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Laparoscopic intracorporeal knot tying using a novel device

Fung-Chao Tu · Wen-Yih Wu · Ho-Hsiung Lin · Sheng-Mou Hsiao

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Abstract
Background Laparoscopic intracorporeal knot tying has traditionally been considered the most difficult skill in laparoscopic surgery. We developed a novel device for assisting laparoscopic intracorporeal knotting that transforms a pre-tied slip knot into a secure double sheet bend. The aim of this study is to check the feasibility of using this novel device to assist in performing laparoscopic knot tying.
Methods We used a laparoscopic trainer with a piece of plastic artificial skin as an experimental model. Twenty laparoscopic device-assisted double sheet bends (experimental group) and 20 traditional laparoscopic two-turn flat square knots (control group) were performed in random order. After cutting the loop and the ends of each knot, all 40 knotted threads and an additional eight unknotted threads were transferred to a tensiometer to test their strength using the single-strand method. Post-knotting variables of the two groups were compared.
Results Knot strength (mean ± standard deviation) did not differ between the two groups (experimental group: 2.26 ± 0.50 kg vs. control group: 2.03 ± 0.94 kg; $P = 0.51$). The knot efficiencies of the experimental and control group were 60.6 and 54.4% ($P = 0.51$), respectively. However, the experimental group had a lower knot failure rate (5 vs. 40%, $P = 0.02$) and shorter knotting time (37.0 ± 9.2 vs. 107.0 ± 47.7 s, $P < 0.001$) compared with the control group.
Conclusions This novel device significantly shortened the knotting time of laparoscopic intracorporeal knot tying, and did not compromise the success rate or strength of the knot.

Keywords Laparoscopic intracorporeal knot tying · Device-assisted knot tying · Double sheet bend · Two-turn flat square knot

Laparoscopic intracorporeal knot tying is traditionally considered as a difficult skill in laparoscopic surgery, and learning to tie knots intracorporeally in a two-dimensional environment, especially with limited visibility and depth perception and awkward angles, is a challenging and frustrating experience for most inexperienced surgeons [1–4]. To address these inherent problems of laparoscopic knot tying, various devices, suture-free alternatives, and even a robotic system have been designed and developed with the hope of making knot tying quicker and easier [1–9]. Each of the laparoscopic knot-tying devices has distinct advantages [2].

We also developed a novel knot-tying device to assist laparoscopic intracorporeal knot tying. The aim of this study is to investigate whether this novel device could shorten the time of laparoscopic intracorporeal tying and help the surgeon to tie secure knots.

Materials and methods

We designed and patented a novel tubular device (Fig. 1, device patented in Taiwan) to assist with laparoscopic

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F.-C. Tu · W.-Y. Wu · S.-M. Hsiao (✉)
Department of Obstetrics and Gynecology, Far Eastern Memorial Hospital, No.21, Sec. 2, Nanya S. Rd, Banqiao, New Taipei 220, Taiwan
e-mail: smhsiao2@gmail.com

H.-H. Lin
Department of Obstetrics and Gynecology, National Taiwan University College of Medicine and National Taiwan University Hospital, Taipei, Taiwan

intracorporeal knot-tying techniques. The tubular device consists of a small metallic tube (Fig. 1A, 5 mm in length, 0.8 mm in diameter) and a small square plastic plate (Fig. 1A, 5 × 4 × 1 mm^3 in size) attached with a metallic flexible holding wire (Fig. 1A, open arrow head) at the top of the plate to hold the loop of a pre-tied two-turn slip knot (PTSK, Fig. 1, small solid arrow), and another soft thread for holding the other end of the thread (Fig. 1A, large solid arrow). Before using the device, a PTSK is tied on the device. With the aid of the device, we can easily tie a laparoscopic double sheet bend (DSB, Fig. 2A) from a PTSK in a few steps. The steps for performing the device-assisted laparoscopic DSB are described in the legend of Fig. 3 and the short video clip (Video).

We used a laparoscopic trainer (LiNA Laparo; Lina Medical, Glostrup, Denmark) with a piece of plastic artificial skin as an experimental model. Device-assisted laparoscopic DSB (Fig. 2A, experimental group) and traditional device-free laparoscopic two-turn flat square knot (TFSK) (Fig. 2B, control group) using 1/2 circle-shape 30-mm needles connected with wax-treated braided silks of size 0 (Unik Surgical Sutures Mfg Co., New Taipei, Taiwan) were tied in randomized order, based on computer-generated random numbers. All knots were tied by a single surgeon (Wu). Knotting time was calculated from the beginning to the end of knot tying.

The loops of knotted threads were cut and removed from the training box after completion of knot tying. Both non-loop ends of threads were trimmed to 3 mm length, and then the knot strength was measured using a tensiometer (Gotech Testing Machines Inc., Taichung, Taiwan). Gradually increasing force was applied to one loop end of the knotted thread or one end of unknotted threads after fixation of the other end [10]. Knot strength was determined as the force required for the knot to slip or break [10–12]. Additionally, thread strengths of eight unknotted threads were also measured. Knot failure was defined as breach of the knot or slippage exceeding 3 mm [10]. Knot efficiency was defined as the knot strength divided by the mean thread strength of unknotted threads.

Tera and Aberg reported that a sample size of five had power of 0.8 and significance level of 0.05 to detect a difference in mean strength of about 0.8 kg [11]. Therefore, we tied at least five knots in each group to determine differences in knot strength between the groups.

STATA software (version 8.0; Stata Corp, College Station, TX) was used for statistical analysis. The Wilcoxon rank-sum test or Fisher's exact test was used as appropriate. $P < 0.05$ was considered statistically significant.

Results

Twenty knots in the experimental group, 20 knots in the control group, and eight unknotted threads were measured for strength (Table 1). The mean thread strength of the eight unknotted threads was 3.73 ± 0.48 kg. The mean

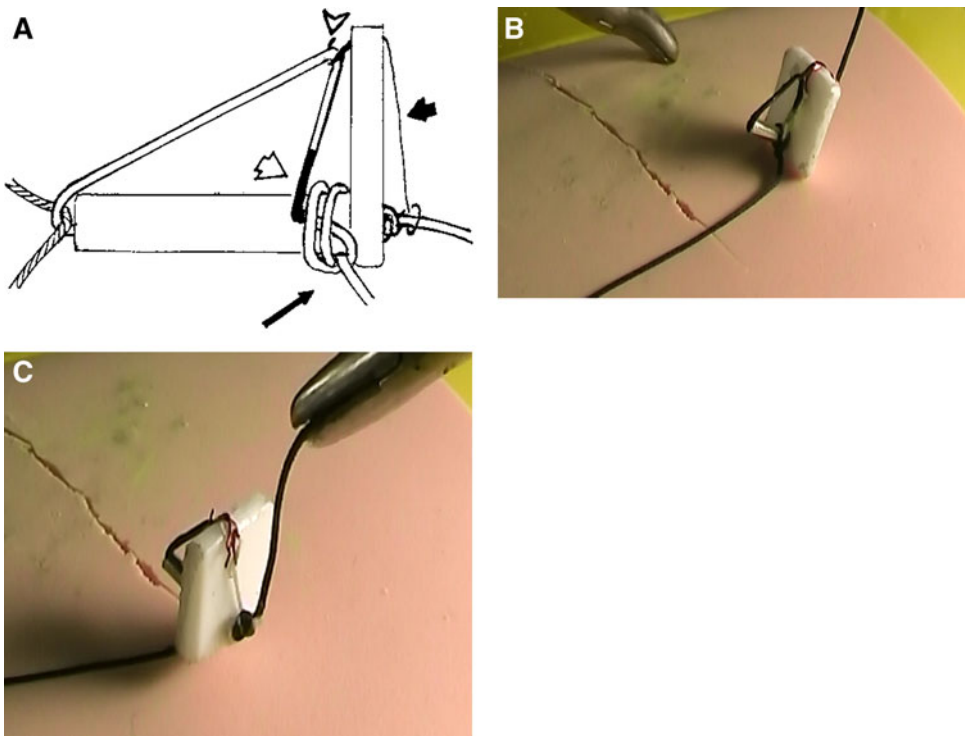

Fig. 1 **A** The novel tubular device for assisting laparoscopic intracorporeal knot tying (*open arrow head:* metallic flexible holding wire, *small solid arrow:* pre-tied two-turn slip knot, *large solid arrow:* a soft thread for holding the non-needle end of the thread, *open arrow*: the color marker). **B** Picture of the tubular side of the device. **C** Picture of the other side of the device

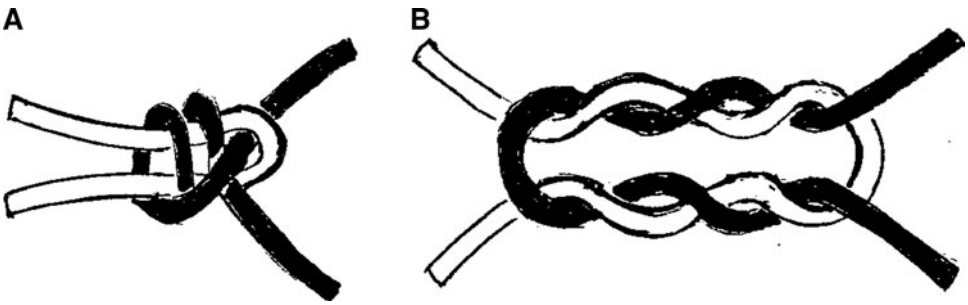

Fig. 2 The geometric structures of **A** double sheet bend and **B** two-turn flat square knot

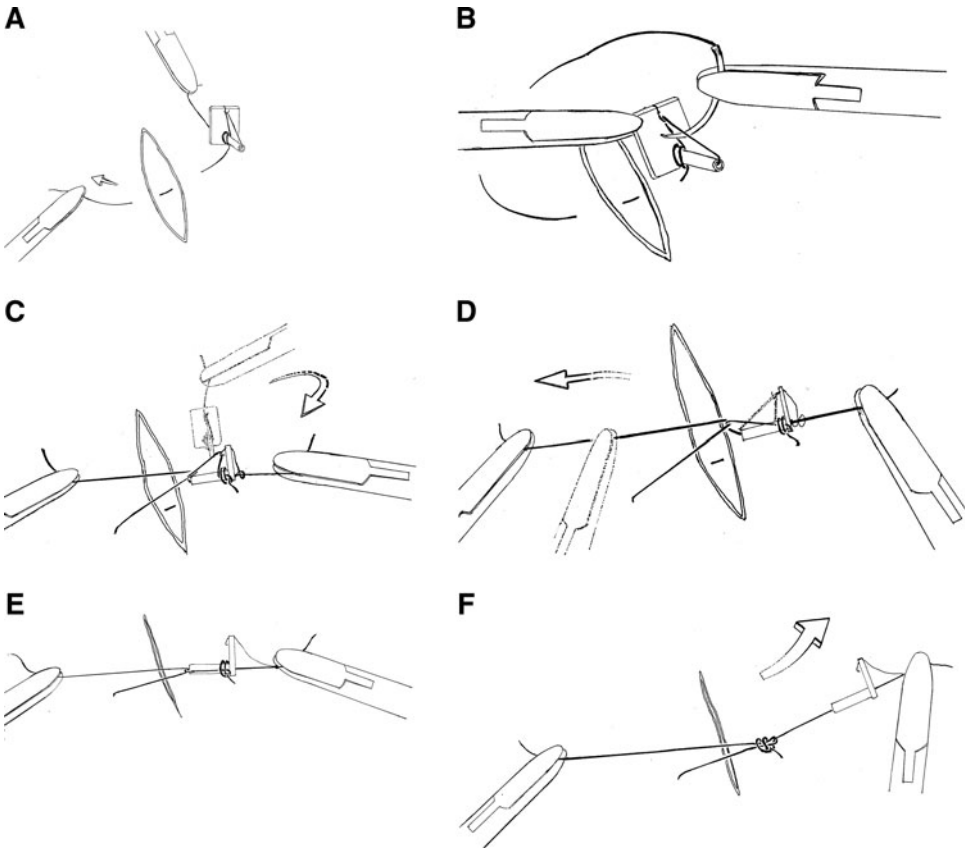

Fig. 3 The serial steps of performing a device-assisted laparoscopic intracorporeal double sheet bend: **A** penetrate the target wound with a 1/2 circle-shape needle; **B** hold the plate by one needle holder, then pass the needle through the loop of the pre-tied two-turn slip knot and make a U-turn opposite to the direction of the non-needle end of the thread; **C** hold the needle end of the thread, rotate the device clockwise, and pull the non-needle end of the thread in the direction perpendicular to the wound; **D** pull the needle end of the thread slowly to dislodge the loop of the pre-tied two-turn slip knot from the metallic flexible holding wire; **E** adjust the knot tension to close the wound with both needle holders; **F** pull the non-needle end of the thread swiftly to dislodge the pre-tied two-turn slip knot from the tube of the device, thus automatically resulting in a secure double sheet bend

knot efficiencies of laparoscopic DSB and laparoscopic TFSK were 60.6 and 54.4% ($P = 0.51$), respectively.

While the knot strengths and efficiencies did not differ between the two groups, the knot failure rate and knotting time were lower in the experimental group, compared with the control group (Table 1).

Discussion

Knot strength and stability are the most important considerations in selecting a knot during every surgery, because knot failure can cause surgical failure and even liability of the surgical team [13]. The laparoscpic TFSK is recognized as the strongest laparoscopic intracorporeal knot [14, 15]. The knot efficiency (60.6%) of our laparoscopic DSB was similar to that (range: 55 $\sim$ 63%) of the TFSK performed by hand in Trimbo's study [10]. Additionally, the mean knot strength did not differ between the device-assisted laparoscopic DSB and device-free laparoscopic TFSK groups in our study. Based on these findings, our novel

Table 1 Comparisons of post-knotting variables between experimental and control groups

Variable	Experimental group ($n = 20$)	Control group ($n = 20$)	P*
Knot strength (kg)	2.26 ± 0.50	2.03 ± 0.94	0.51
Knot failure	1 (5%)	8 (40%)	0.02
Knotting time (s)	37.0 ± 9.2	107.0 ± 47.7	<0.001

Values expressed as mean ± standard deviation or n (percentage)

* Wilcoxon rank-sum test or Fisher exact test

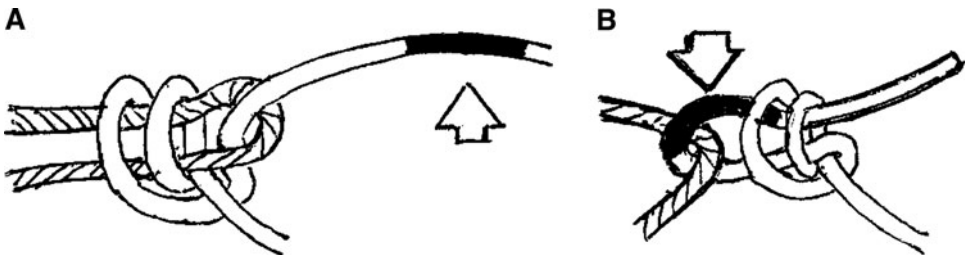

Fig. 4 The distance between the color marker and the knot for **A** a successful and **B** failed double sheet bend

device could help surgeons tie laparoscopic intracorporeal knots with adequate knot strength.

With the aid of this novel device, we experienced fewer knot failures for laparoscopic DSB in our study. Thus, we believe that our device would help surgeons to tie stable laparoscopic intracorporeal knots. One reason for our success is that we tied a PTSK extracorporeally, which was transformed rapidly into the DSB intracorporeally, with several simple pulling steps, thus resulting in good stability. Additionally, a symmetrical geometric structure is strictly needed to maintain maximal knot strength of the TFSK, and such a symmetrical structure is not easy to achieve laparoscopically.

We also experienced shorter knotting times with the aid of this novel device. Therefore, the device helped us improve laparoscopic intracorporeal knot-tying times. We believe these differences could be due to the PTSK and simplified pulling steps using the device, without two-turn tying intracorporeally.

The ideal type of knot should have adequate knot strength, but it may be difficult for a surgeon to judge whether a laparoscopic intracorporeal knot has good knot strength intracorporeally. We overcame this difficulty with a color marker (Fig. 1A, open arrow) in the loop of the PTSK before laparoscopic intracorporeal use, which served to detect knot failure. After tying, the distance between the color marker and the knot could be easily detected (Fig. 4A, B). Thus, we could evaluate whether the laparoscopically tied knot was successful or not by evaluating the distance between the knot and color marker. In our experience, distances of more than 5 mm resulted in successful knots and distances of less than 5 mm or the color marker in the knot resulted in knot failure (Fig. 4A, B).

From our experience, we identified two clues for tying a good laparoscopic DSB with our device. First, we pulled the thread by one needle holder at a time, and just held (not pulling) the other end of thread by the other needle holder simultaneously. Second, we performed all steps in a plane close to the tissue surface.

Our study was limited by the lack of a specialized tensiometer for strain testing by the loop method [10, 16]. The loop method has many advantages over the single-strand method and is used in many previous knot-tying studies [10]. Second, the present study was performed in a laparoscopic trainer. Therefore, further clinical studies should be performed to confirm our findings in a human model.

In conclusion, this novel device significantly shortened the time for tying laparoscopic intracorporeal knots in our laparoscopic training model, and did not compromise the success rate or strength of the knots. We believe that we would have similar success with this novel knot-tying device when used to assist with knot tying in laparoscopy patients. Further clinical studies should be performed to confirm our findings.

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Disclosures Author Fung-Chao Tu is the inventor of this novel device. Authors Wen-Yih Wu, Ho-Hsiung Lin, and Sheng-Mou Hsiao have no conflicts of interest or financial ties to disclose.

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