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# Investigation of the Closing Forces Involved in Re-Approximation of the Renal Remnant Following Partial Nephrectomy

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### Investigation of the Closing Forces Involved in Re-Approximation of the Renal Remnant

Following

Partial Nephrectomy

Donald M Endres II

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

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## **Dedication**

<span id="page-2-0"></span>This thesis is dedicated to all those that have assisted me along the way. Like nearly all significant undertakings, this work would not have been possible without the assistance and guidance of many people, at many levels.

Special recognition is owed to the research team which assisted me in the lab. The skilled hands of Dr. Brian Lane from Spectrum Health were invaluable in preparing and testing specimens for suture tension. He and I both appreciated the knowledge and effort Conrad Tobert, who took time from his own medical studies at Michigan State University, brought to the lab bench. Similarly appreciated are the sharp eye, willing hands and clear head of Professor Bossemeyer, PhD, Grand Valley State University, who made sure we were focused on the objective, stepped in to assist whenever needed and made important observations.

Members of the first Master of Science in Engineering - Biomedical cohort and the Biomedical faculty at Grand Valley State University also played an important part in making this a successful endeavor. Unlike universities where students succeed at the expense of others, our group worked together to navigate through the first years of a new program. From the discussions of theoretical concepts behind coursework to sharing the procedural tips to overcome registration problems, the daily communications were critical.

Most importantly, thanks go to my wife and children who made the time for me to participate in this program. They helped with household tasks on many occasions so that I could focus on my studies.

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<span id="page-3-0"></span>The following individuals and organizations have contributed to this work:

Dr. William Baer, MD, Pharm.D, VARI-Clinxus, LLC was instrumental in bringing the research team together. Without his extensive knowledge of the skills and expertise in the Grand Rapids medical community, the research team may have never met.

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Grand Valley State University and Spectrum Health System contributed to the space and supplies necessary for both the fabrication of the tools used in the experiments and the research itself.

The National Science Foundation providing funding through a grant to Prof. Samhita Rhodes and Prof. John Farris to establish the new graduate level program at Grand Valley State University. That funding played a major role in financing the first cohort of the program.

### **Abstract**

<span id="page-4-0"></span>Partial nephrectomy has become the preferred method of treatment in certain renal diseases, including small, peripheral tumors. However, re-establishment of hemostasis in the remaining tissue remains a challenging procedure. To better understand the forces involved in re-approximation of the renal remnant, this study measures the suture tensions reached in sliding clip renorrhaphy, as well as the ability of the tissue to support those tensions, and reviews how long suture material might be expected to survive those forces.

Three separate groups of experiments were conducted on fresh, porcine kidney tissue. Treatment groups were compared using commercially available software to compute appropriate descriptive statistics and generate regression lines.

Suture tension was measured at  $2.8 \pm 0.7$  Newtons (N) (mean  $\pm$  standard deviation) in ischemic organs,  $3.2 \pm 0.7$  N in kidneys at normal perfusion and  $3.4 \pm 0.7$  N at perfusion levels over 200 mm Hg (107 inches  $H_2O$ ).

Other experiments measured the tension required to cause tissue in both complete sutures (terminated on both ends with surgical clips) and half sutures (placed in a hemisphere of tissue and terminated with a clip only on the trailing end) to be torn from the organ. Positive relationships were shown between the amount of enclosed tissue (margin size) and the tension at failure for both complete and partial sutures. Margins below 1 cm in size failed at levels which could affect their usefulness in closing the parenchyma. Also, a positive correlation between failure tension and angle of applied force relative to the capsule surface was observed for angles in the range of 0º to 90º.

In a related experiment, different diameter sutures were tested on standard sized specimens. Differences in the force required to cause the suture to cut through the samples were not shown in the small sample.

The tensile strengths of suture material at eight different durations of exposure to select environmental conditions were tabulated so that materials appropriate for renorrhaphy can be identified. Tensile strength before and after exposure, size, and environmental conditions were listed. Data indicates that appropriate materials can be selected from available suture.

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## <span id="page-11-0"></span>**Introduction**

Since the advent of solid state electronics in the mid-twentieth century, clinical medicine has leveraged new technologies in the diagnosis and treatment of numerous ailments. Stable electronic components and digital processors, which can withstand the clinical use environment and operate without skilled electronics technicians present, make expert systems available to medical professionals in all settings.

One of the most frequently applied advancements is the use of improved imaging, such as computed tomography. With the innovation of new imaging modalities and three dimensional representations, internal medicine has seen an increase in the early diagnosis and treatment of many abnormalities. $^1$  Unusual growths can be located and identified with minimal impact on the patient.

The benefits of technology and improved diagnosis have impacted the practice of urology as much as any other discipline. The internist is now able to detect small tumors in the kidney at very early stages. Once a renal tumor is identified, the oncologic urologist must determine a course of treatment. Frequently, the preferred treatment plan includes surgical removal of the tumor. Currently, in an effort to reduce the amount of pain during healing and speed recovery, there is emphasis on the use of minimally invasive techniques to accomplish removal of renal tumors. Aided by improvements in laparoscopic tools since 1960, a growing number of procedures are undertaken using laparoscopic or robot-assisted techniques.

Also driven by the interest in improving patient outcome, there is a trend toward surgical removal of only that renal tissue which has been, or is expected to become, affected by

disease. The previously prevalent use of complete kidney removal is falling into disfavor as the consequences are becoming better understood and better methods become available. The result is that, increasingly, the urologist must close the site of a tumor resection within a functioning organ. Methods to achieve hemostasis in the remaining tissue have been developed based on practice and techniques used for other soft tissues.

This research attempts to achieve a better understanding of renorrhaphy, the sutured closing of a kidney. The goal is to provide oncologists with information useful to improving patient outcome. Tension in a sutured closure in renal tissue, life expectancy of suture material, and tensions causing suture failure are considered. The intent is to provide quantitative estimation of the forces involved in a sutured closure. A better understanding of the relative magnitude of those forces could focus future research activities in the area most likely to improve the products and techniques available to surgeons.

### <span id="page-12-0"></span>**Background**

#### <span id="page-12-1"></span>*History*

The first successful, intentional, surgical removal of a kidney, now referred to as radical nephrectomy (RN) or simply nephrectomy, is thought to have been performed in 1869 by Gustav Simon in Heidelberg, Germany.<sup>23</sup> Twenty-one years later in the same clinic, partial nephrectomy (PN), which is also known as nephron sparing surgery (NSS), was pioneered.<sup>4</sup> Laparoscopic-like procedures, where only small openings were made into the body cavity, were documented as early as the beginning of the twentieth century for

examinations of internal organs. <sup>56</sup> However, their use mainly remained the domain of gastroenterologists, internists, and gynecologists<sup>7</sup> until the latter half of that century when the tools and methods to perform other procedures became available. In their 1992 article entitled, "Laparoscopic Nephrectomy: A Review of 16 Cases", Clayman et al. reported on the use of laparoscopic procedures for nephrectomies beginning in 1990, whereby the kidneys were removed through three or four openings less than an inch in diameter.<sup>8</sup> Early laparoscopic nephrectomies (LNs) were made possible by the advent of tissue capture bags and morcellator devices which were capable of efficiently cutting and capturing the excised tissue. $9\,$  In addition, laparoscopic removal of whole kidneys, frequently termed laparoscopic radical nephrectomies (LRNs), overcame problems with control of bleeding from large vascular structures via the use of surgical staples.

The feasibility of laparoscopic NSS, wherein only diseased tissue is removed and the remainder of the kidney is left intact, was tested in porcine models (swine) the same year as Clayman's article on the first radical nephrectomies and documented the following year.<sup>10</sup> The first laparoscopic partial nephrectomies (LPNs) in human subjects were also performed in 1992 and reported in 1993.<sup>11 12</sup> Since 1993, the use of LPN has grown steadily in the treatment of small, peripheral tumors.<sup>13</sup> Lane et al. found the use of LPN in treating small, localized tumors to have moved from 11% of total procedures during the period between 1998 and 2002 to 81% between 2010 and 2011.<sup>14</sup> Additionally, more challenging cases are treated laparoscopically as LPN procedures more closely mimic proven open methods and robotic devices have become available to assist with the manipulation of laparoscopic tools.

## <span id="page-14-0"></span>*Modern Urologic Procedures*

Partial nephrectomy, where little more than the dysfunctional portion of the organ is resected, is generally accepted to result in better renal function than radical surgeries wherein an entire kidney, part of the ureter and possibly surrounding fat, fascia and lymph nodes are removed.<sup>15</sup> Reports associate NSS with lower overall mortality, lesser likelihood of chronic kidney disease, and lower risk of renal failure.<sup>16</sup> Furthermore, the benefits of LPN over open surgeries have been identified as shorter operative time, decreased blood loss, shorter hospital stay, and faster return to normal activity.<sup>17</sup> However, the nature of laparoscopic procedures is that reduced trauma to the patient is achieved at the expense of limited intra-operative surgical access and diminished visual acuity which results from use of two-dimensional viewing systems and blood in the surgical site. To improve visibility, LPN is generally performed on an ischemic, i.e., bloodless, organ. Ischemia is achieved by occluding blood flow to the kidney in a process described as hilar clamping, where a surgical clamp is applied to the hilum.

Concerns with an ischemic method include the potential for damage to the remnant tissue and the inability to provide hypothermic control.<sup>18</sup> While ischemia enhances visual cues available to the surgeon, it creates a need for urgency in order to prevent tissue damage caused by the lack of nutrient flow. The risk of extended ischemic time and subsequent tissue damage is being overcome with new apparatus, modified procedures and additional experience, as evidenced by the aforementioned rapid increase in the use of the minimally invasive LPN for less complicated cases. Yet, minimally invasive partial nephrectomies (MIPN), whether robot-assisted or not,

continue to be considered challenging procedures, particularly during the establishment of hemostasis.

Because of the highly vascular nature of the kidney, a principal concern in MIPN is the control of blood loss during and after the surgery. Excessive bleeding not only impairs the physician's vision, but can also produce hematoma, or the localized pooling of blood in tissue outside the vessels, and necessitate remedial procedures post-operatively. Consequently, numerous products and methods have been considered in an effort to find the optimal means of managing blood loss both intra and post-operatively. Products evaluated have included both natural and synthetic hemostatic agents and absorbent / hemostatic cloth, as well as tourniquet-like constrictors.<sup>19</sup> The hemostatic agents represent a major class of products intended to assist in reduction of blood loss. These products are intended to promote the containment of blood within the vessels, generally by accelerating clotting. Methods to limit bleeding have included such techniques as thermal ablation.<sup>20</sup> passing multiple sutures through the organ in a line surrounding the resection to constrict blood flow to the area<sup>21</sup> and multiple combinations of products, with and without suturing. $22$ 

Following resection, the surgical site is closed via one of a number of means. Current protocols for the closure of the renal remnant vary. Some researchers have reported success using hemostatic agents and materials applied without the aid of suturing.<sup>23 24</sup>  $25$  Those successes are generally limited to small resections which are peripheral to the collecting system and hilum. More accepted is renorrhaphy or sutured closure, with or without the assistance of a hemostatic product. One such technique involves the placement of absorbable, hemostatic bolsters in the site and re-approximation of the

wound with sutures 'over the bolster'. Because of the need to reduce warm ischemic time and limit the associated risk of tissue damage, as well as the difficulty of performing simple surgical procedures through the laparoscopic trocar (as seen in [Figure 1:](#page-16-0) Donor Nephrectomy Trocar Placement), sutures are frequently terminated with surgical clips rather than knots. Additionally, severed arteries and collecting ducts are frequently clamped with absorbable clips or tied with sutures to aid in hemorrhage control and prevent urine leakage. Effectiveness of the closing method is typically evaluated and improved, if necessary, upon removal of the hilar clamp and perfusion of the renal remnant. In this method suture tension is applied based on the experience of the medical professional, to a level expected to be approximately equal that required for control of bleeding. Following perfusion, suture tension is increased as necessary to control any bleeding which is observed.

<span id="page-16-0"></span>

Figure 1: Trocar Placement (modified lateral camera placement) (From 'Urology 101 RCC by Dr. Brian Lane)

### <span id="page-17-0"></span>*Post-Operative Urologic Complications*

Studies of post urologic complications to date have focused on one of two areas. First, emphasis has been given to assessing the viability of a particular method of treatment. Those efforts have concentrated on documenting the value of undertaking the more rigorous minimally invasive procedures over open ones. The other frequent focus of study is evaluation of one particular product or procedure with respect to another. The literature search has not revealed a quantitative assessment of the means by which post-operative urologic complications occur.

Several studies have analyzed numerous pre-, intra- and post-operative factors to establish correlations which will likely lead to improved patient care.<sup>26 27</sup> Such research has led to the determination that laparoscopic NSS has distinct advantages over radical surgeries.<sup>28</sup> In addition, studies have associated LPN with an improved mortality.<sup>29</sup> Other studies have evaluated various products such as the holding strength of absorbable clips used to terminate sutures $30$  or the ability of hemostatic materials to control blood loss under particular conditions.<sup>31</sup>

These studies have contributed to the best application of materials and methods to achieve more optimal outcomes for the patients. However, at the present time, no publications address the question of how bleeding and urine leakage, which is controlled at the time of closure, becomes uncontrolled at a point 7 to 10 days subsequent. Available statistics only indicated that a urologic complication occurred. They do not identify what underlying cause created hemorrhage or urine leak.

#### <span id="page-18-0"></span>*Concerns with Closure of the Renal Remnant*

The fact that control of bleeding and urine leakage is established and observed prior to closing in LPN and reoccurs at a later time implies an intervening event which changed conditions substantially. Numerous factors exist which could generate the occurrence of 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 control of both bleeding and urine leakage is the closing system. 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.

### <span id="page-18-1"></span>*Related Research*

Existing documentation on suture tensions and how sutures fail is limited.

Manufacturers routinely test suture material for tensile strength as part of quality control procedures. Attempts to estimate life under several conditions have also been recorded by researchers concerned that absorbable sutures support healing until tissues can maintain hemostasis without aid. In addition, some research has been undertaken to evaluate the performance of select products or procedures relative to another. For instance sutures made from natural materials have been compared to synthetic, $32$  and hemostatic agents were contrasted with sutured bolsters.<sup>33</sup> However, no quantitative

assessment of the suture tension required to achieve hemostasis relative to the tension resulting in tissue failure has been identified.

Suture material is frequently tested in a number of ways. Initial suture strength is commonly reported. Material manufacturers regularly test their product and maintain product consistency. Tests of suture material are undertaken using the familiar tensile testing technique set forth in United States Pharmacopeial (USP) monograph  $881<sup>34</sup>$ with only a few parameter variations worthy of note. A "knotted" test which provides a stress point in the form of a knot at the center of the specimen, and generally results in lower tensile strength, is the most frequently reported specimen configuration. Another often identified variation is the means of securing the ends of the suture for testing. Tests are sometimes conducted with the ends of the suture clamped in vise-type holders, although this method is only prescribed for sutures of small diameter. Intermediate and large diameter material requires the use of specialized equipment where the specimen is wrapped around a 19 mm bar and clamped on a 25 mm flat surface to reduce the likelihood of a stress point occurring at the edge of the clamp jaw. The third variable of concern is the speed at which the force is developed. This varies widely between studies. However, standard rates are established by the USP.

As summarized in [Appendix 5:](#page-67-0) Suture Material Strength, several independent comparisons of select suture products have been performed. Some in vitro and animal studies have shown that pH and bacterial activity can affect selected products.<sup>35 36 37 38</sup> A few researchers have conducted in vitro and animal tests of sutures to quantify tensile strength at selected durations of exposure to environments simulating en vivo use. $^{39}$   $^{40}$ All have used tensile testing at predetermined time intervals to estimate life expectancy.

Results from these studies are reported as absolute tensile strength in some cases and normalized to initial strength in others. None of these studies have measured and reported the time to failure at the tension necessary to achieve hemostasis in the perfused kidney.

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).<sup>41</sup> The forces reported were comparable to those measured in this research. However, except in the case of a simple mattress suture, the tension measured was not in the direction necessary for wound closure and how the measured force is related to the closing force was not addressed. Nor did that study consider the use of surgical clips to terminate simple sutures which is common in laparoscopic procedures.

Other researchers<sup>42</sup> have compared the force required to pull suture anchored with two brands of surgical clips through a human kidney. Those tests reported violation of the tissue at 22 Newtons when the suture passed completely through the kidney. While that method was useful in comparison of the two anchors, the results here and in the comparison of suture techniques indicate that sutures fail at lower tensions. Another recent study<sup>43</sup> measured the force at which sutures terminated with surgical clips could be torn from live porcine renal tissue. In that study, the tension was measured outside the animal on the leading suture end which had been extended through the trocar. Tensions recorded were higher than reported in this thesis or in the work of Simon et al.

Studies have also examined the force required to dislodge surgical clips from suture material.<sup>44 45</sup> Those investigations have shown that the larger Weck Hem-O-Lok clip (Refer to [Figure 2:](#page-21-1)  [Surgical Clips\)](#page-21-1) is more likely to slip on the suture than the Ethicon Lapra-Ty unless provided with other support, such as a secondary clip or knot. The Weck Hemo-O-Lok backed by a knot (Refer



<span id="page-21-1"></span>

to [Figure 3: Suture Termination\)](#page-21-2) is used in this project and the current work does not investigate this means of termination further.



Figure 3: Suture Termination

## <span id="page-21-2"></span><span id="page-21-0"></span>**Current Investigation of the Forces**

This research quantifies the suture tension applied by a skilled surgeon during the closure of a renal defect. The maximum force that can be applied prior to tissue

damage and the effect of margin distance on this failure point were also observed. In addition, strength of absorbable

sutures over time which have



<span id="page-22-0"></span>Figure 4: Sliding-Clip Renorrhaphy Configuration

been reported previously are tabulated and considered to assess the importance of suture selection. Provided with such information, it may be possible for medical professionals to minimize the affected tissue and improve outcomes by reducing the margin size to the least amount which will reliably support the suture.

Initial consideration of the sutured closing system identified the suture, the suture termination, and the affiliated tissue which supports the suture as key components in the system. Clearly, the suture will not re-approximate the wound unless it is attached to the tissue being closed. To accomplish this most sutures must be terminated to the parenchyma in some manner, either with a knot or surgical clip (Refer to [Figure 4:](#page-22-0)  [Sliding-Clip Renorrhaphy](#page-22-0) Configuration). In as much as published methods for MIPN<sup>46</sup> recommend the use of surgical clips as a means to minimize warm ischemia time, and that practice is commonly used in local hospitals and major medical centers, a clipterminated suture architecture is considered here.

Critical to evaluating the adequacy of available suture tensile strength and supporting tissue forces is knowledge of the force required to re-approximate the renal remnant. The tension applied to sutures during the process of closing the surgical site is not currently measured in a typical NSS procedure. No studies were identified that

documented these measures during closure of a resected kidney. Without a basic knowledge of the force required to close the wound, it is impossible to assess the sufficiency of the components of the system. Hence, this work examines the closing force in detail.

Estimates of the suture strength are readily obtained using currently available equipment.<sup>47</sup> More difficult is the measurement of in vivo product life expectancy and development of associated time-strength relationships. Conditions approximating those in the reconstructed kidney can only be simulated outside of clinical practice. However, multiple previous studies have derived estimates of suture life expectancy using a variety of approaches. The results of identified works in this area which have been published since 2002 are summarized in the results section below.

Finally, the force generated in the suture must be opposed by an equal force in the tissue. Medical professionals attempt to provide sufficient anchoring of the suture through selectively choosing the amount of tissue to be enclosed within the suture loop. However, placement of the suture is based on experience and not objective data. The ideal amount of tissue required to be enclosed within the suture loop to provide sufficient anchoring is currently unknown. The impact on anchoring ability of changing margins to enclose additional tissue is also unknown. In general, surgeons wish to limit the margin's size to limit the potential for additional tissue damage. The concern is that pressure applied to tissue within the suture loop restricts blood flow and inhibits proper renal function. Consequently, it is desirable to determine the minimal margin that will reliably provide the necessary support for the suture.

#### <span id="page-24-0"></span>*Research Objective*

The initial research considered two forces related to the suture closing system using porcine tissue in in vitro tests. Specifically, applied suture tension and the maximum force that can be supported by renal tissue were identified as key factors in the success of a re-approximation which warranted testing.

The tension necessary to re-approximate renal tissue subsequent to tumor removal was measured in several trials. Actual tension imposed by the oncologic urologist was determined in multiple sutures used to close representative defects. To better understand the impact of systolic blood pressure, conditions representing both normal blood pressure and hypertensive cases were examined. Apparatus and software sufficient to collect the required data were designed and implemented. Revisions were made based on initial trials to improve the method of measurement leading to more consistent data collection. Details are presented in the Methods section below.

Following revisions to the testing method, additional series of data were collected to provide more statistical credence to the mean and deviation values previously computed. The principle change to the suture tension experiment after early trials was the fabrication of a device which supported the force gauge and facilitated application of continuously increasing tension. The suture tear out test was revised from a design which relied on manual application of force, to one in which force was applied through a custom designed apparatus and a computer controlled machine that increased tension in the suture with a constant velocity motion.

Early attempts to measure the ability of the kidney tissue to oppose the suture tension produced varied results. Destructive testing of the closing system was used to investigate the suture tension at which the tissue will no longer support the suture. The initial concept was to relate the amount of tissue enclosed within the suture loop, referred to as margin, to the tension which could be supported. However, tests revealed that the impact of increasing the margin is not the only factor that determines ability to support suture loading and may well be a secondary consideration to other variables. Therefore, an adapted experiment design was executed which sought to quantify the range of values that can be expected. Specifically, the angle of the suture entering the capsule and tensioning speed were better controlled and measured. However, precise control of the angle of applied force proved difficult in working with soft tissue, such as a harvested organ. It was noted in the experiments that samples tend to deform and shift when force is applied to any point. Furthermore, organs in the lab cannot be provided with the uniform support afforded in vivo. Due to the continuous curvature of the renal capsule and variation in placement of each suture, a fixture ideal for testing one suture is imperfect for testing others. Consequently, the later tests were conducted on hemispheres of kidneys which had a flat surface to be placed against the test fixture. The angle of the suture relative to the organ surface was then estimated. The resulting data was examined for relationships between suture angle and force developed, as well as margin size.

Also, a new, auxiliary experiment was added to measure the bearing strength of porcine renal tissue by applying force to a tissue section of known dimension with sutures of selected diameters. In this supplemental test, the suture was observed to determine the applied pressure, at which the suture began to sever the tissue.

Information related to the expected useful life of suture material commonly used in reapproximation of the renal remnant was collected from a review of literature reporting previous research. Identification of suture material, initial strength, testing environment, ending strength, and time-to-final measurement are tabulated and presented below. Multiple studies were identified during a literature review which suggest that some absorbable suture materials' strength remains approximately an order of magnitude higher than average suture tensions needed to control bleeding and urine leakage during the first 10 days after surgery. A sampling of those studies is summarized for comparison with suture tension measurements obtained in this research.

#### <span id="page-26-0"></span>*Materials*

Tissue samples for each round of testing were obtained from one of two plants processing agriculturally raised pork. The office of the Grand Valley State University institutional review board confirmed that tissue acquired from byproducts of normal meat production did not require committee review or approval when used in this study.

Samples were obtained as proximate to the time of testing as possible. The period between harvest and experiment varied from 4 to 80 hours. Quality was preserved by keeping specimens on ice during the storage interval.

Kidneys used in the first experiments were in a condition typical of pork industry byproduct. The capsule and most fatty tissue had been removed. Agricultural inspectors had cut into most organs as part of the inspection process. Those incisions had no impact on experiments to assess failure forces and were incorporated into the defect

being repaired for tensioning measurements. Organs obtained for the last two rounds of testing were complete with all associated fat, capsule, external vessels and ureter.

#### <span id="page-27-0"></span>*Methods*

#### <span id="page-27-1"></span>Suture Tension

Suture tension data was obtained using a Wagner FDV-10 digital force gauge (DFG) with a 10 pound (0 to 44 Newton) load cell in place which reported force to 0.1 N resolution. Calibration was checked by hanging laboratory masses from the force gauge and verifying the display value. Measurements were obtained by having the surgeon place sutures in a manner similar to those used in closing partial nephrectomies on human patients. The surgeon applied tension to the sutures based on visual and tactile queues while applied tension was recorded by the force gauge. Tension was achieved by placing the tip of the tensioning jig against the leading surgical

suture until the appropriate tension was achieved [\(Figure 5:](#page-27-2)  [Tensioning Configuration\)](#page-27-2). Original measurements were attempted with the assembly handheld (Refer to [Figure 6:](#page-28-0)  [Original Handheld Equipment](#page-28-0) and [Figure 7: Handheld Tension](#page-28-1)  [Measurement\)](#page-28-1). Addition of a

clip and pulling on the end of the



Figure 5: Tensioning Configuration

<span id="page-27-2"></span>stand to support the DFG / jig assembly and a worm gear apparatus to apply increasing



<span id="page-28-0"></span>Figure 6: Original Handheld Equipment

force, resulted in a sufficient level of control to acquire useable tension data (Refer to [Figure 8: Stabilized Tension Measurement\)](#page-28-2).



Figure 7: Handheld Tension Measurement

<span id="page-28-2"></span><span id="page-28-1"></span>

Figure 8: Stabilized Tension Measurement

To collect tension measurements, an interface cable was constructed to connect the Wagner force gauge to a Future Technology Devices International Ltd. USB/Serial converter (Refer to [Figure 10: FTDI USB to Serial Converter\)](#page-29-0) connection to a Hewlett-Packard Pavilion dv6 laptop computer running Microsoft Windows 7 (64 bit) with all released updates installed and using the FTDI supplied converter driver (version

<span id="page-29-0"></span>

Figure 10: FTDI USB to Serial Converter

2.8.24.0).

Software was written using the 2012a version of MatLab (The MathWorks, Inc.) to record and post process tension data (Refer to [Figure 9: Data](#page-29-1)  [Collection Process\)](#page-29-1). The program included a graphical user interface (Refer to [Figure](#page-29-2)  [11: Graphical User Interface\)](#page-29-2) which provided START/STOP control with feedback and real-time graphing of force measurements being recorded. Use of post-



<span id="page-29-1"></span>Figure 9: Data Collection Process



<span id="page-29-2"></span>Figure 11: Graphical User Interface

processing eliminated the need for multiple calculations and writing data to the hard drive during the experiment. Postponing those operations until after data collection stopped prevented delays in data collection caused by time consuming routines. This allowed some image (time lapse) collection to be performed simultaneously on the computer used to collect force measurements without detrimental effect on sample collection (Refer to [Appendix 6: Post-Experiment Processing of Data Files\)](#page-76-0).

The 'pause' command was used with a 0.1 second delay parameter in the data acquisition software to limit the number of samples collected. The actual sampling interval varied slightly, presumably due to process burden from other applications (video capture) being run. Examination of randomly selected trials from four different days indicated that the mean interval was slightly greater than 0.21 seconds with a standard deviation of less than 2.5 x 10<sup>-7</sup> (Refer to [Figure 12: Examination of Sampling Interval\)](#page-30-1). This was considered to be adequately fast to capture the changes in tension which

determination was made after noting that one or more data points were recorded during the period of increasing tension in failure experiments.

occurred slowly. That



<span id="page-30-1"></span>

<span id="page-30-0"></span>Tissue Strength

The original goal was to

investigate the relationship of suture margins and depths to the amount of suture tension required to cause failure of the tissue. Tests were conducted using the Wagner

DFG and the same computer arrangement as used for tensioning measurements. For the first trials, the DFG was removed from the jig used for tension tests, attached to each suture, and pulled by hand until the suture was torn from the parenchyma. The tissue samples were restrained by placement behind an acrylic panel with a 1.5 cm slot for the suture tail (Refer to [Figure 13: Acrylic Sample Restraint\)](#page-31-0). Observations made during these tests led to trials using other procedures in an effort to control the force resulting from acceleration and the angle of applied force.

Additional trials were conducted with the DFG mounted on the same jig and support stand used for collection of tension measurements. For these tests, the arrangement of the sample and apparatus was similar to tensioning tests, with the jig placed as near perpendicular to the organ surface at the leading clip location as

<span id="page-31-0"></span>

Figure 13: Acrylic Sample Restraint

possible. Failure tension data was obtained by continuing to increase the force on the suture until the tissue gave way and the tension in the suture decreased rapidly (Refer to [Figure 11: Graphical User Interface](#page-29-2) for an example).

To further control the effect of acceleration on the recorded force and provide easier estimation of the angle of applied force, later experiments utilized mechanical application of force on hemispheres of tissue. Consequently, the suture configuration tested more resembled half of a closing suture, i.e., pulling one anchor toward the defect.



<span id="page-32-0"></span>Figure 14: Revised Failure Test Setup Plan

Implementation of this method employed a MTS Mini-Bionix test station, including system control software running on a desktop personal computer operating Microsoft Windows XP. The Mini-Bionix force transducer was removed from the test frame and a test jig was fabricated and attached to the frame in its place (Refer to [Figure 14:](#page-32-0)  [Revised Failure Test Setup Plan](#page-32-0) and Figure 16: [Revised Failure Test Setup\)](#page-33-0). MTS software was used for the test station ram speed control only. To measure the force applied, the clamping jaw was removed from the MTS, an adapter which allowed a free moving connection was created (Refer to [Figure 15: DFG / MTS Connection\)](#page-33-1), and the Wagner DFG was attached to the Mini-Bionix ram. Travel speed of the ram was adjusted to a constant 1 cm per second to allow the influence of acceleration during the period of tissue failure to be ignored.

The tension force was translated from vertical to horizontal using a small Nylon pulley with metal ball-bearings and raceway. To evaluate friction in the pulley, four revolutions of a suture were wrapped around the pulley and it was accelerated from stationary using the DFG. No appreciable friction was detected.

Samples were retained using the same acrylic sheet used in early tests. Blocks were placed under the specimen as necessary to achieve the desire alignment with the pulley axis. Stabilization

<span id="page-33-1"></span>

Figure 15: DFG / MTS Connection

<span id="page-33-0"></span>

Figure 16: Revised Failure Test Setup

of samples was attempted using plastic bags containing pieces of ice. Ultimately, it was found that the most reliable support was achieved using cushions formed from damp, paper towelettes (Refer to [Figure 17: Sample Support\)](#page-34-0). The ability of the paper to absorb moisture reduced the tendency of each kidney segment to shift during the application of force. Although contact with the paper was not in the area of the sutures being tested, the impact of using an absorbent material on the tension at failure is unknown.

The failure test configuration using the Wagner gauge with the MTS Mini-Bionix test station enabled force measurements to be recorded with the same software used in tensioning experiments. Additional documentation was provided by recording high definition digital video of the failure using a conventional web camera and a third personal computer. This allowed careful review of the failure as it proceeded, as well as providing a means for confirming the test procedure used.

The effect of suture angle on the tissue's ability to support tension was assessed by visually estimating (Refer to [Figure 14: Revised Failure Test](#page-32-0)  [Setup Plan\)](#page-32-0) and recording the angle of the renal capsule at the point of the suture anchor relative to the test fixture. Angle of the anchoring surface was

<span id="page-34-0"></span>

Figure 17: Sample Support

determined by estimating the tangent line and measuring with a protractor.

<span id="page-35-0"></span>Tissue Strength – Auxiliary Experiment

To further define the renal tissue's ability to support applied force, an auxiliary experiment was designed in which a segment of suture material was held taut at a predetermined tension and pressed against a flat surface of porcine kidney tissue until the suture material cut through the parenchyma



<span id="page-35-1"></span>Figure 18: Cross-Section Sample Test Arrangement

(Refer to [Figure 18: Cross-Section Sample Test Arrangement\)](#page-35-1). The tissue samples were segments of organs which were cut to specific dimensions. The concept was to test material surfaces with known dimensions, thereby allowing calculation of normalized (per unit area) bearing forces at failure. Surface area was calculated as the diameter of the suture multiplied by the width of the tissue sample and neglected the effect of the curvature of the suture surface. Suture diameters were assumed to be the manufacturer specified diameter or the USP standard if no manufacturer information was available.

A device to hold 1 and 2 cm square strips of parenchyma was constructed (Refer to [Figure 19: Aux Test Setup\)](#page-36-1). That assembly was secured to the MTS test frame bed.
Suture was stretched between two acrylic pieces suspended from the Wagner force gauge attached to the MTS Mini-Bionix ram. Ram control and data acquisition were achieved in the same manner used for failure tests. The ram was fully extended to allow the suture to rest in a groove below the



Figure 19: Aux Test Setup

tissue slot. Specimens were placed under the acrylic sheet between two blocks which were spaced at the dimension being tested. This resulted in the segment being supported on all sides with a 1 cm gap where the suture could be drawn through (Refer to [Figure 20: Auxiliary Test on Sample\)](#page-37-0).

#### Suture Strength

To assess the strength of suture material, initially a search of PubMed was conducted for English language articles with the terms 'suture' and 'mechanical', as well as 'break' or 'failure', but not 'technique' in any of the fields (Refer to [Appendix 4: PubMed Search](#page-65-0)  [Criteria & Results\)](#page-65-0). The resulting large number (385) citations were scanned and the search narrowed by using the search engine feature which selects publications related to one of the studies<sup>48</sup> which contained useful information on suture strength. The identified documents were reviewed and placed in the spreadsheet shown in [Appendix](#page-67-0)  [5: Suture Material Strength.](#page-67-0) Eleven articles written in English and published in the last



Figure 20: Auxiliary Test on Sample

<span id="page-37-0"></span>ten years (since 2002), which provided useful information about suture useful life, were able to be identified and obtained. Each was reviewed for suture material life expectancy information and information about test conditions.

### *Results & Discussion*

### Suture Tension

Thirty-nine sutures were placed in renal specimens during trials on four different days. Not all sutures provided usable data at each perfusion state due to tearing of the tissue. In addition, early tests were not run at hyper-perfusion pressure. One suture was measured twice with slightly different results. Both values are included in the data set.

Sutures which were missing data points for any of the three levels of perfusion were included in calculating statistics.

Tension values were determined during post-experiment processing using a MatLab algorithm which determined the highest tension recorded in four consecutive sample intervals with a tolerance of  $\pm$  0.1 Newton variation. This method provided an objective means of screening variation resulting from the measurement process. Values obtained with this procedure were similar to those noted by the research team during the experiments.

[Figure 21: Scatter Plot of Suture Tension](#page-39-0) shows the suture tensions recorded with a supported tensioning device. Tensions recorded with the handheld gauge are not included. Values corresponding to ischemic, perfused to 120 mmHg (64.2 inches  $H_2O$ ) pressure and perfused to a hypertensive pressure greater than 220 mmHg (118 inches  $H<sub>2</sub>O$ ) for each suture are shown together along the horizontal axis. It can be seen that in nearly all cases the hypertensive (red) and perfused (blue) values are above the ischemic (green). This is confirmed by comparison of the means and standard deviations as calculated using the 'average' and 'stdev.s' functions in Microsoft Excel 2010. The values obtained are shown i[n Table 1: Suture Tension.](#page-39-1)

An analysis of variance on suture tensions using the software revealed significant effect related to tension ( $p < 0.0001$ ). Tukey HSD post hoc analysis showed that the tensions in a perfused and hypertensive kidney are both significantly greater than in an ischemic kidney (both  $p < 0.0001$ ), which was similar to comparisons using Students T test ( $p <$ 0.0004 and p < 0.0001, respectively). However, no significant difference was detected



<span id="page-39-0"></span>Figure 21: Scatter Plot of Suture Tension

at the 95% confidence level between the tension in a normally perfused specimen and one perfused to more than 200 mmHg ( $p = 0.0584$ ).



<span id="page-39-1"></span>

#### Tissue Strength

The force required to destructively remove (tear) sutures from renal tissue was measured using four different approaches. In the first two trials, a renal defect was closed using sutures having margins of 0.5, 1.0 and 1.5 cm. As shown in [Figure 13:](#page-31-0)  [Acrylic Sample Restraint,](#page-31-0) the sample was then placed behind the slotted acrylic sheet and force was applied to the leading end of the suture with the handheld DFG until failure occurred. [Figure 22: All Handheld Failure Test Data](#page-40-0) shows the measurements obtained in this manner. Although the linear fit line indicates a positive correlation between margin and force required to cause failure, Students' T Test comparison of 1.0 cm versus 0.5 cm and 1.5 cm versus 1.0 cm revealed no significant difference. ( $p =$ 



<span id="page-40-0"></span>

0.1713 and  $p = 0.1066$ , respectively) However, there was a difference between sustainable force when considering 1.5 cm margins to 0.5 cm margins ( $p = 0.0175$ ).

Examination of the trial sessions individually revealed that significant differences occurred in tests on sutures at 1.0 cm and 1.5 cm between the two sessions ( $p = 0.0234$ ) and  $p = 0.0036$ , respectively) even though the procedure did not differ. No significant difference was detected between the two occasions for sutures installed at 0.5 cm ( $p =$ 0.8166). The differences between the two test sessions can be seen in [Figure 23:](#page-41-0)  [Handheld Failure Test by Session.](#page-41-0) Note that the coefficient of determination ( $R^2$ ) for the Session 1 linear fit line is particularly low indicating the inadequacy of that data as a predictor. On the other hand, data from only Session 2 registered a better coefficient of



<span id="page-41-0"></span>Figure 23: Handheld Failure Test by Session

determination and showed a more positive relationship between margin and tension at failure. Comparison of 1.0 cm and 1.5 cm margins to 0.5 cm margins, as well as 1.5 cm to 1.0 cm, revealed significant differences ( $p = 0.0344$ ,  $p = 0.0013$  and  $p = 0.0271$ , respectively) for that trial. Furthermore, the slope of the fit line for Session 2 was similar to the one found in later tests (Refer to [Figure 24: Failure of Model Suture Tested with](#page-42-0)  [Stabilized System\)](#page-42-0).

The second test method employed for measuring failure force data was the same supported test jig arrangement used for tensioning tests. The data shown in [Figure 24:](#page-42-0)  [Failure of Model Suture Tested with Stabilized System](#page-42-0) was obtained during trials on two



<span id="page-42-0"></span>Figure 24: Failure of Model Suture Tested with Stabilized System

separate days by tensioning the sutures with that apparatus until failure occurred. In those tests, sutures were placed by the surgeon and measured to the nearest tenth of a centimeter prior to testing. The result was that the margin assumed additional values. Comparison of the two trial sessions for this method resulted in a relationship between margin and failure force on Session 4 which was inconsistent with Session 2 and Session 3. However, the value of that fit line slope was discounted due to the fact that only five data points were obtained during that trial and one (margin  $= 1.0$  cm, force  $=$ 16.3 N) was considered to be a clear outlier from the other two points at 1.0 cm (mean = 2.85 N). This resulted in the fit line for data from Session 4 having a  $R^2$  = 0.06 compared to 0.33 for the Session 3 data alone and 0.25 for the combined data.

While the Session 4 data points are not considered separately, all five are included with the data shown in [Figure 24: Failure of Model Suture Tested with Stabilized System.](#page-42-0) If those points were removed, the fit line slope changes slightly from 13.7 N/cm to 12.7 N/cm.

In the third experimental configuration, the arrangement was similar to that used in the previous tests. However, in the third protocol the sample was bisected along the line of the defect and tension was applied perpendicular to the exposed parenchyma (Refer to [Figure 25: Failure Test on Organ Hemisphere Using Tension Jig\)](#page-44-0). As shown in [Figure](#page-44-1)  [26: Failure of Half Suture With Tension Device,](#page-44-1) only six sutures were tested in this manner and the coefficient of determination for the fit line was extremely low. ( $R^2$  = 0.04) Removal of the data point at 1 cm / 0.1 N reduced the coefficient of determination even further.

The final data sets for failure force were obtained using the MTS test station to apply force. For those experiments samples were bisected as in the previous group.



Figure 25: Failure Test on Organ Hemisphere Using Tension Jig

<span id="page-44-0"></span>Also, some specimens included the connective tissue membrane, while others were bare organs.



<span id="page-44-1"></span>Figure 26: Failure of Half Suture With Tension Device

[Figure 27: Constant Velocity Failure Force versus Margin -](#page-45-0) All Samples shows the forces measured relative to the margin for each of the angles tested between 30° and 315° (applied upward from the surface at 45° as shown in [Figure 28: Angles of Applied](#page-46-0)  [Tension\)](#page-46-0). Results from tests at angles between 55° and 80° are omitted from this graph because of the irrelevance of margin at such high angles. Measurements at angles approaching 90° (normal to the organ surface) equate to pulling the suture through the sample and the thickness of the sample becomes a more applicable dimension than the margin.



<span id="page-45-0"></span>Figure 27: Constant Velocity Failure Force versus Margin - All Samples



<span id="page-46-0"></span>Figure 28: Angles of Applied Tension

The tension at failure for samples without connective membrane tissue is shown in [Figure 29: Constant Velocity Tests on Samples without Connective Membrane.](#page-46-1) The Pearson statistic, r, which is the square root of the coefficient of determination, was examined for those samples. Critical values were obtained from tables. Despite indication of a positive relationship for both groups on the graph, the Pearson test (critical values equal 0.997 for  $n = 3$  and 0.576 for  $n = 12$ ) revealed no significant relationship in either group at the 95% confidence level.



<span id="page-46-1"></span>Figure 29: Constant Velocity Tests on Samples without Connective

Consideration of measurements made on samples with the connective membrane [\(Figure 30: Constant Velocity Tests on Samples with](#page-47-0) Connective Membrane) appeared to have a negative relationship with margin at an upward angle of 45° (-45° or 315°). However, application of the Pearson test determined that the relationship between margin and tension at failure was not significant (critical value equal to 0.444 for  $n = 20$ ) for tests at 315°. With force applied at 0° (parallel to the organ surface) a positive relationship with slope similar to that recorded in manual, bisected samples [\(Figure 26:](#page-44-1)  [Failure of Half Suture With Tension Device\)](#page-44-1) was seen. Analysis determined a significant (99% critical value equal to 0.798 for  $n = 9$ ) Pearson  $r -$  value of 0.81 for the relationship between force applied parallel to the capsule surface necessary to cause failure and margin.



<span id="page-47-0"></span>Figure 30: Constant Velocity Tests on Samples with Connective Membrane

When analyzing the relationship between angle of applied force and the tension at which failure occurs, it was found that angles between 0° and 90° have a strong positive relationship with the force in specimens without connective membrane tissue present (Refer to [Figure 31: Failure Force at Low Angles in Constant Velocity Tests\)](#page-48-0). The linear fit line was determined to have a Pearson statistic of 0.86 which is significant at the 95% level. (Critical value equal to 0.456 for  $n = 19$ ) Although no correlation was observed for all samples with the membrane intact, consideration of data taken at low angles (Refer to [Figure 31: Failure Force at Low Angles in Constant Velocity Tests\)](#page-48-0) only yields an interesting result. The fit line for those trials has a similar slope and crosses the y axis (zero crossing) at nearly identical tension value as was obtained



**Failure Tension at Low Angles to Surface** 

<span id="page-48-0"></span>Figure 31: Failure Force at Low Angles in Constant Velocity Tests

when data from samples without the connective membrane intact were examined (Refer to [Figure 32: Relationship of Angle to Failure Tension in Samples with Membrane](#page-49-0)  [Intact\)](#page-49-0). In both cases, the linear fitted relationship is between 0.1 and 0.2 Newton per degree over the range of 0° to 90°. Zero crossings are slightly greater than 4 Newtons in both instances. However, caution is warranted in use of the data from samples with their membrane intact inasmuch as only two points greater than 0° were used in the analysis.



<span id="page-49-0"></span>

Tissue Strength – Auxiliary Experiment

An apparatus was prepared to test samples 1 and 2 cm square by approximately 7 cm long. However, at the time of testing, it was determined that adequate specimens with dimensions required for the 2 cm test could not be consistently cut from the organs without involvement of the collecting system. Consequently, tests were performed with 1 cm square samples only.

During testing, some movement of the tissue was noted. Samples would tend to bend upward between the acrylic panel sections retaining the parenchyma. However, the contact surface area and thickness of the sample opposing the suture were not seen to change. Therefore, the data obtained was analyzed.

Three trials were performed using #3-0 Vicryl™. The diameter was assumed to be 0.018 mm, based on manufacture literature. Area of the applied force was assumed to be the suture diameter times the sample width and was calculated to be 0.18 mm<sup>2</sup>. As seen in [Figure 33: Applied Force Required to Penetrate 1cm Segment,](#page-50-0) the mean



<span id="page-50-0"></span>Figure 33: Applied Force Required to Penetrate 1cm Segment

applied force at the time of tissue failure was  $5.5 \pm 0.5$  Newtons. The mean unit pressure was calculated to be  $30.6 \pm 2.9$  MPa.

Six tissue samples were tested using #1Vicryl™. Najibi et al.<sup>49</sup> found the diameter of #1 Vicryl™ to be 0.51 mm through direct measurement. The experimental surface area calculated using that dimension was 5.1 mm<sup>2</sup>. The mean maximum force recorded during testing of #1 size suture was  $6.2 \pm 1.3$  N and the resulting pressure was calculated to be  $1.2 \pm 0.26$  MPa.

Although the chart in [Figure 33](#page-50-0) appears to show a slight increase in bearable force with larger surface area, analysis using the Students T Test found that no significant difference existed for the force borne using the two different suture diameters. ( $p =$ 0.293) However, using the same statistical method to compare the pressure (force per unit area) revealed that there was a significant difference ( $p = 0.003$ ) in the applied pressures calculated using the method for estimating surface area described above.

#### Suture Strength

Reported forces were converted to Newtons and tabulated. When failure data was provided in mega Pascals (MPa), conversion to Newtons was based on the suture diameter provided or on manufacturer information. When data was provided in graphs, rather than tables, the graphs were enlarged and values estimated by inspection. Values obtained in this manner compared well in the few instances where actual values were provided in the article text.

[Appendix 5:](#page-67-0) [Suture Material Strength](#page-67-0) lists the suture life data obtained, as well as the year of publication and principal author's name.

### *Conclusions*

Re-approximation of soft tissue is a delicate task requiring the precise talents of skilled surgeons. Kidneys are among the organs requiring special techniques for the closure of defects. Despite advances in ablation and adhesive hemostatic agents, sutured closure remains a common practice in renal surgery.

Surgeons typically apply closing force by experience and observing changes in the character of the tissue. In this research, the tension in sutures used to close sites similar to those of tumor removal was found to generally be in the range of a few Newtons. In addition, it was observed that the tension required to control leakage and bleeding in a perfused organ is greater than that required simply to achieve approximation. In no instance were tensions over 5 Newtons recorded. However, more than 2 Newtons of tension was always required to achieve hemostasis in the perfused kidney. These conclusions are based on a specific combination of suture diameter, sliding clamp and backstop knot. Different tensions may be required under different conditions, particularly if a clip is employed that has a different surface area in contact with the kidney surface. The particular form of the closure system chosen for this research is the one most commonly in use for current LPN procedures.

Testing of the installed suture to determine the amount of additional tension beyond that necessary for adequate hemostasis which would cause failure of the tissue to provide the force required, is difficult; due in large part to the nature of soft tissue and its tendency to deform under slight pressure. A variety of tests performed on both full and half sutures reveals that arrangements with margins greater than 0.5 cm can provide

two, three or more times the support necessary. Both margin and angle to the capsule surface were shown to affect the sutures' ability to deliver the needed forces.

Indications exist that extremely small margins, particularly less than 0.5 cm, will not be suitable for many tensions and that care should be used in use of margins less than approximately 1 cm.

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. However, the force usually needed for closure is generally applied at an angle near zero. Consequently, medical professionals need to be conscious of the angle of the suture with respect to the organ surface when tension is applied.

While it might be expected that use of a suture with greater surface area would distribute the force over a larger amount of tissue and increase the tissues' ability to support the suture, in experiments on only nine samples in the auxiliary test no trend was evident. Based on the surface area calculation described above, and the measured forces at the time of penetration, the pressure per unit area sustainable by the tissue is not the same. Therefore, it is likely that the model used to estimate the distribution of force is incorrect, samples were not representative of the population, or physical properties of kidney tissue behave in an unusual manner.

Evaluation of peer reviewed literature regarding the longevity of suture materials in a number of environmental conditions found that many suture materials with initial tensile strengths exceeding common renal suture tensions are available. Some have been

shown to maintain their qualities for seven to ten days which is thought to be appropriate for healing following renal closure. However, environmental conditions, particularly bacteria and pH, have been shown to adversely affect suture life expectancy, especially in natural fibers (silk and catgut) and uncoated polyester. Furthermore, some suture materials, particularly small diameter (5-0), have initial tensile strengths which are close to tensions seen in simulated closures of perfused and hyperperfused organs. Consequently, it is important that the medical professional select suture material for renal closure carefully.

### **Topics for Additional Research**

This research exposed a number of opportunities for future work in the subject area. First, while tensions developed in sutures were measured on a number of occasions with enough consistency to provide reasonable insight into the values necessary for hemostasis at closure, less uniformity was achieved in quantifying the tension at failure. A number of techniques were applied in an attempt to find a method representative of tensions that would cause sutures placed by a surgeon to fail. However, this subject warrants further consideration.

Among the topics to be examined with regard to suture failure is a better identification and quantification of the factors which affect the tension developed before failure. This research indicates that both margin size and angle play a role. However, data accounting for additional quantifiable factors is required to determine which are independent and significant. Among the factors which need to be assessed besides margin size and angle are time between harvest and test, temperature, suture depth, inclusion of fibrous membrane tissue and use of pledgets.

The auxiliary experiment performed to provide additional information about failure of the tissue to support the suture tension is limited both by the small sample size and questions raised regarding distribution of force on the surface. A larger sample may reveal that a significant difference in tension supported by different diameter and materials of suture. Differences in sustained unit pressure (force per unit area) may also play a role.

Finally, if additional data confirms that the angle of suture tension relative to the organ surface is an important factor as the initial data indicates, efforts should be made to improve the method of closure. In many cases, the forces required for defect closure are in a direction parallel with the organ surface. If it can be shown conclusively that forces applied in a near normal direction reach greater magnitudes before failure, a method to translate closing forces to a normal direction might be useful in surgical practice.

**Appendices**





## Appendix 2: Suture Failure Data Handheld

### **TEST ID**







- Jul29\_\_\_11\_11\_35\_Failed\_Tr\_O\_Nc\_1 Jul29\_\_\_12\_29\_6\_Tr\_O\_Nc\_0\_Weck-
	- Pledget
- Jul29\_\_\_12\_31\_17\_Tr\_O\_Nc\_0\_Weck-Pledget
- Jul29\_\_\_12\_34\_42\_Tr\_O\_Nc\_0\_Weck-**Pledget**



## Stabilized



### Powered





# Appendix 3: Auxiliary Test Data



### Appendix 4: PubMed Search Criteria & Results

#### <span id="page-65-0"></span>SEARCH CRITERIA:

((((("sutures"[MeSH Terms] OR "sutures"[All Fields] OR "suture"[All Fields]) AND

(break[All Fields] OR failure[All Fields]) AND English[lang])) NOT technique)) AND

mechanical

SAMPLE RESULTS:

1: Roth B, Birkhäuser FD, Thalmann GN, Zehnder P. Novel prototype sewing device, EndoSew(®) , for minimally invasive surgery: an extracorporeal ileal conduit construction pilot study in 10 patients. BJU Int. 2013 Mar 15. Doi: 10.1111/j.1464-410X.2012.11599.x. [Epub ahead of print] PubMed PMID: 23496430.

2: Zhang Y, Tran RT, Qattan IS, Tsai YT, Tang L, Liu C, Yang J. Fluorescence imaging enabled urethane-doped citrate-based biodegradable elastomers. Biomaterials. 2013 May;34(16):4048-56. Doi: 10.1016/j.biomaterials.2013.02.040. Epub 2013 Mar 5. PubMed PMID: 23465824.

3: Niehaus AJ, Anderson DE, Johnson JK, Lannutti JJ. Comparison of the mechanical characteristics of polymerized caprolactam and monofilament nylon loops constructed in parallel strands or as braided ropes versus cranial cruciate ligaments of cattle. Am J Vet Res. 2013 Mar;74(3):381-5. Doi: 10.2460/ajvr.74.3.381. PubMed PMID: 23438112.

4: Chalmers PN, Hammond LJ, Juhan T, Romeo AA. Revision posterior shoulder stabilization. J Shoulder Elbow Surg. 2013 Feb 15. Doi:pii: S1058-2746(12)00545-9. 10.1016/j.jse.2012.11.019. [Epub ahead of print] PubMed PMID: 23415816.

5: Maloul A, Fialkov J, Whyne CM. Characterization of the bending strength of craniofacial sutures. J Biomech. 2013 Mar 15;46(5):912-7. Doi: 10.1016/j.jbiomech.2012.12.016. Epub 2013 Jan 23. PubMed PMID: 23352773.

6: Hapa O, Akşahin E, Erduran M, Davul S, Havitçioğlu H, Laprade RF, Bozdağ E, Sünbüloğlu E. The influence of suture material on the strength of horizontal mattress suture configuration for meniscus repair. Knee. 2013 Jan 19. Doi:pii:

S0968-0160(12)00232-3. 10.1016/j.knee.2012.11.010. [Epub ahead of print] PubMed PMID: 23340094.

7: Borowsky KA, Raghu Prasad V, Wear LJ, Stevenson TE, Trent ND, Bennett AJ, Marsden NJ. Is failure of tuberosity suture repair in hemi-arthroplasty for fracture mechanical? J Shoulder Elbow Surg. 2013 Jan 18. Doi:pii: S1058-2746(12)00404-1. 10.1016/j.jse.2012.09.002. [Epub ahead of print] PubMed PMID: 23333733.

8: Roos MW, Wadbro E, Berggren M. Computational estimation of fluid mechanical benefits from a fluid deflector at the distal end of artificial vascular grafts. Comput Biol Med. 2013 Feb 1;43(2):164-8. Doi: 10.1016/j.compbiomed.2012.11.012. Epub 2012 Dec 20. PubMed PMID: 23260571.

9: Magwene PM, Socha JJ. Biomechanics of turtle shells: how whole shells fail in compression. J Exp Zool A Ecol Genet Physiol. 2013 Feb;319(2):86-98. Doi: 10.1002/jez.1773. Epub 2012 Nov 30. PubMed PMID: 23203474.

10: Jha S, Kowaleski MP. Mechanical analysis of twelve toggle suture constructs for stabilization of coxofemoral luxations. Vet Surg. 2012 Nov;41(8):948-53. Doi: 10.1111/j.1532-950X.2012.01028.x. PubMed PMID: 23198922

# Appendix 5: Suture Material Strength

<span id="page-67-0"></span>
















## Procedure for Post-Processing Files

## **Sequence for processing files:**

- 1. Consolidate files from multiple computers into a single location. Move any files without a complete date – time sequence in the file name to a location outside the target directory and any subdirectories; i.e., the target tree.
- 2. Use 'StandardizeDirectoryNames'<sup>1</sup> to make file and directory name consistent in format.
- 3. Use 'SortFiles2Directories\_r2'<sup>1</sup> to group files by test.
- 4. Identify and move individual test video clips to corresponding test directory. (This is required due to the difference in the time codes of the video clips which can differ by the length of the video. Generally, the clips are in the directory adjacent to the test data when the directories are sorted by name.)
- 5. Add descriptive titles to directories from lab notes.
- 6. Use 'd\_ConvertASCII2xls'<sup>1</sup> to generate Excel spreadsheet files.
- 7. Use 'Determine Tension at Failure Filtered' to create a spreadsheet containing failure (Tear Out) values.

Use 'Determine AUX Force Filtered' to create a spreadsheet containing AUX

test values.

Use 'Determine\_Suture\_Tension\_Filtered' to create a spreadsheet of suture tensions.

 $\overline{a}$  $1$  Titles refer to names of custom scripts written specifically for this project.

function StartStopRecordDataGUI % GUI for collection and recording of ASCII data from serial port % StartStopRecordGUI Starts recording of ASCII data on serial port % after a short delay and records collected data % when start button is pressed. % Stop button stops recording and saves file global wt runcount userinfo numericaldata wt = serial('COM16', 'BaudRate', 2400, 'Terminator', 'CR'); runcount  $= 0$ ; numericaldata $(1) = 0$ ; % Create and then hide the GUI as it is being constructed. guiwindow = figure('Visible','off','Position',[550,130,800,600]); % Construct the components. hStartBut = uicontrol('Style','pushbutton','String','START',... 'BackgroundColor', 'Green', ... 'Position',[625,300,70,25],... 'Callback',{@StartBut\_Callback}); hStopBut = uicontrol('Style','pushbutton','String','STOP',... 'BackgroundColor', 'Red', ... 'Position',[625,360,70,25],... 'Callback',{@StopBut\_Callback}); userinfo = 'Push START button to begin'; htext = uicontrol('Style','text','String',userinfo,... 'Position',[625,250,165,15]); ha = axes('Units','Pixels', 'LineWidth', 2,'Position',[35,125,550,400]); align([hStartBut,hStopBut,htext],'Center','None');

- % % Create the data to plot.
- % peaks\_data =  $peaks(35)$ ;
- % membrane\_data = membrane;
- %  $[x,y] =$  meshgrid(-8:.5:8);
- %  $r = sqrt(x.^2+y.^2) + exp$ ;
- %  $\sin c \cdot \frac{da}{a} = \sin(r) \cdot r$ ;

```
 % Initialize the GUI.
```
% Change units to normalized so components resize

% automatically.

set([guiwindow,ha,hStartBut,hStopBut],...

'Units','normalized');

% Assign the GUI a name to appear in the window title.

set(guiwindow,'Name','LPN Tension Data Collection','MenuBar', 'none')

% Move the GUI to the center of the screen.

```
 %movegui(guiwindow,'center')
  % Make the GUI visible.
  set(guiwindow,'Visible','on');
%%
%
%Call back function for pressing "START"
%
  function StartBut_Callback(~,~)
     global measrd run sampletime datalist numpart timestring 
    run = 1;
    htext = uicontrol('Style','text','String','RUNNING',...
       'Position',[625,250,165,15]);
     fopen (wt);
       mytime = fix(clock); %Get current time
      YR = mytime(1); %Identify year
      MO = mytime(2); %Identify month
      DT = mytime(3);HR = mytime(4);MIN = mytime(5);SEC = mytime(6);timestring = [int2str(YR), '-', int2str(MO), '-', ...] int2str(DT),'_',int2str(HR),'_',int2str(MIN),'_', ...
         int2str(SEC)]; %Compile date / time string for use in file name
     statusmarker = wt.Status;
     if (strcmp(statusmarker, 'closed'))
       htext = uicontrol('Style','text','String','PORT DID NOT OPEN',...
       'Position',[625,250,165,15]);
     end
    while (run == 1)
      runcount = runcount +1;
       fprintf (wt, 'F') %Send ASCII 'D'
      sampletime(runcount, 1:6) = clock;
       clc;
       measrd = fscanf(wt) %Read data from COM port to 'measrd'
      datalist(runcount, :) = char(measrd(1:9)); %Place reading in table
      numpart = cat (1, \text{measrd}(1:6));
       numericaldata(runcount) = str2double(numpart);
       pause on;
       pause(0.1);
       plot(numericaldata, 'LineWidth', 2, 'Marker', 'x');
     end
     htext = uicontrol('Style','text','String','PUSH START TO GET ANOTHER',...
       'Position',[625,250,165,15]);
  end
```
%% %

%Call back function for pressing "STOP"

```
 function StopBut_Callback(~,~)
        htext = uicontrol('Style','text','String','Stopping',... 
       'Position',[625,250,165,15]); %Display shutting down message to acknowledge 
button press
     global run sampletime datalist timestring
                             %Make variable available to other areas
        run = 0; %Setting run to '0' stops loop iterations
        fclose(wt); %Close the serial port 
        filestring1 = ['C:\_Data\TensionData_',timestring,'.csv'];
        dlmwrite(filestring1, datalist, '-append', 'delimiter', '\t', 'newline', 'pc')
        filestring2 = ['C:\_Data\DateData_',timestring,'.csv'];
        dlmwrite(filestring2, sampletime, '-append', 'delimiter', '\t', 'newline', 'pc')
        saveas(figure(gcf),['C:\_data\Graph',timestring,'.jpg']); %Save display as file
       runcount = 0;
       numericaldata = [];
       datalist = [];
       sampletime = [];
       htext = uicontrol('Style','text','String', 'Standby',...
       'Position',[625,250,165,15]);
  end
```
end

Appendix 8: Software for Post Processing

%%

%Use to reformat file and directory names to standard format so that %sorting by directory name is equivalent to sorting by date/time code. ANY %FILE WHICH DOES NOT INCLUDE A FULL DATE TIME SEQUENCE IN THE NAME WILL %CAUSE AN ERROR AND SHOULD BE MOVED OUT OF THE TARGET TREE BEFORE RUNNING %THIS PROGRAM. % % %% % % INITIALIZE / CREATE LIST OF FILES TO CONVERT AND DETERMINE QTY % Clear memory clear % Enter path were data resides --- ENDING WITH \ --  $d$ workfolder =  $cd$ : cd C:\  $[dapath] = uigetdir;$ cd (dworkfolder) filist =  $dir(fullfile(dapath, '*));$ loopers = length(filist); %% % LOOP TO PROCESS EACH FILE % %  $loopcntr = 0$ ; for  $loopcntr = 1:loopers$ ; % Find the file name length danamelen = length(filist(loopcntr).name); % Skip non-directories and roots if  $(\sim\!strong((\text{filist}(loopcntr).name), ('.'))$  ... && ~strcmp((filist(loopcntr).name), ('..')) ... && ~strcmp((filist(loopcntr).name(danamelen-2:end)), '.db')); % if (filist(loopcntr).isdir == 1)  $\& \& \< \text{stromp}(\text{filist}(\text{loop} \text{cntr}), \text{name}), (\text{''})\& \&$ ~strcmp((filist(loopcntr).name), ('..')); % Find any spaces and replace with underscore  $dYr = '2011';$ % dStrgIn = strcat(dapath, filist(loopcntr).name); dStrgIn = filist(loopcntr).name; [dBeginOfDate, dYrMoSeprtr, dMoDySeprtr, dEndOfDate] = dFuncFindDateStrg(dStrgIn, dYr); dStrgNewChar = '-'; dStrgPos = dYrMoSeprtr;

```
[dStrgIn] = dFuncReplace1Char(dStrgIn,dStrgPos,dStrgNewChar);
      dStrgPos = dMoDySeprtr;
     [dStrgIn] = dFuncReplace1Char(dStrgIn,dStrgPos,dStrgNewChar);
      dStrgNewChar = '_'; 
     [dBeginOfTime, dHrMnSeprtr, dMnSecSeprtr, dEndOfTime] =
dFuncFindTimeStrg(dStrgIn, dEndOfDate);
      dStrgPos = dHrMnSeprtr;
     [dStrgIn] = dFuncReplace1Char(dStrgIn,dStrgPos,dStrgNewChar);
      dStrgPos = dMnSecSeprtr;
     [dNewStr] = dFuncReplace1Char(dStrgIn,dStrgPos,dStrgNewChar);
      dNewFiName = strcat(dNewStr(1:dEndOfDate), '___', 
dNewStr(dBeginOfTime:end));
      if isdir(filist(loopcntr).name)
        mkdir(dapath, dNewFiName);
        content = dir(fullfile(dapath, filist(loopcntr).name));
       if ((length(content) >= 3) ...
             && (~strcmp(filist(loopcntr).name, dNewFiName)));
           movefile((fullfile(dapath, filist(loopcntr).name, '\*.*')), 
(fullfile(dapath,dNewFiName, '\')), 'f')
           rmdir(strcat(dapath, filist(loopcntr).name))
        end
      elseif (~strcmp(filist(loopcntr).name, dNewFiName))
        movefile((fullfile(dapath, filist(loopcntr).name)), (fullfile(dapath,dNewFiName)), 'f')
      end
   end
end
```
%%

% SortFiles2Directories\_r2 % % This program is the 2nd step in post-processing data collected using % 'StartStopRecordDataGUI'. Assuming all data and image files are in a % single directory, it prompts the user for the name of that directory % using 'uigetdir'. A directory is created for each unique date/time % sequence contained in a file name. % %REMOVE ALL UNUSUAL FILES FROM DIRECTROY. LEAVE ONLY %DATE, TENSION AND SCREEN SHOT FILES. % %% % % INITIALIZE / CREATE LIST OF FILES TO CONVERT AND DETERMINE QTY % Clear memory clear %% % Determine search criteria  $d$ workfolder =  $cd$ ; cd C:\  $[dayath] = uigetdir;$ cd (dworkfolder) filist =  $dir(fullfile(dapath, '*.^*))$ ; loopers = length(filist); %% % LOOP TO PROCESS EACH FILE % %  $loopcntr = 0$ ; for  $loopcntr = 1$ : $loopers$ ; % Find the file name length danamelen = length(filist(loopcntr).name); % Skip directories & .db files (thumbnails) if (filist(loopcntr).isdir == 0) && ((strcmpi(filist(loopcntr).name((danamelen -  $2$ : danamelen), '.db')) == 0); % Find the time code daplacecntr =  $1$ ; while daplacecntr ~= danamelen;  $\frac{1}{2}$ %Check each letter in name if filist(loopcntr).name(daplacecntr)  $== '2$ ; %When the 1st  $"2"$  is found dabegin = daplacecntr; %Set location of date begining daplacecntr = danamelen; %End search for this file else %If current letter is not a "2" daplacecntr = daplacecntr + 1; %Increment the position counter end

## end  $%Check$  next letter

%Need to add code before this point to deal with files which do not have 2 %in the name.

%

```
%Find the position of the last time code character
     daplacecntr2 = dabegin +1;
     while daplacecntr2 \sim = danamelen;
        if filist(loopcntr).name(daplacecntr2) == '.';
          daend = daplacecntr2 - 1; daplacecntr2 = danamelen;
         else
          daplacecntr2 = daplacecntr2 + 1;
         end
      end
% Make sure there is a directory for this time code and move the file
      dadirectory = filist(loopcntr).name(dabegin:daend);
      mkdir(dapath, dadirectory);
      movefile((fullfile(dapath, filist(loopcntr).name)), (fullfile(dapath, dadirectory)), 'f');
   end
end
```

```
%%
```

```
%
```

```
% This program processes ASCII data and date files collected by the
% 'StartStopRecordDataGUI' script AND have already been sorted into
% directories by the 'SortFiles2Directories' script.
%
% Functions provided by the program include:
% 1. Getting search criteria from user GUI
% 2. Finding files in the specified directory and subdirectories
% 3. Creating an .xls file in each directory which combines date/time
% and data file pairs
% 4. Creating a summary .xls file in the specified directory which
% contains a tab for each date/time and data file pair
% 5. Creating an error log file which lists file pairs which were not
% processed
clear
% Make lists global to pass multiple, variable length lists between
% routines.
global dfilelist dsublist
dfilelist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
dsublist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
%%
% Determine search criteria
dworkfolder = cd:
cd C:\
[dsublist.name] = uigetdir;
cd (dworkfolder)
dcriteria = 'TensionData*.csv';
dsubcriteria = '*';
%%
% Determine files to process
dFuncFindFiles(dcriteria, dsubcriteria);
%%
%
% Determine name for day summary file
[ddayrptname] = dFuncDayRptName;
% %%
% % Initialize spreadsheet communication for day summary
dfullwkbkname = fullfile((dsublist(1,1).name), ddayrptname);
[dxlsfile, dexIday] = dFuncInitialzXIs(dfullwkbkname);
%%
% Convert ASCII data to xls
%
dr6 = size(dfilelist, 1);derrorctr = 0; %Initialize error counter
```
derror = cell(1,2); %Declare derror a cell array dheaders =  $\{DATE\}$ , 'TIME', 'FORCE'}; %Specify table headings for  $di = 1:dr6$  % Format the spreadsheet name  $d$ pathandfile = dfilelist(di,1).name; dstartstr =  $'2012'$ ; doffset  $= 0$ ; dstr2rm =  $\{201.-12-\frac{1}{2}\}\dots$  '201.-11-'; ... '201.-10-'; ... '201.-09-'; ... '201.-9-'; ... '201.-08-'; ... '201.-8-'; ... '201.-07-'; ...  $'201.-7-$ ; ... '201.-06-'; ... '201.-6-'; ... '201.-05-'; ... '201.-5-'; ... '201.-04-'; ...  $'201.-4-';...$  '201.-03-'; ... '201.-3-'; ... '201.-02-'; ... '201.-2-'; ... '201.-01-'; ... '201.-1-'};  $dstr2plc = {^rDec}; ...$  'Nov'; ... 'Oct'; ... 'Sep'; ... 'Sep'; ... 'Aug'; ... 'Aug'; ... 'Jul'; ... 'Jul'; ... 'Jun'; ... 'Jun'; ... 'May'; ... 'May'; ... 'Apr'; ... 'Apr'; ... 'Mar'; ... 'Mar'; ...

- 'Feb'; ...
- 'Feb'; ...
- 'Jan'; ... 'Jan'};

 [dtestrptname] = dFuncTestRptName(dpathandfile, dstartstr, doffset, dstr2rm, dstr2plc);

% Format the individual test Xcel file name

 $[dp,df,dx] = fileparts(dpathandfile);$ 

 $d$ finame = fullfile $(dp, df)$ ;

% Initialize spreadsheet communication for individual test

 $[{\rm dtest}x]$  statest] = dFunclnitialzXls(dfiname);

% Calculate the data to be stored in spreadsheets

[ddatatable, derrorctr, derror] = dFuncConvrtASCII2xls(dpathandfile, derrorctr, derror);

% Write data table to TestRptName file

dxlssheet = 1; %Put on 1st sheet

dFuncWriteArray2OpenXLS (ddatatable, dtestxlsfile, dxlssheet, dheaders,

dtestrptname)

% Terminate communication to individual test report

dFuncTerminateXlsCom (dexltest)

 % Write data to day report file with each test on new tab  $dx$ lssheet = di;

 dFuncWriteArray2OpenXLS (ddatatable, dxlsfile, dxlssheet, dheaders,dtestrptname) end

%%

% Terminate spreadsheet communication to day summary report

dFuncTerminateXlsCom (dexlday)

%%

% Write error log

dFuncWriteErLog(derror, dsublist(1).name)

```
%% Determine Tear Out Tension
% Determine tension by finding highest value repeated the specified number
% of times in a row. Creates and Excel spreadsheet with columns for test
% name, margin, capsule condition, suture angle and each of the specified
% peak widths.
%
%%
%
% INITIALIZE / CREATE LIST OF FILES TO CONVERT AND DETERMINE QTY
% Clear memory
clear all
%%
% Make lists global to pass multiple, variable length lists between
% routines.
dfilelist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
dsublist = struct('name',[1], 'date', [1], 'bytes', [1], 'isdir', [1], 'datenum', [1]);
global dfilelist dsublist
%%
% Determine search criteria
dworkfolder = cd;
cd C:\
[dsublist.name] = uigetdir;
cd (dworkfolder)
%
% Enter the number of times value must appear
dvalfreq = [1, 2, 4, 8, 10];
ddatacols = length(dvalfreq);%
% Enter tolerance for similar values
dbandwidth = 0.1;
%
% Find tension files & directories
dcriteria = 'TensionData*.xls';
dsubcriteria = '*Tear*';
dFuncFindFiles(dcriteria, dsubcriteria)
dr6 = size(dfilelist, 1);derrorctr = 0; %Initialize error counter
derror = cell(1,2); %Declare derror a cell array
dpeakvalues = cell(1);
dpeaktable = cell(dr6, (length(dvalfreq)+1));
```
for di  $= 1$ :dr6 % Make data label



```
dpathandfile = fullfile(dp, df);
   [dtestrptname] = dFuncTestRptNameLg(dpathandfile,dstartstr, doffset, dstr2rm, 
dstr2plc);
  dpeaktable((di),1) =cellstr(dtestrptname);
% Get margin
   dstrgin = dtestrptname;
  [dmargin] = dFuncGetMargin (dstrgin);
  dpeaktable((di), 2) =cellstr(dmargin);
% Get capsule state
  [dcapcond]= dFuncFindCapCond(dstrgin);
  dpeaktable((di),3) = cellstr(dcapcond);
% Get angle
  [dangle] = dFuncGetAngle (dstrgin);
  dpeaktable((di), 4) =cellstr(d)angle);% Find peak values 
   ddatain = []; % Clear variables used in loop
   ddatain = xlsread(dworkfile); % Read data
   ddatain = ddatain * (-1); %****CORRECTION FOR DIRECTION****
  for dk = 1:(length(dvalfreq))
    dwinsize = dvalfreq(dk); [dpeakval, dpeakindex] = dFuncFindFlatWindowWithBandWidth (ddatain, dwinsize, 
dbandwidth);
    dependent(di), (dk+4)) = cellstr(dpeakval); end
end
% Make table headings
dheaders(1,1) = cellstr('TEST ID');
dheaders(1,2) = cellstr('MARGIN');cheaders(1,3) = cellstr('CAPSULE');cheaders(1,4) = cellstr('ANGLE');for dn = 1:(length(dvalfreq))
   dheaders(1,(dn+4)) = cellstr(strcat(num2str(dvalfreq(dn)),' CONSECUTIVE PTS'));
end
```

```
%% WRITE CURRENT DATA SET TO AN EXCEL FILE
%
% Make workbook name
dtempname = dsublist(1).name;
[p,f,x] = fileparts(dsublist(1).name);dwrkbkname = fullfile((dsublist(1).name), strcat(f, '_Tear_Out'));
[dxlsfile, daexl] = dFuncInitialzXls(dwrkbkname);
% Open workbook
dxlsheet = 1:
dtestrptname = ['AutoCalc Tension with BW = ', num2str(dbandwidth)];
```
dFuncWriteArray2OpenXLS\_Tension (dpeaktable, dxlsfile, dxlsheet, dheaders, dtestrptname, ddatacols) dFuncTerminateXlsCom (daexl)

% % % newfiname = strcat(dapath, 'Calcd\_Fail\_Val\_5\_Column.xls'); % % % xlswrite(newfiname, peakval, 'Sheet1', 'A2') % % % fihead = {'Test', 'From Notes', '20 Wide', 'Fifeteen Wide', '15 Counts', 'Ten Wide', '10 Counts'}; % % % xlswrite(newfiname, fihead, 'Sheet1', 'A1')

```
%% Determine AUX Test Force
% Determine tension by finding highest value repeated the specified number
% of times in a row. Creates and Excel spreadsheet with columns for test
% name, margin, capsule condition, suture angle and each of the specified
% peak widths.
%
%%
%
% INITIALIZE / CREATE LIST OF FILES TO CONVERT AND DETERMINE QTY
% Clear memory
clear all
%%
% Make lists global to pass multiple, variable length lists between
% routines.
dfilelist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
dsublist = struct('name',[1], 'date', [1], 'bytes', [1], 'isdir', [1], 'datenum', [1]);
global dfilelist dsublist
%%
% Determine search criteria
dworkfolder = cd;
cd C:\
[dsublist.name] = uigetdir;
cd (dworkfolder)
%
% Enter the number of times value must appear
dvalfreq = [1, 2, 4, 8, 10];
ddatacols = length(dvalfreq);%
% Enter tolerance for similar values
dbandwidth = 0.2;
%
% Find tension files & directories
dcriteria = 'TensionData*.xls';
dsubcriteria = '*Aux*';
dFuncFindFiles(dcriteria, dsubcriteria)
dr6 = size(dfilelist, 1);derrorctr = 0; %Initialize error counter
derror = cell(1,2); %Declare derror a cell array
dpeakvalues = cell(1);
dpeaktable = cell(dr6, (ddatacols+1));
```
for di  $= 1$ :dr6 % Make data label



```
dpathandfile = fullfile(dp, df);
   [dtestrptname] = dFuncTestRptNameLg(dpathandfile,dstartstr, doffset, dstr2rm, 
dstr2plc);
  dpeaktable((di),1) =cellstr(dtestrptname);
%% Get suture type
   dstrgin = dtestrptname;
   [dsutsize, dsuttype] = dFuncGetSutureInfo(dstrgin);
  dpeaktable((di), 2) =cellstr(dsutsize);
  dpeaktable((di),3) = cellstr(dsuttype);
% Find peak values 
   ddatain = []; % Clear variables used in loop
   ddatain = xlsread(dworkfile); % Read data
   ddatain = ddatain * (-1); %****CORRECTION FOR DIRECTION****
  for dk = 1: ddatacols
    dwinsize = dvalfreq(dk); [dpeakval, dpeakindex] = dFuncFindFlatWindowWithBandWidth (ddatain, dwinsize, 
dbandwidth);
    dependent(di), (dk+3)) = cellstr(dpeakval); end
end
% Make table headings
dheaders(1,1) = cellstr('TEST ID');
dheaders(1,2) = cellstr('SUTURE SIZE');
dheaders(1,3) = cellstr('SUTURE TYPE');% dheaders(1,4) = cellstr('ANGLE');
for dn = 1: ddatacols
   dheaders(1,(dn+3)) = cellstr(strcat(num2str(dvalfreq(dn)),' CONSECUTIVE PTS'));
end
%% WRITE CURRENT DATA SET TO AN EXCEL FILE
%
% Make workbook name
dtempname = dsublist(1).name:
[p,f,x] = fileparts(dsublist(1).name);dwrkbkname = fullfile((dsublist(1).name), strcat(f, ' AUX'));
[dxlsfile, daexl] = dFuncInitialzXls(dwrkbkname);
% Open workbook
dxlsheet = 1;
dtestrptname = ['AutoCalc Tension with BW = ', num2str(dbandwidth)];
dFuncWriteArray2OpenXLS_Tension (dpeaktable, dxlsfile, dxlsheet, dheaders, 
dtestrptname, ddatacols)
```

```
dFuncTerminateXlsCom (daexl)
```

```
%% Determine Suture Tension
% Determine tension by finding highest value repeated the specified number
% of times in a row. Creates and Excel spreadsheet with columns for test
% name, perfusion level and each of the specified
% peak widths.
%
%%
%
% INITIALIZE / CREATE LIST OF FILES TO CONVERT AND DETERMINE QTY
% Clear memory
clear all
%%
% Make lists global to pass multiple, variable length lists between
% routines.
global dfilelist dsublist
dfilelist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
dsublist = struct('name',[], 'date', [], 'bytes', [], 'isdir', [], 'datenum', []);
%%
% Determine search criteria
dworkfolder = cd;
cd C:\
[dsublist.name] = uigetdir;
cd (dworkfolder)
%
% Enter the number of times value must appear
dvalfreq = [1, 2, 4, 8, 10];
ddatacols = length(dvalfreq);%
% Enter tolerance for similar values
dbandwidth = 0.1;
%
% Find tension files & directories
dcriteria = 'TensionData*.xls';
dsubcriteria = '*Tension*';
dFuncFindFiles(dcriteria, dsubcriteria)
dr6 = size(dfilelist, 1);derrorctr = 0; %Initialize error counter
derror = cell(1,2); %Declare derror a cell array
dpeakvalues = cell(1);
dpeaktable = cell(dr6, (ddatacols+1));
```
for di  $= 1$ :dr6 % Make data label



```
dpathandfile = fullfile(dp, df);
   [dtestrptname] = dFuncTestRptNameLg(dpathandfile,dstartstr, doffset, dstr2rm, 
dstr2plc);
  dpeaktable((di), 1) =cellstr(dtestrptname);
% Get perfusion level
   dstrgin = dworkfile;
  [dperfusion] = dFuncGetPerfusion (dstrgin);
  dpeaktable((di), 3) = (dperfusion{1,1});
% Find peak values 
   ddatain = []; % Clear variables used in loop
   ddatain = xlsread(dworkfile); % Read data
   ddatain = ddatain * (-1); %****CORRECTION FOR DIRECTION****
  for dk = 1: (ddatacols)
    dwinsize = dvalfreq(dk); [dpeakval, dpeakindex] = dFuncFindFlatWindowWithBandWidth (ddatain, dwinsize, 
dbandwidth);
    dpeaktable((di),(dk+3)) = cellstr(dpeakval); end
% Get sample ID
   [dsampleid] = dFuncGetTestID (dtestrptname, dp);
  dpeaktable((di),(2)) = cellstr(dsampleid);
end
% Make table headings
dheaders(1,1) = cellstr('TEST ID');
dheaders(1,3) = cellstr('PERFUSION LEVEL');dheaders(1,2) = cellstr('SAMPLE ID');
for dn = 1: (ddatacols)
   dheaders(1,(dn+3)) = cellstr(strcat(num2str(dvalfreq(dn)),' CONSECUTIVE PTS'));
end
%% WRITE CURRENT DATA SET TO AN EXCEL FILE
%
% Make workbook name
dtempname = dsublist(1).name;
[p,f,x] = fileparts(dsublist(1).name);dwrkbkname = fullfile((dsublist(1).name), strcat(f, '_Suture_Tension'));
[dxlsfile, daexl] = dFuncInitialzXls(dwrkbkname);
% Open workbook
dxlsheet = 1:
dtestrptname = ['AutoCalc_Tension with BW = \text{'}, num2str(dbandwidth)];dFuncWriteArray2OpenXLS_Tension (dpeaktable, dxlsfile, dxlsheet, dheaders, 
dtestrptname, ddatacols)
```

```
dFuncTerminateXlsCom (daexl)
```

```
% % % newfiname = strcat(dapath, 'Calcd Fail Val 5 Column.xls');
```
% % % xlswrite(newfiname, peakval, 'Sheet1', 'A2')

% % % fihead = {'Test', 'From Notes', '20 Wide', 'Fifeteen Wide', '15 Counts', 'Ten Wide', '10 Counts'};

% % % xlswrite(newfiname, fihead, 'Sheet1', 'A1')

## **Bibliography**

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