4-2015

Comparison of Sutures and Devices Used in Closure Following Partial Nephrectomy Suturing

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A Thesis Submitted to the Graduate Faculty of

GRAND VALLEY STATE UNIVERSITY

In

Partial Fulfillment of the Requirements

For the Degree of

Master of Science in Engineering

Padnos College of Engineering and Computing

April 2015

Dedication

This thesis is dedicated to my mother and father. In addition, I will also like to dedicate to those who have assisted me along the way for the completion of my thesis.

Acknowledgements

This thesis appears in its current form due to the assistance and guidance of several people. I would therefore like to offer my sincere thanks to all of them.

I would like to thank Grand Valley State University and Spectrum Health System for providing the financial assistance to carry out this research. I am grateful to Department of Biomedical Engineering, for providing me opportunity to conduct this research

I heartily thank my supervisors, Dr. Robert Bossemeyer for all the time spent working with me, and for patient and encouraging guidance.

I am eternally grateful to Dr. Brian Lane for the guidance and the preparation of specimens in this research. I would like to express my deep thanks to Dr. Mouafak Tourojman for his support in preparation of specimens during experiment.

I would like to express my deep thanks to Dr. Samhita Rhodes, for her support to complete this research.

I sincerely thank Miss Sabrina for her regular support and research coordination. My appreciation goes to Mr. Jerry Smart for all precious suggestions regarding experimental device design I would like to thank Spectrum Health for helping me in statistical analysis of data. I would like to thank Mr. Ruchir Gupta, Miss. Anisa Tuladhar and Mr. Ravi Bhatta for their continuous support during the research.

Abstract

Laparoscopic partial nephrectomy (LPN) is an effective surgical procedure to remove a small renal tumor, while preserving the remainder of the kidney. However, it is a technically challenging procedure to maintain hemostatic condition on the kidney during LPN suturing. Three different experiments were conducted to explore the characteristics and limitations of the current mechanism for tissue approximation during LPN procedures.

During the first experiment, a standard suture anchor Hem-o-lok device, a standard stop knot, and three prototype devices were compared to each other based on the amount of tension that could be placed on a suture before there was a tear in renal tissue. The renal remnant of a standardized defect in porcine kidneys without an intact renal capsule was sutured using Vicryl 2-0 suture and different suture anchors. The approximate mean tensions at which the renal parenchymal tissue failed using these tested anchors was knots (2.7N ± 0.53N), Prototype 2(4.0 N± 1.6N), Hem-o-lok (5.4 N±0.72N), Prototype 1(5.6 N±0.75N), and Prototype 3(6.0 N±3.39N). Even with a small number of tests (8 for most configurations), there are significant differences at the 95% confidence level. Statistical analysis of the data, however, indicates that there is no significant difference between anchors Hem-o-lok, Prototype 1 and Prototype 3 with a significance level of 0.05.

The second experiment was conducted to determine if different types and sizes of absorbable suture used in partial nephrectomy can sustain a tension of 4N over a 21 day period, which is necessary to achieve hemostasis in the perfused kidney. The results indicate that the sutures commonly used in LPN, i.e. Vicryl 2-0 and Vicryl 3-0 do not break within the 21 day expected life and that failure of other sutures tested before 7 days is commonly due to knot slippage

The final experiment measured and compared the holding strength of a common technique used in LPN surgery to provide anchoring of a suture, a Hem-o-lok device backstopped with a LAPRA-TY. Suture types Vicryl, Monocryl, Chromic, Stratafix and V-Loc were tested in common sizes. The results show that the holding strength of clips (Hem-o-Lok backstopped by LAPRA-TY) for Vicryl 4-0 sutures is the lowest of all types and sizes tested at a mean value of 4.2 N±1.36N and maximum for V-Loc 2-0 sutures at the mean value of 15.9 N±2.58N. The clips hold maximum tension for suture sizes “1” and “0”, whereas minimum tension for suture size 4-0. This experiment indicates that the holding ability of these clips support the application of suture tension greater than 5.5N thought to be necessary for adequate hemostasis following LPN. However, suture types Vicryl 3-0 and Vicryl 4-0 may not be able to maintain hemostatic condition during LPN when used with this anchor method.

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Introduction

Radical nephrectomy is the traditional treatment choice for solid renal tumors in which the entire kidney and surrounding fat are removed during surgery[1]. Partial nephrectomy is the preferred current practice for removal of small renal tumors and for patients who have a risk of kidney failure if one of the kidneys is removed. The benefit of partial nephrectomy when compared to radical nephrectomy is the preservation of as much of the kidney as possible to prevent subsequent problems such as kidney failure[2]. Partial nephrectomy is a less invasive surgery, has a favorable cosmetic result and has a faster recovery period when compared to traditional Radical nephrectomy[3]. Laparoscopic partial nephrectomy (LPN) was first described in 1993. It is a safe and effective way to remove renal tumors while preserving the remainder of the kidney. It has become the preferred method of treatment in certain renal diseases, including small, peripheral tumors[4]. However, during LPN intracorporeal suturing for hemostasis, renal parenchymal repair, and closure of the pelvicalyceal under the constraint of warm ischemia time (WIT) are considered most technically challenging and time-consuming steps[5].

Similarly, post-operative bleeding and urine leakage are the main complications of partial nephrectomy[6]. These challenges have limited the procedure to the most experienced laparoscopic surgeons preventing mainstream application. Numerous factors could generate complications. Investigation of those factors is scant. It is therefore logical to begin with a study of those variables which are known to have changed measurably during the procedure and could change further post-operatively. A major factor in the control of bleeding, urine leakage and parenchymal tissue tear is the closing system[6, 4]. While some small, peripheral tumors have been removed without the aid of sutures, the vast majority of surgeries involve a sutured closing system. The term ‘closing system’ is introduced here to underscore that the suture is not an isolated device which completes the function. Rather, it is one of a number of elements which must perform satisfactorily for the purpose to be served.

Background

Partial nephrectomy is technically more challenging than radical nephrectomy; therefore, it requires proper techniques. Despite various surgical techniques to prevent postoperative adverse events after nephron surgery, the complications associated with it are as follows: 7.4% of persistent urine leak, 4.9% of dialysis, and 2.8% of acute and delayed bleeding[7]. A secure reconstruction technique is required for a high risk patient with large or centrally located tumors. Improvement in renal imaging and detection of small incidental masses has allowed widespread application of laparoscopy in renal cancer surgery[7]. However, laparoscopic partial nephrectomy (LPN) cannot be widely performed due to difficulty in obtaining hemostatic condition and achieving satisfactory renal parenchymal repair. In fact, if the defect is too large to be repaired, open partial nephrectomy (OPN) is also difficult to perform due to the excessive tensile force involved, which destroys the remaining renal parenchyma[7]. During traditional methods of closing the parenchymal defect, the power of cinching the suture down on the renal parenchyma is limited because of the “cheese slicing” effect, i.e. damage to tissue caused by pulling force applied on it through suture of knot tying[8]. To overcome this problem, several techniques were developed to enhance closure strength of renal parenchyma using clips. LAPRA-TY and Hem-o-lok clips are currently in practice[8]. The figure 1 shows a Hem-o-lok and a LAPRA-TY clip.

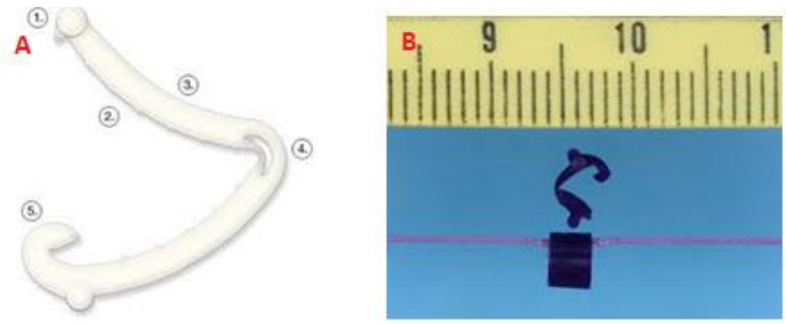

Figure 1: Surgical clips: A. Hem-o-lok clip B. LAPRA-TY clip

The major issue related to partial nephrectomy is the tearing of the parenchymal tissue while placing tension on the suture to achieve hemostatic condition[6]. Research has shown that both tension angle and tension applied are major factors that determine renal parenchymal tissue damage; however, there is still not enough experimental data to conclude the result[4]. The tangential forces applied on parenchymal tissue during suturing results in a “cheese-wiring” effect, so great care must be taken to minimize tissue damage[8]. Research performed on the relationship between tension angle and tissue damage during suturing has shown that force applied near normal direction has greater magnitudes before failure in comparison to the force applied parallel to the surface of the kidney[4]. The ability of the tissue and suture anchor to support applied tension can be improved significantly by increasing the angle of the applied force relative to the organ surface. For angles between 0° and 90° the tension necessary to cause failure increases rapidly with the angle when the kidney is without connective membrane tissue. The force usually needed for closure is generally applied at an angle near zero[4]; finding the angle where tissue can bear maximum tension force helps to make a suturing process with minimum damage to the kidney. There is still limited documentation to determine the angles where tissue bears maximum and minimum tension. Further research on finding the relation between suture tension angle and tissue damage would contribute to understanding suture closing techniques for proper closure of renal tissue[4].

Suturing can be done in two ways: interrupted and continuous. During ex-vivo experiments on porcine kidneys, continuous suturing has shown better initial hemostatic control in comparison to interrupted suturing[8, 9]. In continuous suturing, the suture is prepared with the knot at the end of the suture and clip attached to the proximal side of knot. The loose suture is tightened from far to near with a suitable tension[9]. The tightened suture is fixed with a Hem-o-lok clip. This clip helps to distribute the tension on the kidney over a large surface area, which helps to reduce the tissue damage as shown in Figure 2a and 2b.

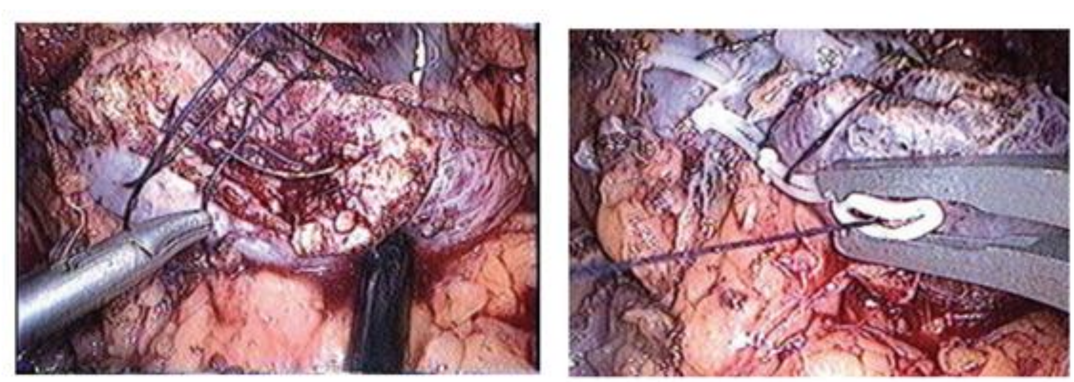

Figure2[9]: Continious suturing technique: a. The parenchyma has been sutured continuously with clear vision without tightening the thread and b.The tightened thread is fixed by an L-sized Hem-o-lok, stitch by stitch with a suitable tension

On the other hand, the standard practice of suturing is interrupted suturing[8]. This type of suturing can be done with any of the following techniques: making knots in the suture, using the clips (i.e. Hem-o-lok and LAPRA-TY), and a combination of clips (i.e. Hem-o-lok) and knot. The common knots in practice are the simple knot, the square knot and the surgeon knot as shown in figure 3. Similarly, surgical clips are used commonly in laparoscopic surgery as suture anchors because the use of knots as anchors is technically challenging, time consuming and can lead to prolongation of warm ischemia time[12].

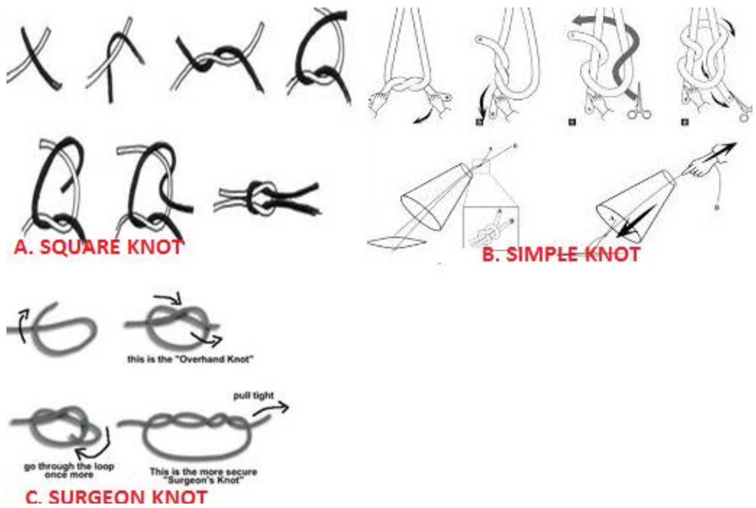

Figure 3: Knot types: a. square knot, b. simple knot and c. surgeon knot

During partial nephrectomy suturing with a Hem-o-lok clip backstopped by LAPRA-TY, the tension will be applied on the tissue against the Hem-o-lok clip. This clip helps to distribute the tension on the kidney over a large surface area, which helps to reduce the tissue damage. This process also helps to readjust the applied tension by sliding a clip towards the damage renal tissue in order to maintain hemostatic condition, i.e. stoppage of the blood leakage [10]. The locking mechanism of LAPRA-TY clips helps to secure the applied tension on renal tissue using a particular suture. This is a standard procedure of partial nephrectomy suturing [10, 11].

During robotic partial nephrectomy (RPN), the method of choice for renorrhaphy is now the sliding-clip technique because it gives the console surgeon precise control over the closure [8]. This is achieved either using two Hem-O-Lok clips or using both LAPRA-TY and Hem-o-lok clips. Using two Hem-o-lok clips is the best technique because they slide smoothly and have the lowest risk of renal violation due to their larger footprint[8, 12.] The process for sliding-clip renorrhaphy for renal partial nephrectomy is as follows: LAPRA-TY clips and Hem-o-lok clips will be placed above a knot tied at the end of the suture and the assistant places a second Hem-O-

Lok clip on the loose end of the suture after the suture has been placed through the opposite ends of the renal parenchyma[13]. The clip is applied so that the suture is in the center of the jaws of the clip because this helps it to slide smoothly[14]. A robotic needle driver with jaws slightly open helps to slide the Hem-o-Lok clip down the suture towards the kidney until tightly opposed to the renal parenchyma. This allows tension adjustment but does not definitively lock the suture in position[8]. Tension adjustment against the renal parenchyma using Hem-o-clip helps in preventing blood leakage after suturing, which is also known as hemostatic condition[11]. Finally, a LAPRA-TY clip is placed to secure the closure as shown in Figure 4.

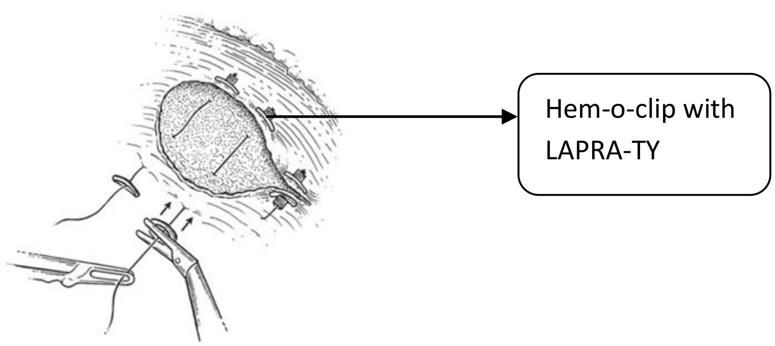

***Figure 6** – Sliding-clip renorrhaphy.*

Figure 4: Sliding-clip renorrhaphy using Hem-o-clip and LAPRA-TY

The critical step during partial nephrectomy is to maintain hemostatic condition, i.e. the arrest of bleeding from the kidney. Renal hemostatic condition depends on the strength of the renal capsule and suturing techniques during partial nephrectomy[15]. There are three patterns of interrupted suturing techniques like simple suturing, horizontal mattress suturing and vertical mattress suturing as shown in figure 5.

Simple suture[17]

- Also known as an interrupted suturing. It is simple, and relatively easy to place
- In this type of suturing individual stitches aren't connected, which keeps the wound together even if one suture fails.

Horizontal Mattress [17]

- Helps to spreads tension along the wound edge so minimize the tension
- Ideal for holding together fragile skin as well as skin under high tension such as the distant edges.
- The procedure of suturing in this technique is such that margin of 1 cm should be maintained in both sides of the wound and the tension should not be applied in suture to reduce the error.

Vertical Mattress [17]

- Provides closure for both deep and superficial layers
- The disadvantage of this suturing is poor vertical alignment of edges which may cause tissue damage
- The procedure of suturing in this technique is such that a margin of 1 cm should be maintained in both sides of the wound and the distance between the upper and lower bites of vertical suture should remain at a half cm.

The current clinical practice for suturing depends on preference of the surgeon. In some cases, surgeons prefer knot-tying as it is less expensive compared to using surgical clips. However, surgical clips are replacing the practice of making knots after suturing as tying a knot is more time consuming and difficult[1]. Surgeons have the impression that one suture technique is superior to the others for the proper closure of wounds and maintaining hemostatic condition after partial nephrectomy. However, experimental data to support these techniques are still lacking[16].

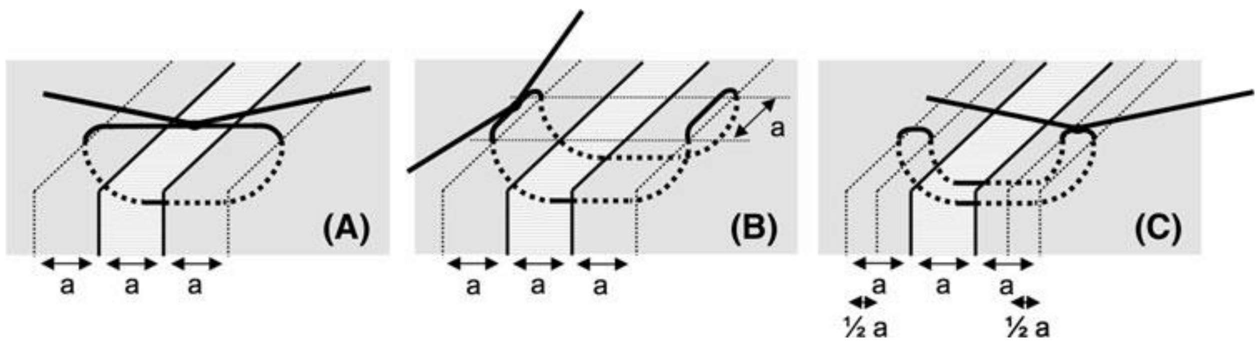

Figure 5[16]: Suturing techniques: A. simple suturing, B. Horizontal suturing, C. vertical suturing

Suture is a piece of thread-like material used to stitch tissues and hold the wound together until healing takes place. It holds the wound tissue together in good apposition until the natural healing process is sufficiently well established to make the support from the suture material unnecessary. The size of the suture is defined by its numbers, i.e. 5,2,1,0, 2-0, 3-0.4-0, 5-0, 6-0, 7-0, 8-0, 9-0 and 10-0[18]. The size and its use are described as follows: [18] Suture 5 is largest and the size 10-0 is the smallest suture. The larger sutures are commonly used for repair of tendons or other high tension structures in large orthopedic. The smallest size suture is used in delicate surgeries like ophthalmic surgery[18].

There are different types of sutures; the two most important properties are Absorbable Vs Non-Absorbable and Braided vs. Non-Braided. Absorbable sutures break down over time in the body. The amount of time for sutures to break down in the body depends on a few factors such as suture type, size and the location it is placed. Examples of absorbable suture include Monocryl, Vicryl, Chromic, and PDS. On the other hand, non- absorbable suture, when used on the skin will be removed, and when used in the body, will be retained inside the tissue. The examples of non-absorbable sutures are as follows: Nylon (Ethilon), Gortex and Silk. Similarly, another important property of suture is braided and non- braided. Braided sutures have a number of strands woven together like a string. Examples of braided sutures are: Silk, Vicryl and Ethibond[18]. Non-Braided or Monofilament Sutures have a single strand such as Monocryl, PDS, and Ethilon Nylon. Monofilament sutures incite less tissue reaction and exhibit less tissue drag, resulting in less tissue tearing because of their smooth surfaces. However, monofilament sutures are less flexible and, are more difficult to tie in a knot as well as have inferior knot security because of their tendency to loosen when compared with multifilament sutures. Ideally, one chooses monofilament sutures in situations where lesser tissue trauma and lower risk of infection are paramount in tissue healing[19]. Suture materials should be chosen based on their physical and biological properties, assessment of local conditions in the particular wound, and the healing rate of different tissues. However, suture selection has often been governed by training, experience, economics, and personal preferences rather than by scientific facts[19]. There are many types of suture which are commonly used in the field of health sector such as PDS (polydioxanone), Plain Gut, Vicryl, Chromic, Polyglycolide etc.

1 Chromic sutures are absorbable and monofilament made from either beef serosa or sheep submucosa. They are most commonly used in OB-GYN surgery and facial plastic or oral surgery. They lose their tensile strength from 21 days and are completely absorbed in 90 days. The color of this suture is brown or blue dyed[18, 19].
2 PDS (polydioxanone) is an absorbable monofilament suture with clear or violet color. The tensile strength of PDS Size 3-0 and larger is 80% at 2 weeks, 70% at 4 weeks, and 60% at 6 weeks. This suture will completely absorb in 183-238 days. PDS is a long lasting absorbable

monofilament suture for soft tissue approximation; it is commonly used to approximate fascia in open abdominal cases [18, 19].

3 Vicryl is a braided absorbable suture which has tensile strength of 75% at 2 weeks, 50% at 3 weeks and 25% at 4 weeks. This suture will completely absorb within 56-70 days. Vicryl suture is either violet or white. It is one of the most common sutures used in all surgical services to approximate soft tissue[18, 19].

4 Plain catgut is monofilament absorbable suture and maintains strength for at least 7 days. It has very high knot-pull tensile strength and good knot security due to special excellent handling features. The color of this suture is straw. It is not recommended for incisions that require sustaining the tissues for a prolonged period of time [18, 19].

5 A barbed suture is a knotless surgical suture that has barbs on its surface. The barb grasps tissue at numerous points providing distribution of tension across the wound and eliminates the need for tying knots. It also helps in continuous suturing technique and prevents backsliding of suture[20, 21]. These sutures have been used for skin and soft tissue closures, gynecologic procedure, flexor tendon repair and anastomosis [20]. There are currently two different absorbable barbed suture products available, V-Loc and Stratafix as shown in figure 6.

V-loc suture has a unidirectional barb, with a circumferential barb distribution. The tensile strength is 90% at 7 days, and 75% at 14 days. The suture absorbs completely at 90-110 days. Stratafix (PGA-PCL) suture is a knotless tissue control device with spiral anchor configuration. It supports tension for 1-2 weeks and completely absorbs in 90-120 days[21.]

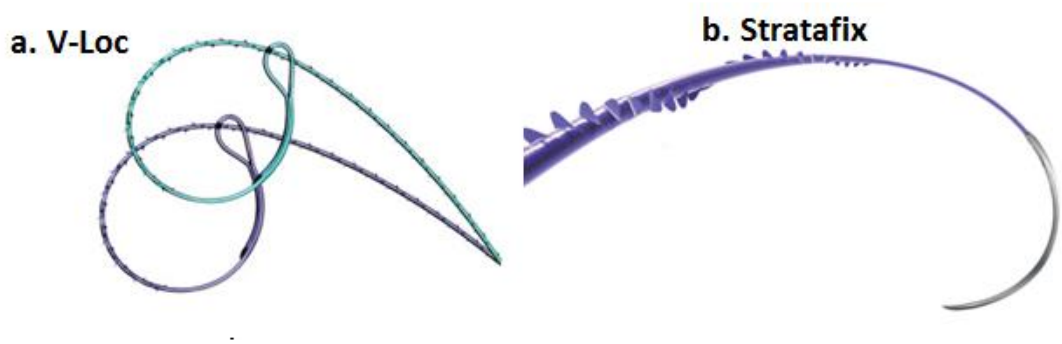

Figure 6: Barbed sutures: a. V-Loc b. Stratafix

The purpose of this Master's thesis is to determine the most secure mechanism for tissue approximation. There are three different experiments which are as follows: 1. to compare prototype suture anchors designed by Dr. Brian Lane from Spectrum Health, with standard anchors (knots and Hem-o-lok) to determine the most secure mechanism for tissue approximation with suture anchoring technique, 2. To analyze the time require for absorbable sutures with a given tension expected to support in a controlled temperature. 3. To investigate the holding strength of Hem-o-lok clip backstopped by LAPRA-TY clip on various suture types and sizes

Experiment 1: Comparison between Prototype suture anchors and conventional suture anchors

Background/Literature review

Failure in suture anchors is common and generally occurs in two situations: 1. Insufficient holding strength of anchor causing slippage of suture 2. Tear of renal parenchymal tissue while applying tension during suturing. This experiment was to compare Prototype suture clips with conventional suture anchors, i.e. knot without clips and Hem-o-lok clips. The comparison was based on the amount of force required for the renal parenchymal tissue to tear using those anchors.

Simon et al. have examined the force required to cause a suture to tear through tissue in frequently used configurations (simple, vertical mattress, and horizontal mattress formats) [16]. However, this experiment did not address the relation between the measured force and the closing force. Nor did that study consider the use of surgical clips to terminate simple sutures which is common in laparoscopic procedures.

The other experiment conducted by Simon Kimm used tensometer to determine the amount of tension necessary to dislodge each of the five different clips from Vicryl suture with an without intervening pledget[11]. The clips investigated were LAPRA-TY, Hem-o-lok, Endoclip II Weck and novel suture clip. The results have shown that Endoclip II Weck and novel suture clips required significantly greater tension to dislodge than the Hem-o-lok and LAPRA-TY[11].

One of the experiments has shown that the holding strength of a single Hem-o-lok clip is more resistant to cause capsular violation, but less resistant to slippage when compared with a single

LAPRA-TY clip[10]. However, when two Hem-o-lok clips are placed in one in front of another, the force needed to slip off the suture exceeds that of one LAPRA-TY clip. Similarly, this experiment shows the use of Hem-o-clip minimizes the renal tissue damage compared to LAPRA-TY. Figure 7 shows the holding strength and tissue violation force for the LAPRA-TY and Hem-o-lok clips. The locking mechanism of LAPRA-TY clips helps to ensure closure of a tissue using a particular suture[10].

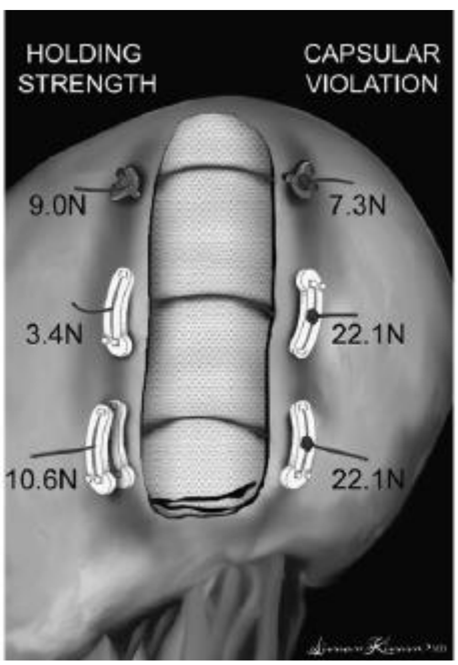

Figure 7[10]: Holding strength using clips Hem-o-clip and LAPRA-TY

Three different types of prototype clips, i.e. Prototype 1, Prototype 2 and Prototype 3, were designed by Dr. Brian Lane, MD PhD, who specializes in Urology. Dr. Lane was participated in this research for preparation of specimens. The size and number of aperture for Prototype clips designed were varied to test different configurations for closure with more than one suture per clip in response to renal tissue damage. The goal was to design a clip with a more optimal surface area to reduce the tissue damage during partial nephrectomy suturing. The Prototype clips were different from each other in shape and size. The approximate area of clips Prototype 1, Prototype 2 and Prototype 3 were 50 mm^2, 138 mm^2 and 160 mm^2 respectively. Both Prototype 1 and Prototype 2 consist of two apertures and slots as shown in figure 8. The slots extend from respective ones of the pair of apertures towards the perimeter of the plate. The slots formed a channel from the perimeter to the respective apertures and, the suture slides through a slot into an aperture during suturing. Hence, double sutures should apply for each clip type, i.e. Prototype 1 and Prototype 2. Further, the Prototype 3 consists of single aperture and slot.

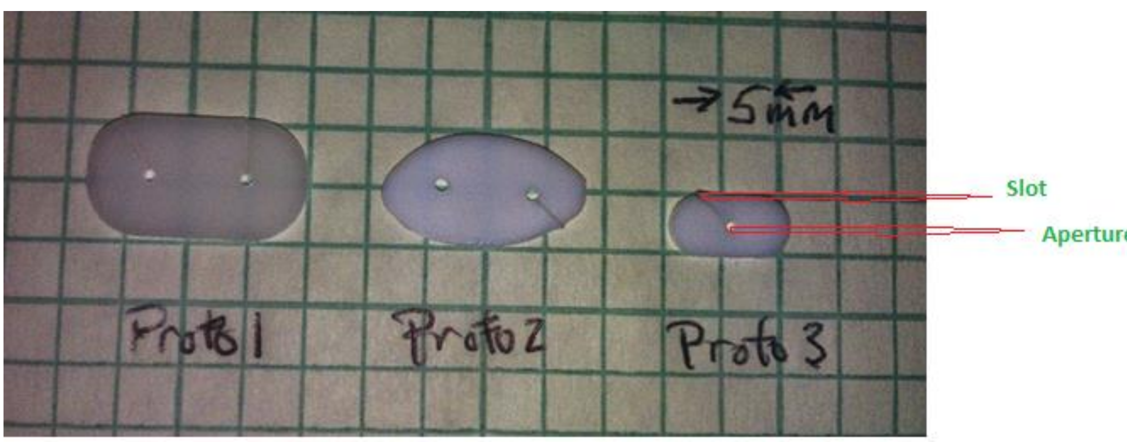

Figure 8: Prototype clips type

The maximum tension holding capability of an anchor is the amount of tension that can be applied on the suture without tissue damage. The prototype clips are not designed to secure the tension on the suture to maintain hemostatic condition, so a knot or LAPRA-TY clip is required to backstop the anchor. Failure in suture anchor generally occurs either with insufficient holding strength of anchor causing slippage of suture or with tearing of renal parenchymal tissue while applying tension during suturing[8].

The objective of this experiment was as follows: 1. To compare prototype anchors (clips) with conventional anchors, i.e. Hem-o-lok anchor 2.To determine the effectiveness of the prototype clips to bolster the suturing so that associated suture strands are less prone to ripping, tearing, or slicing through the tissue adjacent a wound, incision and void. The analysis was based on the clip's size and design. 3. To determine the amount of force that can be applied safely using the suture anchors which helps to prevent postoperative complications including hemorrhage.

Methodology

This experiment was a comparison of prototype suture anchors (clips) with conventional suture anchors, i.e. knot and Hem-o-clips. The comparison was based on the amount of force required for the renal parenchymal tissue to tear using those anchors. This experiment helped to conclude the effectiveness of prototype anchors developed by Dr. Lane as this design was designed to reduce the tearing of the real parenchymal tissue and to increase the tension holding capability of kidney for a hemostatic condition. The kidney samples for a test was came from plants processing agriculturally raised pork. The quality of kidney was preserved by ice during the storage interval.

To apply the tension on renal tissue, an automated material testing system (MTS Mini-Bionix) was used with the Wagner FDV-10 digital force gauge (DFG). The MTS Mini-Bionix controlled the velocity and an acceleration of tension applied on the suture and the DFG measured the force applied on the suture. The DFG is an electronic force gage with an accuracy of ±0.3% ± 1 least significant digit. The MTS Mini-Bionix is a machine used to test peel, tear, shear, tensile, compression, and flex/bend of a material. In this experiment this machine was used to apply tension to an attached suture with control on acceleration and velocity. Movement of the crosshead of this machine determines the amount of tension applied on sutures. The figure 9 shows the MTS Mini-Bionix.

Figure 9: MTS Mini-Bionix

To measure the force applied, the clamping jaw was removed from the MTS and the Wagner DFG was attached to the Mini-Bionix ram as shown in figure 10. Station manager software was used to control the MTS ram speed. Travel speed of the ram was adjusted to a constant 1 cm per second to minimize the effect of acceleration during tension on renal tissue.

Figure 10: DFG with MTS mini Bionix

The calibration of DFG was completed by hanging laboratory masses from the force gauge and verifying the displayed value. The displacement of the MTS Mini-Bionix was calibrated by the ruler. Figure 11 shows the calibration of DFG and MTS Mini-Bionix.

Figure 11: Calibration of DFG and MTS Mini Bionix

The kidney samples for a test came from plants processing agriculturally raised pork. The quality of kidney was preserved with ice during the storage of approximately 5 hours. During an experiment, an approximately 4 cm diameter by 2 cm deep defect was created on the porcine kidney representing the removal of a tumor using techniques regularly employed in laparoscopic partial nephrectomy (LPN) surgeries as shown in figure 12. Similarly, a channel was created at the two ends of the kidney which helped to pass the sutures towards the DFG hook without interfering with tissue during an experiment. The surgeon sutured the void using Vicryl 2-0 sutures and the clips. The slippage of clips was secured with a knot for all clips.

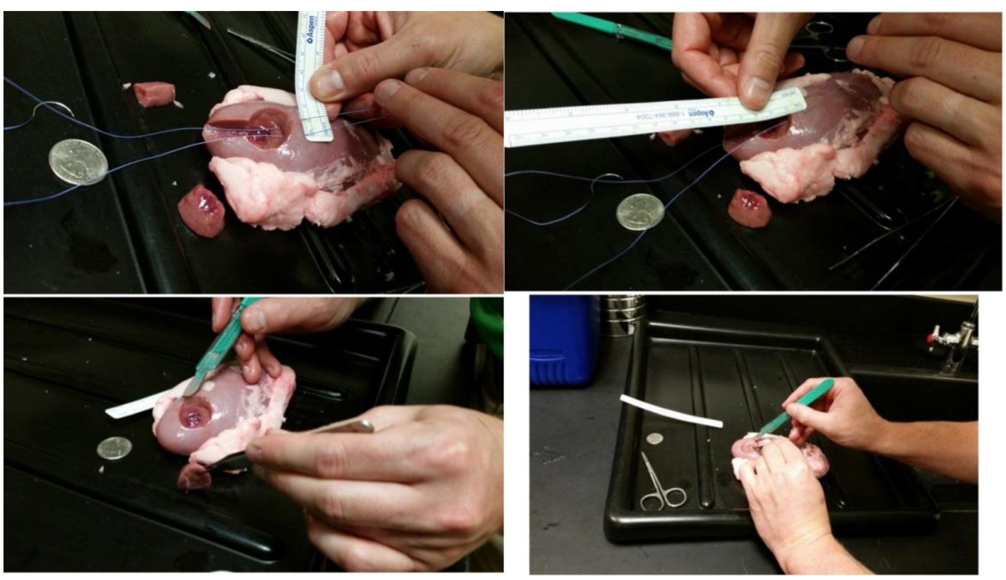

Figure 12: Defect on kidney creating Procedure

During the experiment, two sutures were applied at 1 cm margin from the wound for all different type of anchors to make identical suturing condition with Prototype 1 and Prototype 2. The experiment was performed with double Hem-o-lok clips, double Prototype 3 clips and double knots with a distance between the sutures of 0.8 cm. This distance between sutures is the same as a distance between the apertures in Prototype 1 and Prototype 2 clips. Figure 13 shows the prototype clip and Hem-o-lok clips applied on a porcine kidney.

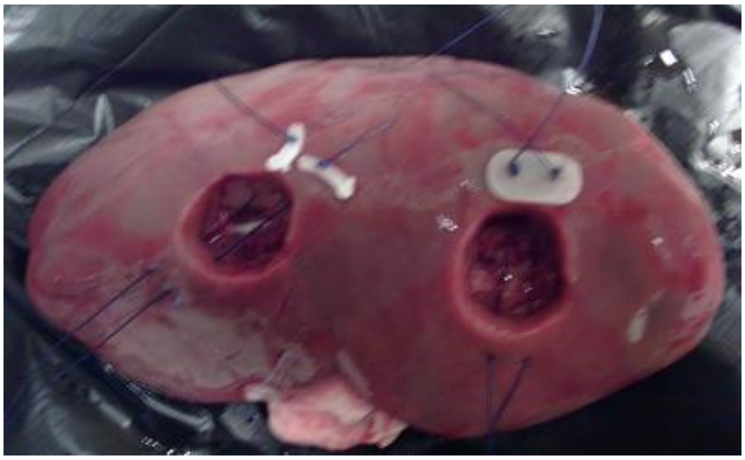

Figure 13: Comparison of prototype clip and Hem-o-lok clips

The revolving holder was designed to position the kidney during an experiment as shown in figure 14. The sampled kidney was positioned in the revolving kidney holder attached with medical leucoplast (medical tape) and latex free self -adherent wrap. The positioned kidney could revolve in different angles and could fix using a locking system on a design.

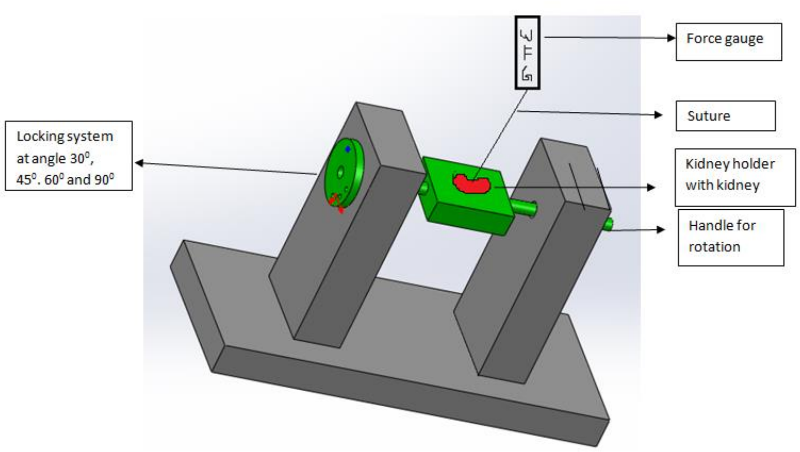

Figure 14: Design of revolving kidney holder

The holder was positioned at vertical plane to represent the suturing force applied on sutured tissue similar to the suturing force applied during a surgery. The tail of the sutures were connected and attached to a Wagner force gauge (WFG) for tension measurement. The revolving holder with MTS Mini Bionix and DFG is shown in figure 15.

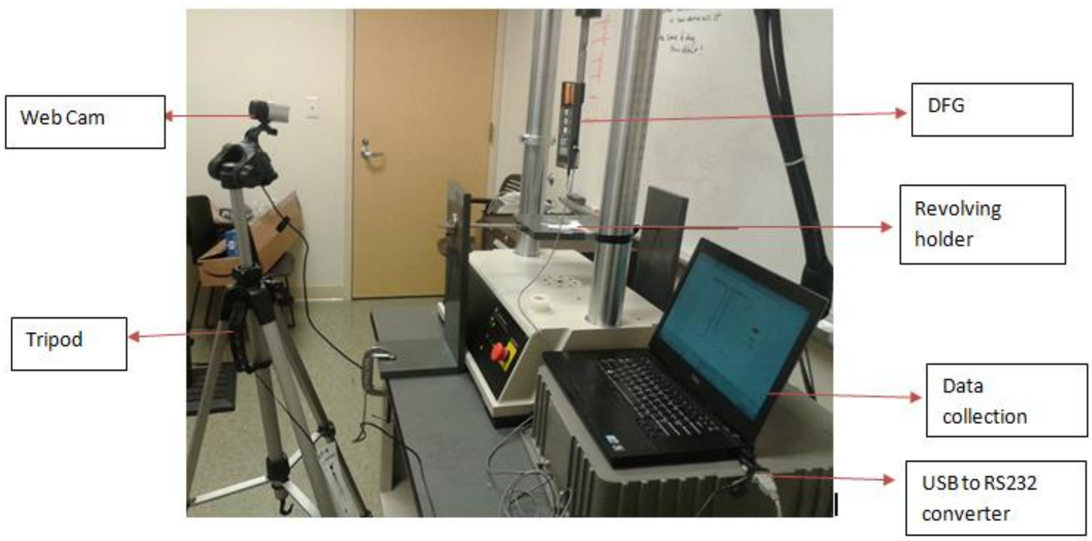

Figure 15: Revolving holder with MTS Mini Bionix and DFG

Suture was pulled with the help of a MTS Mini Bionix machine at a speed of 1 cm per second. The applied tension was directly recorded on a laptop interfaced to the WFG using a Matlab program. Failure tension data was obtained by continuing to increase the force on the suture until the tissue damage occurred which resulted in rapid decrease in applied suture tension as shown in figure 16. The procedure was also visually recorded by a high-definition web camera as shown in experimental setup figure 15[22].

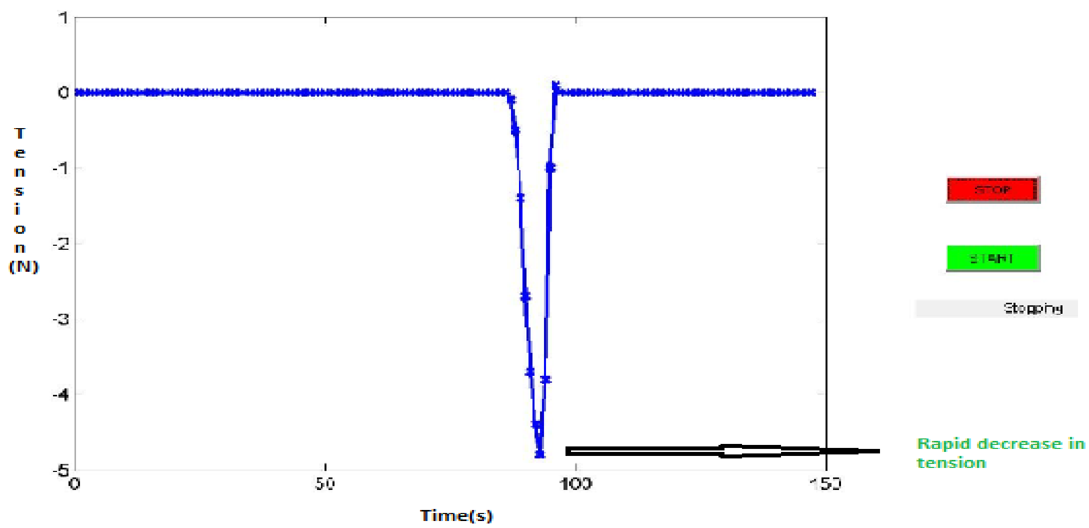

Figure 16: Tension holding strength of renal tissue

Force measured by the DFG was recorded in the computer using a Matlab program to record and post process tension data[23]. The program included a graphical user interface, which provided START/STOP control with feedback and real-time graphing of force recorded by DFG[23]. The Matlab program for post-process tension data eliminated the need of for hand-written calculation as the program collected force measurement directly in an Excel sheet[23]. Digital force gauge with the MTS Mini-Bionix test station and station manager software enabled force measurement. The figure 17 shows the block diagram of data recording procedure for this experiment.

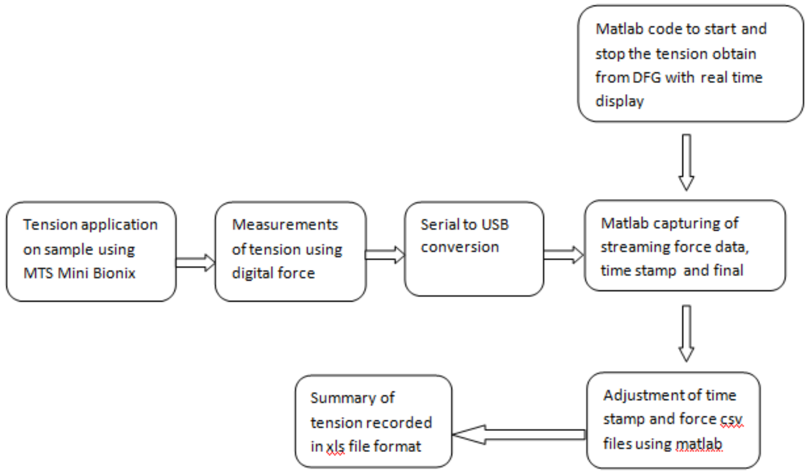

Figure 17: Block diagram of data recording process

Result

The tension at which renal parenchyma tissue failed during an experiment was recorded. The total number of samples for this experiment was 30. The mean failure tensions for suture anchors were knots (2.7N ± 0.53N), Prototype 2(4.0 N± 1.6N), Hem-o-lok (5.4 N+0.72N), Prototype 1(5.6 N±0.75N), and Prototype 3(6.0 N±3.39N). The normality of tissue failure tension recorded for five different anchors was analyzed using Shapiro Wilk test[24, 25]. The p-value of this test was 0.3228 which is greater than significance level indicating that the Studentized Residual of collected data is normally distributed. Levene's test was used to test the equality of the variance for tension data collected for different anchors. Data collected from this experiment has the weak evidence of normal distribution, hence, Levene's test was chosen for variance test. The data collected for different anchors has unequal variance, as a p value is 0.0154, which is less than significance level, i.e. 0.2, for Levene's test.

Welch's test was used to compare the anchors from each other with condition of unequal variance and normally distributed studentized residual[24, 25, 26]. The p-value of Welch's test was 0.0039, which is less than 0.05. The Welch's test provided a significant evidence of difference in mean tension recorded for five different anchors. Figure 18 shows the mean value and S.D of tension data for each anchor type with significant difference between a standard stop knot with anchors Hem-o-lok, Prototype 1 and Prototype3.

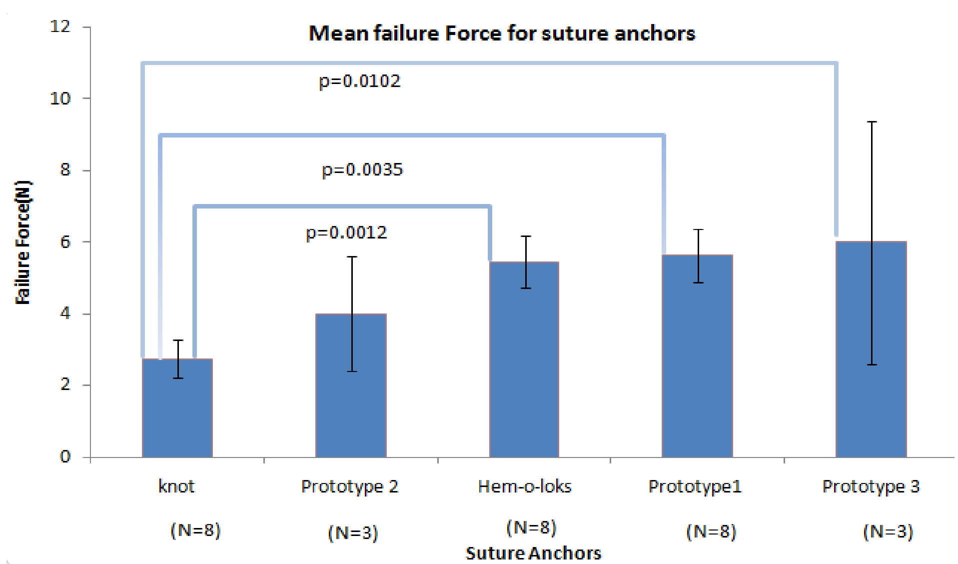

Figure 18: Mean failure force for suture anchors

Multiple comparisons were performed to determine the relationship between five suture anchors using Tukey's HSD test as shown in table 1. The anchors Prototype 1, Prototype 3 and Hem-o-lok were significantly different from anchor knot, as the p value is less than 0.05. The anchors Prototype 3, Prototype 1 and Hem-o-lok were not significantly different from each other. The tension at which renal tissue failed using knots as anchor was significantly different from the other four anchors, as it failed at tension 2.73 N. During partial nephrectomy suturing, the surgeon rarely anchors the suture with knots without additional clips.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Prototype3	knots	3.262500	0.905237	0.60393	5.921067	0.0108*
Prototype1	knots	2.925000	0.668562	0.96152	4.888482	0.0016*
Hem-o-lok	knots	2.712500	0.668562	0.74902	4.675982	0.0036*
Prototype3	Prototype2	2.000000	1.091757	-1.20635	5.206352	0.3785
Prototype1	Prototype2	1.662500	0.905237	-0.99607	4.321067	0.3761
Hem-o-lok	Prototype2	1.450000	0.905237	-1.20857	4.108567	0.5100
Prototype2	knots	1.262500	0.905237	-1.39607	3.921067	0.6366
Prototype3	Hem-o-lok	0.550000	0.905237	-2.10857	3.208567	0.9726
Prototype3	Prototype1	0.337500	0.905237	-2.32107	2.996067	0.9956
Prototype1	Hem-o-lok	0.212500	0.668562	-1.75098	2.175982	0.9976

Table 1: Comparison of mean tension value between different anchors (pairwise comparison Tukey's HSD at the confidence level 95%)

Discussion

The Tukey's HSD test at the confidence level 95% had shown no significant difference in maximum tension holding capability between the anchors Prototype 1, Prototype 3 and Hem-o-lok. However, those anchors were significantly different from knots. Prototype 2 was neither significantly different nor similar to other anchors. This implies that the amount of tension required tearing the tissue during partial nephrectomy suturing increases with increase in clip area. In addition, the mean tension for tissue failure with only knot as an anchor was smaller than other anchors. Furthermore, the configuration of knot as an anchor is significantly different in maximum tension holding capability with the confidence level of 95% from the anchors Prototype 1, Prototype 3 and Hem-o-lok anchors. During an experiment, the suturing of renal tissue using knot as an anchor failed on average at a tension of 2.7 N. The minimum surface area of knot while suture was pulled against tissue caused this failure. Hence, it is not recommended to use only a knot as an anchor during partial nephrectomy suturing. The condition of renal tissue suturing failure was tissue tear for all anchor types. There was no slippage of knots applied on anchors. The approximate mean tensions at which the renal parenchymal tissue failed using anchors were knots (2.7N), Prototype 2(4.0 N), Hem-o-lok (5.4 N), Prototype 1(5.6 N), and Prototype 3(6.0 N) at the 95% confidence level.

The experimental condition, i.e. suturing kidney with different clips as anchor backstopped by a knot closely mimicked the clinical scenario of suturing during partial nephrectomy. This condition was compared with the knot as only anchor without the clips. The experiment has shown that anchors larger than a knot improves the tension holding capacity of renal tissue suturing. The tension required tearing tissue using Prototype 1, Prototype 2, Hem-o-lok and Prototype 3 were more than that of knot. In addition, our findings are consistent with tensions measured by Endres (2013)[8] in a previous experiment to control bleeding during both perfused and non-perfused condition of kidney.

NU-KNIT is soft, pliable weave designed to hold a suture and its appropriate placement on delicate tissue. An experiment was also performed to analyze the efficacy NU-KNIT to increase the amount of tension required to tear the renal tissue throughout suturing. However, there was not enough samples size to conclude the efficacy of NU-KNIT. The renal capsule is a tough fibrous layer surrounding the kidney and is covered in a thick layer of perinephric adipose tissue. It provides some protection from trauma and damage to a kidney. This experiment has shown that the tension required tearing the renal parenchymal tissue increases when capsule is included during suturing. The additional tension can be applied during suturing to maintain hemostatic condition in the presence of the renal capsule.

Limitations of this experiment are as follows: 1. Variation in tension required to tear renal parenchymal tissue was due to variation of suturing depth and margin. Once the pressure on the tissue was dispersed by anchors, the defining factor for tissue tearing was the cutting action of the suture. The properties of renal tissue varied in depth within a kidney; we found that the tension required to tear the outer cortex tissue is less than inner medulla tissue. 2. Variation in amount of capsule in the kidney samples was another limitation. The tension required to tear renal tissue with capsule was more than the tissue without capsule. 3. Preservation of tissue due to variable amount of storage time of the sample kidney. 4. Small number of samples limited the statistical relevance of the tests.

Experiment 2: Analysis of time required for absorbable sutures with a given tension expected to support

Background/Literature review

Manufacturers of suture routinely test suture material for tensile strength as part of quality control procedures. Several independent comparisons of sutures have been performed to determine the suture strength. Some in vitro and animal studies have shown that pH and bacterial activity can affect selected suture products [27, 28]. A few researchers have conducted in vitro and animal tests of sutures to quantify tensile strength at selected durations of exposure to environments simulating in vivo conditions [27]. All have used tensile testing at predetermined time intervals to estimate life expectancy. Results from these studies are reported as absolute tensile strength of the sutures. None of these studies have measured and reported the time to failure at the tension necessary to achieve hemostasis in the perfused kidney.

During suturing, suture type should be chosen based on its physical and biological properties, assessment of local conditions in a wound, and the healing rate of tissue[29]. Normally body tissue heals within 21 days of a surgery. Therefore, it is very necessary for a suture to hold the tension on it for at least 21 days after surgery to maintain homeostatic conditions and to prevent the risk of re-surgery. Absorbable suture materials tend to degrade with time and lose its tensile strength within 60 days, as it will be absorbed by the body. For a partial nephrectomy, the experiment conducted by GVSU master's student Don Endres had shown that the tension required for a homeostasis condition is 3.42 +/- 0.7 N during hyper-tension conditions and 3.2 ± 0.7 N during normal condition. This research helped to understand the tension required for homeostasis during systolic blood pressure representing both normal blood pressure and hypertensive cases[4, 23]. The purpose of this experiment is to analyze the tensile strength of different absorbable sutures used in partial nephrectomy while maintaining similar conditions to the body, i.e. control of temperature and suture tension. This experiment simulates the in-vivo condition with temperature was controlled with the help of saline water, a temperature controlled heater and a circulating pump.

The purpose of this experiment is to analyze the ability of different absorbable sutures to maintain 4.0 N of tension over a period of time required for healing. During partial nephrectomy the amount of tension required to achieve hemostasis in the perfused kidney is 4.0 N [4, 23]. This experiment maintains the in-vivo simulated condition with control of temperature. The result of this experiment will help to explain lifespan of absorbable sutures being used in LPN required for healing defected renal parenchyma tissue after surgery. Further, it also helps to compare breakage time for different types and sizes of sutures. This experiment simulates the in-vivo condition where temperature was controlled with the help of saline water, a temperature controlled heater and a circulating pump.

Methodology

During this experiment a 4ft x 2ft x 1 inch glass tank was used with a suture support frame designed with PVC rod pipe as shown in figure 19. Each suture was attached to a spring balance to apply tension of 4.0 N for simulation of hemostasis in the perfused kidney [4]. The tank was filled with saline solution submerging entire the suture. The spring balances were left dry to reduce the corrosive effect of the saline on the spring element during the experimental period. A heater was placed inside the tank to keep the temperature of the solution at approximately 37 degrees and a recirculation system was used to match the temperature throughout the tank. The temperature of the water was maintained by using a sensor with a feedback system[30].

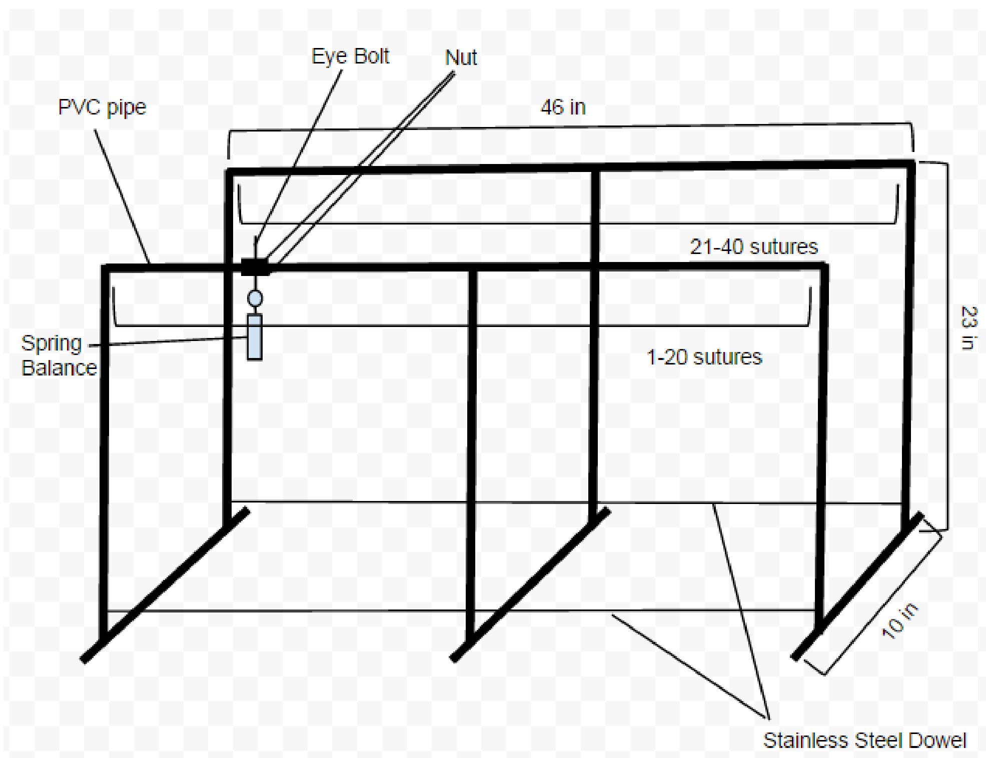

Figure 19: Hook support structure design

During the experiment the spring balance iron hook was replaced by the hook designed by makerbot machine to prevent the iron hook from rusting. The modified hook helped to anchor the suture with the Hem-o-lok clip and knot at 4.0 N of tension. The Hem-o-lok clip helped to apply the amount of tension required, whereas the knot prevented the slippage of applied tension. Two different kinds of polymer hooks were designed as shown in figure 20. The bottom hook was anchored to a tank base rod, whereas the upper hook was designed for use with a spring balance. Further, the hooks with small, 0.05 cm diameter holes in the base provided a place to anchor the suture with the Hem-o-lok and knot. The spring balance helped to detect applied tension on suture which was adjusted by pulling the spring. The spring balance was connected to an upper PVC rod of a tank with the help of upper hook using a bolt and nut system. The system was adjusted by loosening or tightening the nut to change the height of the spring. The change in height of a spring balance helped to adjust the tension on the suture. After setting tension of 4N, lid of the tank was closed to reduce the rate of water loss from evaporation.

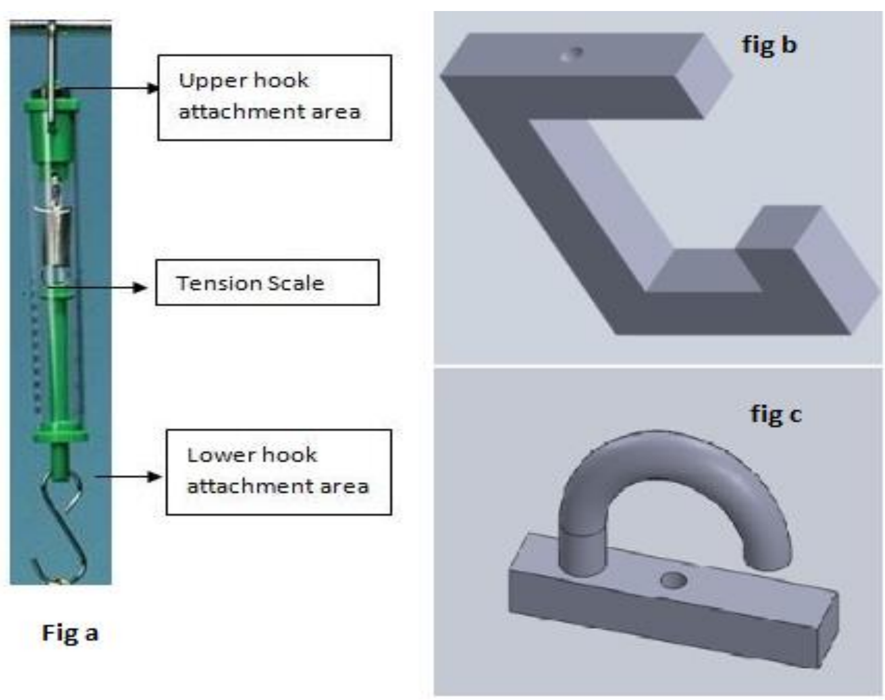

Figure 20: Hooks and spring balance: a. spring balance b. Lower hook design c. upper hook design.

Tension was applied on sutures with the help of designed hooks, spring balances, Hem-o-lok clips, figure '8' knots and the tank arrangement. Both ends of suture were anchored on the hooks with the help of Hem-o-lok clips and knots of the figure '8' type. The knots helped to prevent suture from slippage. The number of figure '8' knots required to prevent the suture from slipping depended on the suture thickness. The thinner sutures required more knots, whereas for thicker sutures even single knots helped to prevent slippage. Figure 21 shows the Hem-o-Lok and knots with a designed lower anchor.

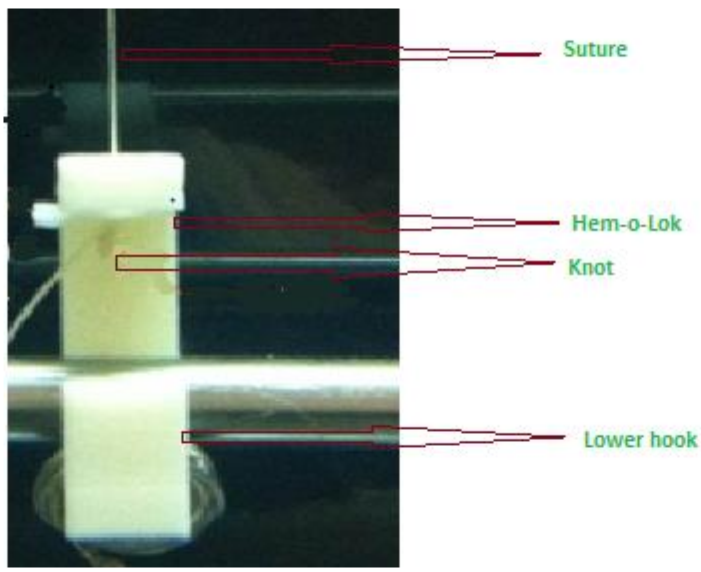

Figure 21: Hem-o-Lok and knots with a lower hook

The steps to make a Figure ‘8’ knot are as follows[32]:

- One end of a suture was taken and folded over itself, but was left space between the end of the suture and the rest of it, forming a bight.
- The end was twisted over the suture itself, which formed a small loop. Finally, placed the end of the suture was placed into the loop and tightened as shown in figure 22.

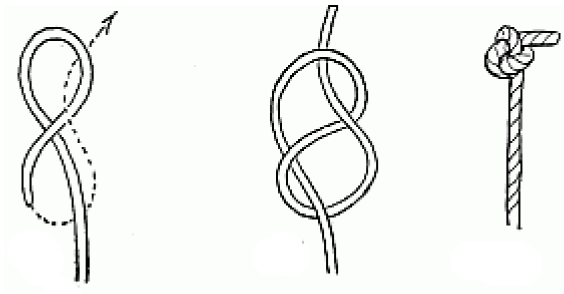

Figure 22: Figure "8" knot

The knots were used to prevent the slippage of the Hem-o-lok clip. The distance between two hooks was adjusted to 12 cm to apply 4.0 N tensions on the suture with the help of the spring balance. Further, the lower hooks were wrapped with steel wire to increase the density of hooks more than density of saline water. The higher density hooks were easy to hook on to the tank base rod inside the saline water. The sutures used for this experiment were as follows: Vicryl 0, Vicryl 2-0, Vicryl 3-0, Vicryl 4-0, Vicryl 5-0 (negative control), Chromic 0, Chromic 2-0, Chromic 3-0, Chromic 4-0, PDS 1(positive control),PGA-PCL 3-0, PGA-PCL 2-0 and PDO Stratafix

The sutures were submerged inside the 0.9% saline water, applied 4.0 N tension and were monitored with the help of a web cam which captures images of the experimental setup at an interval of 15 minutes. The monitoring system was used to determine the time of suture failure. Software to save webcam image save software was downloaded in a laptop and the Microsoft Life cam webcam was connected to the computer. A Google drive folder was used to store the images recorded by the software[22]. Finally, the Google drive folder was used to send the images to the Google drive online. The experimental setup is shown in figure 23.When a suture fails the following steps were taken:

1. All of the sutures fragments and Hem-o-lok clips were taken out of the tank using long forceps without disturbing other sutures.
2. The piece of the failed suture was laid out on a table and a picture was taken with all of the suture fragments lined up.
3. The pieces of the failed suture were examined for the breakage point and this point was noted in a data collection spreadsheet.
4. The suture fragments and the Hem-o-lok clips were placed in an envelope labeled with the date and time of the failure, hanger number and name of the suture.
5. Webcam images taken just prior to failure the one taken just after failure were included in a folder.

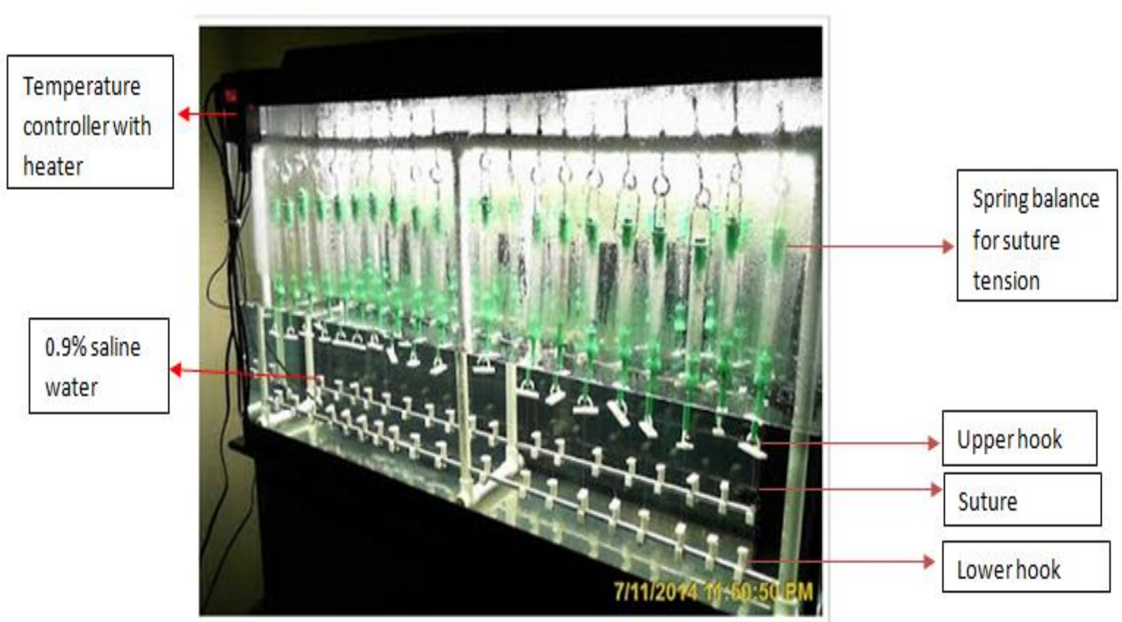

Figure 23: Experimental setup for tensile strength analysis of absorbable suture

Result

Due to the large variance and not symmetrical distribution in the experimental results, the duration of tension holding time was calculated with the help of the median calculation rather than mean. During median analysis the effect of outliers is comparatively less than mean. The negative control had a median duration of 6.5 minutes. The positive control had a median duration of more than 120 days. Besides the Vicryl 5-0 all other sutures had a median duration of 21 days or more than 21 days. The Chromic 2-0 and Chromic 0 had a median duration of more than 120 days. Figure 24 shows the median sutures duration of failure.

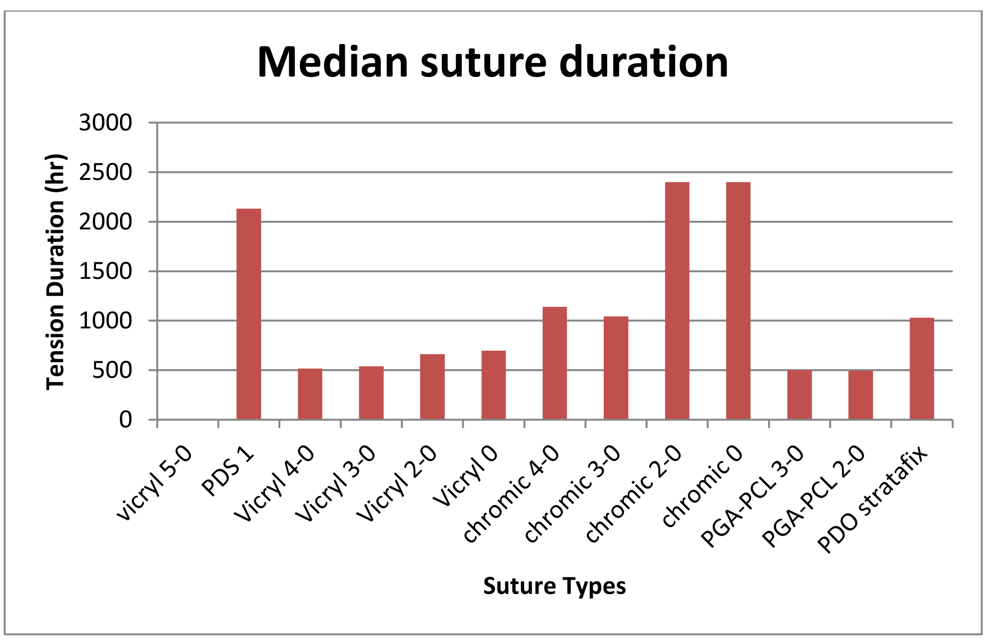

Figure 24: median sutures duration of failure

Discussion

Tables 2 and 3 show the individual suture failures before 7 days and the 21 days respectively. The visual observation of an experiment and failed suture indicates that the suture failed before 7 days are due to slippage of knots from Hem-o-lok clips. And the sutures that failed during 21 days are due to suture breakage. We can conclude from the analysis that the commonly used LPN sutures Vicryl 2-0 and Vicryl 3-0 do not break within 21 days while continuous supporting a tension of 4N. On the contrary, we found that the suture that failed before 7 days are commonly due to knot slippage. Therefore, multiple knots should be applied while using the Vicryl sutures. This experiment shows that the sutures currently in practice for LPN hold 4-0 N tension for at-least 21 day with proper anchor to prevent slippage. However, sutures Vicryl 5-0, Vicryl 4-0 and Vicryl 2-0 with minimum number of knots, i.e. 3-4 knots may not hold 4.0 N tension due to slippage The LAPRA-TY clip helps to prevent the slippage of tension applied during LPN suturing. The LAPRA-TY clip used to backstop the 4.0 N tensions applied on sutures. However, the clip did not hold the tension for all suture types. Hence, the clip was replaced by the figure “8” knot to backstop the tension applied on sutures with hem-o-lok clip. The LAPRA-TY anchor also helps to prevent the slippage of suture; however, according to the manufacturer, it should be used only for the specific sizes of Vicryl sutures.

Suture failure before seven days		
Vicryl 4-0	1 min	knot slippage through Hem-o-lok
Vicryl 5-0	4 min	knot slippage through Hem-o-lok
Vicryl 5-0	5 min	knot slippage through Hem-o-lok
Vicryl 5-0	8 min	knot slippage through Hem-o-lok
Vicryl 5-0	1 hr 34 min	knot slippage through Hem-o-lok
Vicryl 2-0	5 days 18 hr 30 min	knot slippage through Hem-o-lok

Table 2: suture failure before seven days

Suture failure before 21 days		
PGA-PCL 2-0	19 days 1 hr 34 min	breakage near upper knot
PGA-PCL 2-0	20 days 13 hrs 19 min	breakage near upper knot
PGA-PCL 3-0	20 days 18 hrs 30 min	breakage near middle of suture
PGA-PCL 3-0	20 days 7 hrs 29 min	breakage near lower knot
chromic 4-0	20 days 7 hrs 16 minutes	breakage near middle of suture
Vicryl 3-0	20 days 9 hrs 41 minutes	breakage near lower knot

Table 3: suture failure before 21 days

Experiment 3: Investigation on holding strength of a Hem-o-lok backstopped by Lapra-Ty clip on various suture types and sizes

Background/Literature review

LAPRA-TY clips are commonly used in laparoscopic surgery as suture anchors because the knot as an anchor is technically challenging, time consuming and can lead to prolongation of warm ischemia time [9, 12]. Warm ischemia is the time in which the kidney remains at physiological temperature during absence of blood supply due to clamping of the renal hilar [12, 33]. During partial nephrectomy for larger and deeper tumors, the 30-minute cutoff is the accepted safe limit; time beyond this may cause irreversible kidney damage due to absence of blood flow [34]. Many laparoscopic surgeons use a LAPRA-TY clip as a substitute for knot tying to improve efficiency during partial nephrectomy surgery [35, 36]. The manufacturer of LAPRA-TY clip states that the product is intended "for use with single strands of coated Vicryl (polyglactin 910) suture coated with polyglactin 370 and calcium stearate dyed (violet) braided synthetic absorbable sutures (sizes 2-0, 3-0, and 4-0)[37]." However, some laparoscopic surgeons are applying LAPRA-TY clips to monofilament suture during vesicourethral anastomosis during laparoscopic radical prostatectomy. A vesicourethral anastomosis is the most challenging and time-consuming step of radical prostatectomy[37]. It is a process of connecting the bladder neck with the membranous urethra. The experiment on holding strength of LAPRA-TY and Hem-o-lok clips for different sutures helps to find the tension at which the clip starts to slip from the suture.

Robot-assisted partial nephrectomy (RAPN) is an emerging technique for minimally invasive nephron-sparing surgery that may facilitate the technical challenges of sutured renorrhaphy[38].

Barbed suture is a technology that has been used for RAPN as it increases efficiency, decreases warm ischemia time, and creates a non-significant reduction in overall procedure time [20, 21]. The barb grasps tissue at numerous points providing distribution of tension across the wound and eliminates the need for tying knots[211]. However, when faced with newer barbed sutures, many surgeons are initially skeptical with regard to the strength of the knotless, barbed suture lines as compared with traditional knotted, smooth suture lines[21]. There are limited reports regarding the holding strength of Hem-o-lok clips backstopped with LAPRA-TY anchors for barb suture.

In an experiment conducted by Kyle J. Weld, LAPRA-TY holding strength and displacement were determined with 0, 2-0, 3-0, and 4-0 Vicryl, Monocryl, and Polydioxanone suture (PDS) using an automated materials testing system[37]. Material Testing System(MTS) or Automated Materials Testing System (AMTS) help to evaluate the mechanical properties of materials and components using tension, compression, flexure, fatigue, impact, torsion and hardness tests. AMTS recorded raw data and computed the load over time. The holding strength was defined as the maximum load recorded at the instant just before failure (detachment of suture from LAPRA-TY when the load was applied at a constant speed of 12 mm/min on the suture against LAPRA-TY) [37]. Displacement was defined as the distance traveled by the AMTS arm until the failure. The experiment showed that the holding strength for 0 Vicryl and Monocryl was significantly greater than for 0 PDS, for 2-0 Vicryl was significantly greater than for 2-0 Monocryl and PDS, and for 3-0 Vicryl was significantly greater than for 3-0 Monocryl and PDS[23]. The figure 25 shows the result of an experiment conducted by Kyle J. Weld[37].

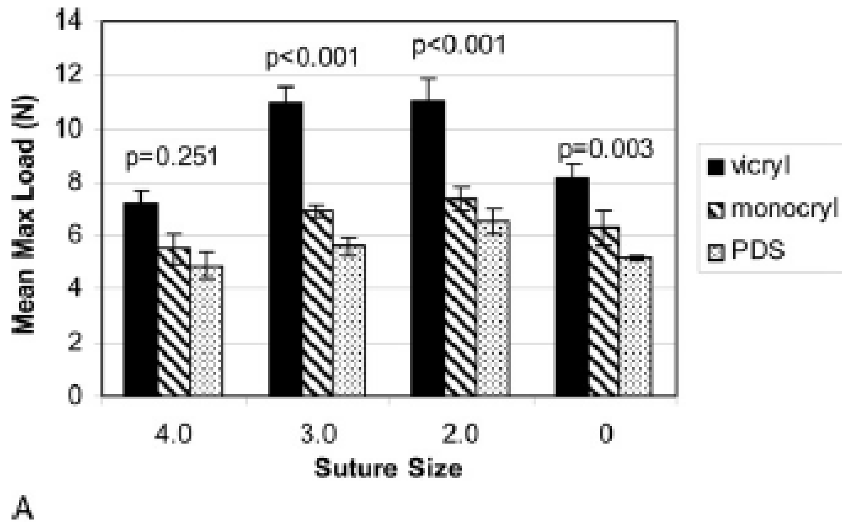

Figure 25[37]: Mean LAPRA-TY holding strength

The experiment conducted by Jesse Sammon described the clinical study of barbed suture for renorrhaphy during RAPN in human patients and compared perioperative outcomes to RAPN with polyglactin suture. The result had shown that the barbed suture simplifies the renorrhaphy technique during RAPN and improves efficiency, allowing for reduced warm ischemia times[20].

During LPN suturing, the holding strength of tissue is defined as the maximum load recorded at the instant just before tissue failure. In this experiment, the holding strength is defined as the maximum tension recorded at the instant just before the LAPRA-TY slippage. The use of LAPRA-TY is common during laparoscopic surgery because the use of knots as anchors is technically challenging and time consuming. LAPRA-TY slippage could cause loosening of the suture, inadequate tissue approximation, and potentially urinary extravasations[39, 40]. The purpose of this experiment is to analyze the tension holding capability of Hem-o-lok backstopped by LAPRA-TY anchor for different sutures: Vicryl, Monocryl, and Chromic, Vloc and Stratafix. From the first experiment, we found that the amount of the tension that can be applied safely without observable tissue damage in renal parenchyma tissue during suturing was approximately 5 N using Hem-o-lok anchors with knots as backstop. This experiment helps to find whether the Hem-o-Lok clip backstopped by LAPRA-TY hold the tension of at least 5 N for a variety of suture types and sizes.

Methodology

The holding strength of LAPRA-TY anchor for different sutures like Vicryl, Monocryl, Chromic, V-Loc and Stratafix was tested using mechanical testing system, MTS Mini Bionix and Wagner FDV (digital force gauge). The Digital Force Gage is an electronic force gage with Accuracy ±0.3% ± 1 least significant digit (LSD). Suture tension can be estimated using a Wagner FDV-10 digital force gauge (DFG) with a 10 pound (0 to 44 Newton) load cell in place with 0.1 N resolutions. Calibration was done by hanging laboratory masses from the force gauge and verifying the display value with graphs recorded from Matlab program. Matlab was used to record tension with time applied to suture. Similarly, the MTS Mini-Bionix machine was used to control the effect of acceleration and velocity during an experiment. Movement of crosshead of this machine determines the amount of tension applied on sutures. To measure the force applied, the clamping jaw was removed from the MTS and the Wagner DFG was attached to the Mini-Bionix ram. Station manager software was used to control the MTS ram speed.

During this experiment the length of the suture and the position of the LAPRA-TY clip were made constant. The length of the suture was 14 cm and a LAPRA-TY clip was applied exactly 1 cm from the end of a suture as a back stop of a Hem-o-lok clip with the help of a LAPRA-TY clip. The suture and LAPRA-TY were submerged in sterile saline just before testing to simulate clinical conditions, i.e. suture passing through healthy tissue. The procedure of clip application on suture is shown in figure 26.

Figure 26: Application of clips on suture

The opposite end of the suture was threaded through a 2-mm hole in a specially designed slab before securing it to the clamp design which was attached to digital force gauge (DFG). The clamp design helped to clamp the suture without slippage and to connect suture with DFG as shown in figure 27. During the calibration of a clamp, the suture was marked at the edge of clamp. Tension was applied on suture until it broke or LAPRA-TY slipped with the help of MTS Mini Bionix. The sutures were either slipped or broke without slippage from the clamp. The DFG applied the load on the suture with the help of MTS Mini Bionix. The 2-mm hole allowed the suture to easily slide through the plate but restrained the Hem-o-lok and LAPRA-TY at a fixed position under the slab designed while the load was applied upward on the suture. The constant load was applied at a speed of 12 mm/min.

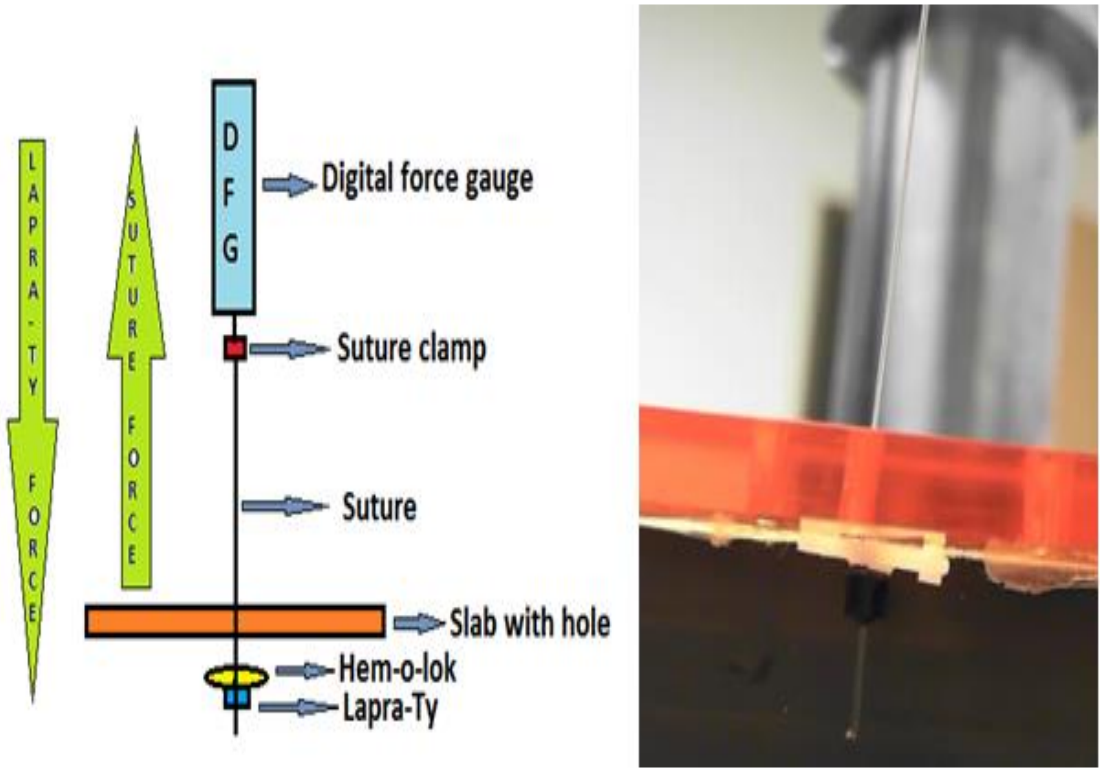

Figure 27: Holding strength of Hem-o-lok back stopped by LAPRA-TY

The applied tension was directly recorded on a laptop as Wagner DFG will interface with the computer so that the force is logged to a file by a Matlab program running on the computer[23]. The increasing tension on the suture will be acquired continuously by the program until the LAPRA-TY slips or suture breaks. This force appears as a sudden sharp decrease on tension recorded by the DFG. USB to serial converter was used as an interface between DFG and computer. Force from DFG was recorded in the computer using Matlab Software. The program includes real-time graphing of force recorded by DFG. Digital force gauge with the MTS Mini-Bionix test station and station manager software enables force measurement. Visual recording of the suture failure will record by the help of high definition web camera. This helps careful review of the suture failure with the applied tension.

The holding strength in this experiment is defined as the maximum load recorded at the instant just before LAPRA-TY slippage. The holding strength of LAPRA-TY clips was recorded for 23 different types of sutures, i.e. Vicryl(1,0, 2-0, 3-0, 4-0), Monocryl(1,0, 2-0, 3-0, 4-0), Chromic(1,0, 2-0, 3-0, 4-0), V-Loc(0, 2-0, 3-0, 4-0) and Stratafix(0, 2, 3, 4). The manufacturer provided tensile strength size, which was used for the Stratafix suture to compare to other sutures. The number of samples for each suture size and type is 7.

Result

The mean holding strength of sutures was determined during post-experiment processing using the Excel software. The holding strength in this experiment is defined as the maximum load recorded at the instant just before LAPRA-TY slippage. The holding strength of clips (Hem-o-lok backstopped by LAPRA-TY clip) was analyzed in two different ways as follows: 1. Comparison of holding strength of clips on different suture types for each suture size. For example, for suture size 2-0 the sutures Vicryl 2-0, Monocryl 2-0, Chromic 2-0, V-Loc 2-0 and Stratafix 2 were compared with each other.

2. Comparison of holding strength of clips on different suture sizes for each suture type. For example, for suture type Vicryl the sutures Vicryl 1, Vicryl 0, Vicryl 1-0, Vicryl 2-0, Vicryl 3-0 and Vicryl 4-0 were compared with each other.

Four different investigations which were conducted in this experiment are listed below:

1. Comparison of holding strength of clips on different suture types for each suture size

2. Comparison of holding strength of clips on different suture sizes for each suture type.

3. Comparison of clips holding time before slippage for suture size 2-0

4. Comparison of holding strength clips for barbed suture, i.e. toward and against barb

1. Comparison of holding strength of clips on different suture types for each suture size

The holding strength of clips (LAPRA-TY clip backstopped by Hem-o-lok clip) was compared from one type to another within the suture size. The sutures Vicryl, Monocryl, Chromic, Stratafix and V-Loc were compared from each other within suture sizes 0, 2-0, 3-0 and 4-0. The suture size 1 does not have type Stratafix and V-Loc. The figure 28 shows the mean holding strength of clips for different suture types within each suture size.

JMP software was used to analyze the ANOVA test and post- hoc test. The steps to perform the analysis using JMP software is shown in appendix A. The ANOVA test was used to determine the significant difference between the mean of sutures. Tukey's HSD test was performed to determine significant difference of each suture from other sutures. Tukey's HSD test is a post-hoc test; it is performed after an analysis of variance (ANOVA) test[26]. Tukey's HSD test calculates a new critical value that can be used to evaluate whether differences between any two pairs of means are significant. The post hoc test table shows the higher mean in positive level and a lower mean in negative level. The difference in the table shows difference between mean in positive and negative level.

The lower and upper confidence level (CL) shows the range of value where difference of mean calculated exists. The p-value shows the significance level between the means. If the p value is less than 0.05 the means are significantly different else no difference.

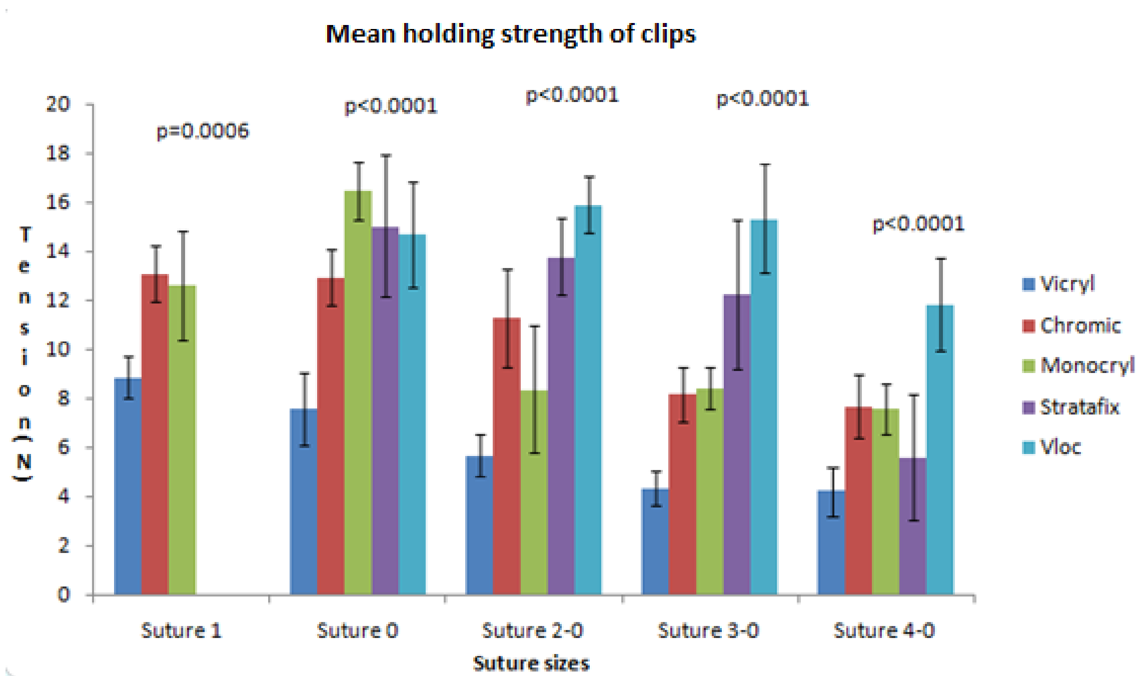

Figure 28: Mean holding strength of clips on different suture types for each suture size

a. Sutures 1

The Shapiro-Wilk W test showed that the holding strength of sutures of size 1 is normally distributed ($p = 0.64 > 0.05$). Whereas, the Levene's test showed that the sutures of size 1 have unequal variance ($p = 0.1551 < 0.2$). Welch's test on suture tensions revealed a significant effect related to tension ($p < 0.0006$).

The Tukey's HSD test was used to determine significant difference of each suture type from other sutures type as shown in table 4. The post hoc test showed that the holding strength of Monocryl 1 and Chromic 1 are significantly higher than the holding strength of Vicryl 1.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Chromic 1	Vicryl 1	4.241071	0.975110	1.75243	6.729711	0.0011*
Monocryl 1	Vicryl 1	3.745833	1.017525	1.14894	6.342724	0.0046*
Chromic 1	Monocryl 1	0.495238	1.048211	-2.17997	3.170445	0.8850

Table 4: Post hoc test for suture size 1 (pairwise comparison Tukey's HSD with confidence interval 95%)

b. Suture 0

The Shapiro-Wilk W test showed that the holding strength of sutures of size 0 is not normally distributed ($p = 0.0272<0.05$). Hence, the normality was checked by obtaining the studentized residual. The Shapiro-Wilk W test of studentized residual showed the holding strength of sutures size 0 normally distributed ($p=0.0842>0.05$). The Levene's test showed that the sutures of size 0 have unequal variance ($p = 0.0787 > 0.2$). The Welch's test on suture tensions revealed significant effect related to tension ($p < 0.0001$).

The Tukey's HSD test was used to determine significant difference of each suture type from other sutures type as shown in table 5. The post hoc test showed that the holding strength of Monocryl -0, Chromic-0, V-Loc 0 and Stratafix 0 are significantly greater than Vicryl-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Monocryl -0	Vicryl -0	8.885714	1.363883	4.92962	12.84181	<.0001*
Stratafix-0	Vicryl -0	7.471429	1.363883	3.51534	11.42752	<.0001*
Vloc 0	Vicryl -0	7.114286	1.363883	3.15819	11.07038	0.0001*
Chromic -0	Vicryl -0	5.383333	1.423210	1.25516	9.51151	0.0058*
Monocryl -0	Chromic -0	3.502381	1.466130	-0.75029	7.75505	0.1462
Stratafix-0	Chromic -0	2.088095	1.466130	-2.16458	6.34077	0.6174
Monocryl -0	Vloc 0	1.771429	1.408612	-2.31441	5.85726	0.7183
Vloc 0	Chromic -0	1.730952	1.466130	-2.52172	5.98362	0.7621
Monocryl -0	Stratafix-0	1.414286	1.408612	-2.67155	5.50012	0.8514
Stratafix-0	Vloc 0	0.357143	1.408612	-3.72869	4.44298	0.9990

Table 5: Post hoc test for suture size 0 (pairwise comparison Tukey's HSD with confidence interval 95%)

c. Sutures 2-0

The Shapiro-Wilk W test showed that the holding strength of sutures of size 2-0 is normally distributed (p = 0.3670), whereas, the Levene's test showed that the sutures of size 2-0 have equal variance (p = 0.2293 > 0.2). An analysis of variance on suture tension revealed significant effect related to tension (p < 0.0001)

The Tukey's HSD test was used to determine significant difference of each suture type from other sutures type as shown in table 6. The post hoc test showed that the holding strength of Vloc 2-0, Stratafix 2 and Chromic 2-0 are significantly greater than the holding strength of Vicryl 2-0, Stratafix 2 and Vloc 2-0 are significantly greater than Monocryl 2-0, and Vloc 2-0 is significantly greater than Chromic 2-0.

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Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Vloc 2-0	Vicryl 2-0	10.21429	1.316892	6.39450	14.03408	<.0001 *
Stratafix 2	Vicryl 2-0	8.08571	1.316892	4.26592	11.90550	<.0001 *
Vloc 2-0	Monocryl 2-	7.54286	1.316892	3.72307	11.36265	<.0001 *
Chromic 2-0	Vicryl 2-0	5.58571	1.316892	1.76592	9.40550	0.0017 *
Stratafix 2	Monocryl 2-	5.41429	1.316892	1.59450	9.23408	0.0024 *
Vloc 2-0	Chromic 2-0	4.62857	1.316892	0.80878	8.44836	0.0115 *
Chromic 2-0	Monocryl 2-	2.91429	1.316892	-0.90550	6.73408	0.2025
Monocryl 2-	Vicryl 2-0	2.67143	1.316892	-1.14836	6.49122	0.2774
Stratafix 2	Chromic 2-0	2.50000	1.316892	-1.31979	6.31979	0.3400
Vloc 2-0	Stratafix 2	2.12857	1.316892	-1.69122	5.94836	0.4990

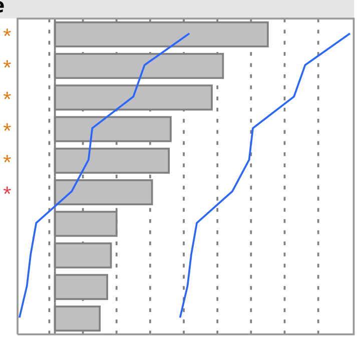

Table 6: Post hoc test for suture size 2-0 (pairwise comparison Tukey's HSD with confidence interval 95%)

d. Sutures 3-0

The Shapiro-Wilk W test showed that the holding strength of sutures of size 3-0 is normally distributed (p = 0.0574). Whereas, the Levene's test showed that the sutures of size 3-0 have unequal variance (p = 0.0143 < 0.2). Welch's test on suture tensions revealed significant effect related to tension (p < 0.0001).

The Tukey's HSD test was used to determine significant difference of each suture type from other sutures type as shown in table 7. The post hoc test showed that the holding strength of Vloc 3-0, Stratafix 3, Monocryl 3-0 and Chromic 3-0 are significantly greater than the holding strength of Vicryl 3-0, Stratafix 3 is a significantly greater than Monocryl 3-0 and Chromic 3-0, and Vloc 3-0 is significantly greater than Monocryl 3-0 and Chromic 3-0.

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Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Vloc 3-0	Vicryl 3-0	10.97143	1.188574	7.52384	14.41902	<.0001 *
Stratafix 3-0	Vicryl 3-0	7.88571	1.188574	4.43812	11.33330	<.0001 *
Vloc 3-0	Chromic 3-0	7.15714	1.188574	3.70955	10.60473	<.0001 *
Vloc 3-0	Monocryl 3-	6.92857	1.188574	3.48098	10.37616	<.0001 *
Stratafix 3-0	Chromic 3-0	4.07143	1.188574	0.62384	7.51902	0.0144 *
Monocryl 3-	Vicryl 3-0	4.04286	1.188574	0.59527	7.49045	0.0152 *
Stratafix 3-0	Monocryl 3-	3.84286	1.188574	0.39527	7.29045	0.0230 *
Chromic 3-0	Vicryl 3-0	3.81429	1.188574	0.36670	7.26188	0.0244 *
Vloc 3-0	Stratafix 3-0	3.08571	1.188574	-0.36188	6.53330	0.0966
Monocryl 3-	Chromic 3-0	0.22857	1.188574	-3.21902	3.67616	0.9997

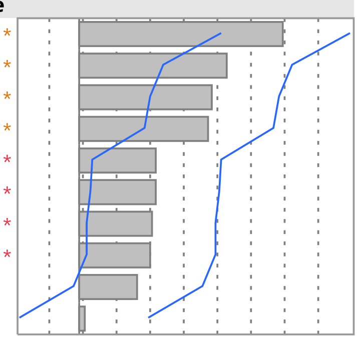

Table 7: Post hoc test for suture size 3-0 (pairwise comparison Tukey's HSD with confidence interval 95%

e. Sutures 4-0

The Shapiro-Wilk W test showed that the holding strength of sutures of size 4-0 is normally distributed (p = 0.0972). Whereas, the Levene's test showed that the sutures of size 4-0 have equal variance (p = 0.5437 > 0.2). An analysis of variance on suture tensions significant effect related to tension (p < 0.0001).

The Tukey's HSD test was used to determine significant difference of each suture type from other sutures type as shown in table 8. The post hoc test showed that the holding strength of Vloc

4-0 is significantly greater than Stratafix 4, Monocryl 4-0, Vicryl 4-0 and Chromic 4-0 and, Chromic 4-0 and Monocryl 4-0 are significantly greater than the holding strength of Vicryl 4-0.

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Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Vloc 4-0	Vicryl 4-0	7.600000	0.9238635	4.92023	10.27977	<.0001 *
Vloc 4-0	Stratafix 4-0	6.214286	0.9238635	3.53452	8.89405	<.0001 *
Vloc 4-0	Monocryl 4-	4.242857	0.9238635	1.56309	6.92263	0.0007 *
Vloc 4-0	Chromic 4-0	4.157143	0.9238635	1.47737	6.83691	0.0008 *
Chromic 4-0	Vicryl 4-0	3.442857	0.9238635	0.76309	6.12263	0.0067 *
Monocryl 4-	Vicryl 4-0	3.357143	0.9238635	0.67737	6.03691	0.0085 *
Chromic 4-0	Stratafix 4-0	2.057143	0.9238635	-0.62263	4.73691	0.1976
Monocryl 4-	Stratafix 4-0	1.971429	0.9238635	-0.70834	4.65120	0.2326
Stratafix 4-0	Vicryl 4-0	1.385714	0.9238635	-1.29405	4.06548	0.5705
Chromic 4-0	Monocryl 4-	0.085714	0.9238635	-2.59405	2.76548	1.0000

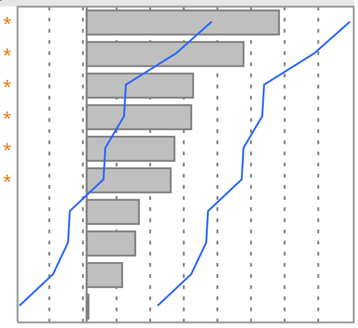

Table 8: Post hoc test for suture size 4-0 (pairwise comparison Tukey's HSD with confidence interval 95%

2. Comparison of holding strength of clips on different suture sizes for each suture type.

The holding strength of clips (LAPRA-TY clip backstopped by Hem-o-lok clip) was compared from one size to another within the suture type. This analysis helps to compare the suture sizes within the suture type. The suture sizes 0, 1, 2-0, 3-0 and 4-0 were compared from each other within suture types, i.e. Vicryl, Chromic, Monocryl, Stratafix and V-Loc. The suture type V-Loc and Stratafix does not have size 1. The figure 29 shows the mean holding strength of clips for different suture sizes within each suture size.

JMP software was used to analyze the ANOVA test and post- hoc test. The steps to perform the analysis using JMP software is shown in appendix A. The ANOVA test was used to determine the significant difference between the mean of sutures. Tukey's HSD test was performed to determine significant difference of each suture from other sutures. Tukey's HSD test is a post-hoc test; it is performed after an analysis of variance (ANOVA) test. Tukey’s HSD test calculates a new critical value that can be used to evaluate whether differences between any two pairs of means are significant. The post hoc test table shows the higher mean in positive level and a lower mean in negative level. The difference in the table shows difference between mean in positive and negative level.

The lower and upper confidence level (CL) shows the range of value where difference of mean calculated exists. The p-value shows the significance level between the means. If the p value is less than 0.05 the means are significantly different else no difference.

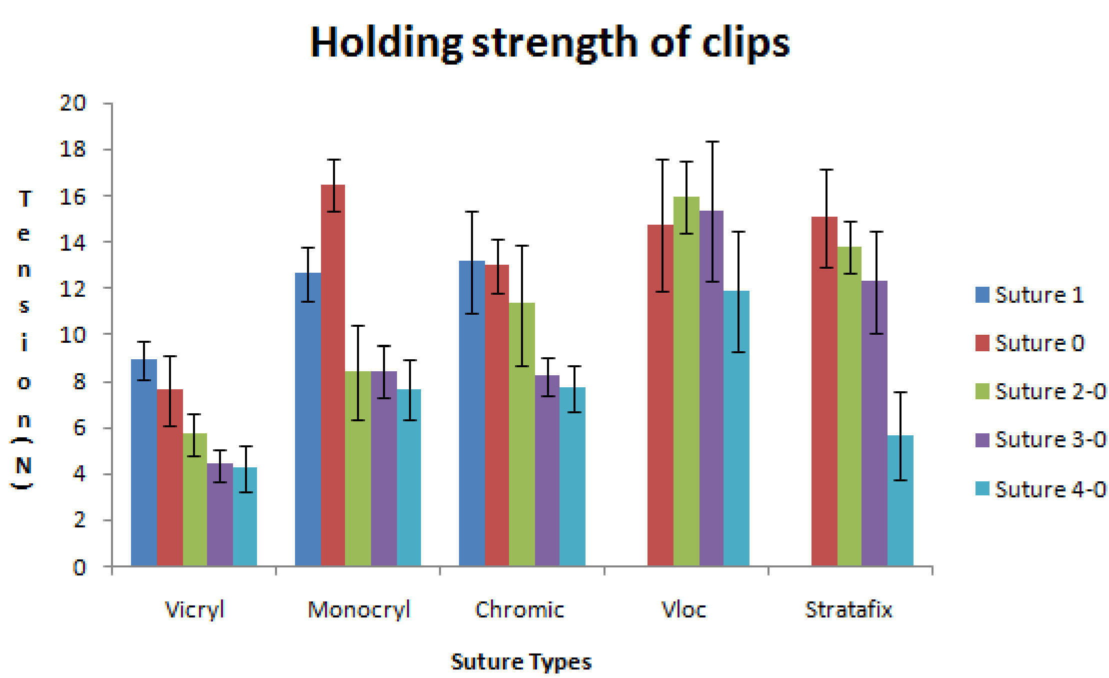

Figure 29: Mean holding strength of clips on different suture sizes for each suture type

a. Vicryl

The Shapiro-Wilk W test showed that the holding strength of Hem-o-Lok clip backstopped by LAPRA-TY clip for Vicryl sutures were normally distributed (p = 0.1570>0.05). Whereas, the Levene's test showed that the Vicryl sutures have unequal variance (p = 0.1158 < 0.2). With a condition of unequal variance, the Welch's test on suture tensions revealed a significant effect related to tension (p < 0.0001).

The Tukey's HSD test was used to determine significant difference of each suture size from other suture sizes as shown in table 9. The post hoc test showed that the holding strength for Vicryl 1 is significantly higher than the holding strength for Vicryl 4-0, Vicryl 3-0 and Vicryl 2-0. Vicryl 0 is significantly higher than Vicryl 4-0 and Vicryl 3-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Vicryl 1	Vicryl 4-0	4.630357	0.7534687	2.45329	6.807428	<.0001*
Vicryl 1	Vicryl 3-0	4.501786	0.7534687	2.32472	6.678856	<.0001*
Vicryl -0	Vicryl 4-0	3.342857	0.7534687	1.16579	5.519928	0.0009*
Vicryl -0	Vicryl 3-0	3.214286	0.7534687	1.03722	5.391356	0.0015*
Vicryl 1	Vicryl 2-0	3.173214	0.7534687	0.99614	5.350285	0.0017*
Vicryl -0	Vicryl 2-0	1.885714	0.7534687	-0.29136	4.062785	0.1152
Vicryl 2-0	Vicryl 4-0	1.457143	0.7781792	-0.79133	3.705612	0.3521
Vicryl 2-0	Vicryl 3-0	1.328571	0.7781792	-0.91990	3.577040	0.4440
Vicryl 1	Vicryl -0	1.287500	0.7279200	-0.81575	3.390750	0.4086
Vicryl 3-0	Vicryl 4-0	0.128571	0.7781792	-2.11990	2.377040	0.9998

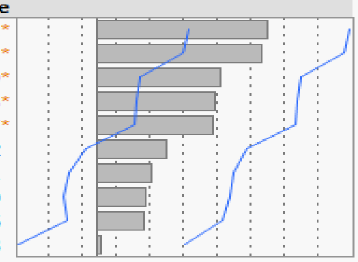

Table 9: Post hoc test for Vicryl sutures (pairwise comparison Tukey's HSD with confidence interval 95%)

b. Monocryl

The Shapiro-Wilk W test showed that the holding strength of Hem-o-Lok clip backstopped by LAPRA-TY clip for Monocryl sutures were normally distributed (p = 0.1041>0.05). Whereas, the Levene's test showed that the Vicryl sutures have unequal variance (p = 0.0399 < 0.2). With a condition of unequal variance, the Welch's test on suture tensions revealed a significant effect related to tension ($p < 0.0001$).

The Tukey's HSD test was used to determine significant difference of each suture size from other suture sizes as shown in table 10. The post hoc test showed that the holding strength for Monocryl 0 is significantly higher than the holding strength for Monocryl 4-0, Monocryl 3-0, Monocryl 2-0 and Monocryl 1. The Monocryl 1 is significantly higher than Monocryl 4-0, Monocryl 3-0 and Monocryl 2-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Monocryl -0	Monocryl 4-0	8.871429	1.205379	5.36761	12.37525	<.0001*
Monocryl -0	Monocryl 2-0	8.100000	1.205379	4.59618	11.60382	<.0001*
Monocryl -0	Monocryl 3-0	8.057143	1.205379	4.55332	11.56096	<.0001*
Monocryl 1	Monocryl 4-0	5.019048	1.254599	1.37215	8.66594	0.0034*
Monocryl 1	Monocryl 2-0	4.247619	1.254599	0.60073	7.89451	0.0162*
Monocryl 1	Monocryl 3-0	4.204762	1.254599	0.55787	7.85166	0.0176*
Monocryl -0	Monocryl 1	3.852381	1.254599	0.20549	7.49927	0.0344*
Monocryl 3-0	Monocryl 4-0	0.814286	1.205379	-2.68954	4.31811	0.9602
Monocryl 2-0	Monocryl 4-0	0.771429	1.205379	-2.73239	4.27525	0.9671
Monocryl 3-0	Monocryl 2-0	0.042857	1.205379	-3.46096	3.54668	1.0000

Table 10: Post hoc test for Monocryl sutures (pairwise comparison Tukey's HSD with confidence interval 95%)

c. Chromic

The Shapiro-Wilk W test showed that the holding strength of Hem-o-Lok clip backstopped by LAPRA-TY clip for Chromic sutures were normally distributed ($p = 0.5722 > 0.05$). The Levene's test showed that the Chromic sutures have equal variance ($p = 0.7692 > 0.2$). With a condition of equal variance, the ANOVA test on suture tensions revealed a significant effect related to tension ($p < 0.0001$).

The Tukey's HSD test was used to determine significant difference of each suture size from other suture sizes as shown in table 11. The post hoc test showed that the holding strength for

Chromic 1, Chromic 0 and Chromic 2-0 are significantly higher than the holding strength for Chromic 4-0 and Chromic 3-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Chromic 1	Chromic 4-0	5.428571	1.000801	2.51942	8.337720	<.0001*
Chromic -0	Chromic 4-0	5.283333	1.041666	2.25540	8.311271	0.0002*
Chromic 1	Chromic 3-0	4.928571	1.000801	2.01942	7.837720	0.0003*
Chromic -0	Chromic 3-0	4.783333	1.041666	1.75540	7.811271	0.0007*
Chromic 2-0	Chromic 4-0	3.600000	1.000801	0.69085	6.509149	0.0096*
Chromic 2-0	Chromic 3-0	3.100000	1.000801	0.19085	6.009149	0.0323*
Chromic 1	Chromic 2-0	1.828571	1.000801	-1.08058	4.737720	0.3781
Chromic -0	Chromic 2-0	1.683333	1.041666	-1.34460	4.711271	0.4996
Chromic 3-0	Chromic 4-0	0.500000	1.000801	-2.40915	3.409149	0.9868
Chromic 1	Chromic -0	0.145238	1.041666	-2.88270	3.173176	0.9999

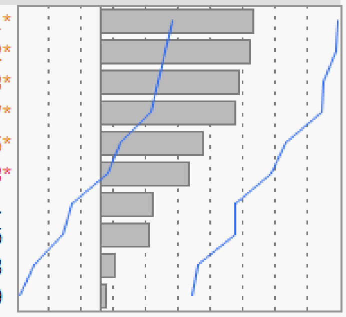

Table 11: Post hoc test for Chromic sutures (pairwise comparison Tukey's HSD with confidence interval 95%)

d. Stratafix

The Shapiro-Wilk W test showed that the holding strength of Hem-o-Lok clip backstopped by LAPRA-TY clip for Stratafix sutures were normally distributed (p = 0.7024>0.05). Whereas, the Levene's test showed that the Stratafix sutures have equal variance (p = 0.5396 > 0.2). With a condition of equal variance, the ANOVA test on suture tensions revealed a significant effect related to tension (p < 0.0001).

The Tukey's HSD test was used to determine significant difference of each suture size from other suture sizes as shown in table 12.The post hoc test showed that the holding strength for Stratafix 0, Stratafix 2 and Stratafix 3 is significantly higher than the holding strength for Stratafix 4.

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Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Stratafix-0	Stratafix 4	9.428571	1.375836	5.63318	13.22397	<.0001*
Stratafix 2	Stratafix 4	8.157143	1.375836	4.36175	11.95254	<.0001*
Stratafix 3	Stratafix 4	6.628571	1.375836	2.83318	10.42397	0.0004*
Stratafix-0	Stratafix 3	2.800000	1.375836	-0.99540	6.59540	0.2034
Stratafix 2	Stratafix 3	1.528571	1.375836	-2.26682	5.32397	0.6864
Stratafix-0	Stratafix 2	1.271429	1.375836	-2.52397	5.06682	0.7923

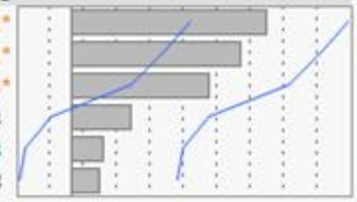

Table 12: Post hoc test for Stratafix sutures (pairwise comparison Tukey's HSD with confidence interval 95%)

e. V-Loc

The Shapiro-Wilk W test showed that the holding strength of Hem-o-Lok clip backstopped by LAPRA-TY clip for V-Loc sutures were normally distributed (p = 0.1190>0.05). Whereas, the Levene's test showed that the V-Loc sutures have equal variance (p = 0.0921 < 0.2). With a condition of unequal variance, the Welch's test on suture tensions revealed a significant effect related to tension (p = 0.0097).

The Tukey's HSD test was used to determine significant difference of each suture size from other suture sizes as shown in table 13. The post hoc test showed that the holding strength for V-Loc 2-0 and V-Loc 3-0 are significantly higher than the holding strength for V-Loc 4-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
Vloc 2-0	Vloc 4-0	4.071429	1.604744	0.75940	7.383458	0.0181*
Vloc 3-0	Vloc 4-0	3.500000	1.604744	0.18797	6.812029	0.0392*
Vloc 0	Vloc 4-0	2.857143	1.604744	-0.45489	6.169172	0.0877
Vloc 2-0	Vloc 0	1.214286	1.604744	-2.09774	4.526315	0.4566
Vloc 3-0	Vloc 0	0.642857	1.604744	-2.66917	3.954886	0.6923
Vloc 2-0	Vloc 3-0	0.571429	1.604744	-2.74060	3.883458	0.7249

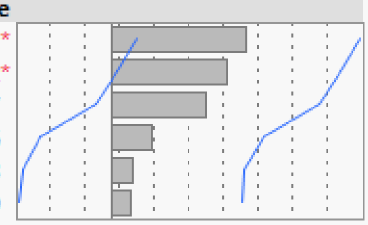

Table 13: Post hoc test for V-loc sutures (pairwise comparison Tukey's HSD with confidence interval 95%)

3. Comparison of time at which clips starts to slip from suture size 2-0

The tension holding time of LAPRA-TY clip with Hem-o-lok clip before slippage was analyzed for sutures of size 2-0 as shown in figure 30. The suture of size 2-0 is more common in use during partial nephrectomy suturing. This analysis with reference figure 32 helps to determine the characteristics of sutures based on their stretch. The approximate mean time(s), at which the clips (LAPRA-TY and Hem-o-lok) start to slip were Vicryl 2-0 (23 s), Chromic 2-0(24 s), Stratafix 2 (90 s), Monocryl 2-0(106 s), and V-Loc 2-0(111 s).

JMP software was used to analyze the ANOVA test and post- hoc test. The steps to perform the analysis using JMP software is shown in appendix A. The ANOVA test was used to determine the significant difference between the mean of sutures. Tukey's HSD test was performed to determine significant difference of each suture from other sutures. Tukey's HSD test is a post-hoc test; it is performed after an analysis of variance (ANOVA) test. Tukey’s HSD test calculates a new critical value that can be used to evaluate whether differences between any two pairs of means are significant. The post hoc test table shows the higher mean in positive level and a lower mean in negative level. The difference in the table shows difference between mean in positive and negative level.

The lower and upper confidence level (CL) shows the range of value where difference of mean calculated exists. The p-value shows the significance level between the means. If the p value is less than 0.05 the means are significantly different else no difference.

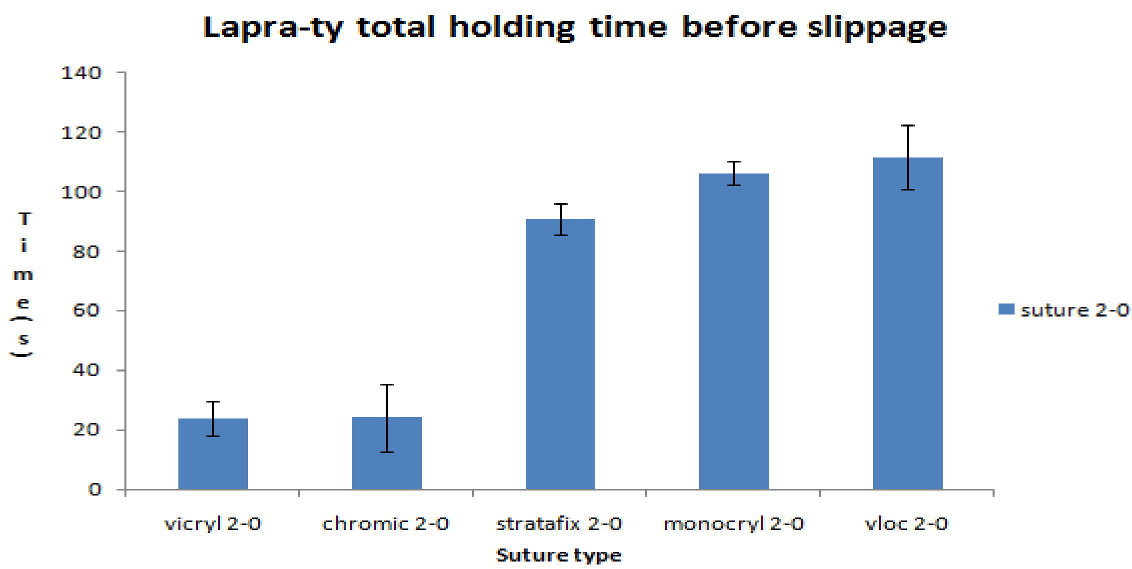

Figure 30: Comparison of time at which clips starts to slip from suture size 2-0

The Shapiro-Wilk W test showed that the tension holding time of Hem-o-Lok clip backstopped by LAPRA-TY clip before slippage for sutures Vicryl, Monocryl, Chromic, Stratafix and V-Loc were not normally distributed ($p < 0.0002 < 0.05$). Hence, the studentized residual data were obtained. The p-value of this test was 0.1932 which is greater than 0.05 indicating that the Studentized Residual of collected data is normally distributed. The Levene's test showed that the holding time of sutures have equal variance ($p = 0.2492 > 0.2$). With a condition of equal variance and normal distribution, the ANOVA test on suture tensions revealed a significant effect related to tension ($p < 0.0001$).

The post hoc test showed that the holding time for V-Loc 2-0 is significantly higher than the holding strength for Vicryl 2-0, Stratafix 2 and Chromic 2-0. The sutures Monocryl 2-0 and Stratafix have significantly higher holding time than Vicryl 2-0 and Chromic 2-0.

Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
V-Loc 2-0	vicryl 2-0	87.57143	5.600572	71.2916	103.8513	<.0001*
V-Loc 2-0	Chromic 2-0	87.28571	5.600572	71.0059	103.5656	<.0001*
Monocryl 2-0	vicryl 2-0	82.30952	5.829260	65.3649	99.2541	<.0001*
Monocryl 2-0	Chromic 2-0	82.02381	5.829260	65.0792	98.9684	<.0001*
Stratafix 2	vicryl 2-0	66.85714	5.600572	50.5773	83.1370	<.0001*
Stratafix 2	Chromic 2-0	66.57143	5.600572	50.2916	82.8513	<.0001*
V-Loc 2-0	Stratafix 2	20.71429	5.600572	4.4344	36.9941	0.0074*
Monocryl 2-0	Stratafix 2	15.45238	5.829260	-1.4922	32.3970	0.0870
V-Loc 2-0	Monocryl 2-0	5.26190	5.829260	-11.6827	22.2065	0.8935
Chromic 2-0	vicryl 2-0	0.28571	5.600572	-15.9941	16.5656	1.0000

Table 14: Post hoc test for Comparison of time at which clips starts to slip from suture size 2-0 (pairwise comparison Tukey's HSD with confidence interval 95%)

The figure 31 shows the total slippage time of sutures Monocryl, Vicryl, Chromic, V-Loc and Stratafix. From the experiment, we found that Monocryl suture required the maximum amount of time to slip LAPRA-TY completely from a 1 cm long suture tail.

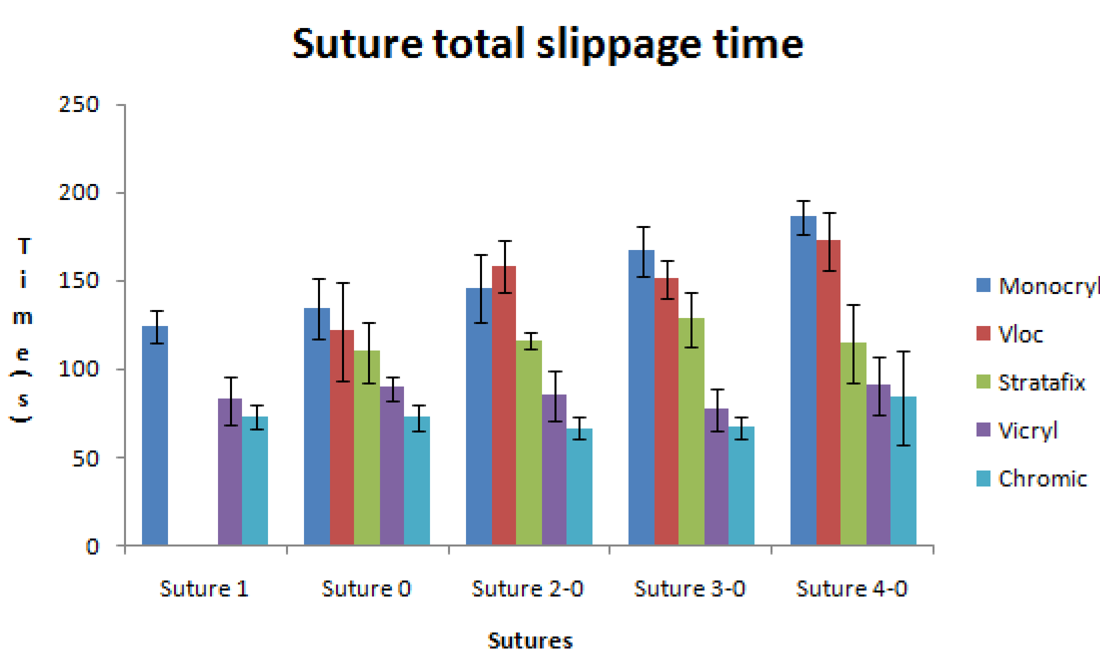

Figure 31: Total slippage time of clips on sutures

Figure 32 shows approximate pattern of tension recorded as holding strength of LAPRA-TY with Hem-o-lok for sutures Vicryl, Monocryl, Chromic, V-loc and Stratafix of size 2-0. The marker shows the maximum holding strength recorded before the clips slippage.

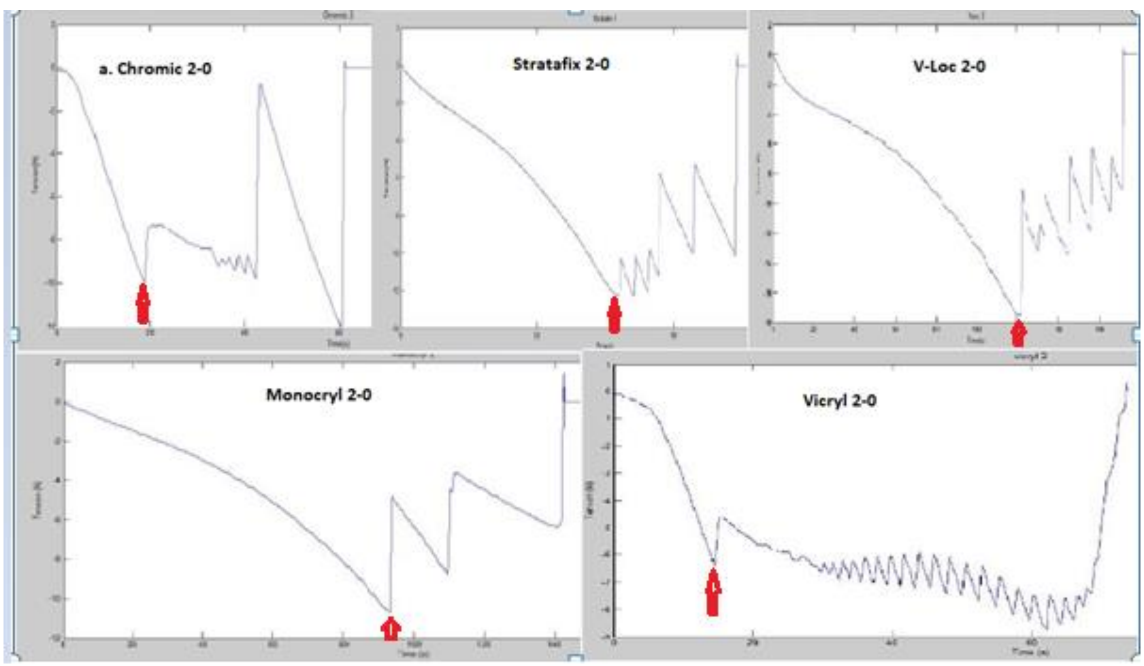

Figure 32: Recorded tensions for sutures of size 2-0

Figure 33 and Figure 34 shows the holding strength recorded for Vicryl 2-0 and Monocryl 2-0 sutures. The graph of each suture has an approximate pattern similar to other sutures only within the same suture size and type. The similarity of pattern only within the same suture size and type implies that the variation in characteristics of sutures with size and type. The Monocryl sutures stretch more than Vicryl suture in reference to figure 30. The figure 30 the time at which the clips starts to slip for Monocryl 2-0 is higher than Vicryl 2-0.   In addition, the graph of Monocryl 2-0 sutures holding strength shows two outliers. Appendix 'J' shows the overall graphs of the data collected during AN experiment "Holding strength of Hem-o-lok backstopped by a LAPRA-TY clip for different sutures".

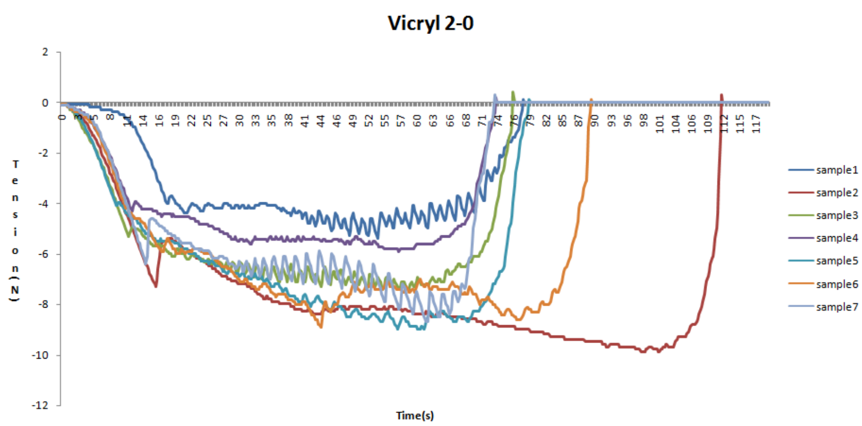

Figure 33: Holding strength for Vicryl 2-0 sutures

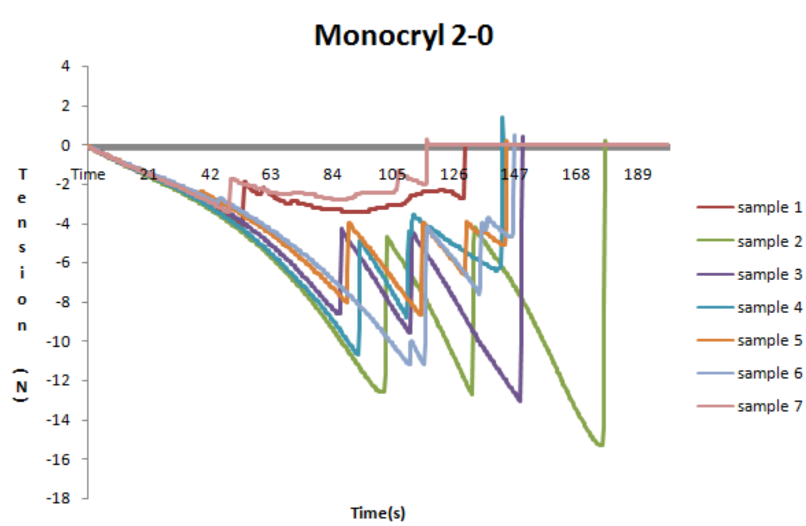

Figure 34: Holding strength for Monocryl 2-0 sutures

4. Comparison of holding strength clips for barbed suture, i.e. toward and against barb

A barbed suture is a type of knotless surgical suture that has barbs on its surface. While suturing tissue, these barbs penetrate inside the tissue and lock them into place, eliminating the need for knots to tie the suture. The Clips on barbed sutures can be applied in two methods, i.e. clips forcing against the barbed direction and with the barbed direction. Figure 35 shows the direction of clips force on barbed suture.

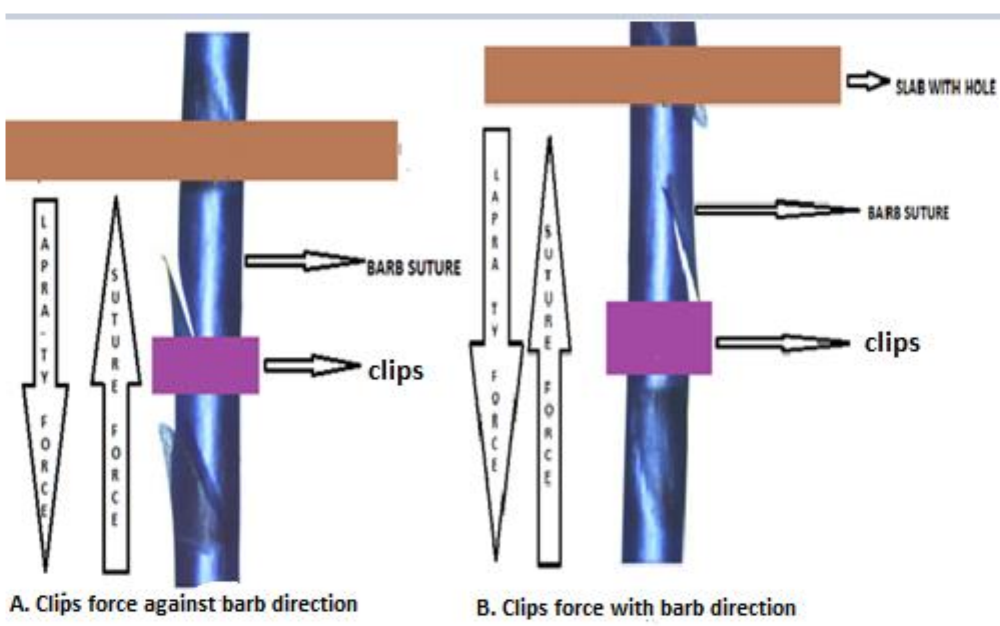

Figure 35: LAPRA-TY clips on barbed sutures: A. LAPRA-TY clip against barb B. LAPRA-TY clip towards barb

The holding strength of LAPRA-TY for barb sutures was analyzed based on the placement of LAPRA-TY on suture, i.e. LAPRA-TY towards the barb or against the barb as shown in figure

35. The comparison was made for 3 different kinds of barb sutures, i.e. V-Loc 2-0, V-Loc 3-0 and Stratafix 3-0 as shown in figure 36. The Wilcoxon Signed Rank Test revealed that there is no significant difference between holding strength of LAPRA-TY towards and against barb with a significance level 0.05. Appendix 'I' shows the statistical for comparison of barbed sutures against and towards barb.

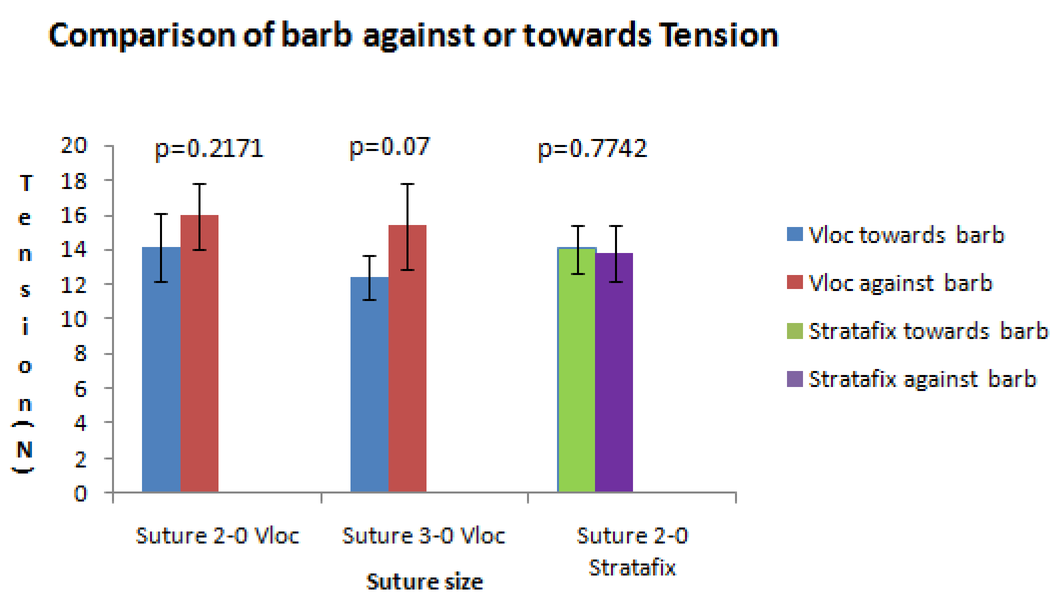

Figure 36: Comparison of clips on barbed sutures (towards and against)

Discussion

The holding tension in this experiment was defined as the maximum load recorded at the instant just before LAPRA-TY starts to slip. During this experiment, the Stratafix suture sizes were tensile strength sizes (0, 2, 3 and 4). The holding strength of clips (Hem-o-lok clip backstopped by LAPRA-TY clip) for different suture types were compared to each other based on suture types on each size of suture. There was a significant difference in holding strength of clips for different suture types within each size, i.e. suture 1(p=0.0006), suture 0(p<0.0001), suture 2-0(p<0.0001), suture 3-0(p<0.0001) and suture 4-0(p<0.0001). The confidence level for this test was 95%. For all suture sizes holding strength of LAPRA-TY was minimum for Vicryl sutures and maximum for V-Loc sutures. The post hoc test showed that only the holding strength of V-Loc 4-0 is significantly greater than Stratafix 4, with a p value <0.0001 and confidence level 95%. In reference to the porcine kidney experiment, the tissue tears at tension on average of about 5.5 N using a standard clipping technique of Hem-o-lok clip with a knot backstop. This experiment shows that the holding tension of a Hem-o-lok backstopped by a LAPRA-TY supports the application of tension greater than 5.5 N except for sutures, Vicryl 3-0 and Vicryl 4-0.

In addition, the holding strength of clips for different suture sizes were compared to each other based on suture types on each size of suture. There was a significant difference in holding strength of clips for different suture types within each size, i.e. Vicryl (p=0.0005), Monocryl (p<0.0001), Chromic (p<0.0001), Stratafix (p<0.0001) and V-Loc (p=0.0097). The significance level for this test was 0.05. The post hoc test showed that the holding strength of clips for sutures size "1" and size "0" are significantly higher than other suture sizes. The holding strength of clips for sutures size "1" and size "0" are not significantly different from each other at 95% confidence level. The suture size "4-0" holds the minimum tension for all the suture types.

The suture of size 2-0 is more common in use during partial nephrectomy suturing. The approximate mean time(s), at which the clips (LAPRA-TY and Hem-o-lok) started to slip were Vicryl 2-0 (23 s), Chromic 2-0(24 s), Stratafix 2 (90 s), Monocryl 2-0(106 s), and V-Loc 2-0(111 s). The mean tension holding time for Vicryl 2-0 and Chromic 2-0 was significantly smaller than Monocryl 2-0 and V-Loc 2-0 with a p value <0.0001 at significance level of 0.05. The holding strength of V-Loc 2-0 is also significantly higher than Stratafix 2 suture. The result corresponding to sutures holding strength graphs from appendix “J” implies that Monocryl and V-Loc sutures stretch more than Vicryl and Chromic sutures.

The analysis of LAPRA-TY position on barbed sutures, i.e. toward and against barb, showed that there is no difference in Clips position for sutures V-Loc 2-0, V-Loc 3-0 and Stratafix 2-0 with a confidence level 95%. The investigation on holding strength of Hem-o-lok backstop by LAPRA-TY for different sutures showed that the holding strength of barbed sutures are comparatively higher than Vicryl sutures for all sutures sizes. The result of this research implies that the holding strength of Hem-o-lok backstopped by LAPRA-TY for barbed sutures is more than Vicryl sutures for all sizes. However, the benefit of increased holding tension using barbed sutures must be weighed against the added cost of these products.

Limitations of this experiment are as follows: First, experiment without tissue model limited simulation of clinical application. Secondly, during an experiment to record holding strength of Hem-o-lok backstopped with LAPRA-TY, load was applied perpendicular to the slab designed to maximize consistency of trials. However, during in-vivo, suturing load is applied tangential to the tissue.

Conclusion

The approximate mean tensions at which the renal parenchymal tissue failed using anchors were knots (2.7N ± 0.53N), Prototype 2(4.0 N± 1.6N), Hem-o-lok (5.4 N+0.72N), Prototype 1(5.6 N±0.75N), and Prototype 3(6.0 N±3.39N). The tension required to tear renal parenchyma tissues using the anchors Prototype 1 and Prototype 3 were not statistically different to that of Hem-o-lok clips with a significance level of 0.05. The anchor Prototype 2 failed at a lower tension in comparison to Prototype 1 and Prototype 3 at the confidence level 95%. The amount of tension holding capability of anchors Prototype 1 and Prototype 3 is similar to anchor Hem-o-lok. The amount of tension required to tear renal parenchyma tissue using a knot as an anchor was only 2.7N on average, far less than is necessary for hemostasis. For this reason, a simple knot is not used as an anchor during partial nephrectomy suturing.

During experiment 2, the sutures that failed before 7 days under the condition of 4N applied tension were due to slippage of the knots from Hem-o-lok clip .The sutures that failed during 21 days were due to suture breakage. The sutures commonly used in LPN, i.e. Vicryl 2-0 and Vicryl 3-0 are able to hold a tension of 4.0 N for more than 21 days. Multiple knots should be applied behind the Hem-o-lok clip while using the Vicryl sutures since knot slippage through the closed Hem-o-Lok is a common mode of failure.

Finally, from experiment 3, we can conclude that the Hem-o-clip backstopped with a LAPRA-TY clip holds maximum tension for suture sizes “1” and “0” and holds minimum tension for suture size 4-0. The holding tension of a Hem-o-lok backstopped with a LAPRA-TY supports the application of tension greater than 5.5 N except for sutures, Vicryl 3-0 and Vicryl 4-0. Hence, the sutures Vicryl(1,0,2-0), Monocryl(1,0,2-0,3-0,4-0), Chromic(1,0,2-0,3-0,4-0), Stratafix(0,2-

0,3-0,4-0) and V-Loc(0,2-0,3-0,4-0) should perform adequately when Hem-o-Lok and LAPRA-TY are properly applied during LPN surgery. The application of clips towards or against the barb on barbed sutures does not appear to affect the holding strength of barbed sutures. In addition, Vicryl sutures have the lowest holding tension capability, despite the fact that the manufacturer specifies that LAPRA-TY’s should only be used with Vicryl sutures.

Topics for additional research

This research exposed a number of future works in the field of partial nephrectomy suturing. This experiment has shown that the holding strength of renal parenchyma tissue is similar while suturing with clips Hem-o-lok, Prototype 1 and Prototype 3. Additional research can be done including the factors like: depth of suture and margin during suturing made, applying tension on tissue at an angle close to the clinical condition, storage time between harvest and test, amount of capsule on test kidney and larger sample that may further reveal the holding strength of anchors based on their sizes and structure.

The holding strength of Hem-o-lok clip backstopped by LAPRA-TY clip is higher for V-Loc sutures and lower for Vicryl sutures. Including tissue model may help to simulate the clinical condition and may provide further information about holding strength of tissue and clips together for different sutures. In addition, further study on holding strength of clips can be done including the directions of tension apply on clips simulating in vivo suturing technique.

Appendices

Appendix A: JMP ANOVA Instructions steps an description

Boxplot to check normality:

Graph → Graph Builder

Click on boxplot in top graphs

Put independent variable on horizontal axis, dependent variable on vertical axis

ANOVA:

Analyze → Fit Y by X

Put independent and dependent variables in corresponding boxes

Right click on OneWay box at top and select Means/Anova

Right click on OneWay box at top and click Means and Std Dev to get sample means and standard deviations

Other normality check:

Analyze → Fit Y by X → Display Options → Box Plots

Analyze → Fit Model

Right click at top of Fit Model results and select Save Columns → Studentized Residuals

Analyze → Distribution → Put Studentized Residuals in and submit

Right click at top of results and select Normal Quantile Plot; Also go to Display Options and select Customize Summary Statistics, check skewness and kurtosis

The skewness and kurtosis values should be between -2 and 2

Right click at top of results, select Continuous Fit → Normal

Right click on Fitted Normal bar and select Goodness of Fit

The Shapiro Wilk p-value should be **greater than 0.05 for normality assumption to be met**

Check Equal Variances:

Analyze → Fit Y by X

Right-click at top of ANOVA results and select Unequal Variances

Use the Levene p-value; if greater than .20, equal variance assumption is met

Welch's Test:

Welch's test is used when equal variance assumption is violated, but normality assumption is met

The Welch's test p-value is output when the Unequal Variances option is selected

If Welch's p-value is less than .05, there is significant evidence that at least one mean measured outcome is significant

Post-Hoc:

Use Tukey's post-hoc to control experiment-wise error

Analyze → Fit Y by X

Right click at top of results and select Means/Anova

Right click again and select Compare Means → Each Pair → Tukey HSD

Analysis

a. Box Plot

Before doing any statistical analysis it is necessary to understand the data type. Box plot helps to determine the normal distribution and the variance of data. It is a standardized way of displaying the distribution of data based on the five number summaries: minimum, first quartile, median, third quartile, and maximum. In the simplest box plot the central rectangle spans the first quartile to the third quartile (the interquartile range or IQR). A segment inside the rectangle shows the median of the data and "whiskers" above and below the box show the locations of the minimum and maximum.

b. Normality check

The graph normal quantile plot helps to visualize the normality of data. The Shapiro Wilk test helps to detect the normality of data at the significance level 0.05. The Shapiro Wilk p-value should be greater than 0.05 for normality assumption to be met. Similarly, the skewness and kurtosis is between -2 and 2 so the studentized residual is normally plot.

c. Studentized residual

When the data does not show the normal distribution, the alternative to check normality is to obtain studentized residual. A residual is the difference between a predicted value and the observed value. A studentized residual is the result of dividing the residual by the standard error of the residual. The adjustment accounts for different variances in the residuals. The variances of residuals for different values of the input field are not the same. To account for these differences, the residual values are divided by the standard error for the residuals. This adjustment is called studentizing. It allows for a standardized comparison among the residuals

d. ANOVA

The **one-way** analysis of variance (**ANOVA**) determines the significant difference between the mean of three or more independent (unrelated) groups. The assumptions of one-way ANOVA are as follow:

- The populations from which the samples were obtained must be normally or approximately normally distributed.
- The samples must be independent.
- The variances of the populations must be equal.

During a statistical analysis if the assumption normal distribution of populations from which the samples were obtained is not met, following two options can be taken (1) transforming data using various algorithms to reshape the non normal distribution into normal distribution or (2) choosing the non-parametric Kruskal-Wallis H Test which does not require the assumption of normality. On the other hand, if the equal variance of the population for each anchor type assumption fails, there are two tests that can be applied, i.e. (1) Welch or (2) Brown and Forsythe test.

Alternatively, we can also run a Kruskal-Wallis H Test. For most situations it has been shown that the Welch tests as best option. In Welch's test p-value is output when the Unequal Variances option is selected. If Welch’s p-value is less than .05, there is significant evidence that at least one mean measured outcome is significant, i.e. significant evidence that at least one of the mean from measured outcome is significant

e. Post hoc test (Tukey’s HSD)

The ANOVA test was used to determine the significant difference between the mean of sutures. Multiple comparison procedures are designed to make multiple mean comparisons while controlling the experiment wise error rate. Tukey's HSD test was performed as multiple comparison tests, to determine significant difference of each suture from other sutures. Tukey's HSD test is a post-hoc test; it is performed after an analysis of variance (ANOVA) test. Tukey’s HSD test calculates a new critical value that can be used to evaluate whether differences between any two pairs of means are significant.

The post hoc test table shows the higher mean in positive level and a lower mean in negative level. The difference in the table shows difference between mean in positive and negative level. The lower and upper confidence level (CL) shows the range of value where difference of mean calculated exists. The p-value shows the significance level between the means. If the p value is less than 0.05 the means are significantly different else no difference.

Appendix B: Statistical analysis for comparison between Prototype suture anchors and conventional suture anchors

The five box plots shown below corresponds to each anchor type, irregularity of box plots obtain from failure tension data for each anchor shows unequal variance. In a box plot, mid segment indicates normality of the data. Box plot shown below indicates that the data obtain from anchors Hem-o-lok, knot and Prototype 1 have nearly normal distribution characteristics. In contrast, tension data obtain from anchors Prototype 2 and Prototype 3 have a characteristic far from normal distribution.

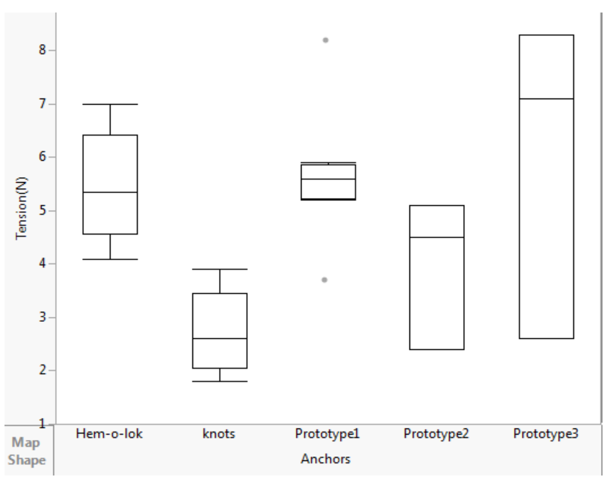

Figure B1: Box plot of tensions recorded for anchors

Studentized residual

The data obtained from the experiment was not normally distributed so the data was transformed into studentized residual to analyze the normal distribution of data. The graph below shows the normal plot of the studentized residual because from Shapiro Wilk test the p value is 0.3228. The

Shapiro Wilk p-value should be greater than 0.05 for normality assumption to be met. Similarly, the skewness and kurtosis is between -2 and 2 so the studentized residual is normally plot.

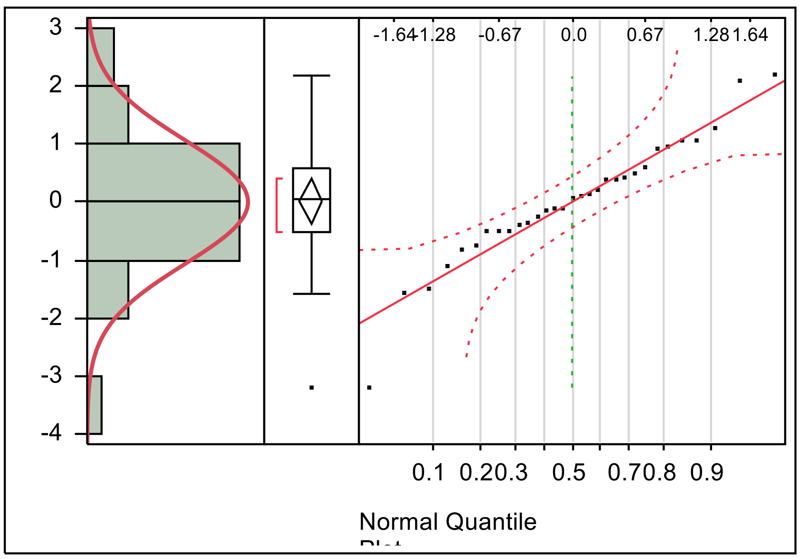

Figure B2: Normality plot of Studentized Residual of tensions recorded for anchors

Levene's test is used to test the equality of the variance. It is an alternative to the Bartlett test. The Levene test is less sensitive than the Bartlett test . If data has the strong evidence of normality, or nearly normal distribution, then Bartlett's test has better performance. If the Levine’s p-value is greater than .20, equal variance assumption is met. Levene's test shown the p value is 0.0154 which is less than 0.2 so; we can say that the data we collected for different anchors has unequal variance.

From the Levene's test and Studentized residual analysis, it was found that the equal variance assumption is violated, but normality assumption is met. Thus, Welch’s test was conducted to analyze the ANOVA[29]. In Welch's test p-value is output when the Unequal Variances option is selected. If Welch's p-value is less than .05, there is significant evidence that at least one mean measured outcome is significant. From our test we found the p value is less than 0.05, i.e. 0.0039. So we can say that there is significant evidence that at least one of the mean from measured outcome is significant

Since, the Welch's test was significant; Tukey's HSD test was performed to determine significant difference between suture anchors. Tukey's HSD test is a post-hoc test; it is performed after an analysis of variance (ANOVA) test[30]. The anchors Prototype 1, Prototype 3 and Hem-o-lok were significantly different from anchor knot, as the p value is less than 0.05. The anchors Prototype 3, Prototype 1 and Hem-o-lok were not significantly different from each other.

	S.N	Prototype 1	Knots	Hem-o-lok	Prototype 3	Prototype 2
	1	3.7	2	5.9	7.1	5.1
	2	5.7	1.8	4.5	2.6	2.4
	3	5.2	2.2	4.8	8.3	4.5
	4	5.3	2.3	4.8		
	5	5.8	3.5	6.6		
	6	5.9	3.9	5.9		
	7	8.2	2.9	7		
	8	5.5	3.3	4.1		
Mean		5.66	2.74	5.45	6.0	4.0
S.D		1.09	0.77	1.04	3.0	1.42

Table B1: Mean tensions at which renal tissue tear using anchors knots, Hem-o-lok, Prototype 1, Prototype 2 and Prototype

Appendix C: Procedure for comparison between Prototype suture anchors and conventional suture anchors

1. Verify power source for MTS Mini Bionix, Wagner force gauge (WFG), CPU and monitor.
2. Verify power switch on pump unit is in ‘ON’ position.
3. Verify all three E-stop buttons of MTS Mini Bionix are PULLED OUT.
4. Turn ‘ON’ power to I/O controller (white switch on back of the control box of MTS Mini Bionix.
5. Turn ‘ON’ CPU and monitor.
6. Logon as Administrator.
7. Open control station software (station manager software).
8. Open file name lpn practice.cfg
9. The manufacturer recommends bringing equipment up to temperature before testing by exercising the unit. Use the ‘function generator’ function to move the cylinder up and down.
   - Reset ‘locks’ with button on screen, if necessary.
   - Start pump with buttons on screen. Click two bars, wait a second, then click three bars. (Two stages: 2 bars = low, 3 bars = normal. Run on normal.)
   - Set the target point in limit either 0mm or 100mm and also set the time to reach target, i.e. 10 second
   - Start signal generator with button on screen, the cylinder move based on the given target value

10. Turn ‘ON’ WFG and make sure the RS232 is turned ‘ON ’ and unit is set on kilogram for calibration
11. Position the Webcam in proper position
12. Calibration of WFG
    - Verify WFG is connected to Laptop with USB\Serial converter
    - Start the Matlab and run the code “startstoprecrddataGUIforwagner”
    - For calibration measure the 2 kilogram, 1 kilogram, 500 gram, 200 gram and 100 gram weight calibrator simultaneously in WFG.
    - Run Matlab code ‘StandardizeDirectoryNames’ to make file and directory name consistent in format.
    - Run Matlab code ‘SortFiles2Directories_r2’ to group files by test.
    - Run the Matlab code ‘d_ConvertASCII2xls’1 to generate Excel spreadsheet files.
    - Verify the weight calibration with both excel file and the graph obtain from Matlab coding.
13. Calibration of MTS Mini Bionix
    - Set the position of the Webcam and length measurement scale.
    - Make sure reset is not active and position the cylinder at zero position
    - Target the cylinder at 100 mm in the control station software
    - Start the Webcam recording
    - Start the MTS Mini Bionix
    - Stop the web cam when cylinder reaches to target.
    - The webcam record the experiment at 30 frames per second, verify the speed of the piston for individual second with 30 frames for 10 seconds finally compare the speed of piston at 10 second

14. Take out a kidney from the cooler and place it in a tray to create defects
15. Create a defect on two poles of first side of kidney using scalpel, blade, coin, forceps and scissor
16. Create a channel towards the pole to minimize the interference of medical bandage during experiment.
17. If necessary rinse the bio-fluid with the tab water.
18. In one of the defect two Hem-o-lok clips should use for suturing and in another defect one of the three prototype clip should use. During the process of test 2-0 Vicryl suture should use.
19. During suturing procedure the margin during suturing should be in between 0.5 cm to 1 cm from the defect created.
20. Suture with Hem-o-lok should prepare before suturing action
21. After completion of one of the two configuration of suturing the kidney sample should place on the rotating device holder where latex free medical bandage and medical tape are used for positioning the kidney sample.
22. Kidney sample should wrap on the holder with the help of bandage leaving space for the defect. After positioning the kidney medical tape can be used to secure the position.
23. The free end of the suture configuration should attach to the WFG hook with the help of the knot made in suture
24. Finally, configuration of WFG, MTS Mini Bionix and web cam should recheck and should run the Matlab code “startstoprecrddataGUIforwagner”
25. Start the web cam and the MTS Mini Bionix.

26. After completion of two suturing configuration test, similarly two defects on opposite side of the kidney should made and the test should be done using two remaining prototype clips
27. In total 8 tear-out tests on each of 4 suture configurations (one configuration using Hem-o-lok clips on 2 parallel sutures, and the other configurations using 3 prototype clips that employ parallel sutures) should be done

Appendix D: Suture life test data

Suture Life Test Data								
Hanger numb	suture	suture tension duration	Experimental Note	Failure descriptio	Average	Median	time (min)	S.d
12	**vicryl 5-0**	1 hr 34 minutes	**(outlier)**	slipped			94	
33	**Vicryl 5-0**	8 minutes	**slip)**	slipped			8	2.0817
33	**vicryl 5-0**	4 minutes	**extra knots (negative control)**	slipped			4	
39	**Vicryl 5-0**	5 minutes	**extra knots (negative control)**	slipped	**27.75 min**	**6.5 min**	5	
17	**Vicryl 4-0**	23 days 8 hrs 50 minutes	extra knots	failure near upper knot			560.83	26.698
18	**Vicryl 4-0**	1 minute	extra knots (assurance of slip)	slipped	**16 days 13 hrs 41.75 min**			
18	**Vicryl 4-0**	21 days 7 hrs 35 minutes	extra knots	failure near upper knot		**21 days 10 hrs 58 min**	511.58	
21	**Vicryl 4-0**	21 days 14 hrs 21 minutes	extra knots	failure near upper knot			518.34	
1	**vicryl 3-0**	22 days 10 hrs 31 minutes		failure near upper knot	**21 days 21 hrs 53 minutes**	**22 days 10 hrs 31 minutes**	538.51	31.795
13	**vicryl 3-0**	22 days 21 hrs 27 minutes		failure near upper knot			549.45	
31	**vicryl 3-0**	20 days 9 hrs 41 minutes		lower knot			489.73	
24	**vicryl 2-0**	29 days 3 min - 31 days 19 hrs 2 min	(image recording stopped)	failure near upper knot			576.04	290.06
28	**vicryl 2-0**	5 days 18 hrs 30 min		slipped		**28 days 23 hrs 59.5 min- 31 days 18 hrs 58.5 min**	138.5	
29	**vicryl 2-0**	28 days 23 hrs 56 min - 31 days 18 hrs 55 min	spring balance broke on 8/4 at 6:36 AM was replaced with new spring balance	lower knot	**24 days 11 min- 25 days 9 hrs 40.5 min**		729.42	
39	**vicryl 2-0**	32 days 6 hrs 15 min		failure near upper knot			774.25	
2	**vicryl 0**	29 days 39 min- 31 days 19 hrs 38 min		lower knot	**hrs 57.33 min- 30 days 20 hrs 36.66 min**	**29 days 38 min- 31 days 19 hrs 37 min**	730.14	20.525
15	**vicryl 0**	29 days 38 min- 31 days 19 hrs 37 min	(image recording stopped)	failure near upper knot			730.12	
25	**vicryl 0**	28 days 22 hrs 35 min		lower knot			694.58	
3	**chromic 4-0**	47 days 12 hrs 40 min	extra knots	lower knot			1140.66	855.02
20	**chromic 4-0**	20 days 7 hrs 16 minutes	extra knots	middle	**52 days 22**		487.26	
20	**chromic 4-0**	20 days 7 hrs 16 minutes	extra knots	middle	**52 days 22 hrs 9.33 min**	**47 days 12 hr40 min**	487.26	
27	**chromic 4-0**	90 days 22 hrs 32 min	extra knots, spring balance broke and was replaced	lower knot			2182.53	
8	**chromic 3-0**	45 days 3 hrs 46 min		lower knot	**41 days 3 hrs 2.5 min - 41 days 15 hrs 20 min**		1083.76	120.42
9	**chromic 3-0**	42 days 8 hrs 36 min		2 cm under upper knot			1016.6	
22	**chromic 3-0**	43 days 23 hrs 3 min		middle		**43 days 11 hrs 49.5 min**	1055.05	
32	**chromic 3-0**	33 days 0 hrs 45 min - 35 days 1 hr 55 min	(image recording stopped)	1 cm above lower knot			817.33	
16	**chromic 2-0**	More than 120 days						
26	**chromic 2-0**							
34	**chromic 2-0**							
7	**chromic 0**	more than 120 days						
14	**chromic 0**							
35	**chromic 0**							
4	**PDS 1**	83 days 19 hrs 0 min	**Positive control**	failure near upper knot	**87 days 5 hrs 52 min**	**88 days 19 hrs 42 min**	2011	71.855
30	**PDS 1**	88 days 19 hrs 42 min		middle			2131.7	
38	**PDS 1**	89 days 2 hrs 54 min		lower knot			2138.9	
10	**PGA-PCL 3-0**	20 days 18 hrs 30 min		middle	**20 days 17 hrs 47.33 min**	**20 days 18 hrs 30 min**	498.5	9.9692
19	**PGA-PCL 3-0**	20 days 7 hrs 29 min		lower knot			487.48	
37	**PGA-PCL 3-0**	21 days 3 hrs 23 min		failure near upper knot			507.38	
5	**PGA-PCL 2-0**	22 days 5 hrs 4 min		middle			533.06	
11	**PGA-PCL 2-0**	19 days 1 hr 34 min		failure near upper knot	**20 days 14 hrs 39 min**	**20 days 13 hrs 19 min**	457.56	37.768
23	**PGA-PCL 2-0**	20 days 13 hrs 19 min		failure near upper knot			493.31	
6	**PDO stratafix**	39 days 23 hrs 6 min		upper knot	**42 days 21 hrs 56 min**	**42 days 21 hrs 56 min**	956.1	102.29
36	**PDO stratafix**	45 days 20 hrs 46 min		middle			1100.76	

Table D1: Suture life test data

Appendix E: Holding strength of Sutures just before LAPRA-TY slippage

Holding strength of Sutures just before LAPRA-TY slippage				
S.N	**Suture Types**	**Mean Tension**	**S.D**	**Num of samples**
1	Vicryl 0	7.6	2.15	8
2	Vicryl 1	8.89	1.23	8
3	Vicryl 2-0	5.71	1.19	7
4	Vicryl 3-0	4.39	0.92	7
5	Vicryl 4-0	4.26	1.36	7
6	Monocryl 0	16.49	1.59	7
7	Monocryl 1	12.63	2.78	6
8	Monocryl 2-0	8.39	1.14	7
9	Monocryl 3-0	8.43	1.14	7
10	Monocryl 4-0	7.61	1.38	7
11	Chromic 0	12.98	1.43	6
12	Chromic 1	13.13	1.55	7
13	Chromic 2-0	11.3	2.72	7
14	Chromic 3-0	8.2	1.54	7
15	Chromic 4-0	7.7	1.75	7
16	Vloc 0	14.71	4.1	7
17	Vloc 2-0	15.93	2.58	7
18	Vloc 3-0	15.36	3.34	7
19	Vloc 4-0	11.86	1.19	7
20	Stratafix 0	15.07	2.87	7

21	Stratafix 2	13.8	1.56	7
22	Stratafix 3	12.27	3.01	7
23	Stratafix 4	5.64	2.59	7

Table E1: Holding strength of Sutures just before LAPRA-TY slippage

Appendix F: Holding strength of clips on different suture types for each suture size

The normality test of tension recorded for different sutures were analyzed using Shapiro Wilk test. The p-value greater than 0.05 indicate normal distribution of data obtain. Levene's test was used to test the equality of the variance, where p value greater than 0.2 is consider as homogeneity in variance. Welch's test was used as ANOVA test for a condition of unequal variance and normal distribution of data. Welch's test provided a significant evidence of difference in mean tension recorded for different sutures. The p value less than 0.05 indicated the significant difference in mean tension for sutures. The ANOVA tests followed by Tukey HSD post hoc analysis were conducted on sutures Vicryl, Monocryl, Chromic, Stratafix and V-Loc based on suture sizes. The results were shown below:

a. Suture size "1"

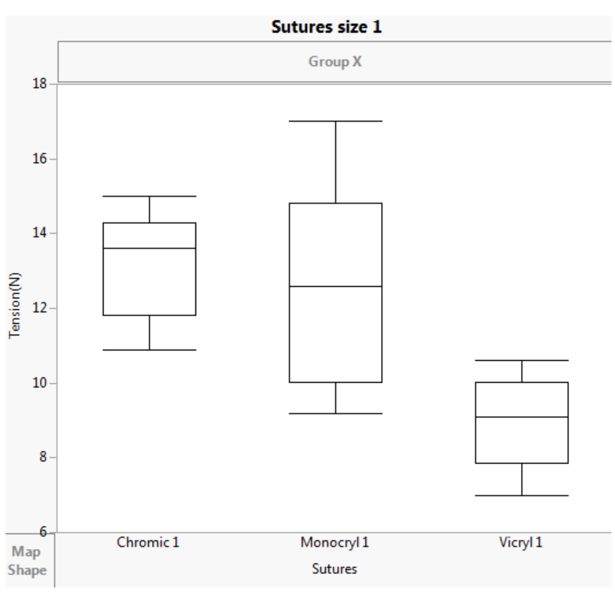

Figure F1: Box plot for sutures of size "1"

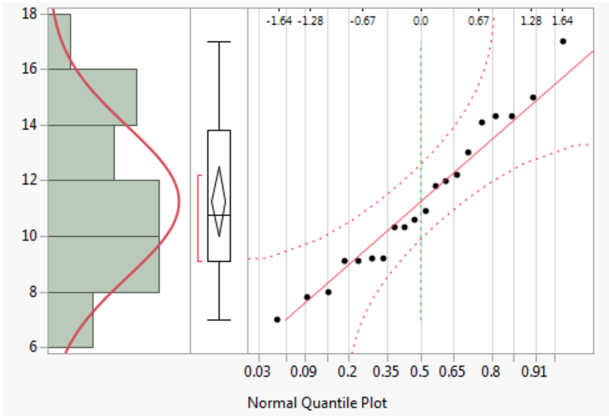

Figure F2: Normal quantile plot for suture size "1"

Goodness-of-Fit Test

Shapiro-Wilk W Test

W	Prob<W
0.964645	0.6402

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table F1: Shapiro-Wilk W test for suture size "1"

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	2.3472	2	18	0.1242
Brown-Forsythe	1.8850	2	18	0.1806
Levene	2.0706	2	18	0.1551
Bartlett	2.0184	2	.	0.1329

Table F2 Levene's test for suture "1"

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
17.4233	2	9.9867	0.0006*

Table F3: Welch's test for suture size "1"

b. Suture size “0”

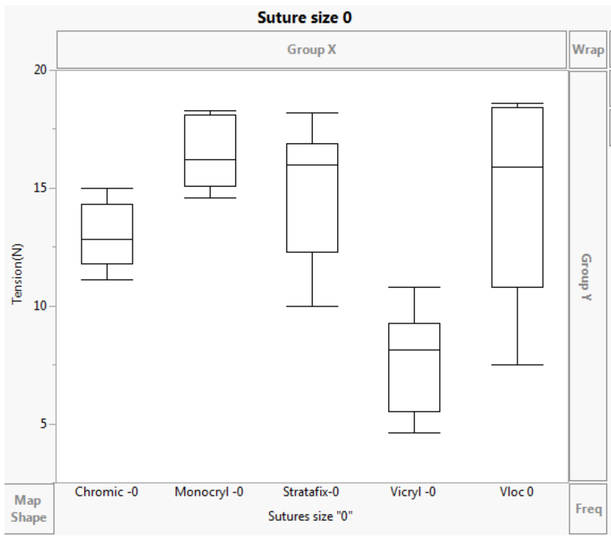

Figure F3: Box plot for sutures of size “0”

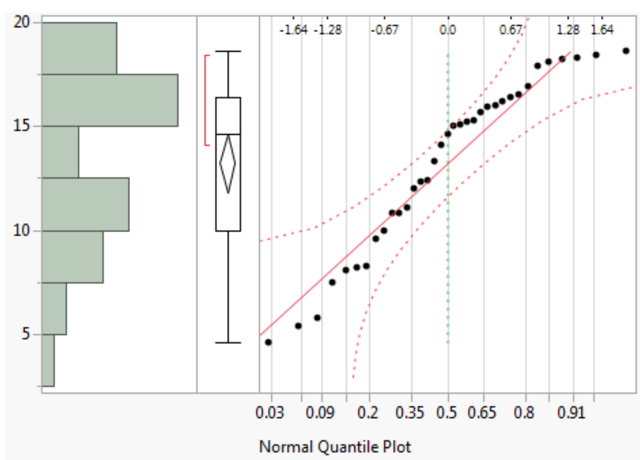

Figure F4: Normal quantile plot for suture size “0”

Shapiro-Wilk W Test

W	Prob<W
0.945806	0.0842

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table F4: Shapiro-Wilk W test for suture size “0”

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	1.8478	4	30	0.1457
Brown-Forsythe	0.8713	4	30	0.4926
Levene	2.3299	4	30	0.0787
Bartlett	2.0288	4	.	0.0874

Table F5:Levene’s test for suture size “0”

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
19.3921	4	14.711	<.0001 *

Table F6: Welch’s test for suture size “0”

c. Suture size 2-0

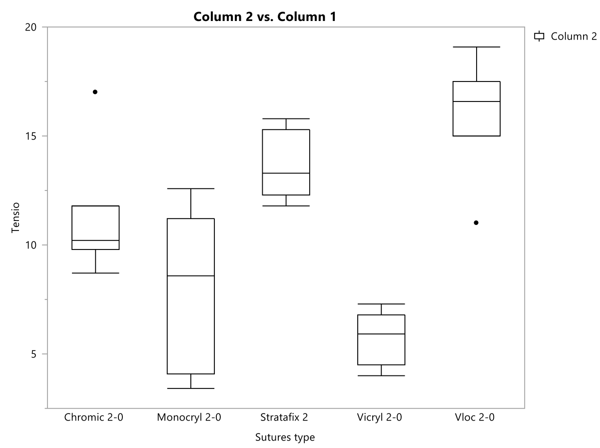

Figure F5: Box plot for sutures of size “2-0”

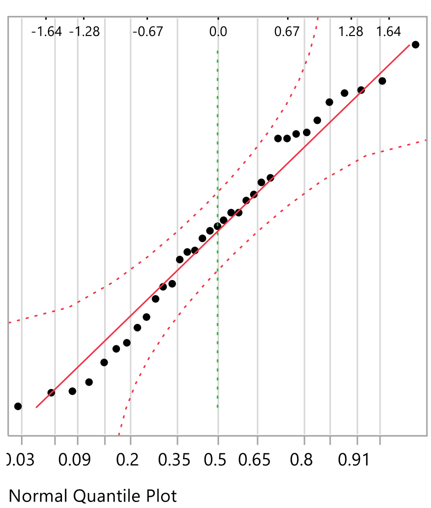

Figure F6: Normal quantile plot for suture size “2-0”

Goodness-of-Fit Test

Shapiro-Wilk W Test

W	Prob<W
0.967030	0.3670

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table F7: Shapiro-Wilk W test for suture size “2-0”

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	1.2952	4	30	0.2942
Brown-Forsythe	1.0913	4	30	0.3787
Levene	1.4927	4	30	0.2293
Bartlett	1.8983	4	.	0.1077

Table F8: Levene’s test for suture size 2-0

Levene’s test show equal variance

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Column	4	468.93543	117.234	19.3146	<.0001 *
Error	30	182.09143	6.070		
C. Total	34	651.02686			

Table F9: ANOVA test for suture size “2-0”

d. Suture size 3-0

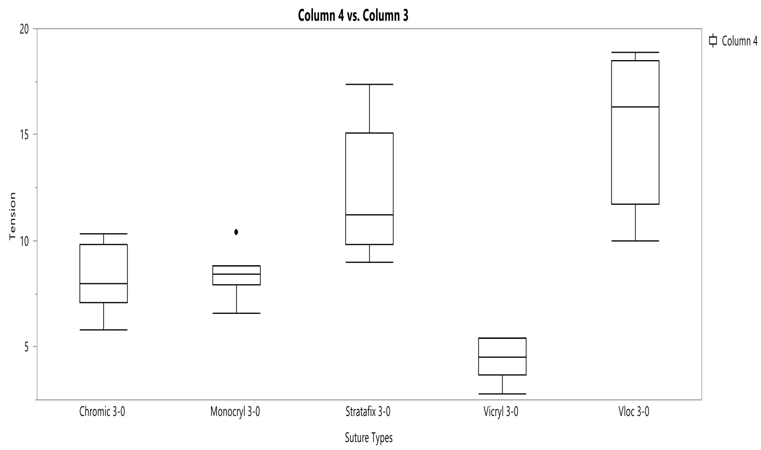

Figure F7: Box plot for sutures of size "3-0"

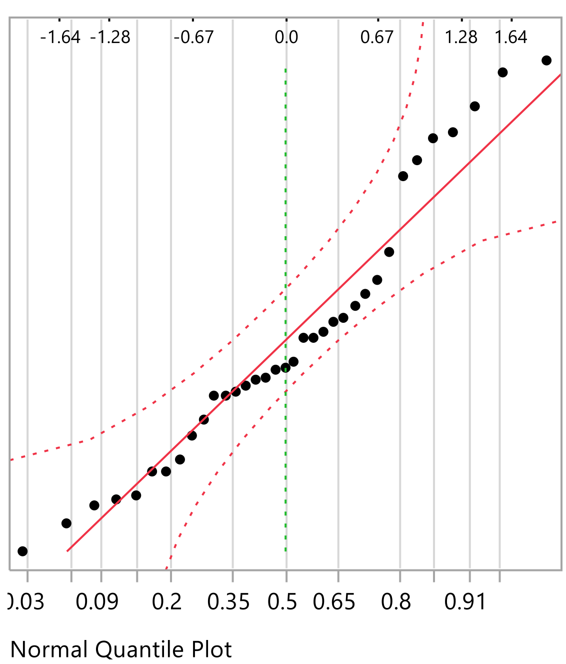

Figure F8: Normal quantile plot for suture size "3-0"

Goodness-of-Fit Test

Shapiro-Wilk W Test

W	Prob<W
0.940358	0.0574

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table F10: Shapiro-Wilk W test for suture size “3-0”

Test	DFNum	DFDen	Prob > F
O'Brien[.5]	4	30	0.0621
Brown-Forsythe	4	30	0.1360
Levene	4	30	0.0143
Bartlett	4	.	0.0087

Table F11: Levene’s test for size 3-0 sutures

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
30.0300	4	14.417	<.0001*

Table F12: Welch’s test for suture size “3-0”

e. Suture size "4-0"

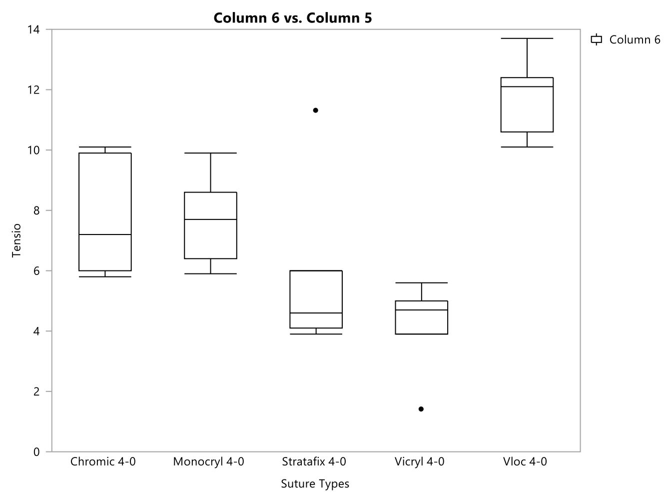

Figure F9: Box plot for sutures of size "4-0"

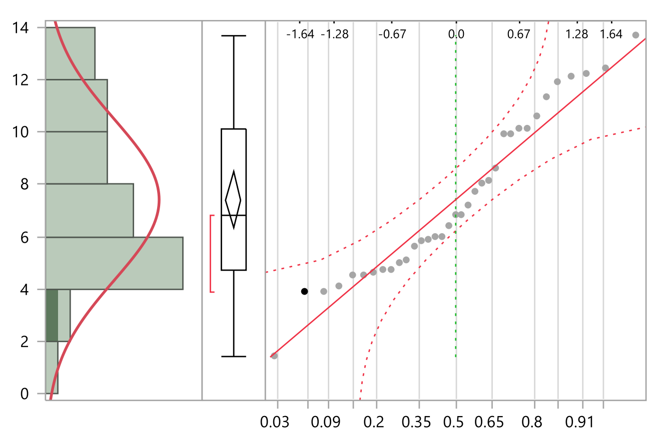

Figure F10: Normal quantile plot for suture size "4-0"

Goodness-of-Fit Test

Shapiro-Wilk W Test

W	Prob<W
0.947829	0.0972

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table F13: Shapiro-Wilk W test for suture size “4-0”

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	0.6437	4	30	0.6356
Brown-Forsythe	0.3180	4	30	0.8637
Levene	0.7855	4	30	0.5437
Bartlett	1.1822	4	.	0.3163

Table F14: Levene’s test for size 4-0

Welch's Test

Velch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
29.2467	4	14.831	<.0001*

Table F15: Welch’stest for suture size “4-0”

Appendix G: Holding strength of clips on different suture sizes for each suture type

The normality test of tension recorded for different sutures were analyzed using Shapiro Wilk test. The p-value greater than 0.05 indicate normal distribution of data obtain. During an analysis, if the data obtained from the experiment was not normally distributed, the data was transformed into studentized residual to analyze the normal distribution of data. A residual is the difference between a predicted value and the observed value. A studentized residual is the result of dividing the residual by the standard error of the residual. The adjustment accounts for different variances in the residuals. The variances of residuals for different values of the input field are not the same. To account for these differences, the residual values are divided by the standard error for the residuals. This adjustment is called studentizing. It allows for a standardized comparison among the residuals. Significance in normality test for studentized residual data achieves the requirement of normal distribution of data.

Levene's test was used to test the equality of the variance, where p value greater than 0.2 is consider as homogeneity in variance. For a condition of unequal variance, Welch's test was used as ANOVA test for a condition of unequal variance and normal distribution of data. Welch's test provided a significant evidence of difference in mean tension recorded for different sutures. The p value less than 0.05 indicated the significant difference in mean tension for sutures. The ANOVA tests followed by Tukey HSD post hoc analysis were conducted on sutures Vicryl, Monocryl, Chromic, Stratafix and V-Loc based on suture Types. The results were shown below:

a. Vicryl Sutures

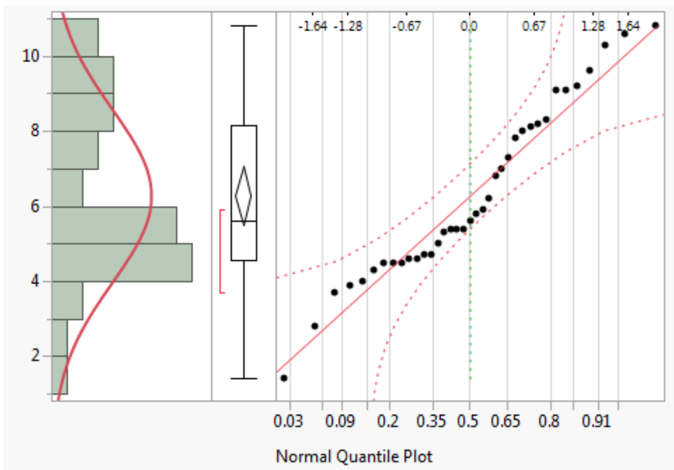

Figure G1: Normal quantile plot for Vicryl sutures

Shapiro-Wilk W Test

W	Prob<W
0.956567	0.1570

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table G1: Shapiro-Wilk W test for Vicryl sutures

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	1.8944	4	32	0.1355
Brown-Forsythe	1.1215	4	32	0.3637
Levene	2.0159	4	32	0.1158
Bartlett	1.2988	4	.	0.2678

Table G2: Levene's test for Vicryl sutures

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
18.0090	4	15.845	<.0001*

Table G3: Welch's test for Vicryl sutures

b. Monocryl Sutures

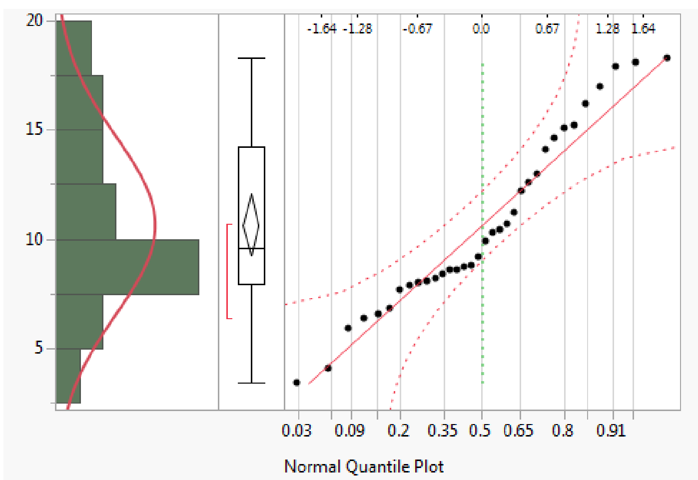

Figure G2: Normal Quantile plot for Monocryl sutures

Shapiro-Wilk W Test

W	Prob<W
0.947610	0.1041

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table G4: Shapiro-Wilk W test for Monocryl sutures

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	2.9873	4	29	0.0351
Brown-Forsythe	2.6592	4	29	0.0527
Levene	2.8843	4	29	0.0399
Bartlett	2.5380	4	.	0.0379

Table G5: Levene's test for Monocryl sutures

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
34.4543	4	13.825	<.0001*

Table G6: Welch's test for Monocryl sutures

c. Chromic Sutures

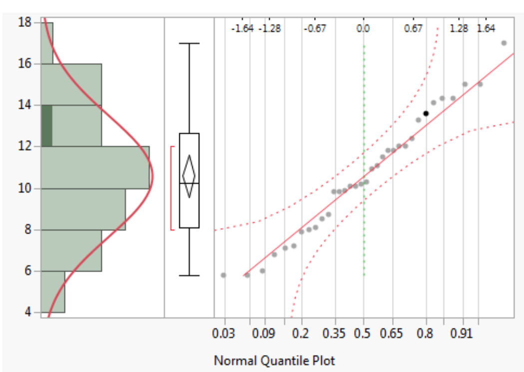

Figure G3: Normal Quantile plot for Chromic sutures

Shapiro-Wilk W Test

W	Prob<W
0.973755	0.5722

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table G7: Shapiro-Wilk W test for Chromic sutures

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	0.6597	4	29	0.6249
Brown-Forsythe	0.1845	4	29	0.9446
Levene	0.4533	4	29	0.7692
Bartlett	0.8489	4	.	0.4939

Table G8: Levene's test for Chromic sutures

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Column 5	4	181.45620	45.3641	12.9404	<.0001*
Error	29	101.66262	3.5056		
C. Total	33	283.11882			

Table G9: ANOVA test for Chromic sutures

d. Stratafix Sutures

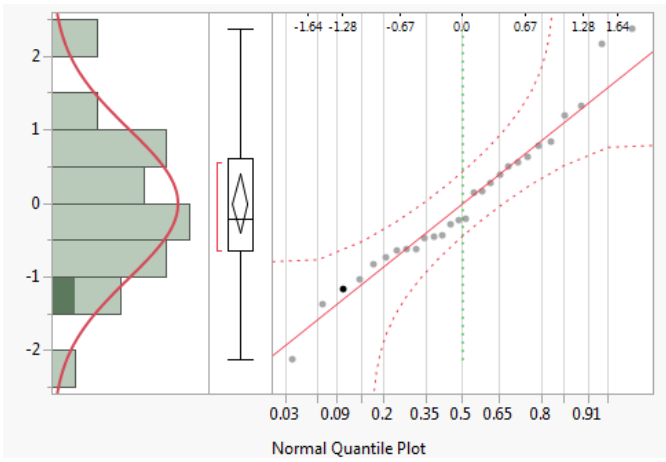

Figure G4: Normal Quantile plot for Stratafix sutures

Shapiro-Wilk W Test

W	Prob<W
0.974419	0.7024

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table G10: Shapiro-Wilk W test for Stratafix sutures

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	0.4967	3	24	0.6880
Brown-Forsythe	0.3367	3	24	0.7989
Levene	0.7383	3	24	0.5396
Bartlett	0.8367	3	.	0.4735

Table G11: Levene's test for Stratafix sutures

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Column 7	3	369.54393	123.181	18.5927	<.0001*
Error	24	159.00571	6.625		
C. Total	27	528.54964			

Table G12: ANOVA test for Stratafix sutures

e. V-Loc Sutures

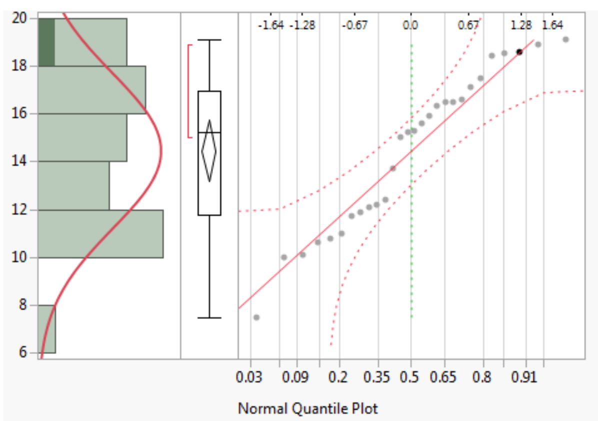

Figure G5: Normal Quantile plot for V-Loc sutures

Shapiro-Wilk W Test

W	Prob<W
0.941257	0.1190

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table G13: Shapiro-Wilk W test for V-Loc sutures

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	1.4491	3	24	0.2534
Brown-Forsythe	1.1352	3	24	0.3548
Levene	2.4068	3	24	0.0921
Bartlett	2.4528	3	.	0.0613

Table G14: Levene's test for V-Loc sutures

Welch's Test

Welch Anova testing Means Equal, allowing Std Devs Not Equal

F Ratio	DFNum	DFDen	Prob > F
6.0307	3	11.877	0.0097*

Table G15: Welch's test for V-Loc suture

Appendix H: Comparison of time at which clips starts to slip from suture size 2-0

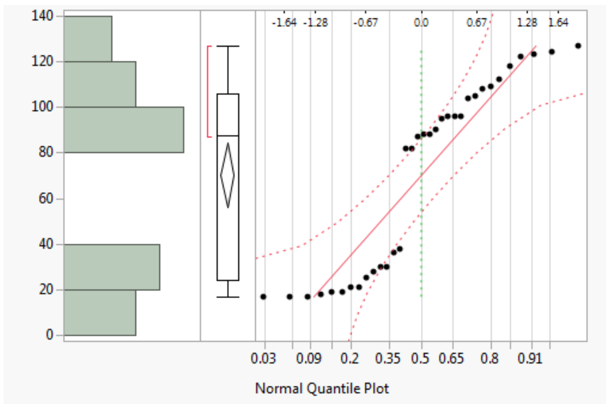

Figure H1: Normal Quantile plot of tension holding time of clips before slippage for sutures size 2-0

Goodness-of-Fit Test

Shapiro-Wilk W Test

W	Prob<W
0.843453	0.0002*

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table H1: Shapiro-Wilk W test for tension holding time of clips before slippage for sutures size 2-0

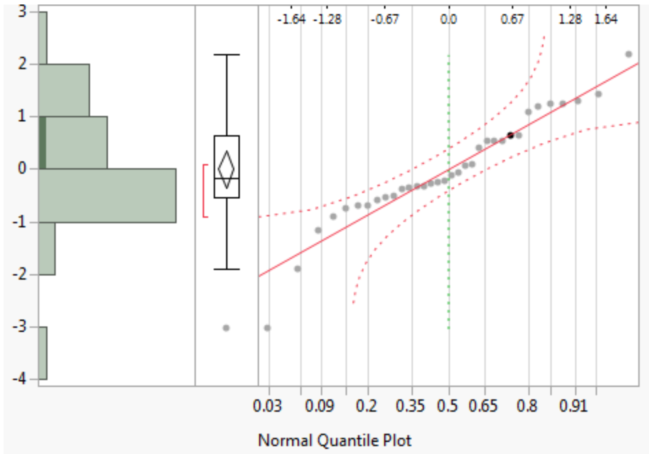

Figure H2: Normal Quantile plot of studentized residual obtain from tension holding time

Shapiro-Wilk W Test

W	Prob<W
0.956602	0.1932

Note: Ho = The data is from the Normal distribution. Small p-values reject Ho.

Table H2: Shapiro-Wilk W test of studentized residual data obtained for tension holding time of clips before slippage for sutures size 2-0

Test	F Ratio	DFNum	DFDen	Prob > F
O'Brien[.5]	1.2286	4	29	0.3204
Brown-Forsythe	1.0538	4	29	0.3969
Levene	1.4299	4	29	0.2492
Bartlett	1.9986	4	.	0.0918

Table H3: Levene's test for tension holding time of clips before slippage for sutures size 2-0

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Column 1	4	52488.427	13122.1	119.5283	<.0001*
Error	29	3183.690	109.8		
C. Total	33	55672.118			

Table H4: ANOVA test for tension holding time of clips before slippage for sutures size 2-0

Appendix I: Holding strength of clips with its placement towards and against barb

1. Comparison of holding strength of LAPRA-TY with its placement towards and against barb for V-Loc 2-0 suture (towards and against barb)

Moments			
N	7	Sum Weights	7
Mean	-1.8142857	Sum Observations	-12.7
Std Deviation	3.15406012	Variance	9.94809524
Skewness	0.58464867	Kurtosis	-1.3472999
Uncorrected SS	82.73	Corrected SS	59.6885714
Coeff Variation	-173.84583	Std Error Mean	1.19212267

Table I1: Data analysis of V-Loc 2-0 sutures

Conditions:

Since the sample size is so small (n=7) we need to use a non-parametric alternative to the paired t-test. The skewness of .5846 is between -1.0 and 1.0 so lack of symmetry is not an issue, thus we can use the Wilcoxon Signed Rank Test to compare medians.

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	-1.5219	Pr> |t|	0.1789
Sign	M	-1.5	Pr>= |M|	0.4531
Signed Rank	S	-8	Pr>= |S|	0.2188

Table I2: Wilcoxon Signed Rank test for V-Loc 2-0 sutures

Wilcoxon Signed Rank:

The p-value of .2188 is not significant. There is not a statistically significant difference between the median strength of suture between the two directions (toward and against) for Vloc2.

2. Comparison of holding strength of LAPRA-TY with its placement towards and against barb for V-Loc 3-0 suture (towards and against barb)

Moments			
N	7	**Sum Weights**	7
Mean	-2.9142857	**Sum Observations**	-20.4
Std Deviation	4.87627883	**Variance**	23.7780952
Skewness	0.72770556	**Kurtosis**	-0.8344105
Uncorrected SS	202.12	**Corrected SS**	142.668571
Coeff Variation	-167.32329	**Std Error Mean**	1.84306016

Table I3: Data analysis for V-Loc 3-0 sutures

Conditions:

Since the sample size is so small (n=7) we need to use a non-parametric alternative to the paired t-test. The skewness of .7277 is between -1.0 and 1.0 so lack of symmetry is not an issue, thus we can use the Wilcoxon Signed Rank Test to compare medians.

Tests for Location: Mu0=0				
Test	**Statistic**		**p Value**	
Student's t	**t**	-1.58122	**Pr> |t|**	0.1649
Sign	**M**	-1.5	**Pr>= |M|**	0.4531
Signed Rank	**S**	-9	**Pr>= |S|**	0.1563

Table I4: Wilcoxon Signed Rank test for V-Loc 3-0 sutures

Wilcoxon Signed Rank Test:

The p-value of .1563 is not significant. There is not a statistically significant difference between the median strength of suture between the two directions (toward and against) for Vloc3.

3. Comparison of holding strength of LAPRA-TY with its placement towards and against barb for Stratafix 2-0 suture (towards and against barb)

Moments			
N	7	Sum Weights	7
Mean	0.27142857	Sum Observations	1.9
Std Deviation	2.28743982	Variance	5.23238095
Skewness	0.36076071	Kurtosis	-1.3278339
Uncorrected SS	31.91	Corrected SS	31.3942857
Coeff Variation	842.740988	Std Error Mean	0.86457099

Table I5: Data analysis for Stratafix 2-0 sutures

Conditions:

Since the sample size is so small (n=7) we need to use a non-parametric alternative to the paired t-test. The skewness of .3608 is between -1.0 and 1.0 so lack of symmetry is not an issue, thus we can use the Wilcoxon Signed Rank Test to compare medians.

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	0.313946	Pr> |t|	0.7642
Sign	M	0	Pr>= |M|	1.0000
Signed Rank	S	0.5	Pr>= |S|	1.0000

Table I6: Wilcoxon Signed Rank test for Stratafix 2-0 sutures

Wilcoxon Signed Rank Test:

The p-value of 1.00 is not significant. There is not a statistically significant difference between the median strength of suture between the two directions (toward and against) for Stratafix2.

Appendix J: Graphical representation of holding strengths

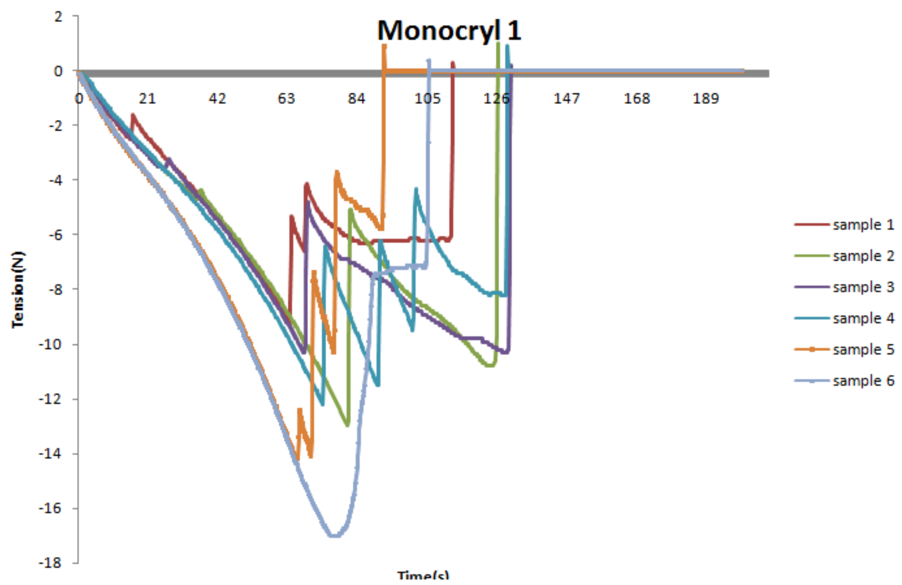

Figure J1: Holding strength for Monocryl 1 sutures

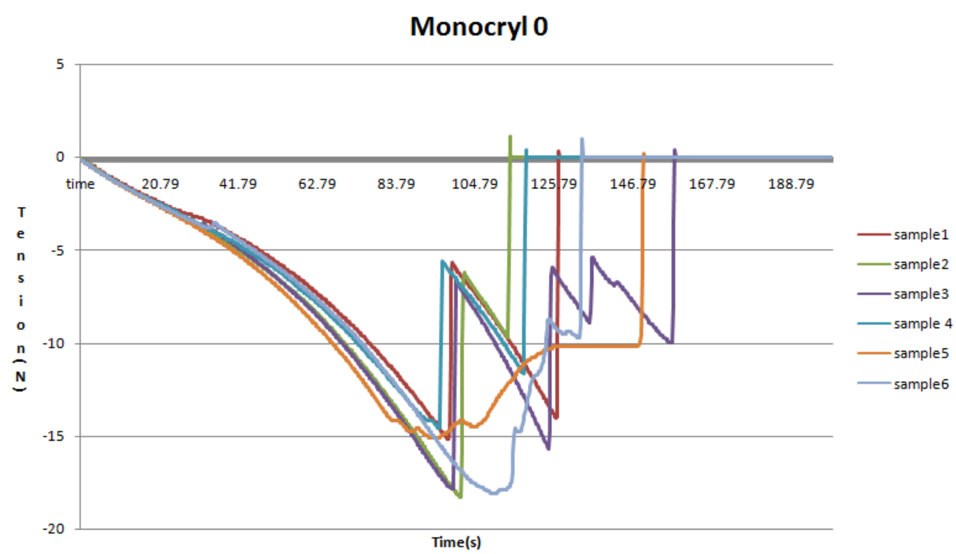

Figure J2: Holding strength for Monocryl 0 sutures

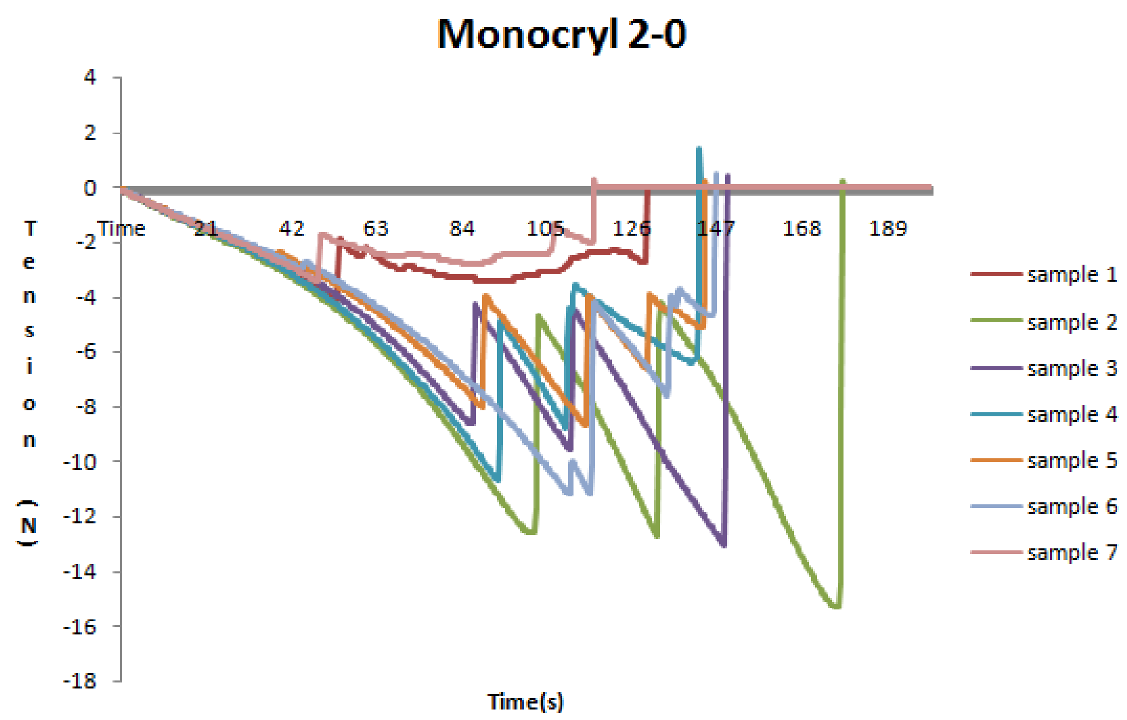

Figure J3: Holding strength for Monocryl 2-0 sutures

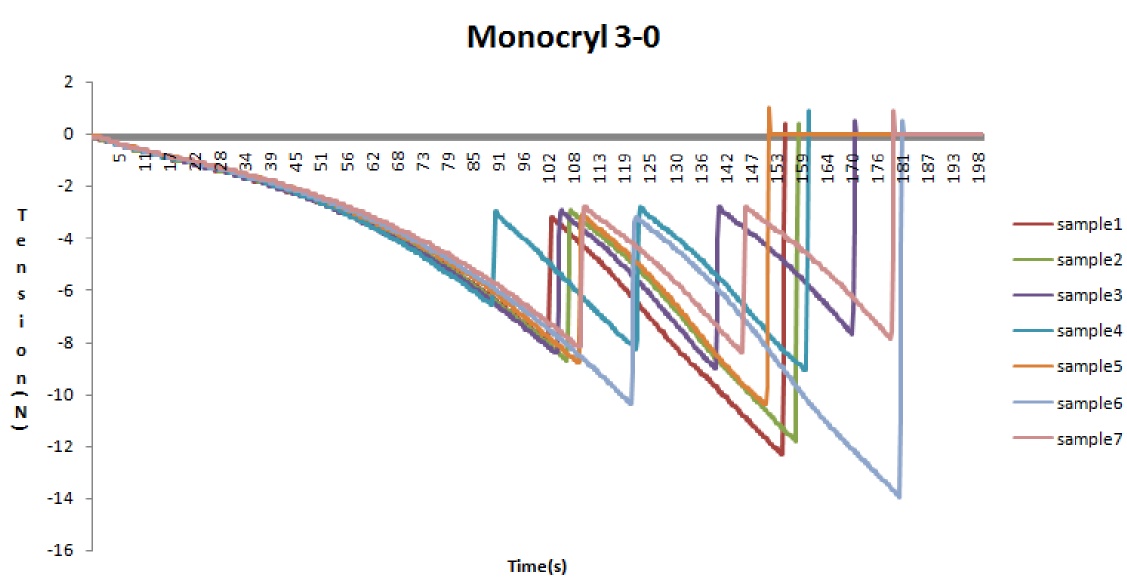

Figure J4: Holding strength for Monocryl 3-0 sutures

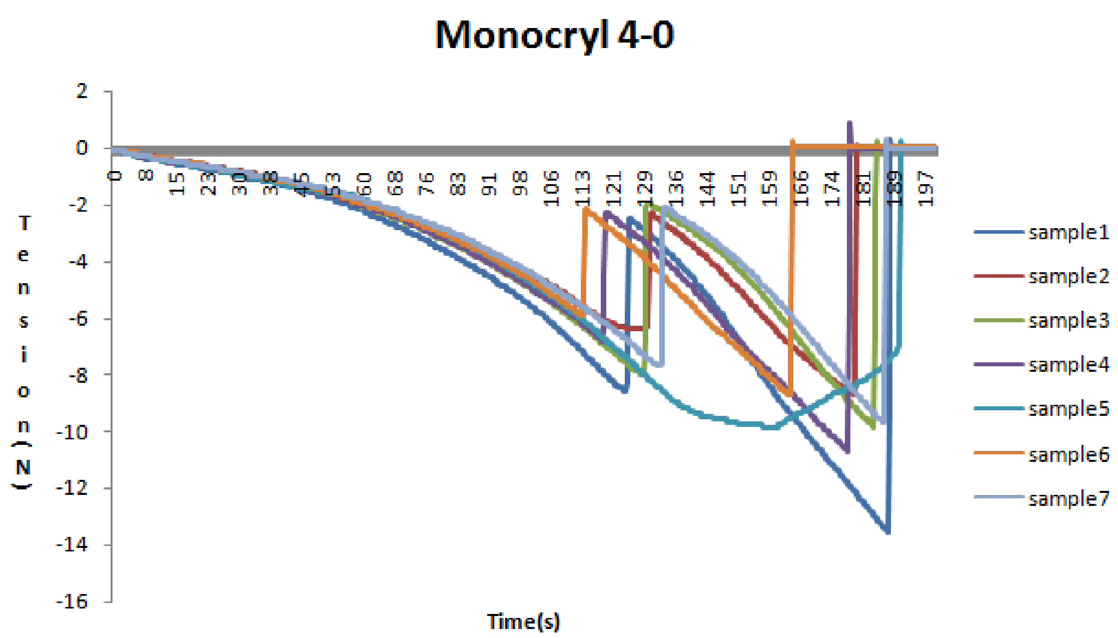

Figure J5: Holding strength for Monocryl 4-0 sutures

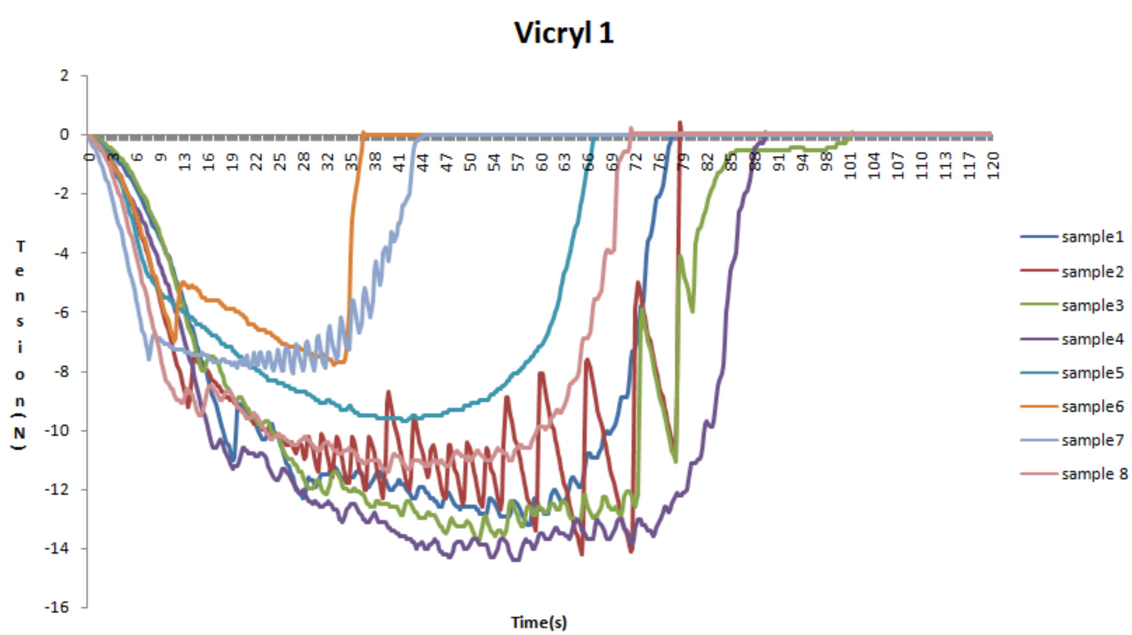

Figure J6: Holding strength for Vicryl 1 sutures

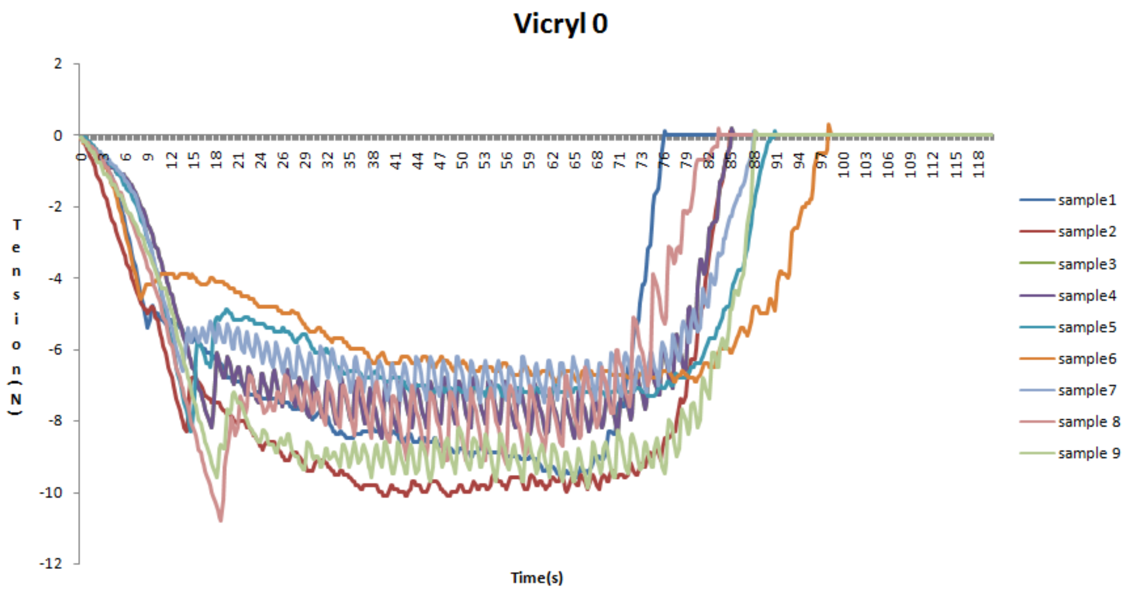

Figure J7: Holding strength for Vicryl 0 sutures

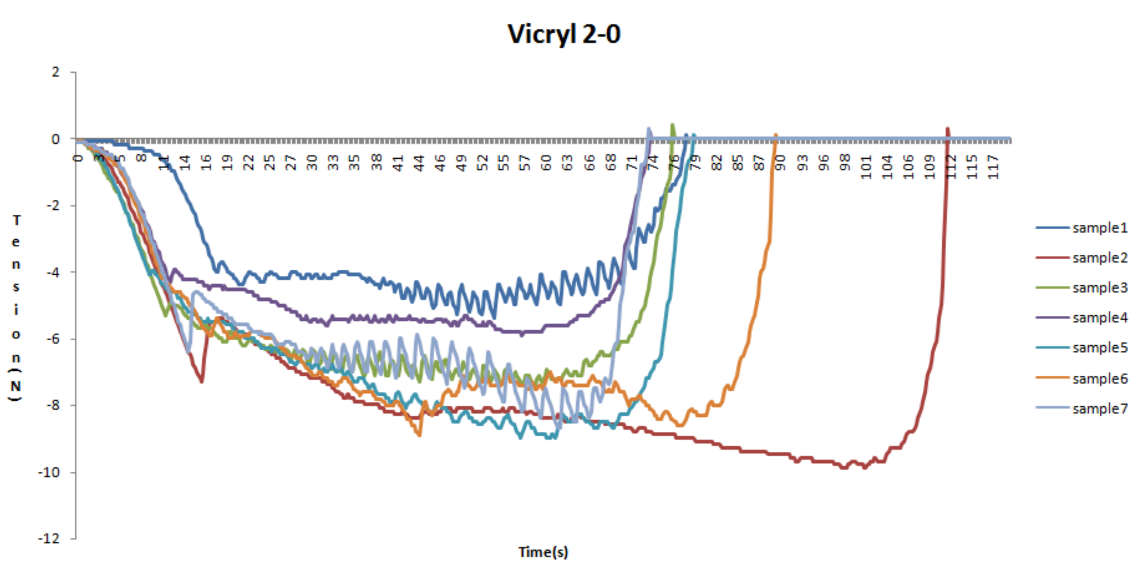

Figure J8: Holding strength for Vicryl 2-0 sutures

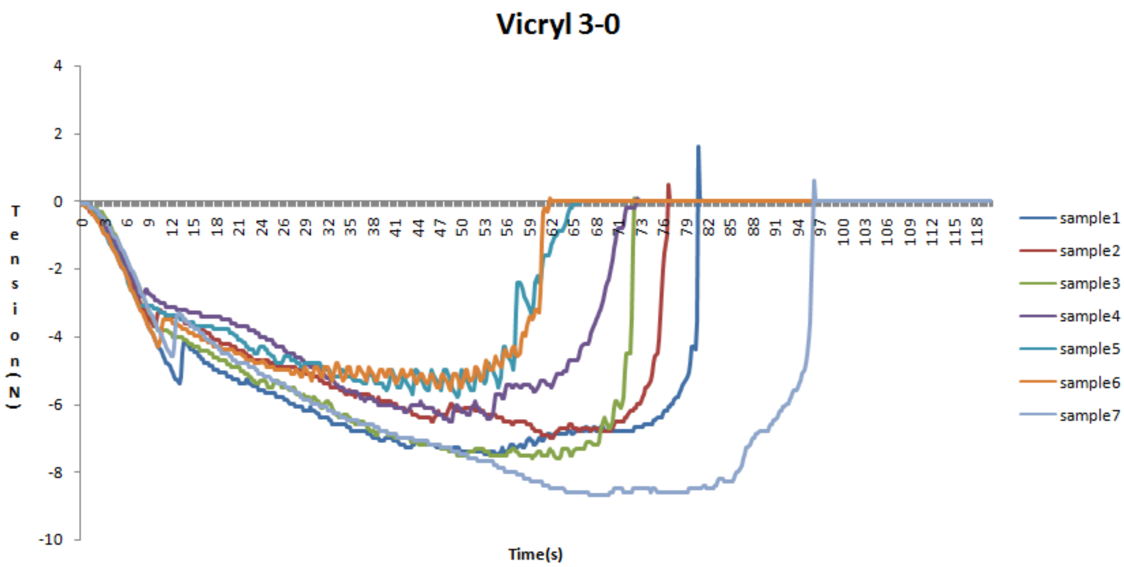

Figure J9: Holding strength for Vicryl 3-0 sutures

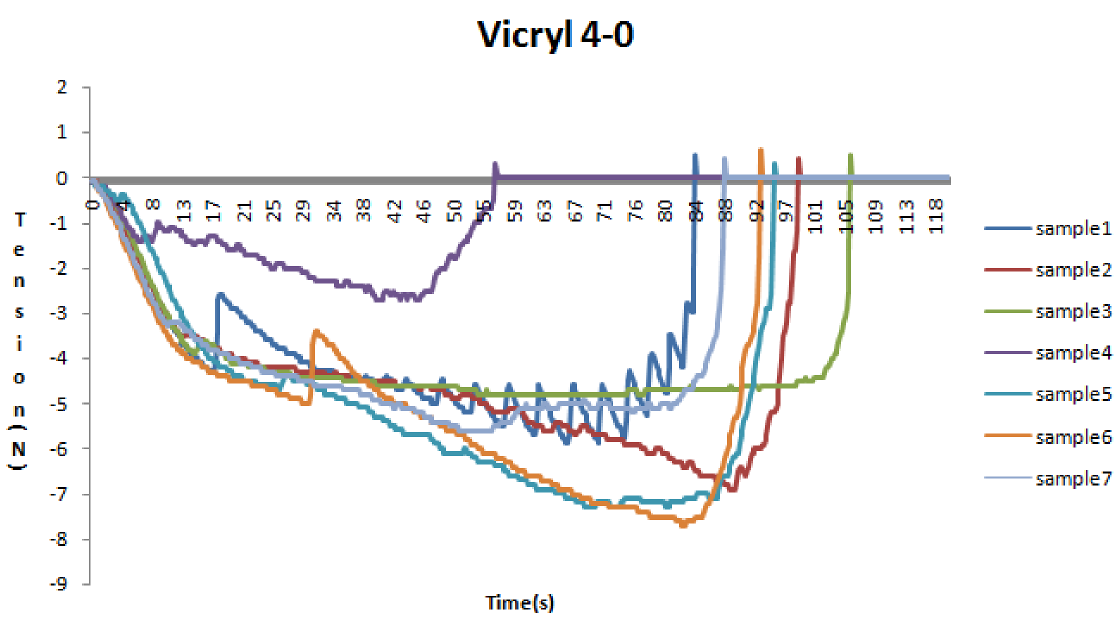

Figure J10: Holding strength for Vicryl 4-0 sutures

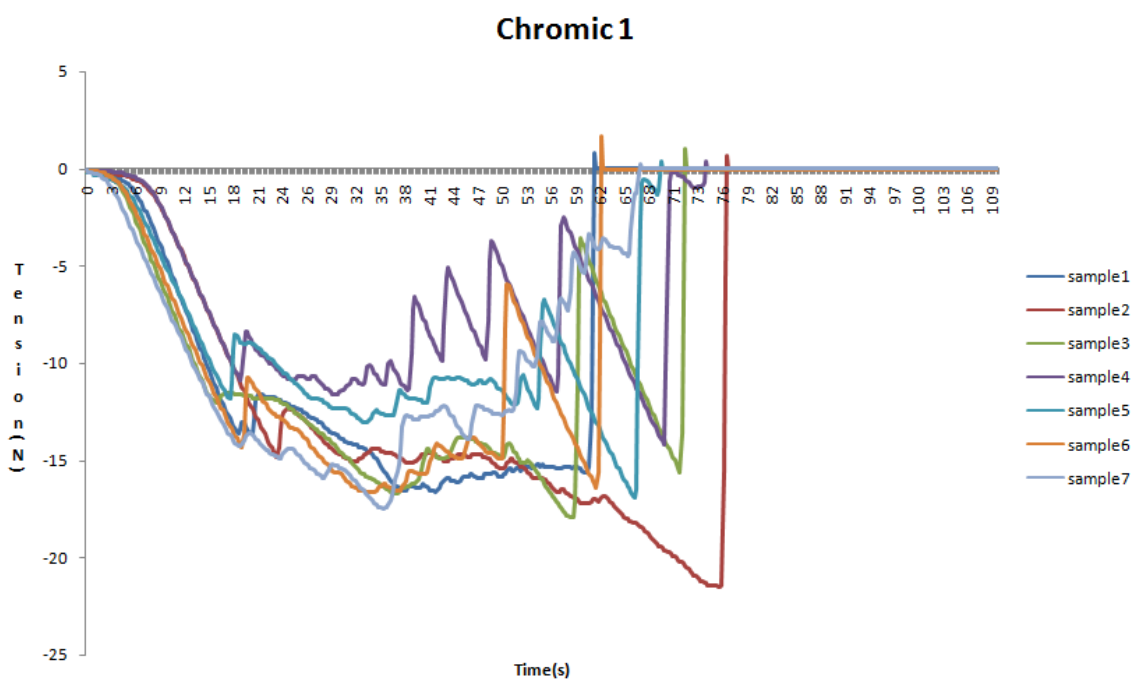

Figure J11: Holding strength for Chromic 1 sutures

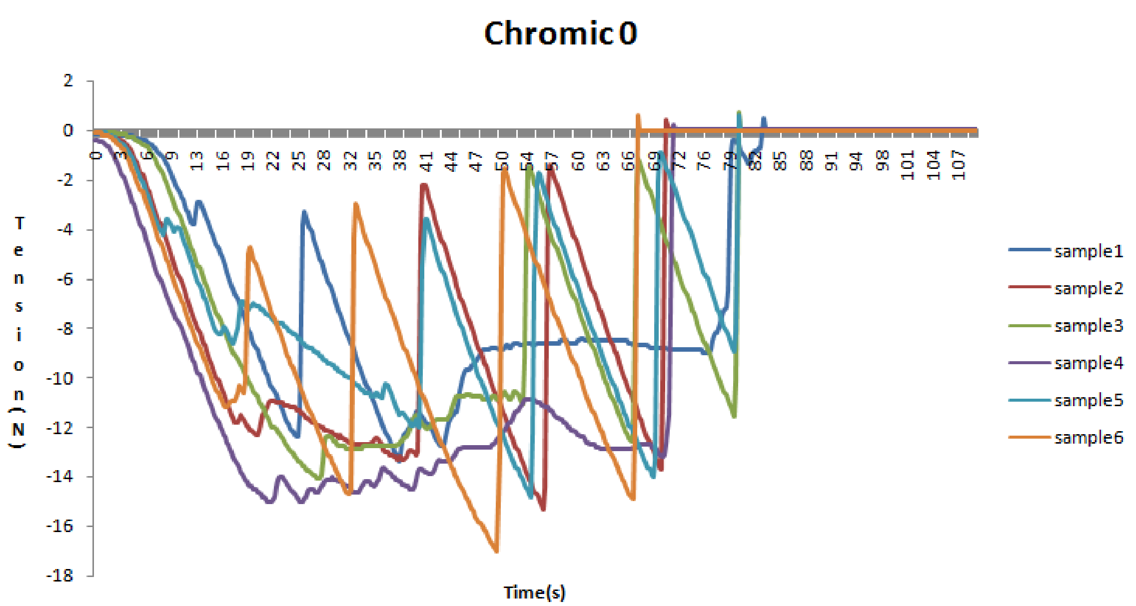

Figure J12: Holding strength for Chromic 0 sutures

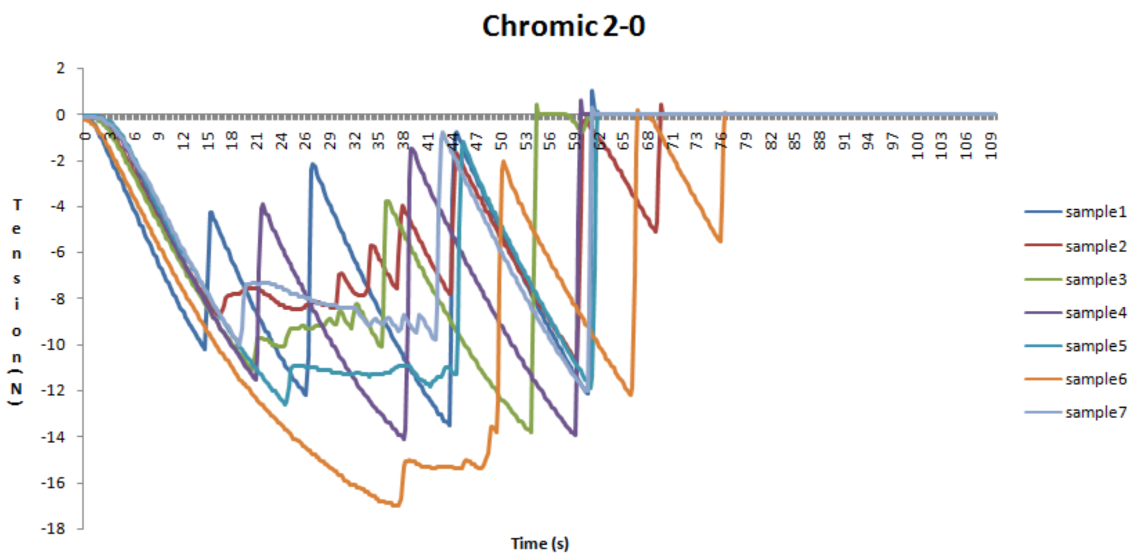

Figure J13: Holding strength for Chromic 2-0 sutures

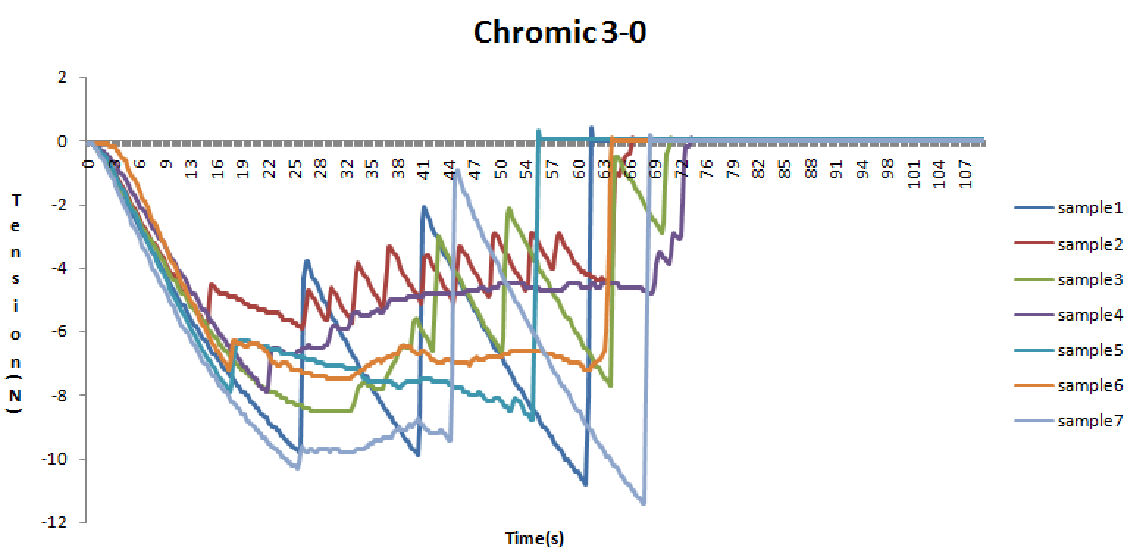

Figure J14: Holding strength for Chromic 3-0 sutures

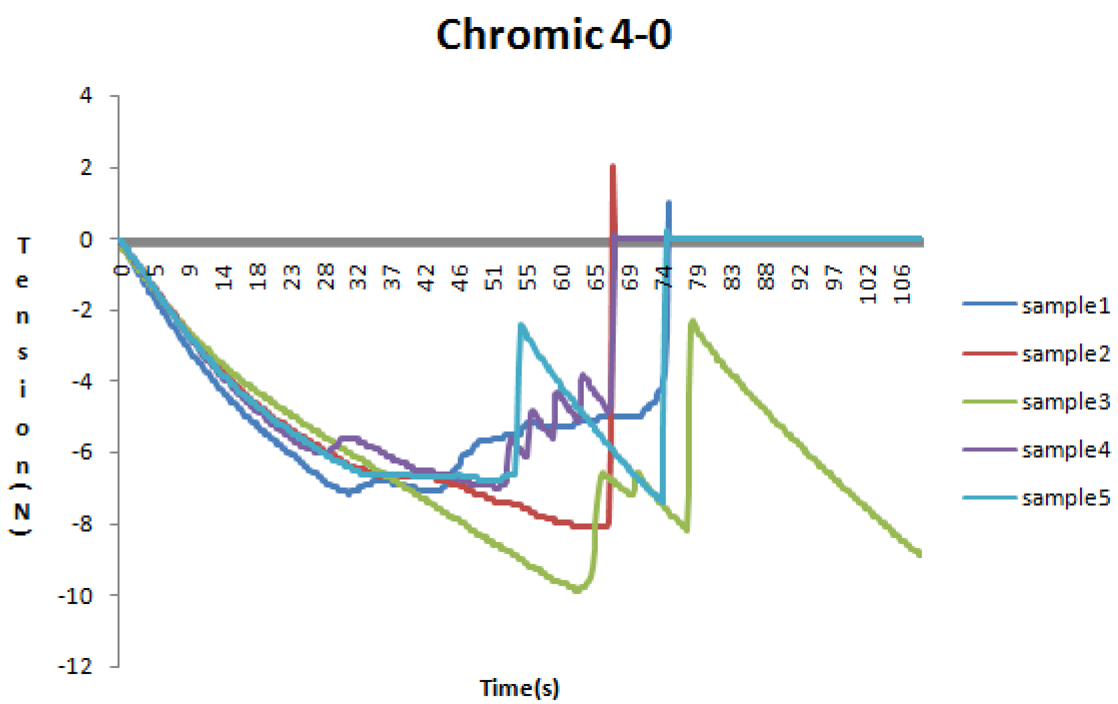

Figure J15: Holding strength for Chromic 4-0 sutures

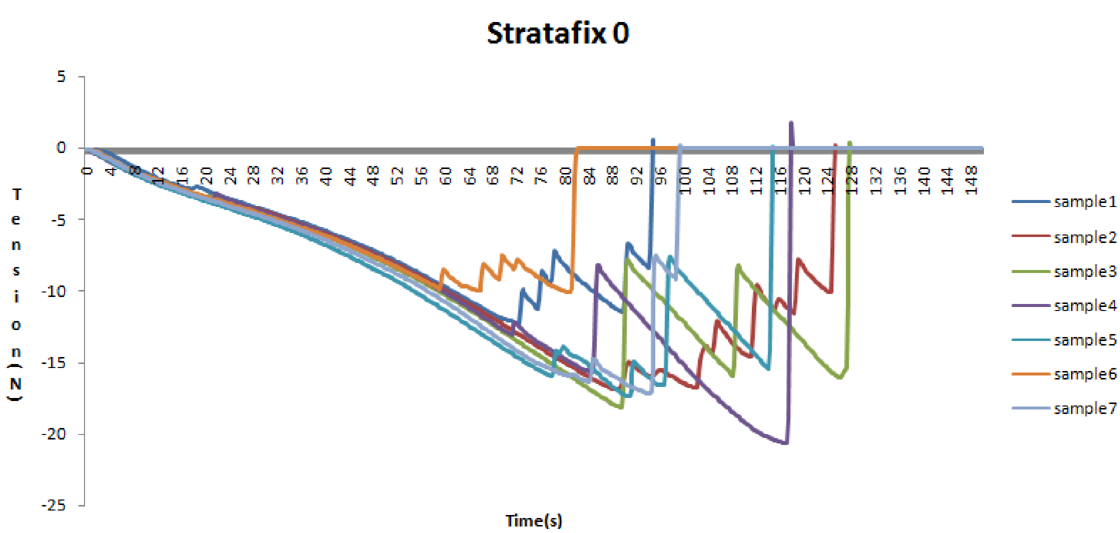

Figure J16: Holding strength for Stratafix 0 sutures

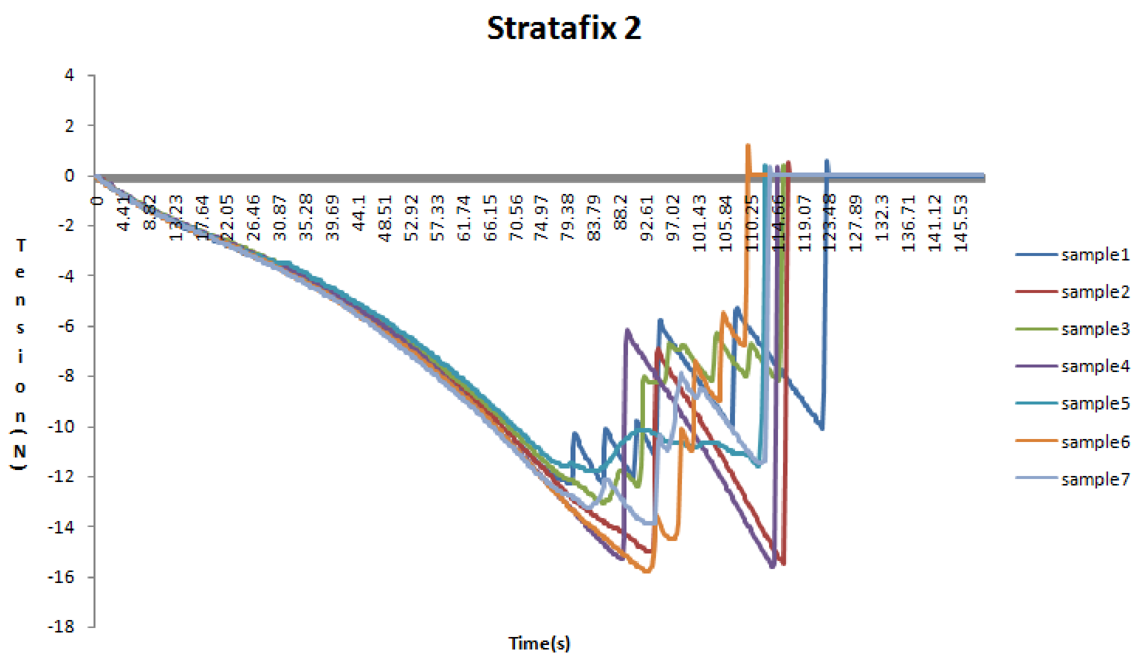

Figure J17: Holding strength for Stratafix 2 sutures

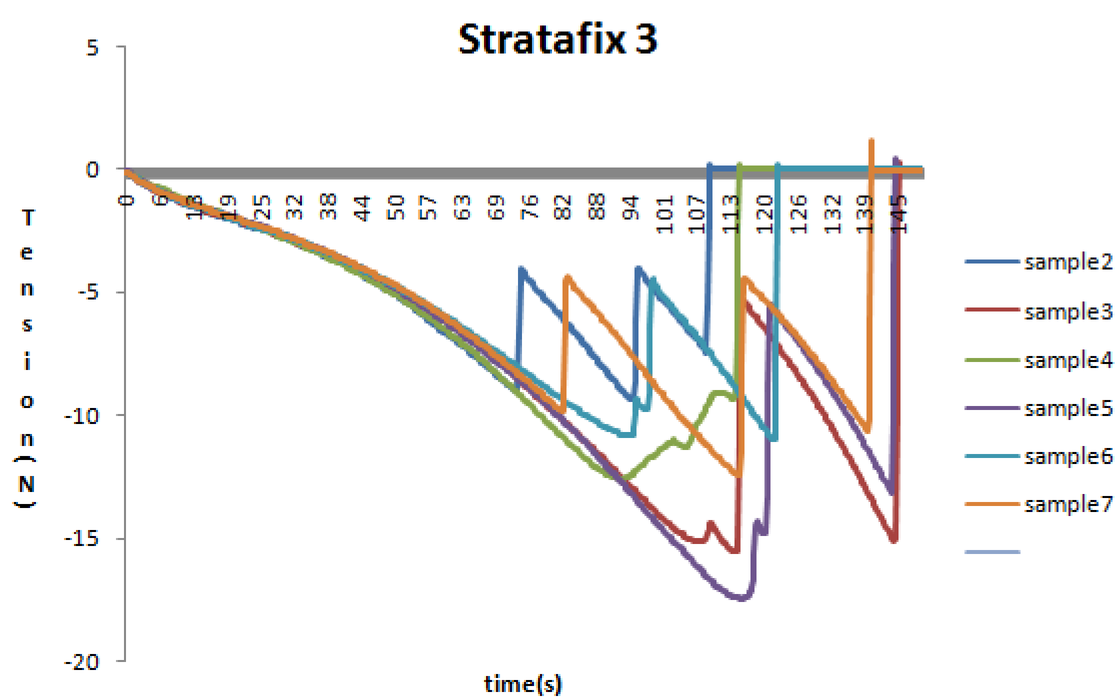

Figure J18: Holding strength for Stratafix 3 sutures

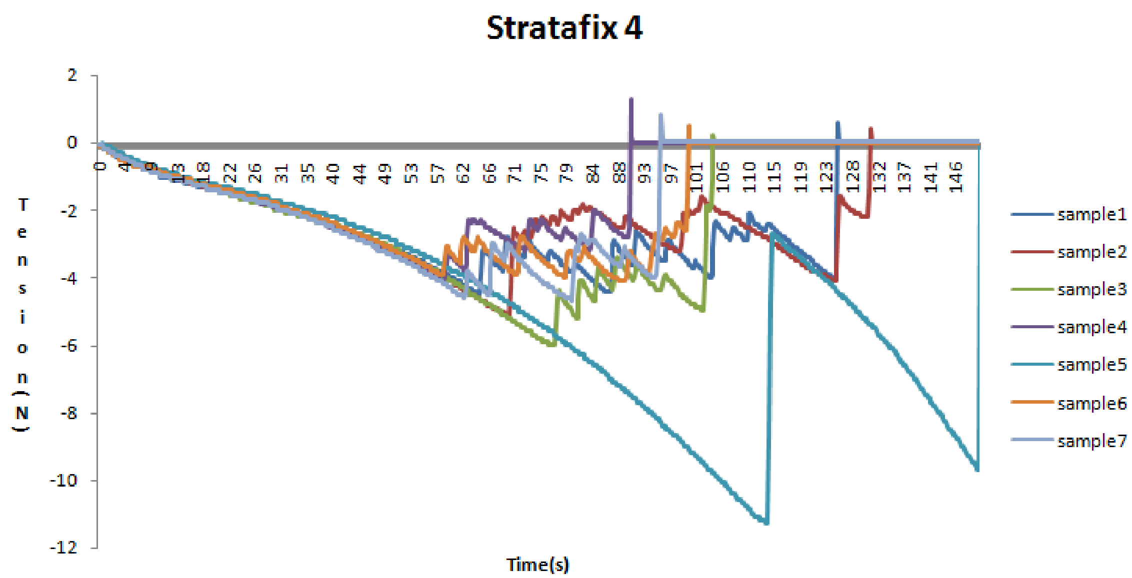

Figure J19: Holding strength for Stratafix 4 sutures

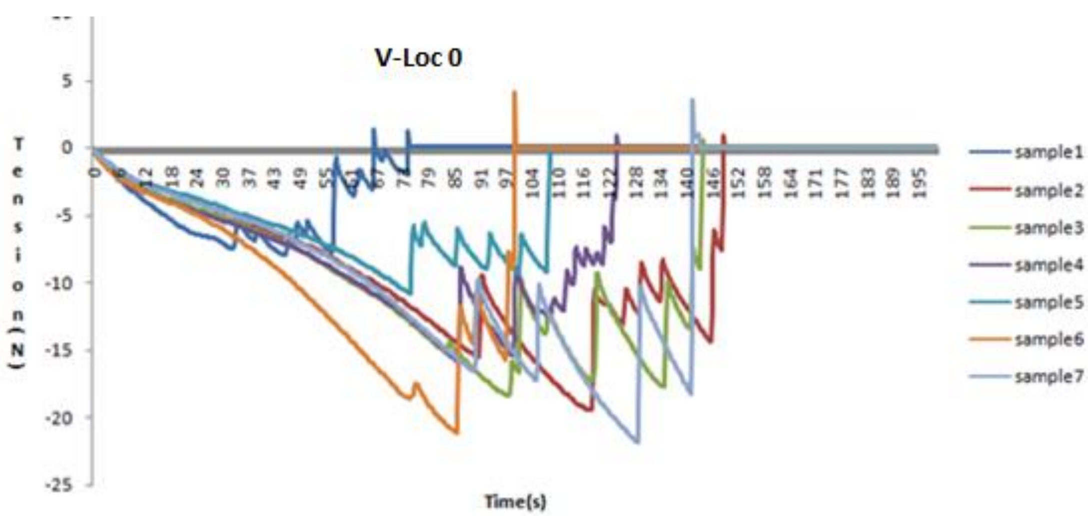

Figure J20: Holding strength for V-Loc 0 sutures

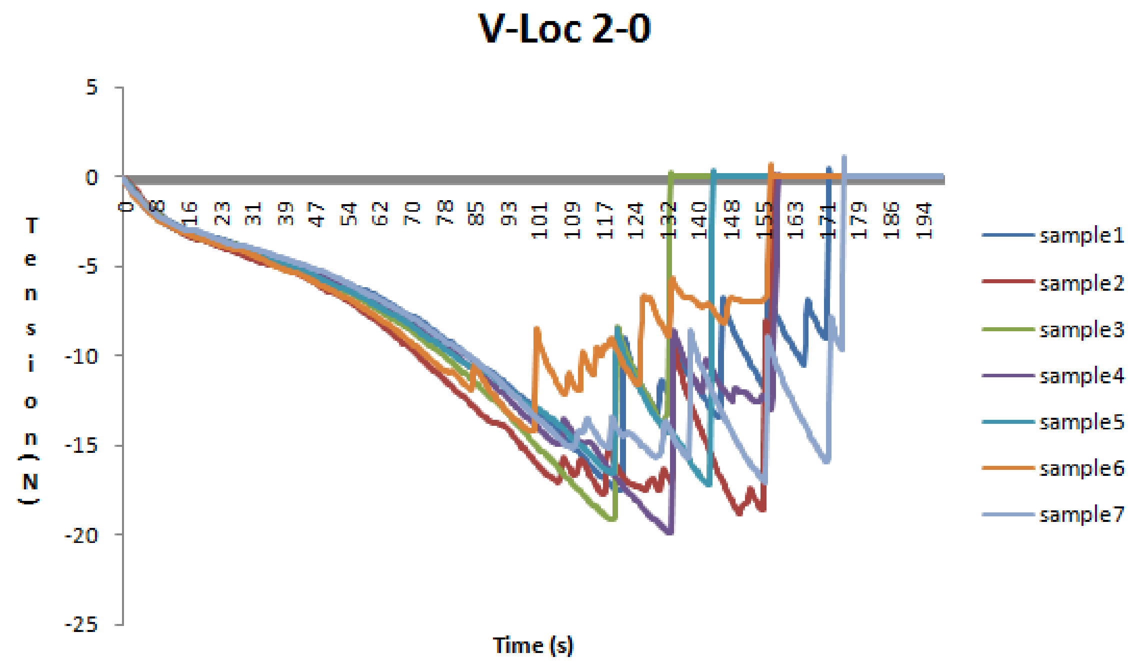

Figure J21: Holding strength for V-Loc 2-0 sutures

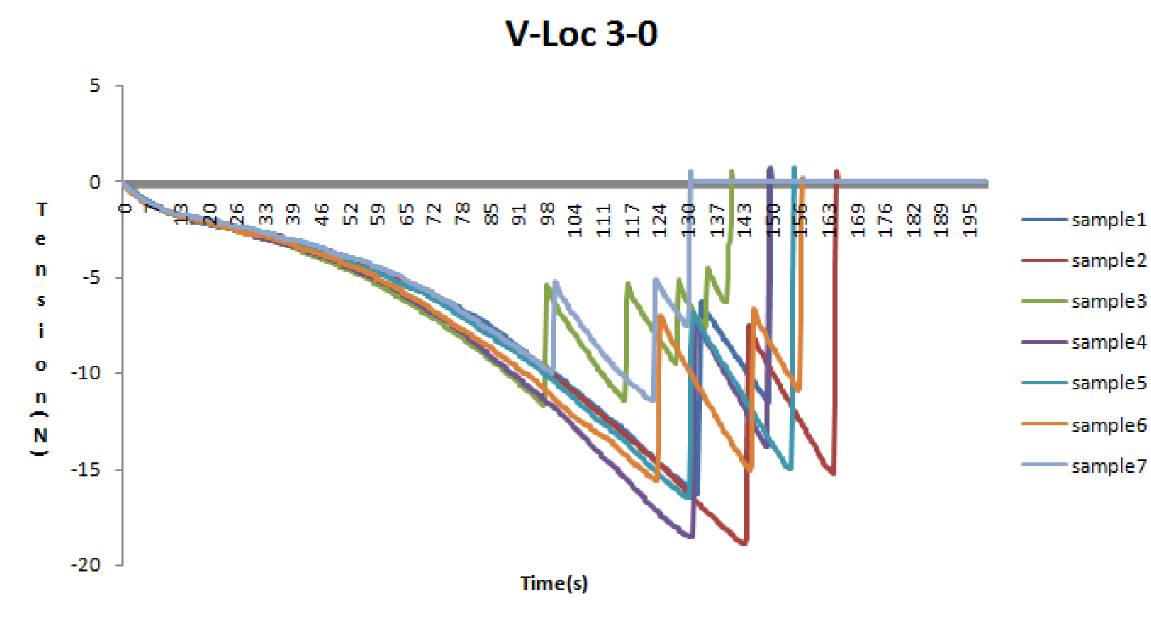

Figure J22: Holding strength for V-Loc 3-0 suture

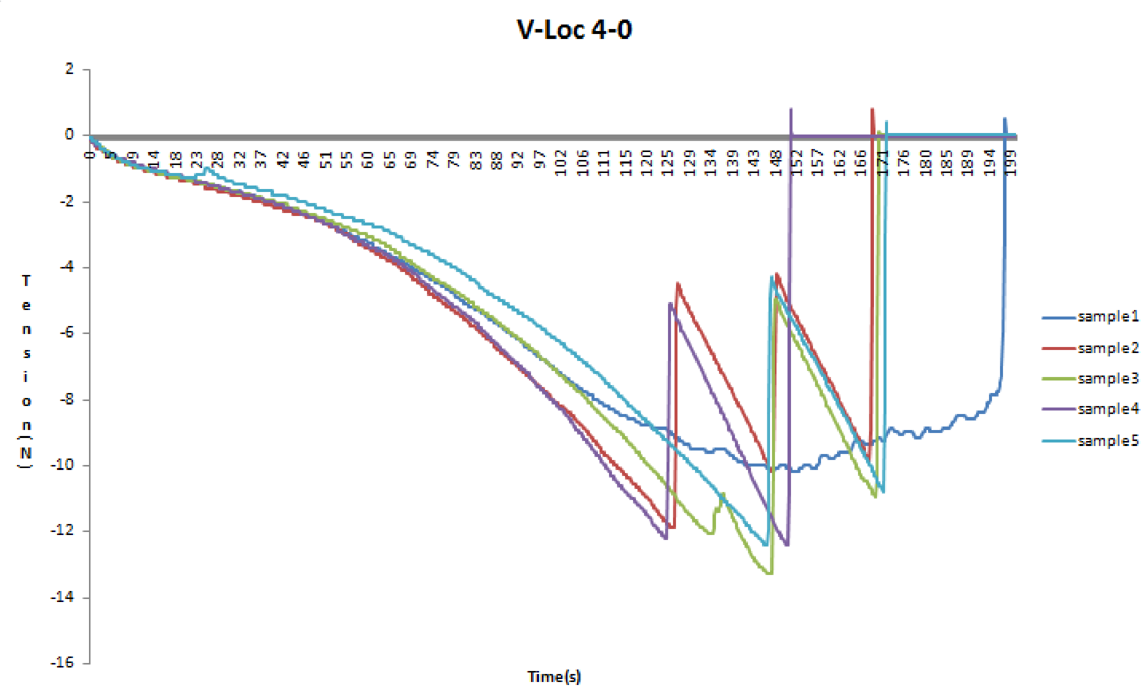

Figure J23: Holding strength for V-Loc 4-0 sutures

Bibliography

1. Fracchia JA, Glickman LI, Javit D, et al. Contemporary management of small renal tumors. J Community Support Oncol 2014.;2(6):112-221.
2. Bhat S. Role of surgery in advanced/metastatic renal cell carcinoma. Indian J Urol 2010;26(2):167–176.
3. Jared RB, Mohamad EA. Laparoendoscopic single-site surgery in urology. TherAdvUrol 2009; 1(5): 259–266.
4. Endres DM, Bossemeyer RW, Tobert CM, Baer WH, Lane BR. Investigation of the closing forces Involved in re-approximation of the renal remnant following partial nephrectomy. Urol 2014; 84 (4):971-975.
5. Shang JW, Ma X, Zhang X, Li HZ, Shi TP.Comparison of two different renorrhaphy techniques in retroperitoneal laparoscopic partial nephrectomy for complex tumor. Chin Med J 2013;126 (24):4629-4632
6. Breda A, Finelli A, Janetschek G, Porpiglia F, MontorsiF.Complications of Laparoscopic Surgery for Renal Masses: Prevention, Management, and Comparison with the Open. EurUrol 2009; 55(4): 836–850.
7. Park DS, Jang WK. Secure reconstruction technique after partial nephrectomy irrespective of tumor size and location. IntBraz J Urol 2009;35(4):416-26.
8. Ghani KR, Anderson C. Closing the deal: Renorrhapy during Laparoscopic and robotic Partial nephrectomy. BJU Int 2011;108(1):2-4.
9. Makiyama K, Nakaigawa N, Miyoshi Y, Murakami T, Yao M, Kubota Y .Improvement on parenchymal suturing technique in laparoscopic partial nephrectomy. Int J Urol 2008; 15(9): 854–855

10. Tarin T, Kimm S, Chung B, Shinghal R, Reese J. Comparison of holding strength of suture anchors on human renal capsule. J Endourol 2010; 24(3): 293-297.
11. Ames CD, Perrone JM, Frisella AJ, Morrissey K, Landman J. Comparison of holding strength of suture anchors for hepatic and renal parenchyma. J Endourol. 2005 ;19(10):1221-1225.
12. Fernando P. Secin "Importance and Limits of Ischemia in Renal Partial Surgery: Experimental and Clinical Research. AdvUrol 2008;102461
13. Ghani KR, Trinh QD, Sammon J, Jeong W, Dabaja A, Menon M. Robot-assisted urological surgery: Current status and future perspectives. Arab J Urol.2012;10(1):17–22
14. Benway BM1, Wang AJ, Cabello JM, Bhayani SB. Robotic Partial Nephrectomy with Sliding-Clip Renorrhaphy: Technique and Outcomes.EurUrol 2009;55(3): 592–599
15. Bernardo NO, Gill IS. Laparoscopic partial nephrectomy: current status Arch. EspUrol 2002;55(7):868-880
16. Simon J, Finter F, Ignatius A, Meilinger M, Dürselen L. Maximum tensile force of different suture techniques in reconstruction of the renal remnant after nephron-sparing surgery. SurgEndosc 2011;25(2):503-507.
17. Zuber TJ. The Mattress Sutures:Vertical,Horizontal, and Corner Stitch. Am Fam Physician 2002;66(12):2231-2236.
18. Surgical Instrument Pictures[Internet];[cited 2015 March].Available from:http://www.surgical-instrument-pictures.com/suture.html
19. Kudur MH, Pai SB, Sripathi H, PrabhuS.Sutures and suturing techniques in skin closure. Indian J DermatolVenereolLeprol 2009;75(4):425-434.

20. Sammon J, Petros F, Sukumar S, Bhandari A, Kaul S, Menon M, Rogers C. Barbed Suture for Renorrhaphy During Robot-Assisted Partial Nephrectomy J Endourol. 2011;25(3): 529-533.

21. Jeon SH, JungS , Son HS, Kimm SY, Chung BI. The unidirectional barbed suture for renorrhaphy during laparoscopic partial nephrectomy: Stanford experience. J LaparoendoscAdvSurg Tech A .2013;23(6):521-525

22. Microsoft Hardware.LifeCam Studio[Internet] United states;2015[cited 2015 March].Available from: http://www.microsoft.com/hardware/en-us/p/lifecam-studio#overview

23. Endres DM. Investigation of the closing forces involved in re-approximation of the renal remnant following partial nephrectomy. Grand Rapids: Grand Valley State University; 2013 April

24. Laerd Statistics[Internet]: One-Way ANOVA 2013[cited 2015 March 2] Available from: https://statistics.laerd.com/statistical-guides/one-way-anovastatistical-guide-3.php

25. Ghasemi A, Zahediasl S. Normality Tests for Statistical Analysis: A Guide for Non-Statisticians. EndocrinolMetab2012;10(2):486-489.

26. Handbook of biological statistics[Internet].McDonald JH: One-way ANOVA 2014;[cited2015March].Availablefrom:http://bcs.bedfordstmartins.com/resdoc5e/RES5e_ch11_s10003.html#RES5e_ch11_p0070

27. Chung E, McPherson N, Grant A," Tensile Strength of Absorbable Suture Materials: In Vitro Analysis of the Effects of pH and Bacteria. Journal of Surgical Education 2009;66(4):208-211.

28. Greenberg CB, Davidson EB, Bellmer DD, Morton RJ, Payton ME .Evaluation of the tensile strengths of four monofilament absorbable suture materials after immersion in canine urine with or without bacteria. Am J Vet Res 2004; 65(6): 847-853.

29. Monnet E.New suture materials offer more options for wound closures[Internet];2002 Oct 01[cited 2015 March], Available from: http://veterinarynews.dvm360.com/new-suture-materials-offer-more-options-wound-closures

30. Aquarium Answers. Aquarium Heaters; Review, Size, Heater Information[Internet]; [cited 2015 March].Available from: http://www.aquarium-pond-answers.com/2007/01/aquarium-heaters-preset-vs-non-preset.html

31. Makiyama K, Nakaigawa N, Miyoshi Y, Murakami T, Yao M, Kubota Y.Improvement on parenchymal suturing technique in laparoscopic partial nephrectomy. Int J Urol 2008;15(9):854–855

32. Todd Gunson,DermNet NZ. Suturing techniques[Internet];2014[cited 2015 March].Available from: http://www.dermnetnz.org/procedures/suturing.html

33. Koo HJ, Lee DH, Kim IY. Renal hilar control during laparoscopic partial nephrectomy: to clamp or not to clamp. J Endourol. 2010;24(8):1283-1287.

34. Park DS, Jang WK.Secure reconstruction technique after partial nephrectomy irrespective of tumor size and location. Int Braz J Urol. 2009;35(4):416-26

35. Masumori N1, Itoh N, Takahashi S, Kitamura H, Nishida S, Tsukamoto T .New technique with combination of felt, Hem-o-lok and LAPRA-TY for suturing the renal parenchyma in laparoscopic partial nephrectomy. Int J Urol 2012;19(3):273-276.

36. Orvieto MA1, Lotan T, Lyon MB, Zorn KC, Mikhail AA, Rapp DE, Brendler CB, Shalhav AL Assessment of the LapraTy Clip forFacilitating Reconstructive Laparoscopic Surgery in a Porcine Model. Urology. 2007;69(3):582-585
37. Weld KJ, Arzola J, Montiglio C, Bush AC, Cespedes RD.LAPRA-TY holding strength andslippage with various suture types and sizes. Urology 2008;71(1):32-35
38. Gorin MA, Ramanathan R, Leveillee RJ. Laparoscopic Techniques Applied to Open Surgery: Sliding-clip Renorrhaphy. Urology 2010;77 (3):751-753
39. Canales BK, Lynch AC, Fernandes E, Anderson JK, RamaniAP.Novel Technique of Knotless Hemostatic Renal Parenchymal Suture Repair During Laparoscopic Partial Nephrectomy. Urology 2007;70(2):358-359.
40. Miller M, Anderson JK, Pearle MS, Cadeddu JA .Resorbable Clip migration in the collecting system after Laparoscopic Partial Nephrectomy. Urology 2006; 67(4):845