Technological Improvements in Ligation and Suturing Techniques: 
A Comparison in the Material Strength of Ligating Clips and Suturing Devices

by
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Treatment of extrahepatic portosystemic shunts provides many options, including cellophane banding. These cellophane bands are secured with a ligation clip. Weck® offers two forms of these: the stainless steel Hemoclip, and the polymer Hem-o-lok. This in vitro study compares the mechanical strength of these two of types of clips by simulating clinical performance in occluding an extrahepatic portosystemic shunt, where the cellophane band has been triple-layered and four alternating clips hold it together. It is found, in this study, that these clips most often slip one after the other, and that the metallic Hemoclip is significantly stronger than the Hem-o-lok.

With many options available for suturing, research into the biomechanical differences between suturing materials, such as absorbable and non-absorbable materials, and new technologies, such as devices, is important. This study is a comparative, ex vivo, mechanical evaluation of porcine skin wounds sutured using 3-0 nylon simple interrupted sutures, both with and without 910 polyglactin absorbable buried sutures. Suturing with the 3-0 nylon sutures was done both with and without SutureLock devices, with the SutureLock devices secured with a mattress suture. Mechanical tests were done using samples of Yucatan miniature white hairless swine skin wounds on the day of operation, 10 days post-operation, and 42 days post-operation. These tests have also found that there was no statistically significant difference between suturing methods. This result agrees with previous studies.

Key Words: cellophane banding, ligation clips, suture, tensile test

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I. Literature Review

Ligation Clips

Cellophane banding is a common surgical technique used in the treatment of extrahepatic portosystemic shunts. Portosystemic shunts (also referred to as varices) can result in a multitude of complications in the liver, bile duct, and veins spreading throughout the body [1]. Treatments for these can either be medical or surgical; medical treatments include using antibiotics, lactulose and starting a hypoproteic diet. Surgical treatments consist of ligation of the shunting vessel, whether partial or complete [2]. Although cellophane banding is just one method of attenuation, two materials of ligation clips used to fasten these bands onto the shunts are examined: the metal Hemoclip, which has been in use for fifty years, and the newer polymer Hem-o-lok clip.

Portosystemic Shunts

Congenital extrahepatic portosystemic shunts occur as complications from liver disease and portal hypertension [1]. They are known as vessels that join together the portal and venous circulation, which allow some of the blood meant for the liver to bypass it and directly enter circulation [2, 3]. Major complications from this include hepatic encephalopathy, cystic calculi, stunted growth, vomiting, and diarrhea [3]. Although these can appear in humans, they are often found in young, small dog breeds, although they can be found in older, larger dog breeds as well [3, 4].

The image below (Fig 1.1) shows drawings of three scenarios of a calf’s veins. Figure 1.1(A) shows a normal liver. Figure 1.1(B) displays how an intrahepatic portosystemic shunt can appear in the vein through the liver. Figure 1.1(C) shows the extrahepatic portosystemic shunt attaching from the portal vein to the vena cava, which carries deoxygenated blood into the heart [5]. Although the connection may be slightly different for other species, the basis remains the same. Extrahepatic portosystemic shunts divert blood that should be going to the liver elsewhere.
These varices are commonly detected with three methods: computed tomography angiography—or CTA—ultrasonographic evaluation, and scintigraphy [1, 2, 3, 4, 6, 7]. Using these has led to an increased ability to identify the extrahepatic portosystemic shunts and better care for them. Computed tomography angiography has helped to provide a more thorough understanding of the orientation of varices and their relationship with nearby organs [1]. It is especially useful when seeking the exact location for patients who are in need of a surgical procedure, which can be complicated by unpredictable portosystemic shunts [1]. Ultrasonographic evaluation is the other preoperative option; it is useful for studying velocity of portal blood flow, it is a common imaging technique, and does not require anesthesia, making it noninvasive. While CTA is far more accurate, it necessitates anesthesia and is far more expensive [4].

Treatment Options

Extrahepatic portosystemic shunts can either be congenital or acquired. The focus of most studies is on congenital shunts, stemming from liver disease and portal hypertension [1]. However, acquired shunts can be just as dangerous, if not more, than congenital ones. These can come about as a result of closing the vessel too hastily during surgical attenuation and can cause death of the patient [6]. Another complication of surgery is hypertension, which can occur by
forcing blood to flow through portal veins instead of an attenuated shunt [7]. It is because of these that the testing of many options of treatment have been done. There are medical techniques—as opposed to surgical ones—and varying modes of surgeries. Surgical options for treating varices comprise of partial or complete attenuation of the extrahepatic portosystemic shunt. This can be done using silk or polypropylene ligatures, or with a gradually occluding device, often in the form of a constricting ring, or material wrapped around the abnormality [6]. These gradual occluding devices include the ameroid constrictor ring and the aforementioned cellophane banding method.

A study published in 2003 compared the results of using medical versus surgical techniques in 14 dogs of varying breeds [2]. It was limited, as many of these studies are, to dogs with a single congenital extrahepatic portosystemic shunt. It found that one year after treating the varices, both surgery and medical treatment were generally successful, although medical treatment resulted in more complications than its counterpart. Dogs that had been medicated developed fibrosis in the portal vein, a thickening of the walls making it more difficult for blood to pass through [2]. It was also found that although medical therapy was effective in the control of resulting hepatic encephalopathy, it was far less effective modifying the hepatic trophism [2]. While medical treatment is far less invasive than surgical, this study found that, despite assisting in the fix of a shunt, it did not do this nearly as effectively as ligation.

Sometimes partial attenuation of extrahepatic portosystemic shunts is necessary. In surgery, complete closure of the shunt can induce more shunts and lead to complications. Some studies state that there is no difference in the result of small animals being treated by partial or complete ligation [5]. Unfortunately, others find that dogs which only have partial attenuation show clinical recurrence in up to 50% of patients [8]. In a study published in 2004, six out of fourteen dogs that had been partially attenuated showed recurrence or persistence of their shunts [7]. Like medical treatment, partial ligation can be of assistance, but only complete ligation returns blood flow velocity of the portal vein to normal ranges [2].

Ameroid ring constrictors (ARCs) have been considered in surgery in order to reduce the danger of portal hypertension, one of the major complications after operations. A study comparing these to cellophane banding in attenuation of 168 dogs describes the ameroid ring constrictor as being composed of an outer and inner ring, where the outer ring is composed of stainless steel, and the inner ring is a casein that expands when immersed in fluid. It has an open
slot for vessel placement and a key to prevent slipping. For clarification, there is also the image below (Fig. 1.2), showing the cylinder, and the key slot allowing for insertion.

![Figure 1.2. An Ameroid Ring Constrictor, with stainless steel outer ring, ameroid casein inner ring, and cylindrical key, with 5 mm reference size. [38]](image)

After inserting this ring around the extrahepatic portosystemic shunt, the ameroid fibers of the casein expand, providing a fibrous tissue reaction to the ring constrictor and thrombosis. These result in attenuation of the shunt [8]. This, too, has its own obstacles, post-operation. Dogs in fair and poor cases had abdominal distension, seizures, and mild portal hypertension, accounting for 10% of the results. 7.1% of dogs died. However, it did have an 80% success rate [8].

The act of cellophane banding to treat extrahepatic portosystemic shunts is common, as cellophane is easily accessible and cheap. To attenuate a shunt, a strip of cellophane is wrapped around the vein and held closed with a ligating clip. This is typically done in a fully exploratory surgical method, such as ventral midline celiotomy, where the cellophane is triple layered by folding to approximately 4 mm wide [9]. It is inserted around the vessel with forceps and secured with the clip [9].
The effectiveness and safety using cellophane bands has been proven in multiple studies [10]. Especially when triple-layered—as opposed to a single sheet—it increases frictional forces of a clip on the band, it is a fibrous and a foreign body post-operation, an inflammatory reaction is incited leading to fibrosis of the extrahepatic portosystemic shunt [8]. This causes a gradual occlusion of the vessel—in this case, a shunt—to help reduce portal hypertension in surgery; however, it continues to be unpredictable once in the body [10].

The Hemoclip

According to the manufacturer, Weck® metal ligation clips, or Hemoclips, “satisfy your need for traditional metal ligating clips for use in cardiovascular and general surgical applications” [11]. These have three material selections: titanium, tantalum, and stainless steel. Although these have been in use for over fifty years, they are not without their flaws. One problem with metal clips is that they distort the images of CT scans. It has been found that reconstruction of highly-attenuated objects, such as metal implants, in soft-tissues often contains star-shaped artifacts and streaks [12]. Computer scientists have largely solved this issue with adjusted coding, but the metal of Hemoclips nonetheless creates error when doing necessary imaging.

The strength of ligating clips has also been in question. Weck® has indicated on their website that their ligating clips “are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies” [11]. Although this is not the treatment specifically for
extrahepatic portosystemic shunting, evidence of Weck® clips slipping showed a weakness in strength, which has led to studies addressing this issue. There have been publications directly contradicting each other, where some retrospective reports indicated that there had been clip malfunctions, which led to the contraindication, while other publications found there no serious complications from using Weck® clips [13]. One study, completed in 2009, tested the strength of metal vascular clips—designed very similarly to Hemoclips—in a cellophane banding tensile test. Comparing size, number of clips, and clip orientation, the ideal setup was arranging four ligating clips in an alternating configuration. This provided the highest resistance in tensile testing of all other configurations [10]. This result provided an average yield force of $5.18 \pm 0.35$ N for 9 mm clips and $7.46 \pm 0.32$ N for 11.5 mm clips [10]. Despite this being an in vitro test, it gives a sense of the biomechanical strength of metal ligament clips.

The Hem-o-lok

Hem-o-lok polymer ligating clips also come from the Weck® brand, with the company’s website boasting improvements upon the previous Hemoclip design [11]. Released to the public in 1999, Hem-o-lok clips are non-absorbable and their curved design allows for expansion in thick tissue, as well as high closing strength in thin tissues [14, 15]. The polymer is more flexible than its metallic counterpart, making it a more universal solution, and the manufacturer claims it is radiolucent, reducing the Hemoclip’s issue of image distortion in CT scans.

![Figure 1.4. A graphical representation of a Hem-o-lok clip. (1) Boss for clip retention (2) Integrated teeth interface (3) Locking mechanism (4) Bow shape for removal (5) Hinge for flexibility (6) Non-absorbable polymer [11]](image_url)
The design, as well as the material of the Hem-o-lok, differs from the Hemoclip. Hemoclips rely mainly on surface area with the cellophane band to increase friction forces [10]. However, the Hem-o-lok has an “integrated teeth interface” as an alternate solution to preventing slippage [11].

Despite the contraindication of safety for laparoscopic nephrectomies labeled on the Weck® website, Hem-o-lok clips have gone through many more studies proving their safety and efficacy. According to a study published in 2006, many devices have been created to ease the process of obtaining control of the renal vasculature in laparoscopic radical nephrectomy, and the Hem-o-lok closure system is highly reliable and economical [14]. The effect of Hem-o-lok clips have been documented in over 1,000 procedures and have been shown to be generally safe [16].

In addition to the material and design benefits above, antimicrobial studies have been conducted, confirming resistance to bacterial growth around Hem-o-lok clips [17]. Although they do not have the radiolucency that is claimed by the manufacturer, and can be misidentified in imaging as something malignant, cases of malfunction have been shown to be rare [18]. They have been shown to be very useful in laparoscopic nephrectomy, their polymer material choice is helpful against infection, although their radiolucency may be oversold.

There may be no signs of true malfunction of the Hem-o-lok clips. But there have been repercussions long term due to the grip of the clips. This can be seen in migrations and raised bile acid concentrations. In some cases, human patients who were ligated with Hem-o-lok clips showed that they had later migrated into the bladder 3 to 6 months after surgical procedures [15]. Using follow-up cystoscopy, objects have been found in bladder cuffs and removed with a resectoscope [15].

The other trouble, which is directly related to the treatment of extrahepatic portosystemic shunts, is bile acid concentration. This is known to be a sensitive indicator of varices [19]. When using the Hemoclips around cellophane bands, 28% of animals continued to have raised bile acid concentrations, signifying that with high bile acid came multiple acquired portosystemic shunts, added to the shunt through the original vessel [19].

Relevance

In vitro tests provide a baseline on which to perform any further in vivo tests. These are generally cheaper and far simpler than in vivo tests, which require approval for animal or human samples [17]. They also allow for better isolation of variables. Performing a comparative in vitro tensile test on both the Hemoclip and the Hem-o-lok clips provide an understanding of
whether either clip may have higher mechanical strength. Any recommendation resulting from mechanical strength could provide insight for further studies.

Hypothesis

Due to the surface of integrated teeth that the Weck® website boasts, this should increase the surface area of the Hem-o-lok clips on the cellophane band, as opposed to the Hemoclip’s flat surface [10, 11]. Because frictional forces should be compressing the cellophane, this increased surface area should result in the Hem-o-lok clip having the ability to experience increased loads, as opposed to the metallic Hemoclip. As slipping is the major concern in many studies, it is expected that the clips will primarily experience slippage [10, 15].

Sutures

Surgery is an oft-necessary aspect of a person’s life. At some point, most people will need surgery. However, there has been debate over the best ways to seal up the skin afterward. This is, most often, left up to the surgeon’s preferences. In the case of sutures, the best suture should have high tensile strength, minimal tissue reactivity, ease of handling, and quality knot security [20]. In achieving this, many options have come available: staples or sutures, superficial or subcutaneous sutures, absorbable or non-absorbable sutures, knotted or knotless. Recently, another option has been tested: the suture device.

Comparison: Sutures and Staples

One concern with surgery is infection. This is also known as an SSI, or a surgical site infection, and is defined as an infection affecting the incision site, whether superficial or deep, within 30 days post-operation or within one year, if an implant remains inside the patient [21]. If a former patient has an SSI, they often have high hospital readmission rates and annual increases to their healthcare costs of up to 300% [21]. This is one reason that many look to the first decision when sealing the wound. Surgical staples and sutures are both used in closing a surgical cut, also known as an incision [22]. Monofilament sutures are considered generally useful in infection prevention [22]. However, the issue of sutures or staples shows that, in terms of SSIs, there is no discernable difference. Patients who receive staples versus knotted sutures post-
operation show no significant difference in infection rates [21]. While this may not be a concern between sutures and staples, there is also time to seal the wound and cost of each. Staples are much faster than sutures and, according to one study, using staples may save 35 minutes per 5 surgeries, reducing overscheduling costs [21]. On the other hand, sutures are far cheaper and require fewer dressing changes than staples [22]. The differences between these appear to be minimal, leaving this decision up to the surgeon’s preferences.

**Comparison: Superficial and Subcutaneous Sutures**

Superficial sutures are sewn into the skin near the surface of the surgical site, and come in the form of interrupted sutures, meaning they are knotted [23]. These are incredibly useful for precise approximation of skin location [24]. Superficial sutures are considered to produce fewer surface wound complications, although deeper wound dehiscence can be an obstacle [24].

Subcutaneous sutures are buried beneath the surface, eliminating the necessity for removal. This is one method within traditional suturing that seeks to be stronger and last longer to better improve the patient’s health after surgery. However, a study done removing ulcerative colitis found that fistula and granulation increase when certain materials, such as braided multifilament sutures, are used for subcutaneous sutures [22]. In this particular study, both braided and thinner monofilament sutures were inserted subcutaneously. This increase in fistula and granulation using the braided sutures is relatively small compared to muco-cutaneous fistula, which occurred more often with the monofilament sutures. This likely due to the issue of absorption in non-removable monofilament sutures, where long absorption times may cause injury or foreign body reactions at the incision [22]. This study declared monofilament sutures unsuitable for subcutaneous use, meaning that material choice is important when choosing a subcutaneous suture.

**Comparison: Absorbable and Non-Absorbable Sutures**

Absorbable sutures are meant to remain in the body for extended periods of time, as they dissolve into the skin or the organ lining. Non-absorbable sutures are the more traditional sutures, which are often removed after ten to fourteen days [25]. Many absorbable sutures, however, can remain in body tissue for approximately 180-230 days [26]. In terms of effect from heat and chemotherapy, there is no significant effect of this on absorbable sutures [20].
The tensile strength, however, is where the two may differ. It has been found that there are biomechanical differences between absorbable and non-absorbable suturing materials [26]. Some studies have found that the non-absorbable sutures are stronger. Although not significantly, in terms of signs of recurrence, recurrent hernia rates occurred in 26% of absorbable and 4% of non-absorbable sutures, in one study [27]. However, when knotting, absorbable sutures have been shown to retain their strength better than non-absorbable. In one study, after adding a single knot, non-absorbable nylon sutures lost 62% of their load strength, and absorbable polypropylene only lost 19% [28].

Comparison: Knotted Sutures and Barbed Sutures

One trouble with suturing is the knot. It is known to be the weakest part of a suture, and the site in which a suture will fail [25, 29]. The knots have also been known, depending on the location of surgery, to impede on blood supplies to the surgical sites and therefore cause interference with healing [30]. There are four common knots in simple interrupted sutures that end up being used on small animals and humans: the square knot, the surgeon’s knot, the granny knot, and the sliding half hitch. The latter two of these four typically come about from an error [25]. If a knot fails, this can lead to some minor complications, such as slowed healing, incorrect scarring, and minor infections, as well as more major obstacles, in the case of wound separation, dehiscence, or deep infections [25]. It is known that sliding knots, such as granny and sliding half hitch knots, have been found not to perform as well as surgeon’s knots or square knots [29]. This is due to the way that the knot is thrown, where the “better” knots have a crossing and the “worse” ones do not. This seals the suture more securely [29].

To remove this issue, knotless sutures have been developed. These are most often barbed sutures. Knotless sutures have been shown to have strength comparable to simple sutures [31]. Barbed sutures, specifically, have been developed to have a unidirectional nature, facilitating unrestricted passage in the direction of the barbs, as well as resistance to passage against the direction of the barbs [30]. Most mechanical studies have only researched barbed sutures in a laboratory setting, rather than in vivo trials [26]. These ex vivo and in vitro trials have not found any significant differences between barbed and traditional sutures [26]. In terms of mechanical strength, these do not provide anything traditional sutures do not also provide. In case study tests, however, they have proved to have two advantages over knotted sutures. The first is speed
of insertion. Barbed sutures are faster to apply as no knotting is required [30]. The second is that barbed suture materials reduce bulk at the surgical site [32]. While they do not provide extra strength, there are still advantages to the barbed suture.

**Mattress Suturing**

In the study conducted in this paper, mattress sutures are used to suture the suture device. Mattress suturing, while not being a subcuticular suture technique, digs into the subcutaneous tissue of the skin, but is interrupted, rather than continuous. In the case of a simple suture, the technique used for the incisions without devices, the needle completes a circle through the skin before making a knot, whereas the mattress suture makes two passes at the surgical site, first entering deeply into the skin, and then near the surface before making a knot. This means that, in mattress suturing, there is more suture material used for each knot than with a simple suture [31].

![Figure 1.5](image)

*Figure 1.5. Graphic representations of (A) a simple interrupted suture with proper knotting technique and (B) a vertical mattress suture using the far-far near-near method [37].*

It has been shown that mattress sutures are mechanically superior to simple interrupted sutures [31]. This study, however, refers to the strain failure of a mattress suture—where strain failure is measured as 2 mm of permanent displacement—rather than peak force. The breaking strength of a mattress suture appears to have no significant difference compared to other suturing techniques [23]. It has also been found to lower the leakage in distal pancreatectomy [33]. In general,
mattress sutures have higher elastic strength, but comparable breaking strength to other suturing types.

The SutureLock Device

The SutureLock device, which is being tested in this paper, holds superficial sutures above the skin, preventing ingrowth and holding the strength of the suture itself. It can be adjusted in surgery to increase or decrease tension in the sutures. As it is made with stiff material, it may cut more easily through soft tissue. This means that over time it may cut into the tissue which has recently been operated on. Its strength and strength long after surgery is still experiencing experimentation.

Relevance

There have been many in vitro strength-comparative tests done on different suture materials, and many in vivo case studies on single forms of suturing techniques [21, 22, 26, 28, 32, 36]. The in vitro comparative tests can only provide a baseline, as they display the strength of the suture itself, not the strength of the wound [28]. In vivo case studies typically show the effect of one suture material and how it may react within the body, but do not provide a comparative base for many sutures. An ex vivo comparison of the mechanical strength of a device with the strength of a mattress suture is incredibly useful for high tension surgical areas, such as the back, where the peak strength of a suture may be needed [24]. With a stronger suturing technique, the skin can heal much faster. Comparing the strength of the wound with many forms of suturing techniques—in this study, mattress sutures, buried absorbable sutures, and devices—may provide a recommendation for the best choice of suture technique.

Hypothesis

Because absorbable sutures have been shown to display higher mechanical strength when knotted in vitro, it is predicted that these will correlate to a higher wound strength in an ex vivo mechanical test as well [28]. It is also predicted that the devices, because they allow the suture to raise further above the skin to prevent ingrowth, will prove stronger than the sutures alone. This, again, is expected to correlate with increased wound strength post-operation.
II. Materials and Methods

Ligation Clips

Materials

This experiment was a comparison of tensile strength between two ligation clip materials in two different sizes. The first material was the stainless steel Hemoclip in Medium-Large (9 mm long) and Large (11.5 mm long) sizes. This is considered to be the more traditional form of the clip. The second material was the Hem-o-lok, made from polymer and built with a ridged inner edge for gripping. This also was tested in the Medium-Large (9 mm long) and Large (12 mm long) sizes.

Testing Procedures

Clips were first fastened onto commercially available cellophane bands—12 mm long and folded longitudinally twice to create a 4 mm wide triple layer—these were folded in half in a latitudinal direction. The first clip was applied near the center of this folded band, creating an opening on one end and an excess length on the other. This clip was applied perpendicular to the long axis of the band. Four clips of the same size, either Hemoclip or Hem-o-lok, were attached to the cellophane in horizontal alternating directions.

Figure 2.1. (A) a SolidWorks drawing of the custom-built fixture, prior to the 1 mm gap in the 10 mm extruded cylinder and (B) a test setup of the extending triple-layered cellophane band with four alternating Hemoclip clips.
These cellophane bands were loaded onto a custom-built stainless steel fixture with a split circular jaw of a total diameter of 10 mm and a gap starting at 1 mm wide. This fixture was attached to an Instron 8501 servohydraulic tensile test machine with a 50 N capacity load transducer. This was calibrated prior to testing. The room in which it was located had an average temperature and relative humidity of 22 °C and 39%.

Instron’s WaveMaker software was used to extend the fixture at 0.1 mm/s and collect force-displacement data. Once it was obvious that the clips had reached their peak force and failed, either by visually slipping off the cellophane, or by looking at the plot generated from the WaveMaker program, the program was stopped and the cellophane was removed. The system was then reset and a new cellophane band with identically-applied clips was loaded onto the fixture. This was done in ten repetitions (N = 10) for each material (N = 2) and size (N = 2) of clip. Failure was recorded in every case as being a slip of the clips.

**Statistical Analysis Procedures**

Yield loads were calculated from the initial slip point and will be discussed further in the Results section. These yield loads underwent a one-way ANOVA statistical analysis in order to compare the effect of both size and material on the strength of the ligation clips. Pairwise comparisons were made using a post-hoc Tukey’s test requiring a p < 0.05 to be statistically significant.
Sutures

Materials

The materials used in the comparative tensile tests were superficial 3-0 nylon simple interrupted sutures and 3-0 polyglactin 910 subcutaneous absorbable sutures. These were tested alone, combined, and with and without polymer SutureLock devices—which were secured with mattress sutures—which would attach to the sutures. The skin sample these were tested on was Yucatan miniature white hairless swine skin wounds.

Testing Procedures

Three separate tests were conducted testing varying strength of sutures on samples of pig skin. These samples were approximately 4 cm in length, each measured and recorded before beginning mechanical testing. In all cases, the skin was inserted into Instron screw side action grips attached to a load transducer rated at 5 kN on an Instron 8501 servohydraulic tensile test machine. The samples were inserted with the direction of displacement being perpendicular to the wounds. Tensile tests were run on every sample at a displacement rate of 0.667 mm/s using Instron’s WaveMaker software and was stopped and reset when all sutures had broken and force-displacement plots showed the force returning to zero. The test setup can be seen in Figure 2.2. The room in which the Instron 8501 was located had an average temperature and relative humidity of 24 °C and 32%.

The first set of tests were run on the day of operation (day zero). Porcine samples were removed, post-operation. This tested the strength of superficial mattress sutures versus SutureLock devices. There were two tests run (N = 2) of each of the following: two mattress sutures, four mattress sutures, two mattress sutures with devices, and four mattress sutures with
devices. For these tests the grips were torqued to 25 Nm.

The second and third set of samples were randomized and tested blind, and were run at 10 days after operation and 42 days after operation. Porcine samples were removed, post-operation, from four pigs. Each sample contained either the superficial simple interrupted sutures, the superficial simple interrupted sutures and absorbable sutures, or the previous two options with SutureLock devices attached with superficial mattress sutures. There were four tests run of each form of these comparisons (N = 4) on both days. On the test run at 10 days after operation, the grips were torqued to 25 Nm, but to prevent slippage from the increased strength at day 42, the grips were torqued to 50 Nm.

Statistical Analysis Procedures

For the day 10 and day 42 wound tests, a multifactor analysis of variance (ANOVA) test was performed. This compared the wound strength at day 10 and at day 42, also considering strength—using peak loads—of superficial sutures, this with buried absorbable sutures, traditional sutures and sutures with devices. Due to the small sample size for the day zero tests, no statistical analysis was performed.
III. Results

Ligation Clips

First, all load-displacement curves for the ligation clip tests were separated into three categories: single slip, multiple slip, and breakage. Upon examination of these scenarios, most clips failed in multiple slips. To detect this, peaks were looked for, to find distinct points in which the clips yielded due to the force applied by the fixture. The case of single slip was found where there was only one peak before lowering to zero, seen in Figure 3.1(A). Multiple slip showed between two to four slips of the clips before either remaining at a semi-constant load and then lowering, or simply lowering immediately. It was decided that the first point of slip would be the one analyzed. Figure 3.1(B) is an example of multiple slip.

![Graphical representations of (A) a single slip scenario, where initial slip is measured at the peak, (B) a multiple slip scenario, where initial slip is measured at 5% deviation from linearity, and (C) a breakage scenario, which only occurred after initial slip.]

Lastly, there was the breakage scenario, which only occurred twice throughout the experiments. When the load-displacement curves were analyzed, it appeared as though the clips had already gone through single or multiple slip beforehand. A multiple slip scenario, with breakage, can be seen in Figure 3.1(C).

When processing the yield load of the clips, the single slip versus multiple slip scenarios became important. For the multiple slip case, a trendline was formed from a selection of the linear portion of the load increase. The yield was measured at the first 5% deviation from this trendline. In the case of the single slip, yield was measured at the first peak load.
Table 3.1. Table depicting the frequency of slip type and their associated slip values for each size and material of clip. Asterisks denote samples that had breakage after slipping.

<table>
<thead>
<tr>
<th>Slip Value (N)</th>
<th>Slip Type</th>
<th>Slip Value (N)</th>
<th>Slip Type</th>
<th>Slip Value (N)</th>
<th>Slip Type</th>
<th>Slip Value (N)</th>
<th>Slip Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.87</td>
<td>Multiple</td>
<td>2.65</td>
<td>Multiple</td>
<td>4.85</td>
<td>Multiple</td>
<td>6.40</td>
<td>Multiple</td>
</tr>
<tr>
<td>1.88</td>
<td>Multiple</td>
<td>2.58</td>
<td>Multiple</td>
<td>3.08</td>
<td>Multiple</td>
<td>7.54</td>
<td>Single</td>
</tr>
<tr>
<td>1.08</td>
<td>Multiple</td>
<td>2.34</td>
<td>Multiple</td>
<td>5.06</td>
<td>Multiple</td>
<td>9.47</td>
<td>Single</td>
</tr>
<tr>
<td>0.36</td>
<td>Multiple</td>
<td>1.72</td>
<td>Multiple</td>
<td>9.16</td>
<td>Multiple</td>
<td>7.16</td>
<td>Multiple</td>
</tr>
<tr>
<td>2.08</td>
<td>Multiple</td>
<td>2.08</td>
<td>Multiple</td>
<td>5.76</td>
<td>Multiple</td>
<td>9.16</td>
<td>Multiple</td>
</tr>
<tr>
<td>1.23</td>
<td>Multiple</td>
<td>2.31</td>
<td>Multiple</td>
<td>5.15</td>
<td>Multiple</td>
<td>3.30</td>
<td>Multiple</td>
</tr>
<tr>
<td>2.36</td>
<td>Single</td>
<td>1.88</td>
<td>Multiple</td>
<td>6.18</td>
<td>Multiple</td>
<td>5.50</td>
<td>Multiple</td>
</tr>
<tr>
<td>1.17</td>
<td>Single</td>
<td>2.03</td>
<td>Multiple</td>
<td>8.65</td>
<td>Single</td>
<td>8.65</td>
<td>Single</td>
</tr>
<tr>
<td>1.88</td>
<td>Multiple</td>
<td>4.88</td>
<td>Multiple</td>
<td>4.50</td>
<td>Multiple</td>
<td>9.88</td>
<td>Multiple*</td>
</tr>
<tr>
<td>2.36</td>
<td>Single</td>
<td>5.50</td>
<td>Multiple</td>
<td>7.39</td>
<td>Multiple*</td>
<td>11.49</td>
<td>Multiple</td>
</tr>
</tbody>
</table>

Figure 3.2. Comparative load of all sizes and materials of ligation clips. Displays the average of all slip types, the average of multiple slip, and the average of single slip. Error bars are displayed based on standard deviation; there are no error bars for single slip on Medium-Large Hemoclip due to only one single slip. Different letters denote a statistically significant difference between the average values.
The table above, Table 3.1, shows that there were many more multiple, as opposed to single, points of slip.

In Figure 3.2, the average comparison plot shows the averages for each size and material of clip. The Medium-Large Hem-o-lok clip has the lowest averages, but also the smallest standard deviations. The largest averages and standard deviations belong to the Large Hemoclip clips. However, when comparing the percentage of the average in the standard deviation, the Large Hemoclip clips have the lowest percent standard deviation, at 30%, and the Medium-Large Hem-o-lok clips have the second largest percent standard deviation of 40%. The post-hoc Tukey’s analysis showed a significant difference between each clip pairing, except for between the two sizes of Hem-o-lok clips.

Sutures

All load-displacement curves had clear peak loads from which to measure the suture/skin strength.

<table>
<thead>
<tr>
<th></th>
<th>Average Peak Force (N)</th>
<th>Average Force per Suture (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Suture</td>
<td>51.6</td>
<td>25.8</td>
</tr>
<tr>
<td>4 Suture</td>
<td>113.1</td>
<td>28.3</td>
</tr>
<tr>
<td>2 Device</td>
<td>76.6</td>
<td>38.3</td>
</tr>
<tr>
<td>4 Device</td>
<td>139.4</td>
<td>34.9</td>
</tr>
</tbody>
</table>

*Table 3.2. A table displaying the average peak force and average peak force per suture of all suture and device materials.*

At day 0, the number of sutures and number of devices were measured in peak loading force and peak loading force per suture. When correlating number of sutures with devices, such as 2 sutures with 2 devices, the devices always had higher average peak forces.
Figure 3.2. Two graphical depictions showing (A) average peak loads in each sample type, with all error bars being equal to their standard deviations and (B) average peak loads per suture/device in each sample type, where error bars are equal to one standard deviation above and below the average.

Although the samples with 2 devices had the highest average load per suture (Fig 3.2(B)), they also provided a high deviation from that average, displaying data that was more inconsistent than the mattress sutures or the 4 device samples. In Figure 3.2(A), the 4 device sample has the highest average peak force, and in Figure 3.2(B), the 2 device sample has the highest average peak force per suture.

<table>
<thead>
<tr>
<th></th>
<th>SutureLock/Normal</th>
<th>Superficial/with Deep</th>
<th>Average Force (N)</th>
<th>St. Dev. Force (N)</th>
<th>Average Force/Length (N/mm)</th>
<th>St. Dev. Force/Length (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SutureLock</td>
<td>Superficial</td>
<td>93.1</td>
<td>25.6</td>
<td>2.3</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>SutureLock</td>
<td>with Deep</td>
<td>111.9</td>
<td>14.3</td>
<td>2.8</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>Superficial</td>
<td>111.5</td>
<td>38.9</td>
<td>2.9</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>with Deep</td>
<td>120.5</td>
<td>22.8</td>
<td>3.0</td>
<td>0.6</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.3. Displays results from the day 10 tests, comparing strength of sutures with the SutureLock device, without (Normal), superficial mattress sutures, and the combined superficial sutures with buried subcutaneous sutures.

At day 10, all wounds from their respective sutures had comparable strength, with an average peak force ranging from 93 N to 120 N, seen in Table 3.3, and an average peak force per unit length ranging from 2.3 N to 3.0 N.
### Day 42

<table>
<thead>
<tr>
<th>SutureLock/Normal</th>
<th>Suture Type</th>
<th>Average Force (N)</th>
<th>St. Dev. Force (N)</th>
<th>Average Force/Length (N/mm)</th>
<th>St. Dev. Force/Length (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SutureLock</td>
<td>Superficial</td>
<td>788.3</td>
<td>128.7</td>
<td>18.4</td>
<td>2.1</td>
</tr>
<tr>
<td>SutureLock</td>
<td>with Deep</td>
<td>855.9</td>
<td>131.4</td>
<td>20.8</td>
<td>4.6</td>
</tr>
<tr>
<td>Normal</td>
<td>Superficial</td>
<td>1039.9</td>
<td>323.8</td>
<td>27.2</td>
<td>8.4</td>
</tr>
<tr>
<td>Normal</td>
<td>with Deep</td>
<td>971.9</td>
<td>178.0</td>
<td>26.2</td>
<td>3.9</td>
</tr>
</tbody>
</table>

*Table 3.4.* Displays results from the day 42 tests, comparing strength of sutures with the SutureLock device, without (Normal), superficial mattress sutures, and the combined superficial sutures with buried subcutaneous sutures.

By day 42, the difference in peak force had increased. As evidenced by Table 3.4, samples containing sutures without the device had higher average peak loads than sutures with the device. The average force per unit length describes this similarly.

#### Figure 3.3(A)

*This graph displays the increase in strength from the day 10 trials to the day 42 trials, measured in average peak force. Error bars displayed are one standard deviation above and below the average Different letters denote a statistically significant difference between the average values.*

Using Figure 3.3(A) to compare the change in average peak force, all samples had vastly increased in strength from day 10 to day 42. While no significant difference is seen, the superficial normal sutures display the highest average peak strength.
Figure 3.3(B). This graph displays the increase in strength from the day 10 trials to the day 42 trials, measured in average peak force per unit length. Error bars displayed are one standard deviation above and below the average. Different letters denote a statistically significant difference between the average values.

Figure 3.3(B) displays similar trends as Figure 3.3(A), with the highest average peak force, as well as highest standard deviation appearing with the superficial normal suture samples.
IV. Discussion

Ligation Clips

Although slippage is discussed in many studies as being the primary method of failure for ligation clips, the way that they may slip has not been previously discussed [8, 10, 11, 13]. In the vast majority of cases, the clips slipped one after another in cellophane banding tensile tests. This is likely due to the vertical extension of the circular jaw stretching out the cellophane, reaching each clip individually. In most samples, the clips were not initially touching each other when applied, so when one clip began to slip, it would join with the next one, increasing the slip force of each progressive number of clips. This can be seen in Figure 3.1(B) and Figure 3.1(C), where each load plateau and increase led to another clip’s slip. In the case of single slips, the clips were often placed closer together, leading to a slip of all of the clips at once. Sometimes this was a higher value than multiple slip cases, but they were just as often lower than multiple slips, and were far less common. No statistical analysis was performed on slip type, but it is likely that this does not have an overall effect on the load that ligation clips can withstand.

Stainless steel Hemoclip®s were found to be stronger than the polymer Hem-o-lok® clips. This is shown to be statistically significant, as well, as seen in Figure 3.2. The clips never broke, and cellophane only broke after the clips had already slipped, therefore it is unlikely that there was a failure of the material itself, but rather the interaction between the clips and the cellophane. This interaction has to do with the coefficient of friction between the clip material and the cellophane and the mode of grip on the cellophane. As stated before, the Hemoclip relies entirely on surface area and its stiffness to induce a frictional grip [10]. Because it makes complete contact with the band and can compress into the thick triple layer of cellophane, it can maintain loading up to 11.5 N for the large clips. However, the teeth are what hold onto the cellophane in the case of the Hem-o-lok®, as seen in Figure 1.4. In theory, these should increase the surface area that holds onto the cellophane, where the ridges as well as the surface of the clip grips onto the cellophane [11]. However, in application, this polymer may have a lower coefficient of friction with cellophane than stainless steel does, as well as a lower normal force, both of which directly affect the frictional forces preventing movement in the clips. Weck® also touts the flexibility of the polymer clip. While this has its benefits, stiffness is preferred for biomechanical strength. Therefore, the ridges to improve gripping strength are outweighed by a
lower frictional coefficient and the added flexibility of the polymer. If a ligating clip is going to be placed around a cellophane band that is likely to need high expansion, causing high loads on the clips, this study shows that the Hemoclip is the stronger material choice.

When describing the sizes of the clips, the only pairing between which there was no significant difference was the large and medium-large Hem-o-lok clips. This is denoted with the same letter in Figure 3.2. Although there was an increase from the 9 mm clips to the 12 mm ones, this was shown not to be statistically significant. With the Hemoclip, there was a significant difference between sizes. Because this strength is frictional, as previously discussed, this means that the increase in surface area on the cellophane from the Hem-o-lok clips between sizes was not enough to differentiate them above the sample-to-sample scatter. In contrast, there was a size effect in the case of the Hemoclips. This is further indication that the full surface of the Hem-o-lok clips was not adding enough frictional force on the cellophane, and instead the Hem-o-lok clips were depending on the teeth for meaningful grip.

The biggest limitation on this study was it being in vitro. Although it is now known what forces these clips can handle, veins and organs expanding around the cellophane clips are not likely to reach the same extension as a mechanical test. These clips are also not likely to stretch unidirectionally, as in a tensile test, but rather outward, changing the load distributions on the clips. Tensile tests for these objects give a general sense of what the cellophane bands and the clips can handle without any other interfering forces. Externalized forces that could be affecting the load capability of ligation clips in an in vivo test include fluid drag forces and lubrication of the materials. [10]

Sutures

Day 0 testing displayed the strength of the sutures and devices immediately after being inserted across the incision. Therefore, when measuring the strength of these, it was measured on a per-suture basis since there was no defined length of wound healing. Although no statistical tests were done on these results, the devices tested consistently stronger than the mattress sutures. This means that, according to these ex vivo tests, the force that a single device can hold is higher than that of a single mattress suture. Strength of the suture itself is incredibly important in the first week post-operation when the skin has not yet healed. This appears to be the reason
why many in vitro tests have been completed on varying suture types [29, 32, 34]. During this time the strength of the suture alone protects the skin and keeps it in place, especially for a high-tension area, such as the back, knee, and hip [24, 29].

At day 10 and day 42 post-operation, strength was measured in terms of force per length. This is because these tests were no longer examining the strength of the sutures, but rather the strength of the wound. It is helpful to see that both the total load and the load per unit length on the wound display largely the same trends, as seen in Figure 3.2(A) and Figure 3.2(B). At day 10, the force per length was comparable in all sutures—superficial alone or with subcutaneous sutures added—and with or without devices. At day 42, however, a difference in the mean strength could be seen more clearly, where wounds with devices and wounds with subcutaneous absorbable sutures were weaker. There was no statistical significance between these values, however. Significant differences only appeared between all strengths at day 10 compared to day 42 and this was true for all suture types tested.

Although not statistically significant, it has been found that an absorbable suture may not allow skin to heal as quickly as certain removable non-absorbable sutures in rabbit skin [26]. This same principle may be applied to this study. In vitro tests have shown that absorbable sutures can be stronger, especially when comparing decrease of strength with knots [28]. Higher suture strength does not appear to be better for healing a surgical wound. Perhaps this is also the case with the SutureLock devices. The strength of a suture with a device attached is stronger, as seen in the day 0 tests, but this mechanical strength does not appear to translate to longer-term wound strength.

No wound dehiscence or other complications were found in this study, as can mechanically be seen in the increase of strength of all samples from day 10 to day 42. However, this could be seen as a limitation to this test. A comparative test of percentage of patients with signs of wound complications using these varied suturing techniques may not concur with wound strength.
V. Conclusions

Ligation Clips

In all cases, the clips failed by slippage, though in two samples the cellophane also broke, but this occurred long after a slip. The Hemoclip, in both sizes, showed statistically significant increased average strength over the Hem-o-lok clip. Although surface area contact has been discussed as a factor in the study of metallic clips, it appears as though the much larger influence in the strength of a clip is flexibility, or lack thereof. The flexibility that is advertised as being an improvement of the polymer Hem-o-lok clip is likely lowering its strength, as opposed to the stiffer Hemoclip. This likely also combines with the Hemoclip having a higher coefficient of friction than the Hem-o-lok clip, although further tests may need to be conducted to have a final conclusion on this.

Sutures

Strength of a suture or an alternative suturing technique does not appear to significantly affect strength of a wound at 10 and 42 days. The wounds with added absorbable sutures were not mechanically stronger than the wounds with only superficial sutures, and the wounds with the SutureLock device were not stronger than those without. Apparent differences in strength at 10 or 42 days were not shown to be significantly different, however. The SutureLock device, although it provides the suture with extra strength on the first day, does not provide the wound with this additional strength.
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