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Caroline D. Ames
Washington University School of Medicine in St. Louis

Juan M. Perrone
Washington University School of Medicine in St. Louis

Alison J. Frisella
Washington University School of Medicine in St. Louis

Kevin Morrissey
Washington University School of Medicine in St. Louis

Jaime Landman
Washington University School of Medicine in St. Louis

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Comparison of Holding Strength of Suture Anchors for Hepatic and Renal Parenchyma

CAROLINE D. AMES, JUAN M. PERRONE, ALISON J. FRISELLA, KEVIN MORRISSEY, and JAIME LANDMAN, M.D.

ABSTRACT

***Background and Purpose*: Various laparoscopic devices have been described for suture anchoring during solid-organ parenchymal closure. Application of these devices expedites the closure of parenchymal defects and minimizes ischemia time. We compared different technologies as suture anchors for parenchymal closure.**

***Materials and Methods*: A tensometer was used to determine the amount of tension necessary to dislodge each of five different clips from Vicryl suture alone or against two different substrates (fresh pig kidney and liver) with and without an intervening pledget. The clips investigated were the Lapra-Ty (Ethicon), Endoclip II (US Surgical), small Horizon Ligating Clips (Weck), Hem-o-lok Medium Polymer Clips (Week), and a novel Suture-clip (Applied Medical). ANOVA and two-sided Fisher's exact test provided statistical analysis.**

***Results*: The force required to dislodge the Lapra-Ty clip from bare suture for both 0 and 1 Vicryl (7.0 N) was approximately fourfold the force required to dislodge the Endoclips or the 5-mm or 10-mm Hem-o-lok clips ($p < 0.01$). When clips were applied to suture running through renal or liver parenchyma, the novel Suture-clip required the greatest tension to dislodge ($P < 0.01$), followed by the Horizon and Lapra-Ty clips. There were no statistically significant differences in the tension required to dislodge a given clip from the two parenchymal substrates or in the presence or absence of a pledget.**

***Conclusions*: In our experimental model, the Suture-clip, Lapra-Ty, and Horizon clips required significantly greater tension to dislodge than the Hem-o-lok and Endoclip clips. The addition of a pledget did not improve tension resistance.**

INTRODUCTION

IN 1993, McDOUGALL AND COLLEAGUES[1] first described laparoscopic partial nephrectomy in a porcine model. Winfield and coworkers[2] later published the first clinical experience with laparoscopic partial nephrectomy for benign disease in a patient with a lower-pole diverticulum. Subsequently, Gill and colleagues[3] described a series of 50 laparoscopic partial nephrectomies in which the authors attempted to duplicate open surgical techniques, applying intracorporeal knots over bolsters to achieve hemostasis of the renal parenchyma following tumor resection.

The major challenges of laparoscopic solid-organ parenchymal closure are obtaining renal parenchymal hemostasis, closure of the collecting system, and the lack of a simple and effective technique for organ hypothermia when atraumatic vascular control is applied. These challenges have limited the procedure to the most experienced laparoscopic surgeons, preventing mainstream application. We evaluated various clips to determine the most secure mechanism for tissue approximation with suture anchoring technique.

In our clinical experience with laparoscopic partial nephrectomy, we have applied suture anchors (Lapra-Ty) instead of intracorporeal suturing to expedite closure of large parenchymal defects over bolsters, thus minimizing ischemia times. Other laparoscopic centers have described application of a Lapra-Ty[4] or alternative device (Hem-o-lok clip) for the same purpose (J. Kaouk, personal communication, Sept. 2003). Among the various techniques is the use of clips as suture anchors instead of intracorporeal knot tying, although individual clips have not been compared to determine the strongest mechanism. As such, we evaluated currently available devices to determine the most secure mechanism for suture anchoring.

Division of Urology, Washington University School of Medicine, St. Louis, Missouri.

MATERIALS AND METHODS

For the initial set of experiments, each of four clips: Lapra-Ty (Ethicon Endo-Surgery, Cincinnati, OH), Endoclip II (Autosuture, US Surgical, Norwalk, CT), and 5- and 10-mm Hem-o-lok clips (Weck Closure Systems, Research Triangle Park, NC) were placed with their recommended applier on both a 0 and a 1 Vicryl suture. The tension required to dislodge the clip was measured on a tensometer (Chatillon TCD200; Ametek, Inc., courtesy of Kensey Nash Corporation, Exton, PA) (Fig. 1). The suture was pulled upward at a rate of 0.50 inches/min while a double-pronged hook anchored the clip in place. This design simulated the action of forcefully pulling suture material and anchor against a stationary surface while the suture anchor holds steady at the distal site. The force (in Newtons) required to pull the suture material free of the clip was recorded 15 times for each clip on each suture diameter.

Next, to make the experiment more relevant clinically, we added a 2-cm section of fresh solid-organ parenchyma (porcine liver or kidney) to determine if this affected the force required to dislodge the clip. In half the experiments, a pledget was placed between the clip and the parenchyma.

The clips investigated for the second set of experiments were Lapra-Ty, Endoclip II, small Horizon Ligating Clips (Weck Closure Systems), Hem-o-lok Medium Polymer Clips, and the novel Suture-clip (Applied Medical, Rancho Santa Margarita, CA) (Figs. 2 and 3). Each clip was placed on a 10-cm length of 0 Vicryl suture that was passed through a 2-cm slice of tissue with capsule along the top. Half the time, an 0.8×0.8-cm Surgicel Nu-knit absorbable hemostat pledget (Ethicon) was placed between the clip and the parenchyma. This design simulated the pulling of suture material and anchor against the renal or hepatic parenchymal surface in order to document the force required for dislodgement of the suture anchor or for cracking of the parenchyma. If the parenchyma fractured, we continued to apply force until the suture slipped within the clip. The force, measured in Newtons, required to pull the suture material free of the clip was recorded five times for each clip for both liver and kidney tissue with and without a pledget.

A total of 50 observations were analyzed. The ANOVA and two-sided Fisher's exact test provided statistical analysis, with $P < 0.05$ considered significant.

RESULTS

For the initial experiments, the mean force required for clip dislodgement from suture is documented in Table 1. The Lapra-Ty suture anchors required 7.00 N, which was significantly (approximately fourfold) greater than force required for dislodgement from both the 0 and the 1 Vicryl compared with either the Endoclip (1.22 and 1.63 N) or the Hem-o-lok (5-mm 1.52 and 1.58 N; 10-mm 1.37 and 1.64 N) clips ($P < 0.01$). There were no significant differences among the other three clips or between the two suture sizes.

For the experiments involving solid-organ parenchyma, the novel Suture Clip required the greatest tension to dislodge from the suture ($P < 0.01$), followed by the Horizon and Lapra-Ty,

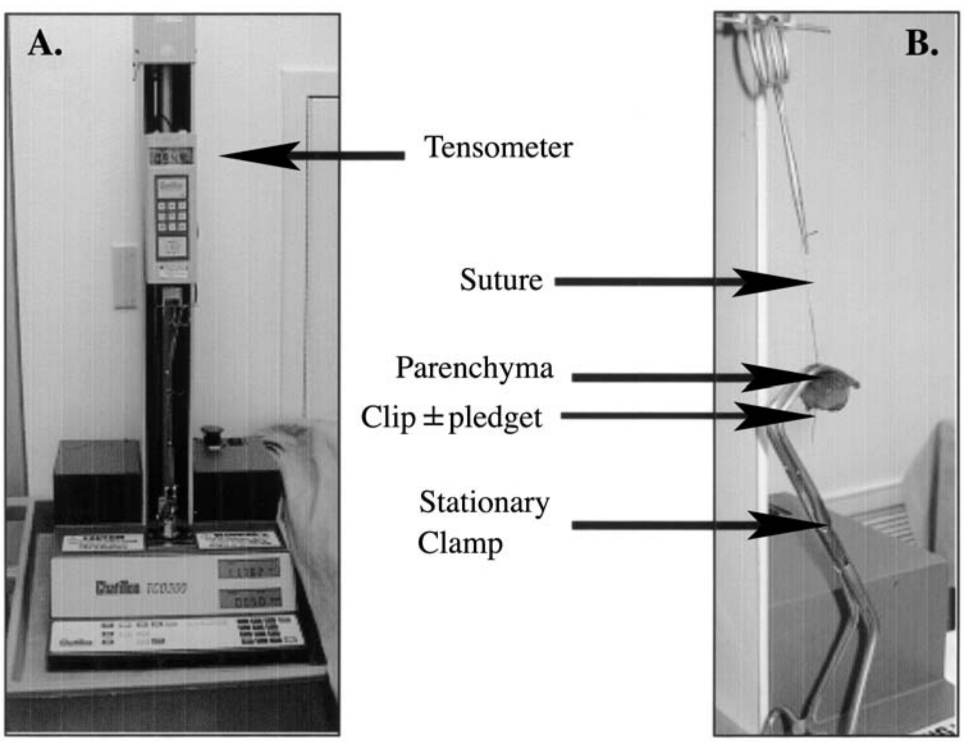

FIG. 1. Tensometer measuring force of dislodgement of clips from bare suture (**A**) or suture on solid-organ parenchyma with or without intervening pledget (**B**).

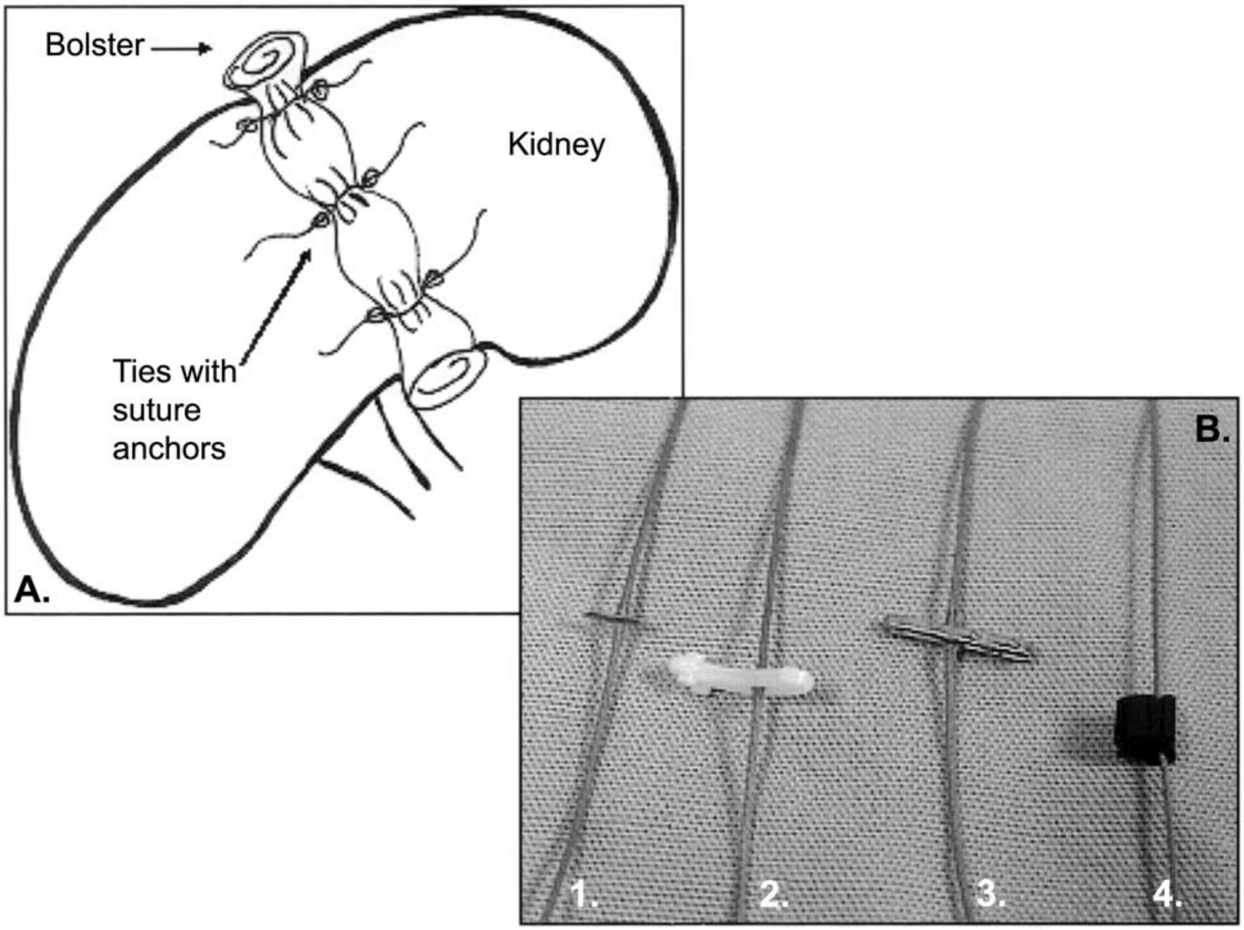

FIG. 2. Pledget technique and clips. (**A**) Potential use of Lapra-Ty as suture bolster after partial nephrectomy. Either simple or mattress suture closure can be performed with suture anchors. (**B**) Commercially available clips used in this study: 1. Horizon, 2. Hem-o-lok, 3. Endoclip, 4. Lapra-Ty.

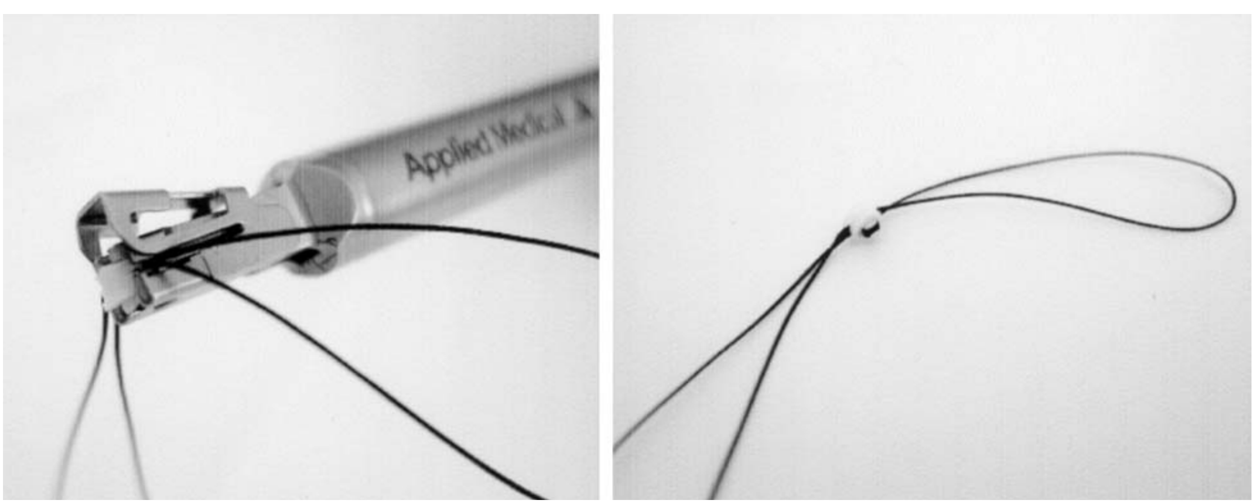

FIG. 3. Applied Medical Suture Clip System (not commercially available).

TABLE 1. MEAN (SD) FORCE NEEDED FOR CLIP DISLODGEMENT (NEWTONS) FROM SUTURE (WITHOUT PLEDGET)

Clip type	*0 Vicryl*	*No. 1 Vicryl*
Hem-o-lok (5 mm)	1.52 (0.46)	1.58 (0.40)
Hem-o-lok (10 mm)	1.37 (0.60)	1.64 (0.44)
Endoclip	1.22 (0.29)	1.63 (0.75)
Lapra-Ty	7.03[a] (1.55)	7.04[a] (1.00)

[a] $P < 0.01$ compared with other clips.

which were statistically equivalent. These three clips as a group required significantly more force to dislodge than the Endoclip and Hem-o-lok clips ($P < 0.05$).

Additionally, there were no statistically significant differences in the tension required to dislodge each clip from kidney versus liver tissue or in the presence or absence of a pledget (Table 2). Parenchymal lacerations were seen in 48% of the trials when pledgets were used and in 52% of the trials when pledgets were not used.

Lacerations of both liver and renal parenchyma were observed at 2.2 ± 0.3 N. The documentation of parenchymal lacerations at this force suggests that the two clips that slipped when subjected to lower forces (Hem-o-lok and Endoclip) will potentially slip off the suture at forces less than are required for parenchymal reapproximation, whereas the clips that held with the strongest force (Suture Clip, Lapra-Ty, and Horizon clips) resisted supraphysiologic forces (i.e., force greater than needed to cause parenchymal laceration). Forces such as those required to reapproximate renal or hepatic tissue without tearing can be withstood by the three stronger clips (Lapra-Ty, Horizon, and Suture Clip), but the weaker ones (Hem-o-lok and Endoclip) are at risk for slipping, potentially causing delayed bleeding.

DISCUSSION

Advanced laparoscopic procedures such as solid-organ parenchymal resections are available to patients at only a limited number of innovative laparoscopic centers. Within urology, laparoscopic partial nephrectomy is rapidly emerging as an important minimally invasive approach for the treatment of small renal masses. As laparoscopic urologists become more adept with laparoscopic techniques and intracorporeal suturing, larger and more endophytic masses may be treated in this manner. However, a technique for laparoscopic intracorporeal renal hypothermia has not yet been perfected, and the laparoscopic surgeon is under a relative time constraint of 30 minutes of warm ischemia time in which to close the pelvicaliceal system as well as to provide hemostatic control of the renal parenchyma.

Anderson and Clayman[5] described application of Lapra-Ty clips to facilitate reconstruction of the lower urinary tract. Those authors describe construction of a small loop on the end of a strand of suture material. Alter passing the needle through the tissue edges to be approximated, they passed the needle back through the loop, finally securing the suture with a Lapra-Ty clip. This is the mechanism of action originally intended by the manufacturer.

Application of Lapra-Ty clips (see Fig. 2) also allows the laparoscopic surgeon to use visual cues such as dimples or cracks in the surface of the organ being reconstructed to determine the amount of tension to be applied for optimal approximation of the edges of the surgical defect. This is of great value, as tactile feedback is limited during laparoscopic surgery.

The original design of the clips tested in this study was not to provide strength when stressed in a horizontal fashion. However, these clips have been applied in clinical practice as suture anchors during laparoscopic partial nephrectomies. Our *in-vitro* evaluation demonstrates that the Lapra-Ty and Horizon clips remain the most secure suture anchor clinically available.

The clips used in this experiment differ in cost. The Lapra-Ty, while one of the most secure, is also the most expensive. Application of the Lapra-Ty clips requires a one-time purchase of a reusable laparoscopic applicator ($2375.41), and a cartridge of six clips costs $106.48. Alternatively, the small laparoscopic Horizon clip applier cost is $1295, and a cartridge of six clips costs $5.15, a significant cost advantage over the Lapra-Ty system. The Hem-o-lok system is less costly, with a reusable applicator list price of $1195 and a cartridge of six medium clips costing $27. Finally, the list price of the disposable Endoclip II

TABLE 2. MEAN (SD) FORCE NEEDED FOR DISLODGEMENT (NEWTONS) OF FIVE CLIPS FROM TWO SUBSTRATES (FRESH PIG KIDNEY AND LIVER) WITH AND WITHOUT PLEDGET BETWEEN TISSUE AND CLIP

	Liver		*Kidney*	
	Pledget	*No pledget*	*Pledget*	*No pledget*
Suture-clip	8.5 (2.6)	7.6 (2.1)	11 (3.05)	8.6 (3.78)
Horizon	6.5 (3.38)	3.7 (0.85)	6.9 (3.42)	4.0 (0.82)
Lapra-Ty	4.6 (1.34)	4.4 (1.12)	4.9 (0.86)	5.8 (4.31)
Endoclip	3.0 (1.61)	2.1 (0.93)	2.0 (0.3)	2.0 (1.09)
Hem-o-lok	1.4 (0.1)	1.3 (0.15)	2.1 (0.17)	2.4 (1.2)

titanium clip system is $208.76, which ultimately results in a higher per-patient cost because of the nonreusable nature of the equipment.

The Applied Medical Suture Clip System consistently provided the highest holding strengths, but it is currently not clinically available (see Fig. 3).

Lapra-Ty clips are locking polydioxanone (absorbable) devices that can be used for both single suture placement or running sutures. These clips hold their strength for 14 days and are totally absorbed by 13 weeks. The Lapra-Ty clip is designed to anchor a single strand of Vicryl suture.

Traditional surgical clips, such as the Endoclip II and Horizon are of the crush type; however, the Horizon clip performed consistently well. As shown in previous studies[6,7] and confirmed by our data, an Endoclip can resist rather low and variable tensions, and it should not be used as a suture anchor. Hem-o-lok clips are made from a nonabsorbable polymer and provide distinct tactile feedback that confirms closure.[8] However, they were designed to hold vessels or tissue structures ranging from 3 to 10 mm in diameter, larger than sutures, likely explaining why they provided the least holding strength in the present study. They should not be used as suture anchors.

Pledgeted sutures are used to prevent tissue damage produced by the tension applied by the suture and for hemostasis in some cases.[9] In our study, the addition of a small pledget did not make a difference in terms of either parenchymal laceration or the holding strength of the different suture anchors.

In our model, parenchymal lacerations were observed at 2.2 ± 0.3 N. We infer from these data that the amount of force required to reapproximate renal tissue should be less than that required to fracture the tissue. Because the tension required to cause parenchymal laceration is well below the holding strength of Suture-clip, Lapra-Ty, and Horizon clips, we consider them able to withstand supraphysiological tensions and to be appropriate for the technique of suture anchoring. A potential drawback of our study was the fact that *ex-vivo* porcine kidney and liver may have fragility different from that of the *in-vivo* human kidney. Therefore, the force required for parenchymal fracture in our study may not be identical to that found in the clinical setting.

CONCLUSIONS

The Lapra-Ty suture anchor and the Horizon clip are the most secure suture anchoring mechanisms currently available. Application of suture anchors may expedite and simplify techniques of closure of solid-organ parenchymal defects.

In our experimental model, the Lapra-Ty, Suture clip, and Horizon clips required significantly greater tension to dislodge them than did the Hem-o-lok and Endoclip clips. The addition of a pledget did not improve tension resistance. Incorporation of any of the top three clips—Suture Clip, Lapra-Ty, or Horizon—may constitute a reasonable alternative to intracorporeal knot tying.

ACKNOWLEDGMENTS

Ethicon supplied the Lapra-Ty clips and applicator. Weck Closure Systems supplied the Hem-o-Lok and Horizon clips and applicators. Applied Medical Supplied the Suture-clips and applicator, and US Surgical supplied the Endoclips.

REFERENCES

1. McDougall EM, Clayman RV, Chandhoke PS, et al. Laparoscopic partial nephrectomy in the pig model. J Urol 1993;149:1633.
2. Winfield HN, Donovan JF, Godet AS, Clayman RV. Laparoscopic partial nephrectomy: Initial case report in benign disease. J Endourol 1993;7:521.
3. Gill, IS, Desai MM, Kaouk JH, et al. Laparoscopic partial nephrectomy for renal tumor: Duplicating open surgical techniques. J Urol 2002;167:469–476.
4. Orvieto MA, Chien GW, Laven B, Rapp DE, Sokoloff MH, Shalhav AL. Eliminating knot tying during warm ischemia time for laparoscopic partial nephrectomy. J Urol 2004;172:2292–2295.
5. Anderson KR, Clayman RV. Laparoscopic lower urinary tract reconstruction. World J Urol 2000;18:349–354.
6. Kumar UK, Albala DM. Newer techniques in intracorporeal tissue approximation: Suturing, tissue adhesives and microclips. Urol Clin North Am 2001;28:15–21.
7. Nelson MT, Nakashima M, Mulvihill SJ. How secure are laparoscopically placed clips? An in vitro and in vivo study. Arch Surg 1992;127:718–720.
8. Andrews SM, Lewis JL. Laparoscopic knot substitutes: An assessment of techniques of securing sutures through the laparoscope. Endosc Surg Allied Technol 1994;2:62–65.
9. Riskin DJ, Schwaitzberg SD. A comparison of holding strength of various surgical clips. Surg Endosc 2003;17:654–656.

Address reprint requests to:
Jaime Landman, M.D.
Division of Urology
4960 Children's Place, Campus Box 8242
St. Louis, MO 63110

E-mail: landmanj@yahoo.com