Integrating Laparoscopic Intracorporeal Suturing and Knot Tying into a Single Procedure Using a Novel Knotting Device

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We previously reported our experience with a device-assisted intracorporeal knot tying technique in experimental conditions.[1] The encouraging preliminary results demonstrated that this device-assisted intracorporeal knot tying technique is a valuable alternative to traditional intracorporeal knot tying techniques.[1] To further simplify the procedure of intracorporeal suturing and knotting, we renewed our original device design and developed a novel advanced tubule-assisted knotting device that integrates intracorporeal suturing and knotting into a single procedure. It retains every advantage of the original device and provides the additional advantages of performing intracorporeal suturing and knotting in an easier and simpler way. This study evaluated the efficacy and feasibility of using this novel device to speed up and ease the task of performing laparoscopic suturing and knotting.

METHODS

Our novel knotting device (patent pending) consists of 2 parts: a working part and a control part (Fig. 1). The working part includes a small collar tubule (1.5 mm in diameter, 34 mm in length, Fig. 1, a) that is inserted into a shorter outer sheath (2.6 mm in diameter, 23 mm in length, Fig. 1, b); an excess 2.5 mm of the small collar tubule is uncovered.

The free end of a "0" coated silk with a needle was inserted into the small collar tubule (Fig. 1, a), and the free end was hitched with a tiny metallic ring (Fig. 1, c). We used the middle portion of the silk to produce a pre-tied 2-turn slip knot (Fig. 1, d) at the uncovered portion of the small collar tubule and a size changeable loop formation (Fig. 1, e) over the rim of the tubule end. The control part includes a long sleeve (Fig. 1, f), which acts as an introducer with a grooved end (Fig. 1, g) for loading or unloading the working part (Fig. 1, a and b). The other end is a large tube handle (Fig. 1, h) that is equipped with a control button (Fig. 1, i). The button can slide over the calibrated groove (Fig. 1, j) to control the movement of the pre-tied slip knot (Fig. 1, d) of the working part by a metallic wire between the working and control parts.

The steps for performing the novel device-assisted laparoscopic suturing and knotting are described in the legend of Figure 2 and the short video clips (Video).

We used a laparoscopic trainer (LiNA Laparo Trainer, Lina Medical) with a piece of plastic artificial skin as an experimental model. The laparoscopic device-assisted, suturing-integrated, double sheet bends (the device group) and traditional device-free, intracorporeal, 2-turn flat square knots (the control group) using the half-circle shaped 30-mm needles connected with wax-treated braided silks of size 0 (Unik Surgical Sutures Mfg Co), were performed in a randomized order, based on computer-generated random numbers. Knots were tied by 3 surgeons. The youngest laparoscopist was surgeon 1, and the most experienced laparoscopist was surgeon 3. The suturing and knotting time was calculated from the beginning of suturing to the end of knot tying.

The loops of knotted threads were cut and removed from the training box after the completion of knot tying. Both non-loop thread ends were trimmed to 3 mm in length, and the knot strength was measured using a tensiometer (Gotech Testing Machines Inc). Gradually increasing force was applied to one loop end of the knotted thread or to one end of the unknotted threads after fixation of the other end.[2] The knot strength was determined by measuring the force required for the knot to slip or break.[2-4] The thread strengths of 5 unknotted threads were also measured. Knot failure was defined as a breach of the knot or slippage exceeding 3 mm.[2] Knot efficiency was defined as the knot strength divided by the mean thread strength of unknotted threads. The coefficient of

Disclosure Information: Nothing to disclose.

Received August 13, 2014; Revised September 26, 2014; Accepted September 29, 2014.

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http://dx.doi.org/10.1016/j.jamcollsurg.2014.09.024
ISSN 1072-7515/14

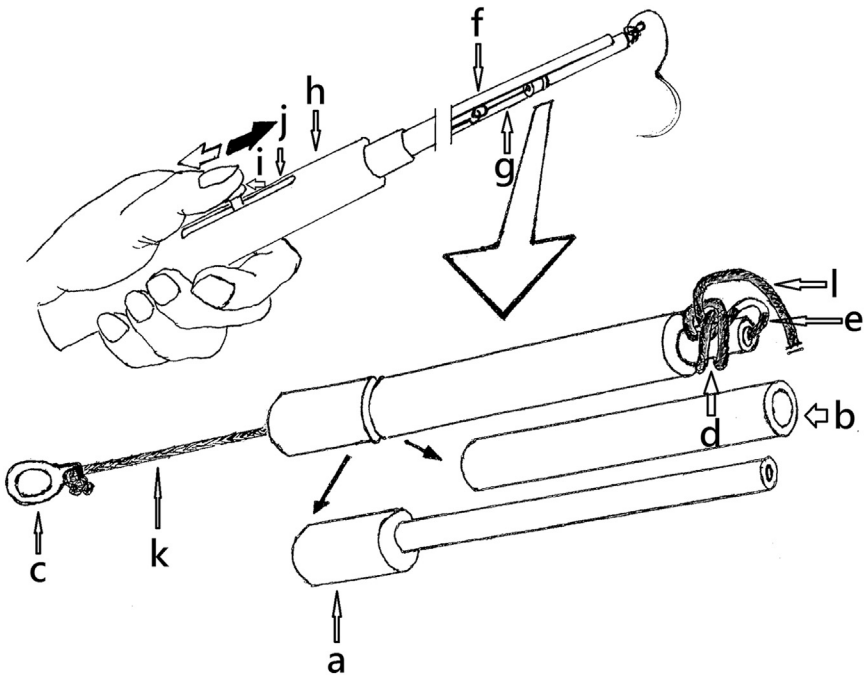

Figure 1. Components of the novel device for assisting laparoscopic intracorporeal suturing and knot tying: a, collar tubule; b, outer sheath; c, tiny metallic ring; d, pre-tied 2-turn slip knot; e, loop formation with a white marker; f, sleeve; g, groove for loading/unloading working part; h, handle; i, control button; j, groove for sliding button; k, thread to metallic ring; and l, thread to swaged needle.

variation (%) of knots was defined as the standard deviation of the knot strength divided by the mean strength of the knot.

Tera and Aberg[3] used a sample size of 5, with a power of 0.8 and a significance level of 0.05, to detect an approximately 0.8-kg difference in mean strength. Therefore, we tied at least 5 knots in each group to determine the differences in knot strength between the groups.

The STATA software (Version 11.0, Stata Corp) was used for the statistical analyses. The Wilcoxon rank-sum test or Fisher's exact test were used, as appropriate. A p value < 0.05 was considered statistically significant.

RESULTS

Three surgeons tied 10 knots in the device group and 10 knots in the control group. All knots and 5 unknotted threads were measured for strength (Table 1). For successful knots, the knot strength and the knot efficiency did not differ between the groups for all 3 surgeons.

The knot strength of the device group was higher in surgeons 1 and 2 (Fig. 3), the knot failure rate of the device group was lower in surgeons 1 and 2, the suturing and knotting time of the device group was lower for all 3 surgeons, and the coefficient of variation of successful knots in the device group was lower for surgeons 1 and 3, compared with the control group (Table 1).

Taking all data together, the device group had a higher knot strength (2.4 ± 0.5 kg vs 1.5 ± 0.9 kg, $p = 0.001$), a lower knot failure rate (3.3% vs 57%, $p < 0.001$), and a shorter suturing and knotting time (33.1 ± 7.6 seconds vs 80.4 ± 11.9 seconds, $p < 0.001$), compared with the control group (Table 1). The knot strengths of successful knots in the device group ($n = 29$ vs 13) were compatible to those for the control group (2.4 ± 0.2 kg vs 2.4 ± 0.4 kg, $p = 0.71$).

DISCUSSION

Laparoscopic intracorporeal suturing and knotting is one of the most challenging aspects of laparoscopic surgery, but the procedure has fundamental importance in certain reconstructive surgery without any mechanical substitute. Conventional intracorporeal suturing and knotting is a direct translation from an open instrument tying technique. Regardless of being a difficult and time-consuming task, it has the advantages of low material cost and adequate knot strength, if the knot is tied properly. Most endoscopic surgeons have used this process for a long time. Traditional knot tying has inherent problems in real practice to address the current dogma of surgery.

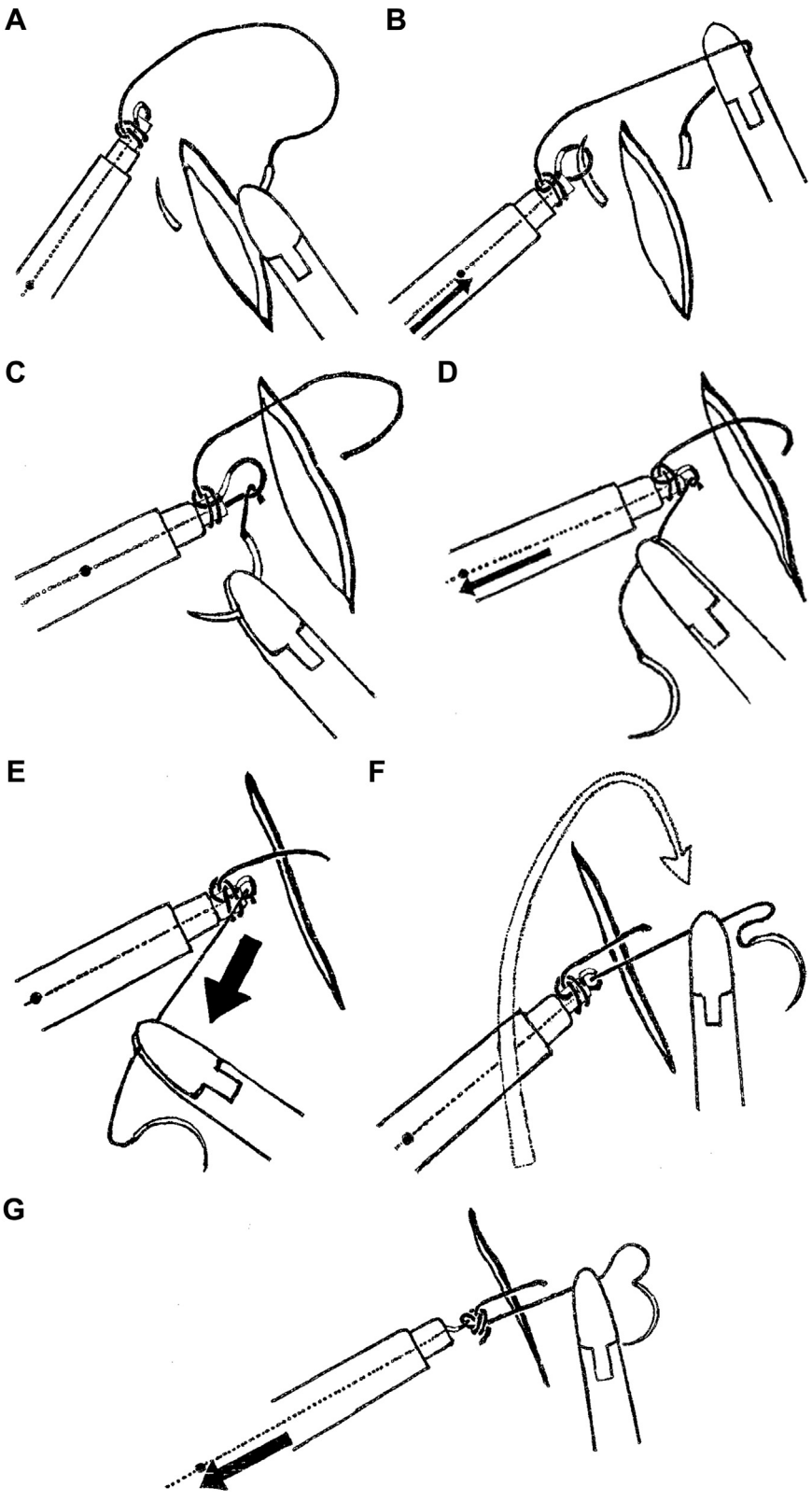
A
B
C
D
E
F
G

Table 1. Comparisons of Suturing and Knot-Tying Variables Between the Device and Control Groups

Variable	Surgeon 1			Surgeon 2			Surgeon 3		
	Device (n = 10)	Control (n = 10)	p Value*	Device (n = 10)	Control (n = 10)	p Value*	Device (n = 10)	Control (n = 10)	p Value*
Knot strength, kg†, mean ± SD	2.2 ± 0.8	1.0 ± 0.9	0.03	2.4 ± 0.2	1.4 ± 0.9	0.03	2.4 ± 0.2	2.1 ± 0.7	0.33
Knot failure†, n (%)	1 (10)	7 (70)	0.02	0 (0)	7 (70)	0.003	0 (0)	3 (30)	0.21
Suturing/knotting time† mean ± SD	35.8 ± 9.0	76.6 ± 8.6	<0.001	31.3 ± 5.3	81.6 ± 12.3	0.002	32.4 ± 7.8	82.9 ± 14.5	<0.001
Knot strength of successful Knots, kg, mean ± SD	2.4 ± 0.3	2.2 ± 0.6	0.78	2.4 ± 0.2	2.5 ± 0.2	0.31	2.4 ± 0.2	2.1 ± 0.7	0.33
Knot efficiency of successful knots, mean ± SD	0.59 ± 0.06	0.53 ± 0.14	0.78	0.58 ± 0.05	0.61 ± 0.06	0.31	0.59 ± 0.04	0.51 ± 0.17	0.33
Coefficient of variation of successful knots, %	12.5	26.4		8.3	8.0		8.3	33.3	

*Wilcoxon rank-sum test or Fisher exact test.
†Significant difference.

It has long been held that reliable knot tying with adequate suture tension is the cornerstone of surgery, and the square knot and the surgeon's knot constitute the great part of a surgeon's skills.[5]

A secure square knot, whether simple or complex and tied using any technique, has a complete symmetrically geometric structure after knotting that is the basic prerequisite to maintaining its maximal knot strength. The symmetrically geometric structure is hard to achieve in laparoscopic surgery because of limited working space and the need for hand-eye coordination. In the process of square knot tying, crossing the sutures during the second knot tying will inevitably release the tension of the first knot and result in poor suture tension, which may cause serious complications, especially for the homeostasis of a vascular pedicle.[2] Contrary to the conventional square knot, the double sheet bend formed by our knotting device is unique in its asymmetrically geometric structure. The double sheet bend has the basic mechanism of a bowline to keep its maximal knot strength, and this double sheet bend is believed to be stronger than the square knot.[6] With the assistance of our tubular device, we can covert a pre-tied 2-turn slip knot into a secure double sheet bend rapidly and automatically to achieve adequate suture tension and knot strength (Table 1 and Fig. 3).

In addition, our novel device integrates intracorporeal suturing and knotting into a single procedure and simplifies the task of performing the difficult work of laparoscopic suturing and knot tying. In the era of single port laparoscopic surgery, our device has great potential to be a valuable tool for intracorporeal suturing and knot tying.

Our novel device transforms a pre-tied knot into another knot in situ instead of tying a knot de novo. This device enables us to perform laparoscopic sutures and knot tying more efficiently and easily in a limited working space compared with conventional laparoscopic suturing and knot tying. In addition, the conventional knot tying technique involves many manual steps that are difficult to repeat in subsequent knot tying. Our knotting device requires only a few predetermined working steps to complete a secure knot tying. The knot strength consistency of device-assisted knot tying is better than that of knot tying done by hand. The results of our study

Figure 2. The serial steps of performing a device-assisted laparoscopic intracorporeal double sheet bend. (A) Stitching the wound to leave the tip and one-third of the needle length protruding from the tissue surface. (B) Pushing the control button to enlarge the loop of the 2-turn slip knot and to entrap the tip and the protruding part of the needle within the loop. (C) Grasping and extracting the needle from the tissue to form a suturing loop. (D) Pulling back the control button to return the enlarged loop size to its original small size. (E) Pulling the needle to attach the thread using the needle holder along the shaft of the knotting device to tighten the suturing loop to the appropriate tension. (F) Rotating the needle to attach the thread approximately 90 degrees from the nearby tissue surface and parallel to the suturing line. (G) While keeping the needle-attached thread under traction steadily, pulling the control button forcefully to withdraw the tubule and dislodge the pre-tied 2-turn slip knot, which is converted into a double sheet bend spontaneously and rapidly.

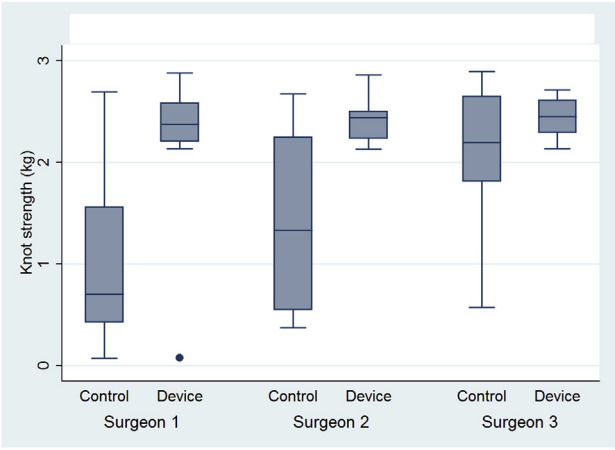

Figure 3. Knot strengths among different surgeons and groups.

indicated that the coefficient of variation (Table 1) and interquartile ranges (Fig. 3) of the successful double sheet bend were smaller than those of the traditional 2-turn square knot.

The decreased sensation of tension applied to the tissue and the knot is one inherent disadvantage of traditional intracorporeal suturing and knot tying. The tip of our long hard stem knotting device keeps in close contact with the tissue during whole working process and provides tactile feedback for handing. The feeling of the tension applied to the tissue using our knotting device is better than that of the traditional technique. Furthermore, after completion of knot tying, our knotting device can evaluate the success of the laparoscopically tied knot by evaluating the distance between the knot and a built-in white marker.[1,7]

A single-strand method was performed to test the strength of each knot in our study. The single-strand method requires cutting of the suture loop before knot strength measurement.[2] Nonetheless, the loop method measures the knot strength with the intact loop, which may mimic the in-vivo conditions more closely, but may have the drawback that the differences in friction between the suture material and the rods might influence the test results.[2]

Our study was performed using a laparoscopic trainer, and the results may not be identical to those in an in-vivo model. Further clinical studies are needed to confirm our findings in a human model.

CONCLUSIONS

In conclusion, our laparoscopic knot tying device produced knots with at least equal tensile strength in a shorter amount of time, as evaluated in a laparoscopic trainer model, and compared with traditional knot-tying methods. We suggest further studies of this knot-tying device in an in-vivo model for confirmation of these advantages.

Author Contributions

Study conception and design: Tu
Acquisition of data: Tu
Analysis and interpretation of data: Hsiao
Drafting of manuscript: Hsiao
Critical revision: Sun, Chuang, Wu, Lin

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