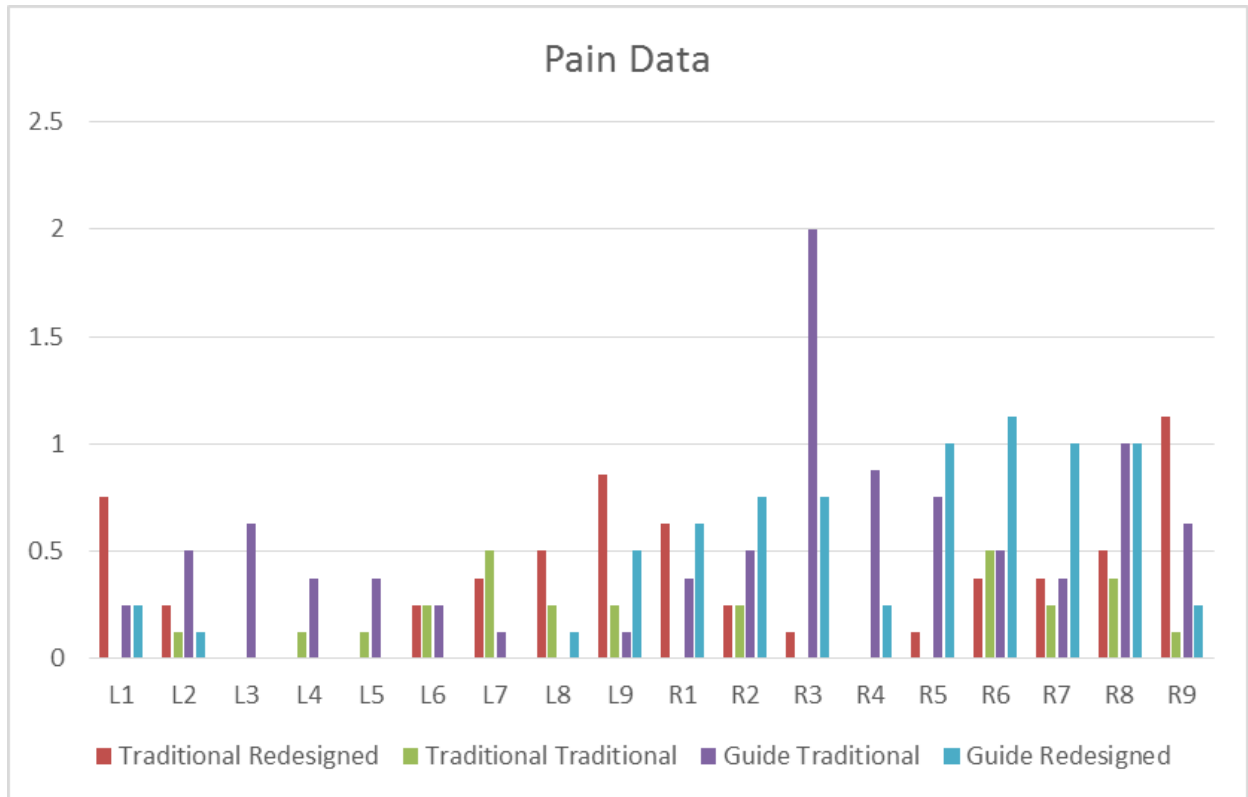


Figure 33: Average of the mean data of pain

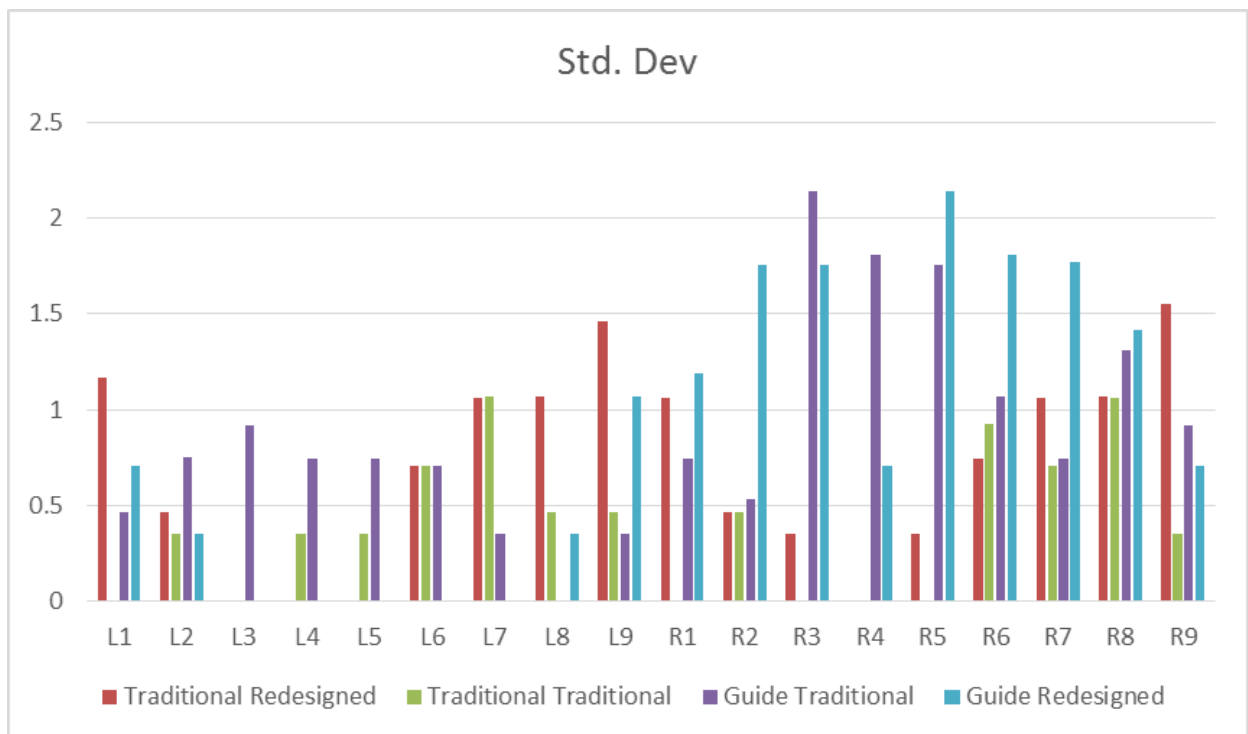


Figure 34: Standard deviation data of pain

For the sake of comparison below is a figure with the pain data pre-experiment and post experiment. The data on left of the table, is pre-experiment and the data on the right is the post experiment. As seen, there is no additional contribution of pain.

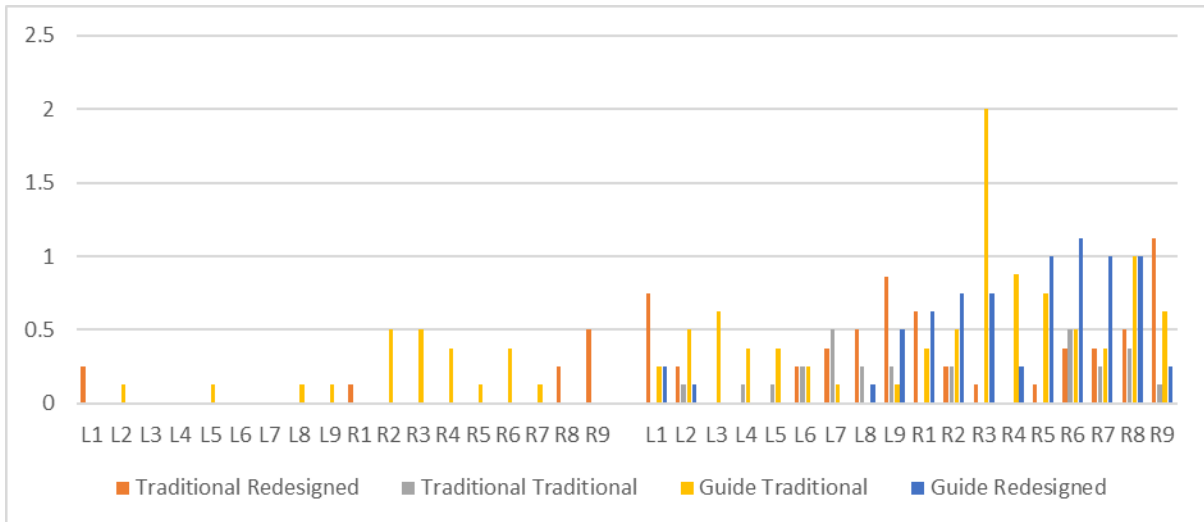


Figure 35: Pain data pre and post experiment

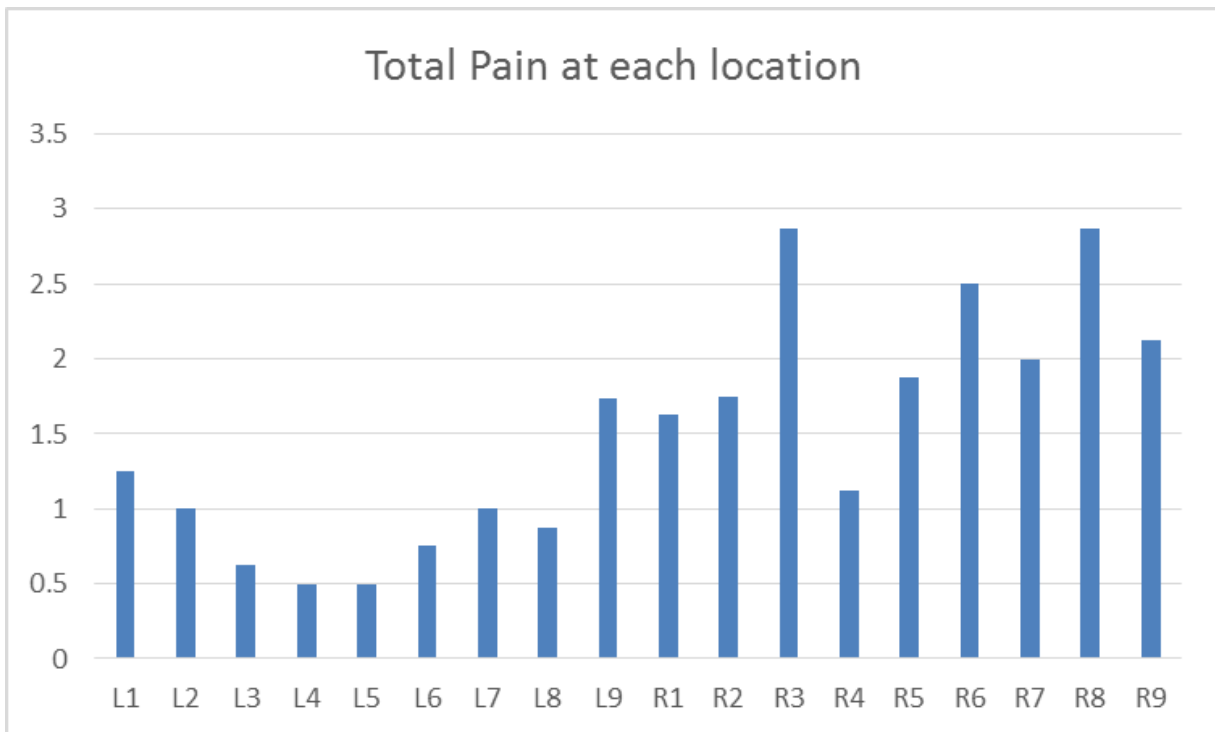


Figure 36: Total pain at each location

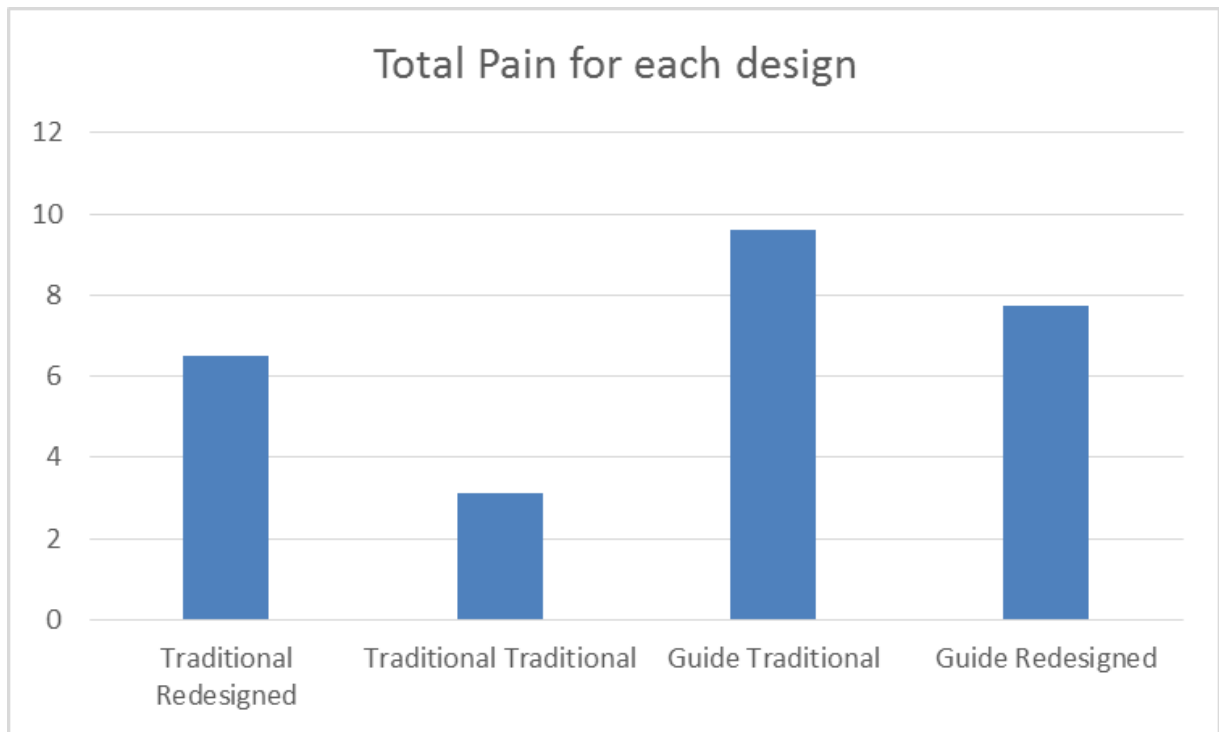


Figure 37: Total Pain for each design

Symmetry Data

As explained in the methods section, the symmetry of the suture is given an absolute score, a suture with the entry and exit hole 4mm away on either side of the straight cut wound is given a score of 1, and a score of 0 if not. Following are the results for symmetry of the sutures.

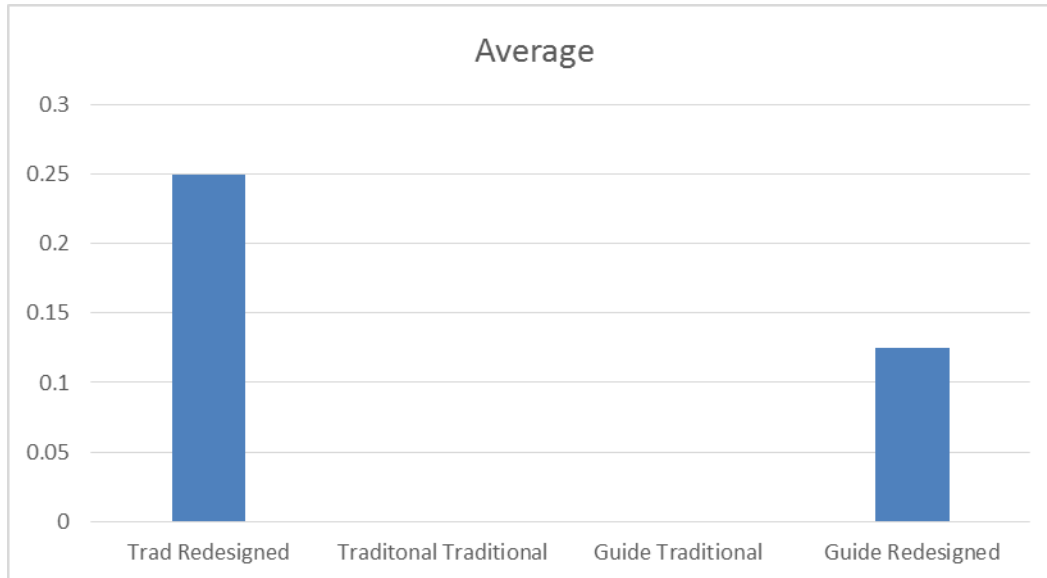


Figure 38: Average symmetry data

The graph records how many times the participants suture symmetrically (4mm on either side of the straight cut wound).

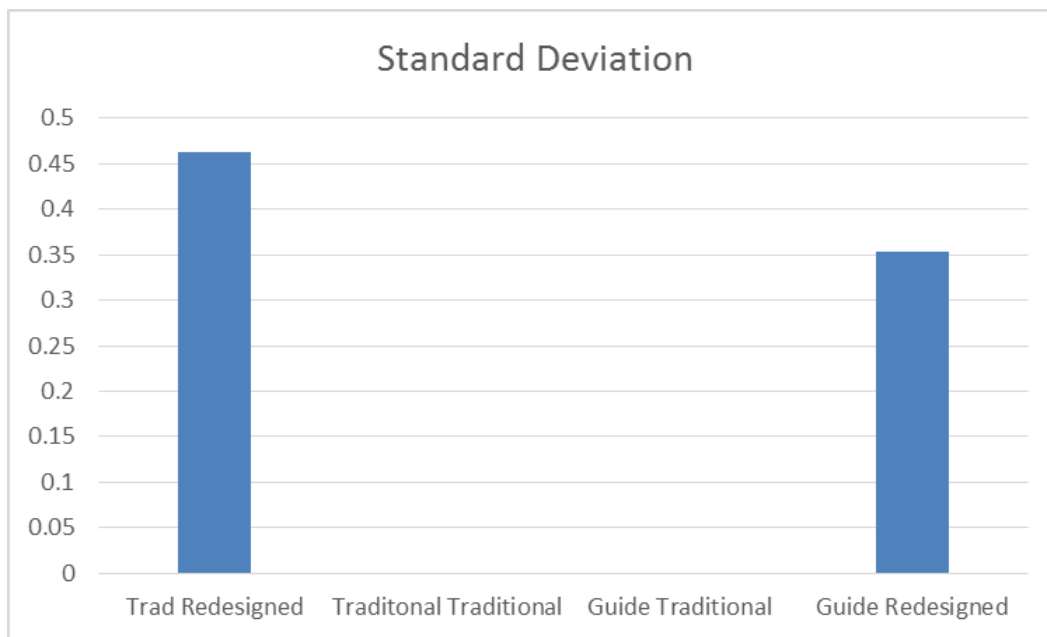


Figure 39: Standard Deviation of the 4 experimental conditions

Discussion

As explained in the methods section, on an average and individually, the task of guiding the suture through the skin takes the highest time, because guiding the suture through the skin involves symmetrically making the entry and exit holes which can be a challenge and it is challenging to get the needle through the skin for novices because of the behavior of the rubber material used for simulating the skin.

A test for normality of the data revealed that the data is not normally distributed, the most common cause being the small sample size of the data for each condition.

A Kruskal-Wallis test which is a non-parametric test was done on the time data with an alpha of 0.05 to analyze the data which revealed a significant difference between Traditional Traditional and Guide Traditional methods of suturing, with guide traditional method taking lesser time, this is because the cognitive load of using the guide in first trial is removed in Guide Traditional group due to which the participants are able to suture quicker. This supports our hypothesis that using the guide increases the learning time of the suture, but decreases the time taken to suture.

There is a significant difference between Traditional Redesigned and Guide Traditional methods, with Guide Traditional method taking lesser time, this result is in conjunction with the previous result, and supports our hypothesis stating that learning with the guide increases the speed of suturing.

Significant difference is seen between Guide Traditional and Guide Redesigned methods which show that the Guide Traditional takes lesser time than Guide Redesigned. In this experimental condition, both the groups learn suturing using the guide in the first phase, the guide redesigned group has the disadvantage that the users have to learn to use the

traditional holder in the first phase and switch to the redesigned holder in the second phase which entails a learning gap explaining the increase in the time.

The participants in the Guide Traditional group take the least time compared to the rest of the groups. It can be safely said while using the guide the way participants suture is restrictive and requires mental and physical resources since it requires precision. This improves the skill set of the participants exponentially as compared to the other types

Discomfort data was collected for the purpose of further research into redesigning the needle holder.

The locations of the hand that have the highest discomfort are R3 and R8. R3 is the location between the thumb and the index finger, and R8 is the central location of the middle finger.

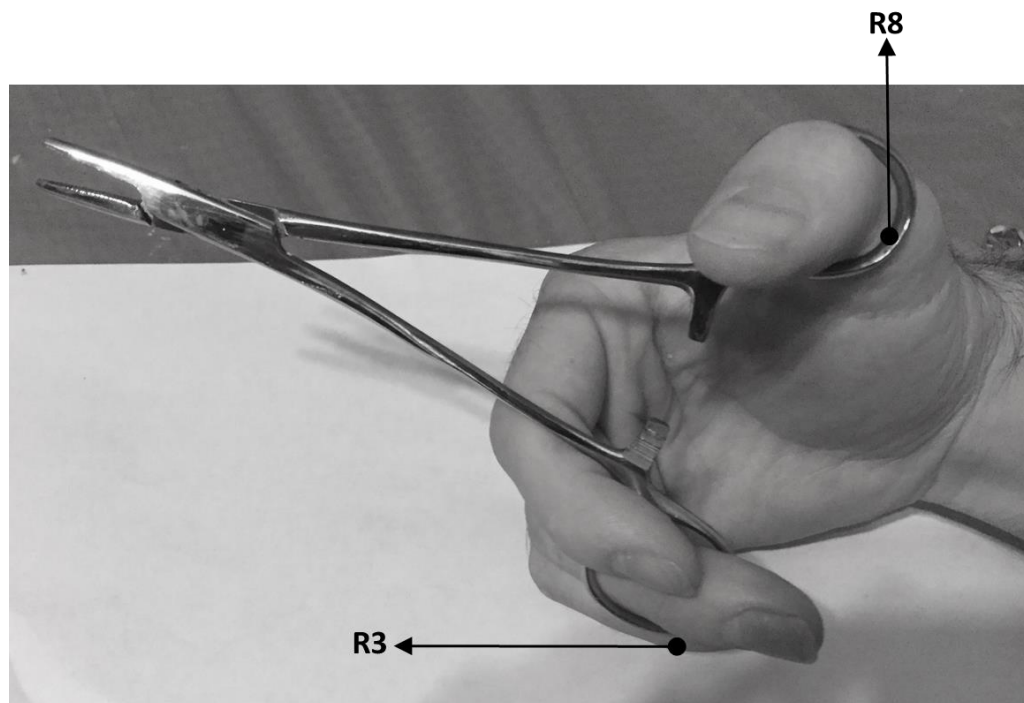


Figure 40: Locations of highest discomfort

When a participant holds the needle holder the points of contact are: the point where the thumb and forefinger meet, and the point where the needle holder meets the ring finger, and while driving the needle holder into the skin R8 is the location that helps in driving the suture through the skin and R3 is the location that keeps the upper part of the needle holder in place.

When the trend for total discomfort for each of the methods is seen, it shows that both the Guide Traditional and Guide Redesigned have higher discomfort as compared to Traditional Redesigned and Traditional Traditional methods, this can be due to the fact that the Guide specifies the location of the entry and exit and the participants are demanded to be precise by 3 mm, which is the diameter of the opening the user should suture through which makes it a challenging task to learn. As the participants learn and achieve the skill to suture with precision, the guide will not cause any additional discomfort.

The results show that the participants tend to suture symmetrically while using the redesigned needle holder for both the designs of the experiment, the Traditional Redesigned and the Guide Redesigned.

The hypothesis suggests that the group of participants who used the guide will suture symmetrically as compared to the participants who did not, but the data analysis revealed that the participants who practiced without the guide and sutured with the redesigned needle holder sutured with better symmetry as well. The same cannot be said for the participants who practiced with the guide in the first phase and sutured with the traditional needle holder.

The common denominator for both the groups with good symmetry is the redesigned needle holder. Further research is necessary to explain why the redesigned holder is leading to better symmetry when used without the guide but if left to speculation it can be said that

using the redesigned holder demands more overall attention by the participants who use them only in the second phase, since there is a learning aspect attached to the trial the users suture symmetrically as compared to while using the traditional holder in both the learning and the second phase.

CHAPTER III

CONCLUSION

The paper attempts to highlight the importance of human factors in the long-standing processes of the healthcare industry. There is no doubt that there is room for improvement in the medical community in the direction of human factors. It makes the process error free, efficient and safe which would help improve a patient's almost excruciating experience of visiting a hospital. Suturing is an important skill in the healthcare community and suturing with quality, precision and speed is a tough skill to learn which needs years of practice.

In conclusion, the learning guide reduces the time taken to perform a simple mattress suture, and the redesigned needle holder increases the symmetry of the suture.

Further research will include using a larger sample size and testing participants with experience, for the redesigned needle holder.

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APPENDIX A

IRB APPROVAL

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
1138 Pearson Hall
Ames, Iowa 50011-2207
515-294-4566
FAX 515-294-4267

Date: 12/16/2015

To: Krishna Rajana
246 North Hyland, Ames IA 50014

CC: Dr. Richard T Stone
3004 Black Engineering

From: Office for Responsible Research

Title: Investigation of Suturing Techniques

IRB ID: 15-555

Approval Date: 12/16/2015 **Date for Continuing Review:** 12/15/2017

Submission Type: New **Review Type:** Expedited

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, including the recruitment materials and informed consent documents that have the IRB approval stamp.
- **Retain signed informed consent documents for 3 years after the close of the study**, when documented consent is required.
- **Obtain IRB approval prior to implementing any changes** to the study by submitting a Modification Form for Non-Exempt Research or Amendment for Personnel Changes form, as necessary.
- **Immediately inform the IRB of (1) all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems** involving risks to subjects or others.
- **Stop all research activity if IRB approval lapses**, unless continuation is necessary to prevent harm to research participants. Research activity can resume once IRB approval is reestablished.
- **Complete a new continuing review form** at least three to four weeks prior to the **date for continuing review** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please be aware that IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g. student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

Upon completion of the project, please submit a Project Closure Form to the Office for Responsible Research, 1138 Pearson Hall, to officially close the project.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

APPENDIX B

SAFETY PROCEDURE APPROVED BY EH&S

Safety procedure and information for the experiment Investigation of suturing techniques

Procedure to follow while suturing:

1. Wear the nitrile gloves before starting to suture.
2. You should have 4 devices in your possession:
 - a. Forceps- for grasping the foam while suturing.



- b. Needle holder- for holding the suture.

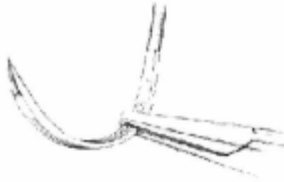


- c. Suture

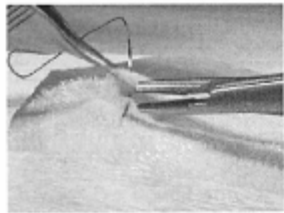


- d. Foam-material for suturing

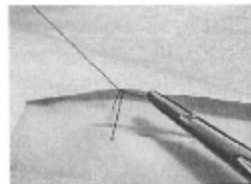
3. The suture should be grasped at the center or 50-60% from the pointed end.



4. The suture should be grasped 1-2mm from the tip of the needle holder.
 5. The first suture is placed by grasping the skin of the foam material and slightly everting it.
 6. The right hand is rotated and the needle will pierce the foam at 90 degrees angle. Place the trailing suture away to avoid tangling.
 7. Drive the needle through by rotating the suture holder, and keeping the shaft of the needle perpendicular the skin at all times.
 8. Now, release the needle and re-grasp it. The forceps have to maintain the grasp throughout to prevent the suture from retracting.



9. The right hand is pronated before grasping the needle, and then supinated to rotate the needle through.
 10. The suture is then drawn through the foam material.
 11. Drop the forceps and grasp the suture material.
 12. The long strand is wrapped around the suture holder to form a loop.
 13. Rotate the suture holder away from yourself and grasp the short end of the suture.
 14. Grasp the short and draw it back through the loop towards yourself.



15. Tighten the loop to approximate the edges of the skin, do not strangulate.
 16. Repeat steps 12 to 15.
 17. Cut the suture leaving 3-4mm tails.

Safe procedure for handling sutures

For your safety and the safety of others, please follow the following instructions while performing the experiment:

1. Dispose the sutures in the red sharps container.
2. Always keep the sharps container upright.
3. Do not handle sutures with bare hands, always use nitrile gloves.
4. Be alert at all the times while handling the suture.
5. Do not look away or get distracted while handling the suture.
6. Do not try to bend the sutures.
7. Do not handle the sutures without supervision.
8. Do not leave the suture you are using unattended.
9. Handle only one suture at any given time.
10. While resting the suture always point it away from you.

Procedure to follow in case of accident or emergency:

1. Wash the wound with soap and water for several minutes.
2. Use the first-aid kit available in the lab as necessary.
3. Obtain medical attention.
4. Report the incident immediately to the principal investigator.

With your signature below, you acknowledge that you have read and understood the contents of the document.

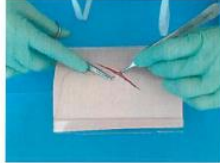
Signature

Date

APPENDIX C**FLYER**

EBU 0001 # 1
15-2555
Approval Date: 16 December 2015
Expiration Date: 15 December 2017

Research Study seeks volunteers



We are researching various suturing techniques. Your participation will be 2 hour sessions for 3 days.

To participate you should be 18 years or older with no fear of blood, or slight pricking of fingers.

Participants would receive a t-shirt as compensation.

To learn more, contact the principle investigator of the study, Krishna Leela Rajana, at 515-441-9802 or leela@iastate.edu

The research is conducted under the direction of Dr Richard T Stone , Department of Industrial Engineering.

APPENDIX D**EMAIL**

ISU IRB # 1	15-565
Approved Date:	16 December 2015
Expiration Date:	15 December 2017

Email to be sent to the participants:

Subject: Participants needed for a research study on suturing

Hi everyone,

You are invited to participate in a research study directed towards improving the suturing techniques. You would learn to suture and perform some basic suturing techniques.

You must be 18 years or older to participate, with no fear of blood, since you might experience slight puncturing of fingers while learning to suture. The experiment will last for a total of 3 days lasting for 2 hours each day.

Your participation in the study is voluntary and the data collected will be kept confidential.

If you are interested to participate or would like to know more about the study please contact me at leela@iastate.edu

You would be given a T-shirt worth 10\$ as a gift on completion of your participation in the study.

APPENDIX E

INFORMED CONSENT FORM

ISU IRB # 1	15-505
Approved Date:	16 December 2015
Expiration Date:	15 December 2017

INFORMED CONSENT DOCUMENT

Title of Study: Investigation of suturing techniques.

Investigators: Krishna Leela Rajana, Dr Richard T Stone.

This form describes a research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Introduction

The purpose of this study is to improve the suturing techniques used for wound closure with the help of ergonomic methods.

You are being invited to participate in this study because you are 18 years or older with 20/20 or corrected vision. You should not participate if you are under 18 years, uncorrected vision or suffering from Hemophobia/Hemaphobia/Hematophobia(which is the fear of blood).

Description of Procedures

If you agree to participate, you will be first asked to answer the screening questionnaire. On qualification after screening, you will be asked to fill a survey if they face any discomfort at locations mainly on the hands.

You will be taught the technique of suturing- mattress and simple; and also will be shown a video to aid in learning.

After which, depending on the group you are in you will perform suturing with or without a suturing guide. You will be observed, and your hands will be video recorded. Nitrile gloves will be given to mitigate the risk of puncturing fingers.

Following this procedure, depending on the group you will be asked to perform another suture with a redesigned or conventional suture holder. The participant's hands will be observed and video recorded during this procedure too.

After suturing the participants will be asked to answer a questionnaire on various aspects of their suturing experience - example pain, difficulty etc.

Your participation will last for a maximum of 3 visits (a total of 6 hours).

Risks or Discomforts

While participating in this study you may experience the following risks or discomforts- The participants run a minimum risk of puncturing their fingers while suturing. You will be given nitrile gloves to mitigate this risk, and you will have a first-aid kit accessible and will be taken to the student health center in the rare chance of an emergency occurring.

Benefits

If you decide to participate in this study, there may be no direct benefit to you. It is hoped that the information gained in this study will benefit society by helping in making the suturing

methods used by doctors error-free and the methods used in this research could further be used for other such procedures.

Costs and Compensation

You will not have any costs from participating in this study. You will be compensated for participating in this study. The participants will receive a t-shirt worth 10\$ as compensation. The participants from IE271 and IE577 classes will be awarded an extra course credit of 5%, the students will be given an alternate assignment if they chose not to participate in the study. There will be no deduction of extra credit based on the number of visits, if participants choose to leave study early, there will be no proration, and they will be awarded full credit.

Participant Rights

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. You can skip any questions that you do not wish to answer.

Your choice of whether or not to participate will have no impact on you as a student/employee in any way.

If you have any questions *about the rights of research subjects or research-related injury*, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

Confidentiality

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy study records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken:

1. Identifiers attached with the data, which are names are used only for screening purposes. They are not attached to the data collected.
2. All the data collected will be under lock and key or password protected.
3. Only the hands of the participants will be video recorded, and any identifying information on the hands will be blurred.
4. Any identifying information will be removed while disseminating the results.
5. The data will be accessible only to the principal investigator and the supervising faculty.

Questions

You are encouraged to ask questions at any time during this study. For further information about the study, contact Krishna Leela Rajana at 515-441-9802 or leela@iastate.edu or Dr Richard T Stone at 515-294-3644 or rstone@iastate.edu.

Consent and Authorization Provisions

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document, and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your participation in the study.

Participant's Name (printed) _____

Participant's Signature

Date

APPENDIX F
SCREENING QUESTIONNAIRE

Screening questionnaire for the study -Investigation of suturing techniques

1. NAME:
2. AGE:
3. GENDER:
4. Did you ever experience hemophobia (fear of blood)?
YES/NO
5. Do you have 20/20 vision (with or without corrective lenses)?
YES/NO
6. Can you read, write and speak in English?
YES/NO
7. Do you have any known bleeding or clotting disorders?
YES/NO