Device for laparoscopic suturing and knot tying

by

Moniz Chan

Abstract

Due to the superior advantages of minimally invasive surgery (MIS) over the traditional open surgery on patients' intra-operative and post-operative conditions, laparoscopic surgeries had been accepted worldwide for therapeutic and diagnostic purposes. While laparoscopic suturing was an essential procedure in most of the laparoscopic surgeries, it was widely regarded as a time-consuming and skill-demanding task. This project aimed at investigating the current challenges faced in managing intracorporeal suturing based on literatures review, and reviewing on the functions and insufficiency of the existing devices, followed by a design and development of a new instrument, the Dual-function suture assistive (DFSA) device, for the facilitation of suturing and knot tying in MIS.

To testify the effectiveness of the DFSA device, several experiments were done. The easy manipulation of thread and the eradication of frequent dropping and picking up the needle by using the DFSA device in replacement of a typical needle holder as assistance have significantly shortened the time needed for suturing and knot tying. And the motion analysis revealed a notable reduction in workspace requirement and total distance traveled by both the main suturing forceps and the assistive forceps if the DFSA device was used as the assistive forceps. The minimal locomotion of the forceps did not only possess privilege in working in the confined environment for the laparoscopic surgery, but it also safeguard the suturing procedure from injuring the surrounding tissues by ensuring the forceps working within the camera's field of view. And the dual function of the DFSA device was realized by allowing the management of suturing thread by the sliding hook feature, independently form the forceps tip which could be reserved for other function like holding tissue.

Although the DFSA device generated optimistic results in term of time and workspace requirement, there were more testing on its functions, quality, and effectiveness required to ensure safe application on patient. And the design could be further modified to maximize its performance.

Acknowledgement

I would like to express my gratitude to Professor Zheng Li, my research supervisors, for his patient guidance, enthusiastic encouragement and useful critiques of this research work. I would also like to thank Dr. Tao Zhang, for his advice and assistance in keeping my progress on schedule. My grateful thanks were also extended to Ms. Yitian Xian for her sample of SOLIDWORKS for my reference, and to Ms. Venus Cheng, Mr. George Chan, and Mr. Hess Chan for being the experimenters.

Finally, I wish to thank my parents for their support and encouragement throughout my study.

Table of contents Pages

(A) Introduction

I. Minimally invasive surgery (MIS)

Laparoscopic surgery had been a widely accepted minimally invasive alternative to traditional laparotomy for both diagnostic and therapeutic purposes. Performing at the abdomen or pelvis using small incisions usually with a size of 0.5-1.5 cm and monitored by laparoscope, it allowed reduction of pain, minimal blood loss, smaller wound size and less postoperative scarring, and shortening of recovery time. Moreover, laparoscopic surgery lowered patients' risk of inflammation and complications by minimizing the exposure of internal organs to external contaminants (Wadlund, 2006). The improved postoperative patient conditions allowed the patients to have shortened hospital stay from 1 week to less than 24 hours after the operation (Calland et al., 2001).

In spite of the significant advantages provided by the laparoscopic surgery, some surgeries were still done in open methods or laparoscopic-assisted methods, such as intestinal resection. The choice against laparoscopic surgery could be due to the difficulty in tissue dissection, the concerns on homeostasis, and the complexity in intracorporeal anastomosis which was however found to have significant benefits in postoperative outcome in comparison with extracorporeal anastomosis (Scatizzi et al., 2010); while laparoscopic suturing played an important role in the latter two reasons.

II. Significant of laparoscopic suturing

In spite of the rapid development in surgical devices and techniques, the complexity of laparoscopic suturing remained a significant obstacle to laparoscopic operation. Laparoscopic suturing and knot-tying was fundamental yet one of the most difficult techniques to master in MIS even for experienced surgeons (Weizman, Maurer, Einarsson, Vitonis, & Cohen, 2015).The counterintuitive movement of the two coupling laparoscopic suturing devices made laparoscopic suturing difficult to manipulate (Gallagher, McClure, McGuigan, Ritchie, & Sheehy, 1998), and further, the limited range of motion and visibility allowed inside the body cavity through a small incision led to the suturing and knot tying process tedious, time-consuming, and frustrating (Lim, Ghosh, Niklewski, & Roy, 2017)

The excessive time consumption for suturing had contributed to the longer need of anesthesia which was associated with risk of postoperative nausea, vomiting, thromboembolism, postoperative core hypothermia, postoperative cardiopulmonary complications, and death (Yoho, O'Neil, & Romaine, 2015). Long surgical times also

involved the intense concentration from surgeons contributing to surgeon fatigue thus increased risk of errors (Gawande, Zinner, Studdert, & Brennan, 2003). Nonetheless, the benefits of MIS to patients were significant thus it was worth investigating on instrument to shorten suturing time and promoted easier manipulation of skills.

III. Project objective

This project aimed at exploring and addressing current challenges faced in suturing and knot tying in MIS based on existing literature, followed up by an design and evaluation of a new instrument for facilitation of suturing and knot tying in MIS.

IV. Overall Schedule (Set on 1st October, 2020)

Before 30th November, 2020	Review on existing suturing device and get familiar with the research background
30th November, 2020 - 30th December, 2020	Hand drawing of the components and the assembly of the suturing assistive device
31st December, 2020 – 15th March, 2020	3D design of the device with SOLIDWORKS
15th March, 2021 – 30th March, 2021	Build the first prototype using 3D printing
30th March, 2021	Assembly of the first prototype
30th March, 2021 – 3th April, 2021	Refine the design and prototype
3rd April, 2021 7th April, 2021	Build the second prototype using 3D printing. Assembly of the second prototype
7st April, 2021 – 30th April, 2021	Perform experimental evaluation of the suturing assistive device, and report.

(B) Literature review

I. Different types of suture/knots in laparoscopic surgery

Before investigation on the limitations faced in suturing and knot tying, a brief introduction was made on the existing types of suturing and knots used in MIS.

There were mainly two types of knots in laparoscopic surgery, namely intracorporeal knots and extracorporeal knots. The former was the knot being made inside the body cavity, while the latter was the knot made outside the body cavity followed by the flipping of the knot, namely relocating the knot from one end of the suture outside the body cavity to another end inside the body cavity (Omar, 2008). Due to the limited space for technical movement inside the abdominal cavity, extracorporeal knot coupled with intracorporeal suturing has been more popular in recent years (Lee, Kim, Chong, Hong, & Lee, 2015). The extracorporeal knot-tying technique was especially beneficial in single port laparoscopic surgery as it allowed a knot tied with comparable strength as the knot tied by two hands in open surgery, whereas the extracorporeal knot can be made by the manipulation of merely one instrument (Murphy, 1995).

Nonetheless, there was narrower variety of knots that should be achieved by extracorporeal knot-tying technique which mainly offered the slipknot, in comparison with the intracorporeal knot-tying techniques offering square knot, surgeon's knot, tumble square knot, Dundee jamming knot, and Aberdeen termination knot, while the square knot and surgeon's knot were the most commonly used knots in laparoscopy attributed to their high strength (Dorsey, Sharp, Chovan, & Holtz, 1995). Moreover, the average load needed to make extracorporeal knots was approximately 37 percent higher than the average load needed to make intracorporeal knots (Xu, Zhu, & Su, 2015). The research done by Xu, Zhu, and Su (2015) showed that the intracorporeal knots made by single hand possessed the advantage of extracorporeal knot-tying technique that it could be performed in single port and within the limited space of abdominal cavity, meanwhile, offering a more optimal results than the extracorporeal knot-tying technique in terms of time, average load taken and the force caused the knot to rupture. According to the research, the time need for intracorporeal one-handed knot-tying technique was 20% less than the extracorporeal knot-tying technique, and the average load needed to make the intracorporeal knot was 25.5% less than the extracorporeal knot, while the intracorporeal knot tolerated higher distraction forces. Thus, this paper focused on the discussion about the available devices for intracorporeal knot-tying and

suturing and further explored the novel device for single-hand intracorporeal knot-tying and suturing.

II. Evaluation of existing devices

In view of suturing and knotting being essential skills in laparoscopic surgery, a number of devices were invented aiming at facilitating the adoption of skills.

a. Knot Tying Laparoscopic Needle Driver

Modification was made on the standard needle holder which widened the jaw opening of the needle grasper from approximately 30 degrees to greater than 90 degrees with a deployable and retractable apparatus, and the tip of the grasper were fabricated in tubular shaft with a concave outer surface at the movable side of the jaw (Benson, 2012). This reduced the chance of the suture line of the throw of knot slipping off the needle holder when the suture was looping around the angled grasper. The mechanism of the device was simple and similar to the conventional needle holders, thus, little additional training being needed for surgeons to adapt its usage. Moreover, the modified needle driver contained a mobile upper jaw which can open to an oblique angle for easier knot-tying, such the two suture instruments could be placed close together or even parallel, allowing its application to single port laparoscopy. However, the suturing with the modified device was still time-consuming and required cooperative and sophisticated control over the two suturing instruments.

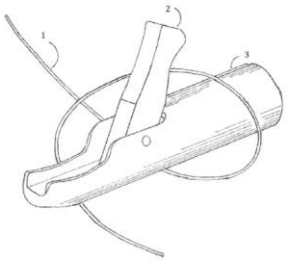


Fig 1. Knot Tying Laparoscopic Needle Driver

b. Tubular knot tying device

To facilitate knot-tying, several devices with a pre-tied slipknot were designed in 2012 while the tubular knot tying device was one of them. This device was designed to transform a pre-tied slip knot into a secure double sheet bend in cooperation with the usage of traditional needle holders (Tu, Wu, Lin, & Hsiao, 2012). It reduced the need of making suture throw on

the suturing instrument and manipulating the long suturing line, and it shortened time needed for knot tying without compensating knot strength or stability. A special feature was offered in detecting knot failure which was presented by a color marker. Nevertheless, the most significant drawback of the device was its one-time usage for each knot, indicating the necessity in consuming few applicators if multiple sutures had to be made. This led to a high cost and time-consuming for inserting and removing the applicators for multiple suturing. Though the device allowed efficient single suturing, the knot-tying at another side of the continuous suturing which was common suturing technique in laparoscopy was not facilitated. Furthermore, it prohibited the readjustment of the suturing insertion site after puncturing the tissue as the end of the suture line was equipped with the pre-tied slip knot at the tubular device. The tiny tubular device also led to a concern of retained foreign body in the body cavity. More importantly, the experiment of the device was done with an artificial skin outside the human body. There was no description about how to put the device into the body cavity for suturing.

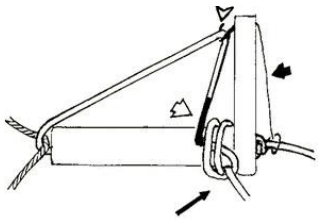


Fig 2. Tubular knot tying device

c. *Suturing and Knotting Integrated Device*

A modified version of the tubular knot tying device created by Tu, Wu, Lin, and Hsiao (2012) to allow the device to be used in laparoscopy. The hand-held integrated device contained a pre-tied slipknot at the tip connected with a suturing needle. The hand-held device allowed the whole system to be inserted into the body cavity, solving the previous query about the inserting of tubular device into body cavity. A standard needle holder was used to manipulate the suturing needle. By passing the suturing needle and pulling the suture thread through the loop of the slipknot at the tip of the hand-held device, the slipknot would be anchored to the suturing site. A simple pulling force could result in the slipknot detached from the fitting section thus completing a suture knot on the designated site (Tu, 2017). The modified version addressed the problem of inserting the pre-tired slipknot into the body cavity, yet remained the drawback of its single usage of tying a knot and other forehead mentioned limitations of the tubular device.

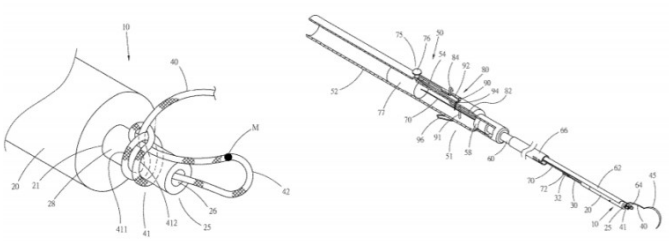


Fig 3. Suturing and Knotting Integrated Device

d. *Laparoscopic Suture Device With Asynchronous in- Line Needle Movement*

The limitation of the single use pre-tied knot devices largely restricted their application to laparoscopic surgery which commonly required multiple sutures. Rather than having a pre-tied knot, devices allowing the passing of needles back and forth between the jaws were suggested, which allowed the intracorporeal knots to be made more easily by single-hand manipulation of the needle along with the suture line around the end of thread being held by a grasper. This device consisted of two arms, namely, a needle throwing arm and a needle receiving arm. The arms moved asynchronously along planes substantially parallel to a longitudinal axis defined by the shaft (Woodard, Shelton, Lesko, & Baxter. 2015). Simply by pressing the device, the needle could be passed back and forth between the two arms. This device allowed single-hand manipulation of the suturing needle and efficient continuous suturing, by minimizing the needs of picking up the needle from the suturing site and passing the suturing needle from needle grasper to needle driver after each tissue penetration. Moreover, the pivotable joint at the jaws of the device could adjust the length of the jaw according to the length of the suturing needle to be held. This allowed the device to be applicable to the penetration of various thickness of tissue.

On top of this, being able to transfer the needle back and forth between the jaws, the device largely facilitated knot-tying. Knot could be made by holding one end of the suture line by a grasper, and then transferring the needle back and forth to loop around the thread. However, the pulling of suture thread during knot tying and continuous suturing highly rely on the non-dominant hand since the dominant hand is fully occupied by holding the needle, which is in contrary to the conventional method where the two needle holders carried by the surgeons could be used to manipulate the suture thread after dropping down the needle.

Moreover, the direction of suturing was limited since the needle could only puncture tissue along the longitudinal axis of the device. In laparoscopy, it was common for suturing happening at an angle deviated from the longitudinal axis of the needling driver and thus the suturing needle was held laterally or semi-laterally corresponding to the direction of the conventional needle driver. As the suturing site might contain a flat surface or be perpendicular to the needle driver, the rigid needle driver tip hindered the angulation of needle incision.

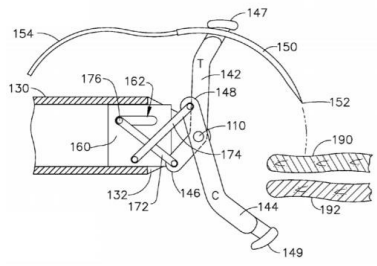


Fig 4. Laparoscopic Suture Device With Asynchronous in- Line Needle Movement

e. *Dual-Action Needle Graspers*

Another version of the laparoscopic suture device with asynchronous in-line needle movement was introduced by James Woodard and Jason Lesko (2014) with the movement of needle maintaining in lateral direction and perpendicular to the needle driver. This device also consisted of two arms that allowed the needle to be passed from one arm to another after penetrating the tissue, and simply by pressing the device, the needle could be passed back to the previous arm for continuous suturing, which was operating with similar mechanism as the laparoscopic suture device with asynchronous in-line needle movement except the difference of the direction of needle movement.

In 2014, the two inventors introduced the dual-action needle grasper receiving a patent. Each jaw of the needle grasper had a needle grasping member operable to align a suture needle along a predetermined arc path and a special double tip needle was designed (Woodard, & Lesko, 2014), so continuous interrupted suturing was allowed without the need of passing the needle back and forth. The modified devices allowed needle insertion in lateral direction and dual direction of needle incision. And the short distance between the two jaws facilitated the knot-tying process. However, only needles with a diameter of curvature matching the distance between the two jaws can be used. And the limitations on the angulation of needle insertion and handling of suture thread were not addressed.

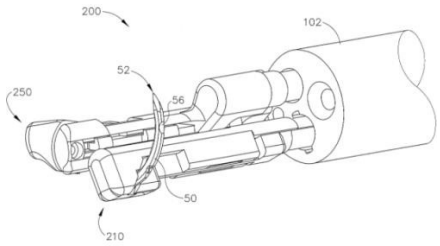


Fig 5. Dual-Action Needle Graspers

f. *Laparoscopic Suturing System by Applied Medical Resources Corporation*

A comparable dual acting device was introduced by the Applied Medical Resources Corporation. The device consisted of two jaws, the driving jaw and the receiving jaw which were interchangeable, such that the dual tip needle could act in both back and forth directions between the two jaws. The needle was specially designed to allow the jaws to release and grasp the needle at each trigger cycle. The needle used was small in size and the needle could be aligned along the jaw of the needle driver by a pivotable jaw member, in other word, hiding the needle along the jaw. In this case, the needle could be maintained in a low-profile stowed configuration for insertion through the small diameter surgical port (Breslin, 2020). The needle could thus be inserted through the 5mm surgical port, instead of a 10mm surgical port, minimizing the wound size. However, owing to the short needle, the thickness of tissue to be penetrated was limited. Also, there was restriction on the length and the curvature of the needle such that it could align with the jaw for instrument insertion into the body cavity, which compromised the thickness of tissue that could be penetrated. Also, the relatively straight needle insertion required the clear vision and wide space right above and below the tissue for safe suturing.

Despite the fact that this device could enhance the speed of continuous suturing and knot-tying with the help of its short distance between the driving and receiving jaw, it did not address issues of limited angulation of needle and difficult thread handling; More importantly, since the penetration of tissue was introduced by the ‘clipping’ mechanism between the jaws, the jaw tips covering the puncture site limited the vision upon the exact needle puncture site.

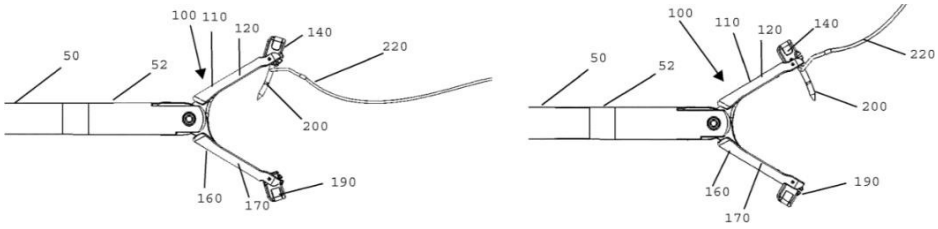


Fig 6. Laparoscopic Suturing System by Applied Medical Resources Corporation

g. *Endo stitch*

Endo stitch was a commercialized single-used laparoscopic suturing instrument by COVIDIEN. The instrument was equipped with two jaws which could compress tissue to promote suturing for tissue with different thickness. The endo-stitch needle was passed back and forth among the jaws by pressing the handles with the toggle lever flipped to transfer the needle between the two jaws. It was found having a significantly smaller time need for stitch placement and knot-tying compared with conventional technique (El-Shazly, Moon, & Eden, 2007). With design based on ergonomy, it allowed comfortable handhold and ergonomic manipulation (Göpel, Härtl, Schneider, Buss, & Feussner, 2011).

Though the efficient suturing and knot tying were allowed through the rapid back and forth motion of the needle between the jaws, the efficiency of the endo stitch manipulation remained highly dependent on the experience and training of the surgeon. The difference in operation time for experienced and inexperienced surgeons was found to be greater than 50% (Risucci, Geiss, Gellman, Pinard, & Rosser, 2001). Difficulties were found in manipulating the thread of suture during the looping of the suture line and pulling the long thread away from the suture site for knot-tying.

The thickness of tissue penetration was limited by the length of the endo-stitch needle and the compression force applied by the jaws. The jaws gap of the device was 4mm, while the devices could penetrate tissue with thickness up to 4.8mm with the help of the compression force (COVIDIEN, 2008). As the usual thickness of the wall of the small intestine and that of the large intestine of human ranged from 1mm to 5mm (Fernandes et al., 2014), the endo-stitch devices could manage most suturing, yet revealing deficiency in suturing thick wall of intestine. The narrow range of penetration depth of was obvious as the tilted needle incision had to be made. As for the gynecological surgery, the uterine wall was 8-25mm (Nandita, Rishma, Hrishikesh, 2012), which was out of the applicable range of the endo stitch device. More importantly, the thicker the tissue, the larger compression force applied during suturing, which potentially damaged the tissue.

Regarding the needle incision, due to the rigid body of the endo stitch, the limitation in angulation of needle insertion remained an issue. And the tip of the applicator blocked the vision of the exact needle incision site. As the thread of the stitch was connected to the side of the endo-stitch needle, a large needle hole was left at the tissue as the needle and thread penetrated tissue in parallel direction (Nagai, & Araki, 1999). And since the diameter of the endo stitch device was large, a 10mm port was required instead of the 5mm port.

On top of these, the high price up to 300USD per instrument, combined with the single usage restriction, made it difficult to be widely applied in public hospital settings.

Fig 7. Endo stitch

h. SILS stitch

SILS was a more advanced version of endo stitch introduced by the COVIDIEN. It offered a higher degree of angulation by allowing distal shaft articulation up to 75 degrees, needle jaw tip rotation up to 360 degrees and additional shaft length. The unparalleled control was especially beneficial to suturing in single-port laparoscopy and it allowed the device to reach tissues in their natural anatomical position, instead of pulling the tissues into the suturing device (Hart, 2012). Despite the improvement in needle angulation, the drawbacks revealed in endo stitch also existed in SILS stitch, and the long suture thread can hardly be manipulated by device such that difficult is found for knot tying as the tip is angulated. And the price of this single-use instrument was set up to 750 USD, further compromising its possibility in being widely applied in general hospitals.

Fig 8. *SILS stitch*

i. Endo 360

The Endo360 device was a device using curved suturing needles for minimally invasive surgery (MIS). The distal tip of the devices could articulate 40 degree and rotated 180 degree for precise needle placement in different planes. The arc of the tip was shaped as the curvature of the needle, thus the needle was apparently hidden in the device. The curved needle rotated 360 degrees at each trigger, such that the needle was ejected along the circular path given by the arc of tip and was received by another end of the arc of tip immediately after the penetration of the tissue, resulting in a complete circle. As the suture line was connected in series to the end of the needle, the penetration of the needle would not generate

large needle hold at the tissue as the endo stitch and SILS stitch did. Also, the endo 360 being reusable, it greatly reduce the use of multiple disposables in one surgical case and the cost of operation.

However, the dimension of the arc of the tip restricted the dimension of the needle that could be used. The depth of bite and thickness of tissue penetrated was 8mm and 6mm respectively (Assute Europe Suture Chirurgiche, 2016), thus the device merely applicable to suturing of thin layers. As the device is mainly used for thin layer suturing, the suture length ranges from 10cm to 45cm (Assute Europe Suture Chirurgiche, 2016). Short suture thread reduces the movement of the device required to pull the end of thread close to the tissue for knot tying. But the short thread could be an obstacle in continuous suturing since the short thread remains closed to the tissue, thus being prone to kinking during each incision. Moreover, suture needle with relatively long suture thread in a length of 70cm is often used in laparoscopic surgery, due to the fact that long suture thread allows more stitches to be made and minimize the needs of getting the needle hold in and out of the body cavity for exchange suture needle. Long suture thread is especially important in suturing thick layer and continuous suturing of tissue such as the closure of cervical opening in total laparoscopic hysterectomy. However, the manipulation of long suture thread during knot tying and continuous suturing remain an issue for most of the suturing devices.

Fig 9. Endo 360

j. *Flexible endoscopic suturing robot*

Other than the rigid surgical devices, flexible working elements had been increasingly popular along the advancement in robotics surgery. Hu, Li, Zhang, and Yang (2019) designed a flexible suturing robot for transanal endoscopic microsurgery that the devices offered a much higher degree of angulation than the traditional rigid needle drivers did. Motions such as pitch, yaw, roll and translation were allowed by the tendon structure. The driving

mechanism of the needle was similar to that of the dual-action needle graspers mentioned, where a small double--tip needle was passing back and forth in between the two jaws.

However, the design suggested was only suitable for transanal endoscopic microsurgery since the two flexible arms were extending form a single lumen and were operating very close to each other. The distance between the two arms limited the applicability to tissues with different thickness and the reachability towards tissues.

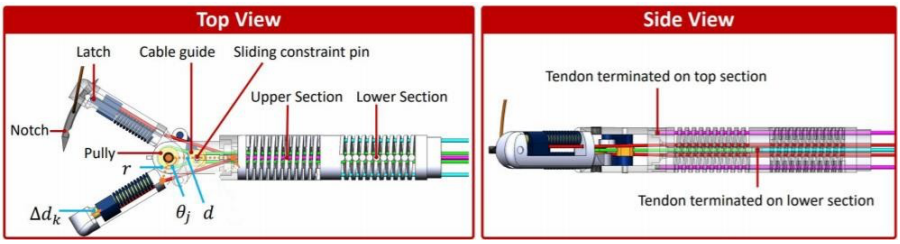


Fig 10. Flexible endoscopic suturing robot

	Features	Pros	Cons
a. Knot Tying Laparoscopic needle driver	- widen jaw opening of needle grasper - for intracorporeal knots	- Reduce chance of suture line slipping off the needle holder during knot-tying - Simple mechanism - Require little or no additional training for surgeons - Easier knot-tying	- Time-consuming - Require sophisticated control over the two suturing instruments for knot tying - Deficiency in managing long suture thread in terms of pulling of thread
b. Tubular knot tying device	- tubular device with a pre-tied slip knot - for extracorporeal knots	- Pre-tied knot largely shorten time needed for knot tying - Offer knot failure detection	- Single use only - High cost - Time-consuming for inserting and removing applicators for multiple suturing - Prohibit readjustment of suturing insertion site after puncture tissue - Concern of retained foreign body - Query about device insertion
c. Suturing and knotting integrated device	- hand-held device integrated with tubular knot tying device - for extracorporeal knots	- Pre-tied knot largely shorten time needed for knot tying - Offer knot failure detection	- Single use only - High cost - Time-consuming for inserting and removing applicators for multiple suturing - Prohibit readjustment of suturing insertion site after puncture tissue - Concern of retained foreign body
d. Laparoscopic suture device with asynchronous in-line needle movement	- two jaws enabled needle to pass back and forth along longitudinal axis of the device	- Single-hand manipulation of needle allowed	- Limited direction of suturing and angulation of needle incision - Deficiency in managing long suture thread

	- for intracorporeal knots		
e. Dual-action needle graspers	- two jaws enabled needle to pass back and forth along lateral direction and perpendicular to needle driver - for intracorporeal knots	- Single-hand manipulation of needle allowed - Allow movement of needle in lateral direction - Convenient continuous interrupted suturing allowed - Efficient knot-tying process	- Limited direction of suturing and angulation of needle incision - Deficiency in managing long suture thread
f. Laparoscopic suturing system by Applied Medical Resources Corporation	- two jaws enabled needle to pass back and forth with low-profile stowed configuration - for intracorporeal knots	- Single-hand manipulation of needle allowed - Allow low-profile stowed configuration of needle during insertion through small surgical port - High speed of continuous suturing and knot-tying	- Limited direction of suturing and angulation of needle incision - Limited thickness of tissue penetration - Restricted length and curvature of needle used - Require wide space above and below the tissue for safe suturing - Limited vision upon puncture site - Possible damage to tissue due to compression - Deficiency in managing long suture thread
g. Endo stitch	- commercialized single-used laparoscopic controlled by a toggle lever to transfer the needle between the jaws - for intracorporeal knots	- Single-hand manipulation of needle allowed - High speed of continuous suturing and knot-tying	- Limited direction of suturing and angulation of needle incision - Limited thickness of tissue penetration - Require wide space above and below the tissue for safe suturing - Limited vision upon puncture site - Possible damage to tissue due to compression - Single use - High cost - Large needle hole

			- Device body is large, requiring 10mm surgical port - Deficiency in managing long suture thread
h. SILS stitch	- advanced version of endo stitch with higher degree of angulation - for intracorporeal knots	- Single-hand manipulation of needle allowed - High speed of continuous suturing and knot-tying - High degree of angulation allowed	- Limited thickness of tissue penetration - Require wide space above and below the tissue for safe suturing - Limited vision upon puncture site - Possible damage to tissue due to compression - Single use - High cost - Large needle hole - Device body is large, requiring 10mm surgical port - Deficiency in managing long suture thread
i. Endo 360	- modified version of Endo stitch using curved suturing needles with greater angulation	- Allow low-profile stowed configuration of needle during insertion through small surgical port - High degree of angulation allowed - Reusable	- Limited thickness of tissue penetration - Device body is large, requiring 10mm surgical port - Deficiency in managing long suture thread
j. Flexible endoscopic suturing robot	- flexible suturing robot for transanal endoscopic microsurgery offering higher degree of angulation	- For endoscopic microsurgery only - High degree of angulation	

Table 1. Comparison among existing devices

III. Short Summary

All in all, the advancement of the laparoscopic suturing device stressed on the single hand manipulation of suture need for efficient suturing and knot-tying. However, common issues concerning the tip angulation of the device for precise needle incision, the depth of penetration constrained by the length of needle, and the management of the long suture thread during the pulling and looping of thread for knot tying, were not addressed.

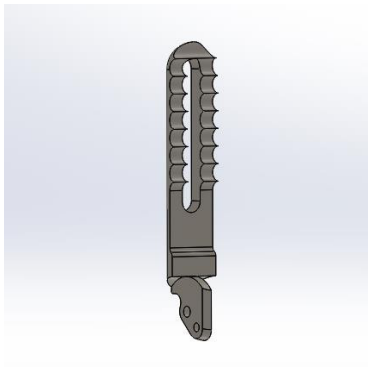
While the improvement on the tip angulation and the depth of the penetrated had to be dealt with the modification of the structure and mechanics of the suturing device, the management of suture thread could be achieved by modifying the assistive device. During laparoscopic suturing, it was common for surgeons holding the suturing device with his or her dominant hand to initiate needle incision, and meanwhile holding the grasping forceps with his or her non-dominant hand to manipulate tissues, needle and suture thread. Though the current design of the suturing device eradicated the needs of manipulating needle by the non-dominant hand, the handling of tissue and suture thread was inevitably reliant on the non-dominant hand. Especially, during knot tying, a tight knot could impossibly achieved by a single suturing device since a tight knot had to be made with the oppositely pulling of threads. Therefore, a Dual-function suture assistive (DFSA) device was suggested accordingly.

(C) Mechanical Design and Prototype

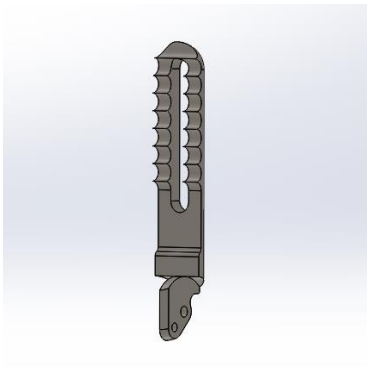
I. First design and prototype

The 3D design of the DFSA device was completed on 15th March, 2021, and a prototype was printed and assembled on 30th March, 2021. The aim of the first prototype was familiarizing the assembly of the different components including the blades, the stem, the handle, shaft, the hook, and the connecting screws, and also evaluating the performance of my first design.

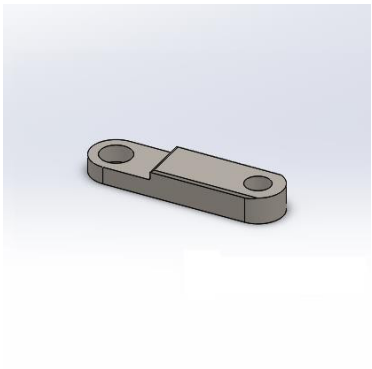
The following figures showed the 3D drawing and printed component of the 1st prototype.



Upper blade of the grasper

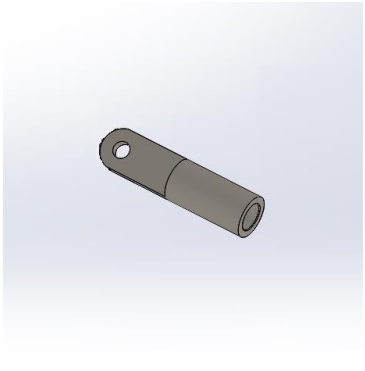


Lower blade of the grasper



Movable plates

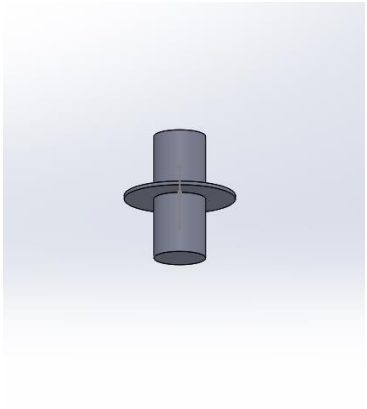
Connecting shaft between tip and body



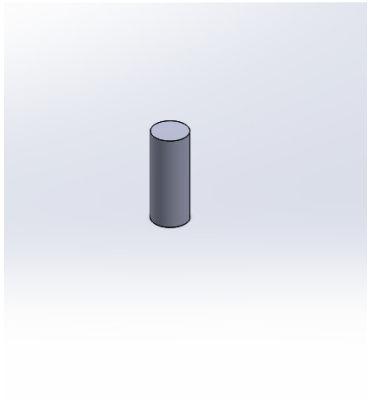
Connecting part between stem and tip

Figure 11: 3D drawing of components of the tip of 1st prototype

Fixed screw between blades and connecting shaft

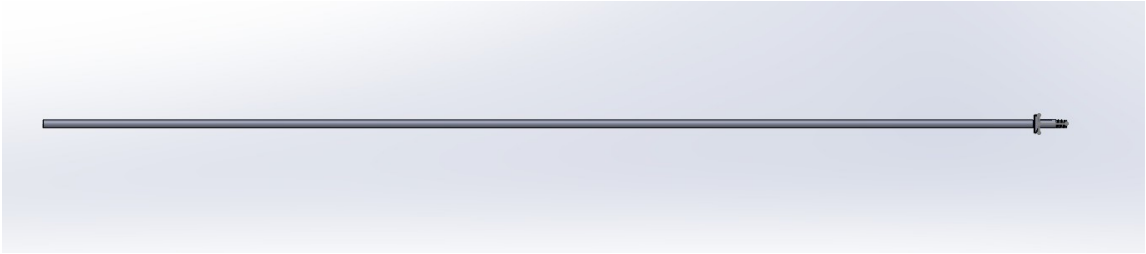


Pin connecting blade and connecting plate

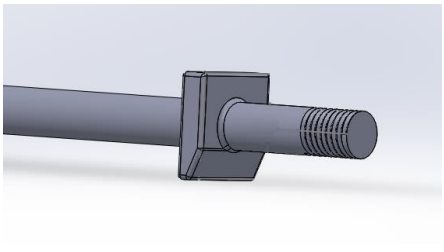


Pin regulating connecting plates

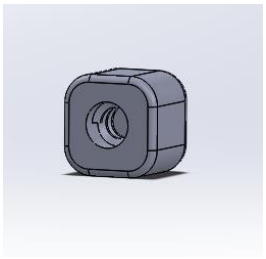
Figure 12: 3D drawing of connecting components of the tip of 1st prototype



Movable Stem

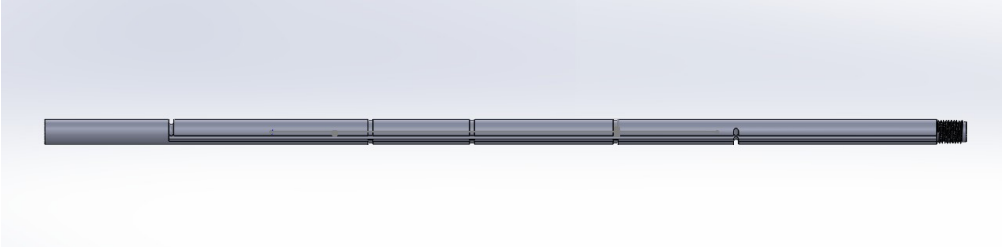


Zoom in of the end part of the stem

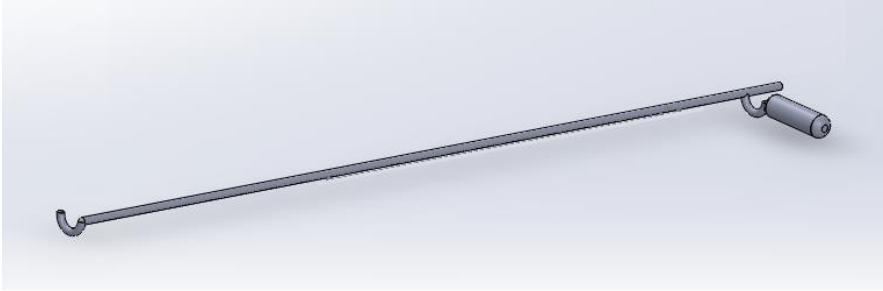


Ending cap for the stem

Figure 13: 3D drawing of components of inner part of 1st prototype



Outer shaft of the device body

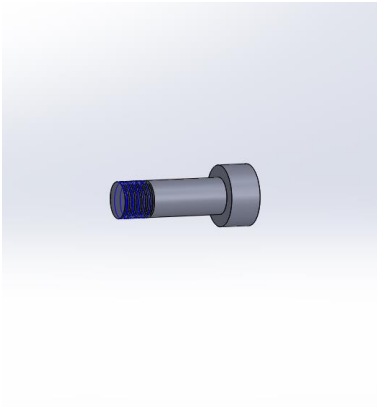


Movable hook

Figure 19: 3D drawing of components of external part of 1st prototype

Fixed part of handle

Movable part of the handle

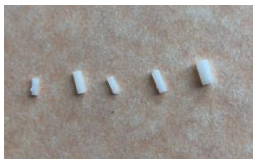


Fixed screw connecting fixed part and movable part of handle

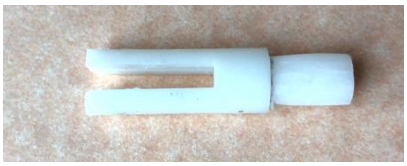
Nut of the fixed screw

Figure 14: 3D drawing of components of handle part of 1st prototype

Connecting part between stem and tip

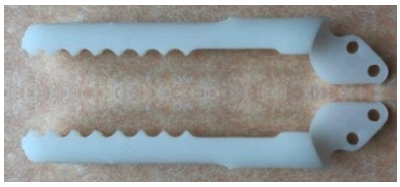


Pins



Connecting shaft between tip and body

Movable plates



Grasper

Figure 15: Printed tip component of 1st prototype

Figure 16: Assembled tip of 1st prototype

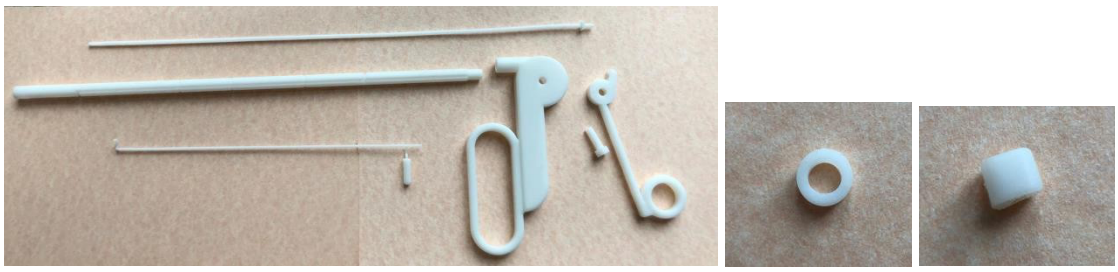


Figure 17: Printed body and handle component of 1st prototype

Figure 18: Printed hook feature of 1st prototype

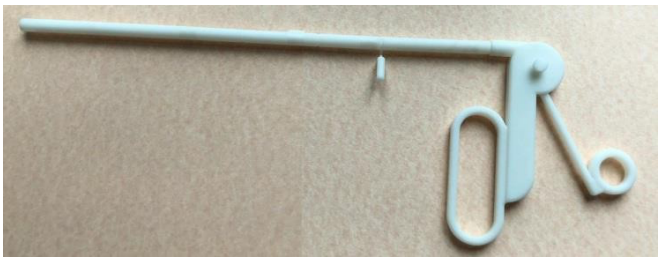


Figure 19: Assembled 1st prototype

Evaluation of the first prototype

The tip of the prototype was working well with wide degree of jaw opening, and grasping and force sufficient to manage the needle and suturing thread. Also, the hook feature could slide along the tunnel of the main body smoothly.

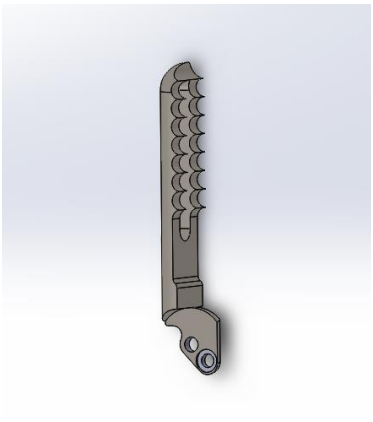
Due to the design of the tip components in small scale, some features were lost at printing. The pins connecting blade and connecting plate were printed out in column shape, losing the disc feature at the middle of the pin. To improve, the dimension of the features designed should be no less than 1mm.

Moreover, though there was no interference between components based on the analysis done with SolidWork, difficulty in insertion and assembly of the printed prototype was found. This was due to the fact that the dimension of different features was designed just fit, namely, if a hollow tube had the inner diameter as 3mm, the inserted component was also in 3mm diameter. However, deviation would be obtained during fabrication and thus some space had to be retained for easier assembly among components.

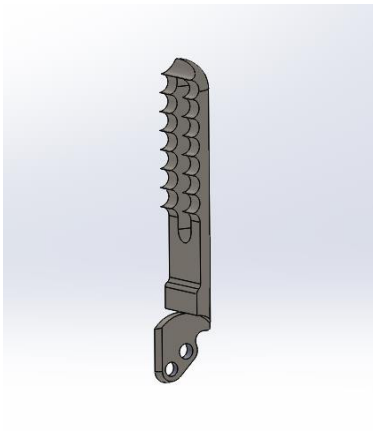
Lastly, the size of the handle part of the first prototype was too large, leading to the impossibility of manipulating the handle and the hook feature with a single hand. The hand part had to be scaled down to around half size of the first prototype, with the consideration about finger ergonomics to promote comfort of the users.

II. Second prototype and prototype

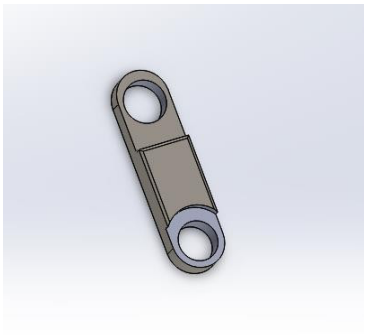
The design of the device was modified to eliminate the insufficiency found based on the first prototype. The following figures showed the 3D drawing and printed component of 2nd prototype followed by table 2 illustrating its specification.



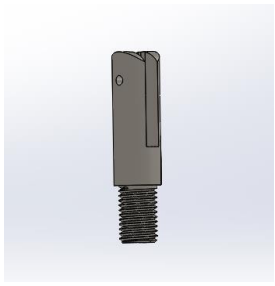
Upper blade of the grasper



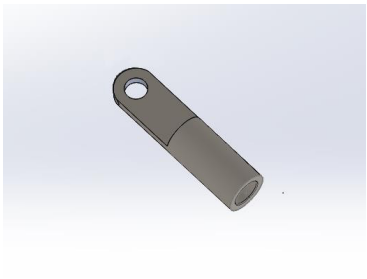
Lower blade of the grasper



Movable plates

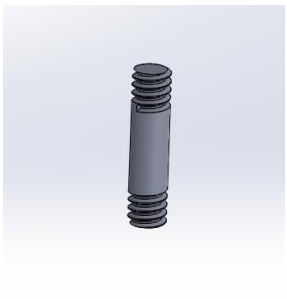


Connecting shaft between tip and body

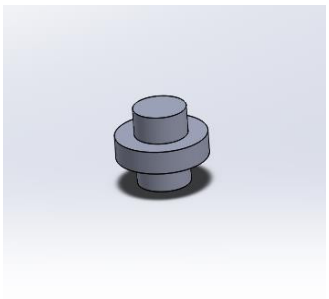


Connecting part between stem and tip

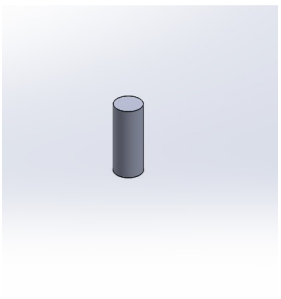
Figure 20: 3D drawing of components of the tip of 2nd prototype



Fixed screw between blades and connecting shaft



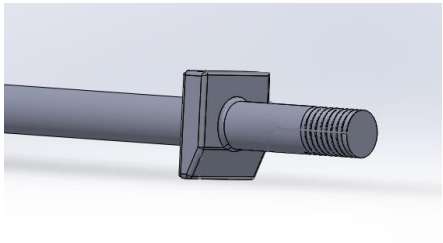
Pin connecting blade and connecting plate



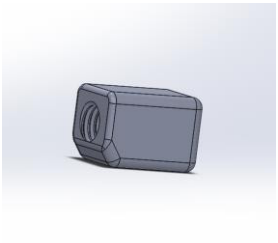
Pin regulating connecting plates

Figure 21: 3D drawing of connecting components of the tip of 2nd prototype

Movable Stem

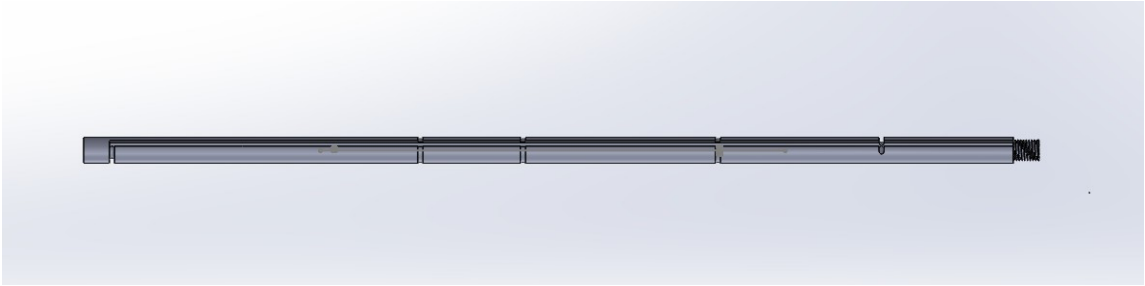


Zoom in of the end part of the stem

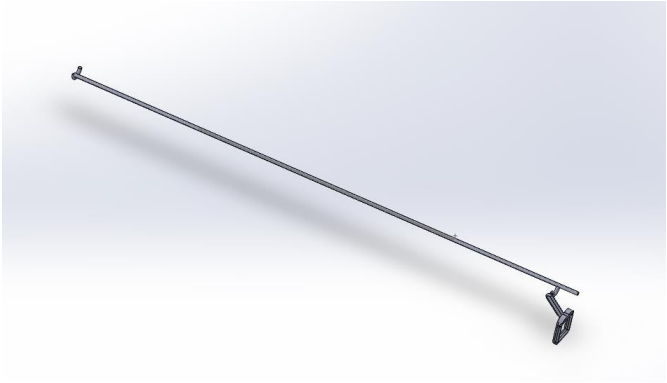


Ending cap for the stem

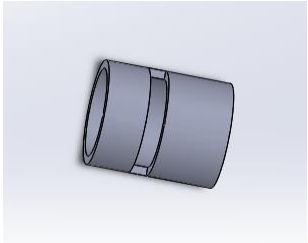
Figure 22: 3D drawing of components of inner part of 2nd prototype



Outer shaft of the device body



Movable hook



Sliding ring

Figure 23: 3D drawing of components of external part of 2nd prototype

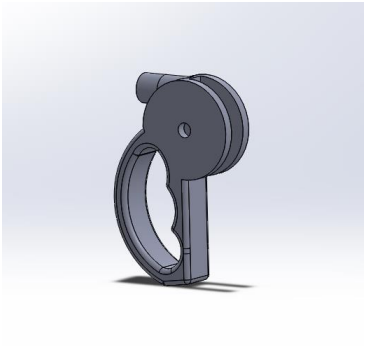


Figure Fixed part of handle

Figure Movable part of the handle

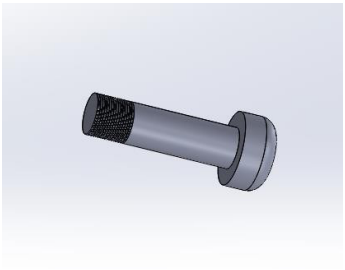


Figure Fixed screw connecting fixed part and movable part of handle

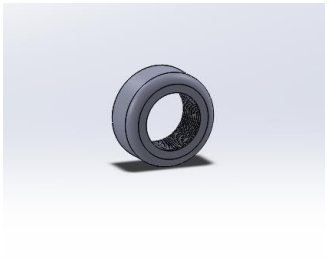


Figure Nut of the fixed screw

Figure 24: 3D drawing of components of handle part of 2nd prototype

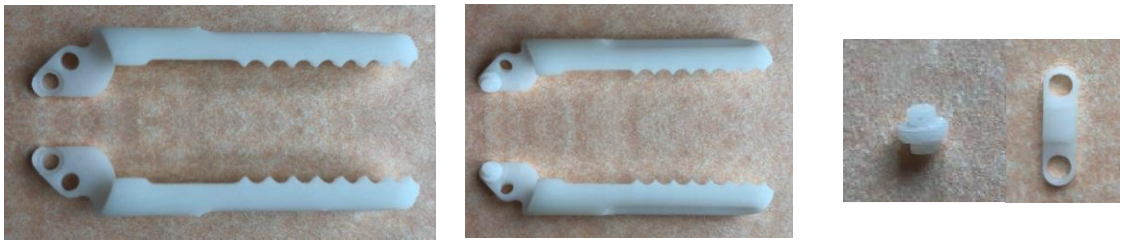


Figure 25: Printed tip component of 2nd prototype

Figure 26: Assembled tip of 2nd prototype

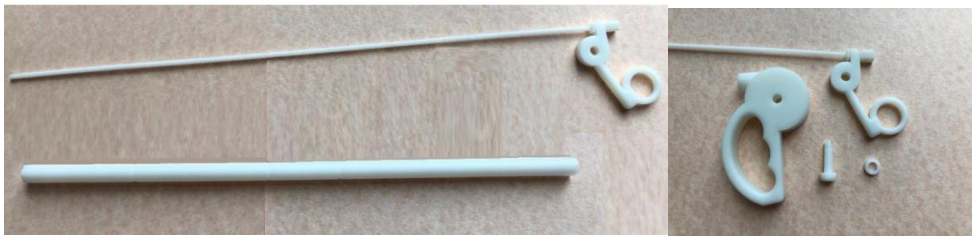


Figure 27: Printed body and handle component of 2nd prototype

Figure 28: Zoom in of the screwing feature at the connecting region between the body and the handle of 2nd prototype

Figure 29: Printed hook feature and sliding shaft of 2nd prototype

Figure 30: Assembled 2nd prototype

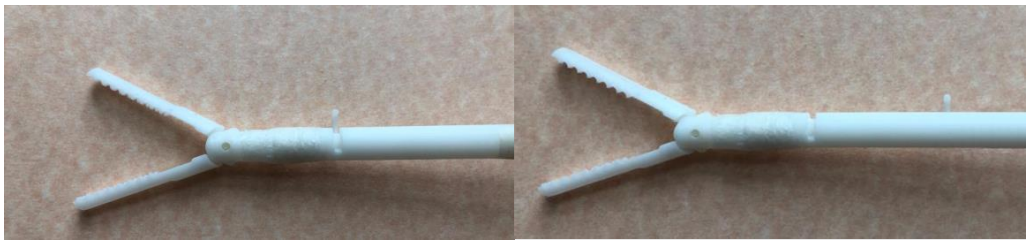


Figure 31: Extruding and sliding the hook feature of 2nd prototype

Dimension of the device	430 x 80 mm
Diameter of the device	0 mm
Dimension of the tip (closed jaw)	10 x 42 x 9.5 mm
Diameter of the hook	2 mm
The protruding length of the hook	6.2mm

Table 2: Specification of 2nd prototype

Evaluation of the second prototype

The dimension of the components was maintained at or above 1mm such that no feature was lost after printing. And the dimension of the hollow component well matched with the dimension of the inserting components, allowing easy assembly. The angle of jaw opening was maximally 65 degree, and the jaw could move smoothly with grasping force sufficient to hold the suture needle, the suture thread, and the polystyrene balls.

The amended handle had a size optimal for manipulation and the three sunken areas offered comfortable sitting of the three fingers. The index finger could be free from holding the device to manipulate the hook feature. The hook feature was able to slide along the device body smoothly and the distal hook was strong enough to sustain the pulling force of the thread. A sliding ring was added to hold the hook tightly aligned at the device's body, and sliding ring slid smoothly with the hook. The proximal part of the hook contained a design different from a simple rod shape used in the first prototype. The modification allowed the pushing and pulling of hook more easily, yet the strength of it could be further enhanced.

(D) Experimental evaluation of the DFSA device

Three experiments were done to evaluate the performance of the DFSA device, including:

Experiment I: Tying a knot on a tissue

Experiment II: Suturing and knot tying between two tissues

Experiment III: Continuous suturing

I. Methodology

a. Hypothesis of the experiments

Experiment I:

The use of DFSA device, in replacement of a typical needle holder, shortened the time required for knot tying on a tissue.

Experiment II:

The use of DFSA device, in replacement of a typical needle holder, shortened the time required for suturing and knot tying between two tissues.

Experiment III

The use of DFSA device, in replacement of a typical needle holder, shortened the time required for continuous suturing.

b. Control setup

The use of typical needle holder as an assistive device for suturing and knot tying

c. Dependent variables

Time required for suturing or knot tying, and the working area for suturing or knot tying

d. Independent variable

The instruments used as an assistive device for the procedures

e. Experimental procedures

Three subjects with no medical background were recruited for the experiments. They were not given any prior information about the content or the aim of the project. The overall experiments were held in two days. The subjects would be instructed to stand in front of the experimental box fixed on the desk. The laparoscopic instruments are held by the subjects and passed through the two trocars into the box. With the trocars, the subjects could move the instruments freely and smoothly.

In the box, there was a platform simulating the cavity of a human to conduct laparoscopy. Polystyrene ball was used to simulate the tissue to be sutured, and it was loosely stuck onto the stage to resemble the movable nature of human tissue. The setting of the polystyrene ball was placed according to the scenario of the experiments as illustrated below;

Figure 32: The setup for experiment I, II, III from left to right

The experimenters were asked to complete the tasks as below;

(i) Day 1 (D1):

1. *Experiment I (Experiment 1A-D1)*

   The subjects were given 30 minutes to learn and master the skill of knot tying with two typical needle holders. Then, the subjects were required to perform 5 trials of knot tying on a tissue with two typical needle holders and the time required to perform each knot tying was counted with a stopwatch.

2. *Experiment I (Experiment 1B-D1)*

   The subjects were given another 30 minutes to learn and master the skill of knot tying with a typical needle holder and the DSFA device. After that, the subjects were required to perform 5 trials of knot tying on a tissue with the typical needle holders and DSFA device, while the time required for each knot tying was counted with a stopwatch.

Figure 33: (Left) The starting posture of control setup (Experiment I)

(Right) The starting posture of experimental setup (Experiment I)

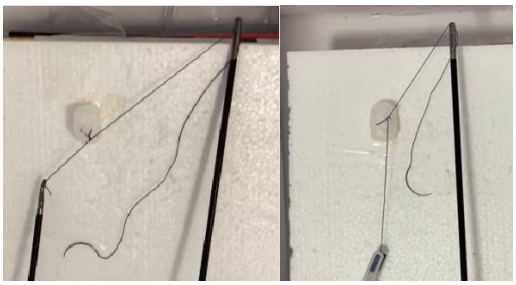


Figure 34: (Left) The ending posture of control setup (Experiment I)

(Right) The ending posture of experimental setup (Experiment I)

3. *Experiment II (Experiment 2A-D1)*

   The second experiment began after a resting time for 15 minutes. Then, the subjects were given 15 minutes to learn and master the skill of using typical needle holders for the suturing and knot tying between two tissues, followed by 5 trials of the procedure with time counted.

4. *Experiment II (Experiment 2B-D1)*

   Next the subjects were given 15 minutes to learn and master the procedure, suturing and knot tying between two tissues with a typical needle holder and the DSFA device, followed by 5 trials of the procedure with time counted.

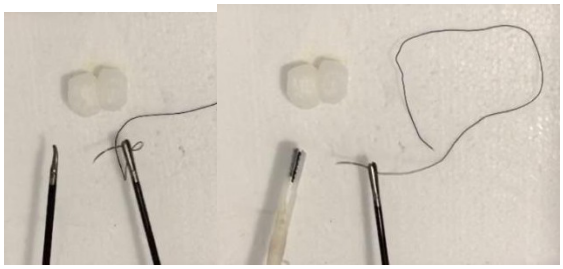


Figure 35: (Left) The starting posture of control setup (Experiment II)

(Right) The starting posture of experimental setup (Experiment II)

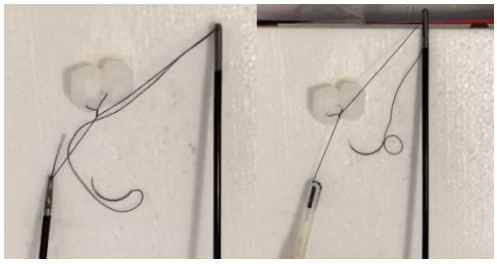


Figure 36: (Left) The ending posture of control setup (Experiment II)

(Right) The ending posture of experimental setup (Experiment II)

5. *Experiment III (Experiment 3A-D1)*

   Regarding the last experiment, it started after a 15-minutes break. A knot had been initially tied onto the first tissue, 15 minutes were given to the subject to learn and master the skill of using typical needle holders for continuous suturing. Then, the subjects were required to perform 5 trials of the procedure with time counted.

6. *Experiment III (Experiment 3B-D1)*

   Lastly, a knot had also been initially tied onto the first tissue. The subjects were given 15 minutes to learn and master the continuous suturing with a typical needle holder and the DSFA device, and were required to perform 5 trials of the procedure with time counted.

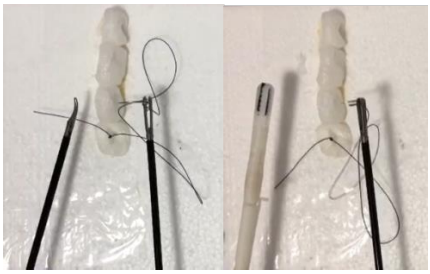


Figure 37: (Left) The starting posture of control setup (Experiment III)

(Right) The starting posture of experimental setup (Experiment III)

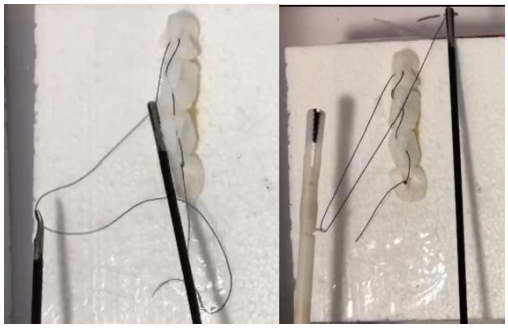


Figure 38: (Left) The ending posture of control setup (Experiment III)

(Right) The ending posture of experimental setup (Experiment III)

Stopwatch was used to count the time in all three experiments. The stopwatch was started when the experimenter reported ready and held the needle holder with the needle and DFSA device in the starting posture as displayed in figures 33, 35 and 37. For experiment I and experiment II, the stopwatch was stopped right after the subject tightened the knot in a way that the two forceps holding the thread straightly in opposite direction and the knot was tied closed to the polystyrene ball visually within 1cm, as shown in figures 34 and 36. As for the experiment III, the stopwatch was stopped after the subject pulled the thread straight and tight, as displayed in figure 38.

(ii) Day 2 (D2):

The procedures were conducted in a reverse sequence as below:

Experiment 1B-D2
Experiment 1A-D2
Experiment 2B-D2
Experiment 2A-D2
Experiment 3B-D2
Experiment 3A-D2

The resting time and the learning time remained unchanged, except the learning time at the very beginning of the experiment changed from 30 minutes to 15 minutes.

f. Potential bias

After the 5 trials at the first part of each of the experiment, namely experiment 1A, 2A, and 3A at day one, the subjects might get more familiar with the skills or might get fatigue, which influenced their performance. The aim of setting up the second stage of the experiment at day two in a reverse sequence was to minimize this potential bias.

Moreover, to avoid fatigue, 15 minutes break was given between experiments. During the break, the subjects were removed from the experimental set-up such that they were not allowed to practice the skills during the break.

To ensure the fairness of the experiment, the stopwatch was controlled by an observer without knowing the purpose of the experiments, yet informed about the criteria of an appropriate start time and end time.

The length of thread could highly influence the experiment result, since a shorter thread could be more easily manipulated. In the experiments, the 1.0 vicryl 1/2c 40mm needle with 30cm thread was used.

II. Experimental result

(a) Time required for suturing or knot tying

The experimental results data was attached in Appendix 1. The data was analyzed below with detailed analysis attached in Appendix 2. All the time differences were calculated with the following equation;

Time required (s) in experimental set up – Time required (s) in control set up.

Thus a negative time difference indicated shorter time required to complete task with the use of DFSA device.

The experiment was designed with reversed sequence of the task in Day 1 and 2 so as to investigate if the sequencing of utilizing and not utilizing DFSA device would contribute to the time difference in completing the tasks. The average time required to complete the tasks by individual subject in Day 1 and 2 were tabulated in Table 3 and 4.

	Subject / Part	1	2	3
Experiment I	Time difference	-9.6	-4.4	-6.4
	Percentage change	-18.7	-7.1	-14.4
Experiment II	Time difference	-10.6	-6.6	-2.4
	Percentage change	-23.6	-12.9	-7.1
Experiment III	Time difference	-21.2	-19	-18.6
	Percentage change	-26	-16.7	-25.4

Table 3: Average time required (s) and percentage changes (%) by individual subject in each experiment at Day 1

	Subject / Part	1	2	3
Experiment I	Time difference	-8.8	-4.8	-4.8
	Percentage change	-18.9	-8.2	-11.7
Experiment II	Time difference	-11.4	-5.4	-2.6
	Percentage change	-23	-11.4	-7.7
Experiment III	Time difference	-21.8	-20.4	-17.6
	Percentage change	-27.7	-16.2	-24

Table 4: Average time required (s) and percentage changes (%) by individual subject in each experiment at Day 2

Subject / Experiment	1	2	3
I	-0.2	-1.1	2.7
II	0.6	1.5	-0.6
III	-1.7	0.5	1.4

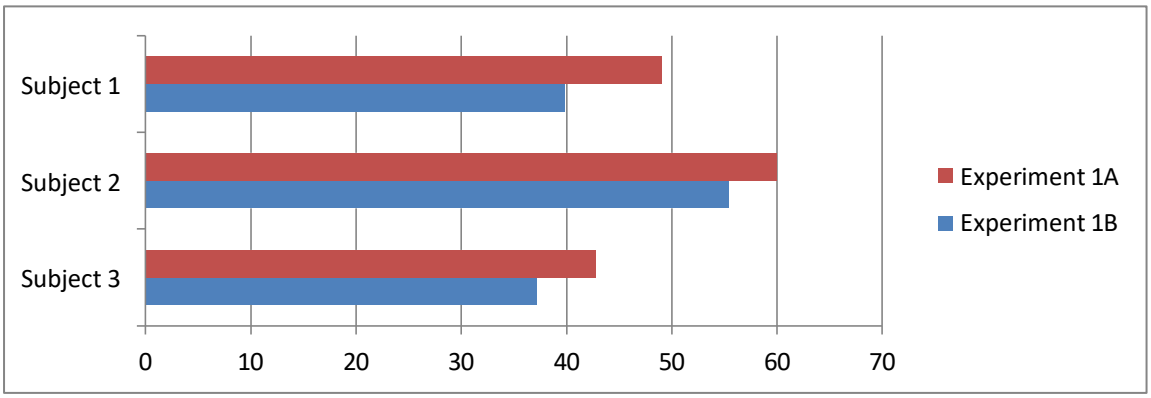
Table 5: Comparison of the percentage difference % of the time needed for completing each set of experiment at Day 1 and Day 2

As shown in table 5, the percentage differences of time needed to complete each task at Day 1 and Day 2 were little, indicating that the task sequencing did not contribute positive effect to the difference in time to completion the tasks. Thereby, the potential contributors of fatigue or familiarization of manipulation of devices inducing the change of completion time could be eliminated.

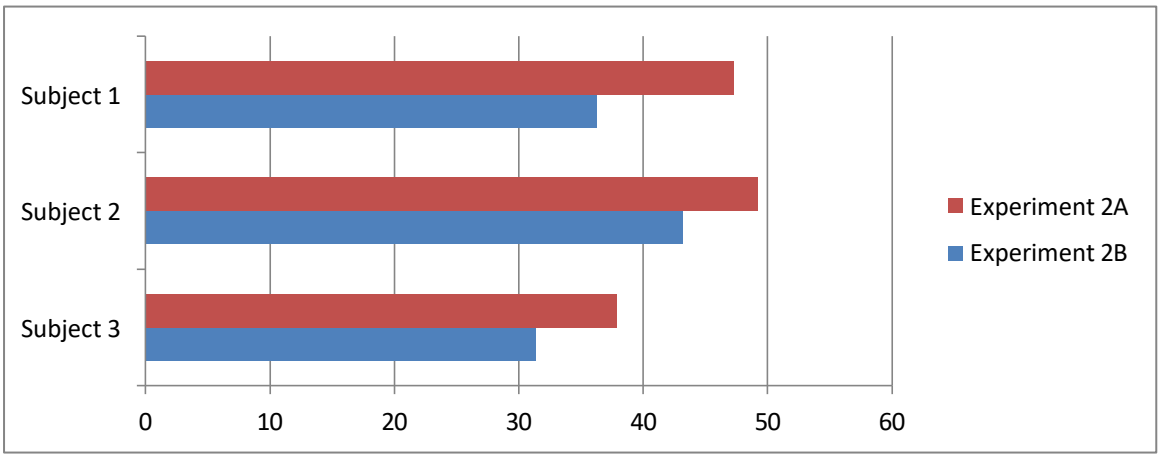
Attributed to the limited effect of the sequence of the task, the data set acquired from Day 1 and Day 2 were combined for analysis, giving a data set of 10 trials of each subject in each part of the experiments.

Subject / Experiment	1	2	3
I	-18.8	-7.65	-13.1
II	-23.3	-12.2	-7.4
III	-26.9	-16.5	-24.7

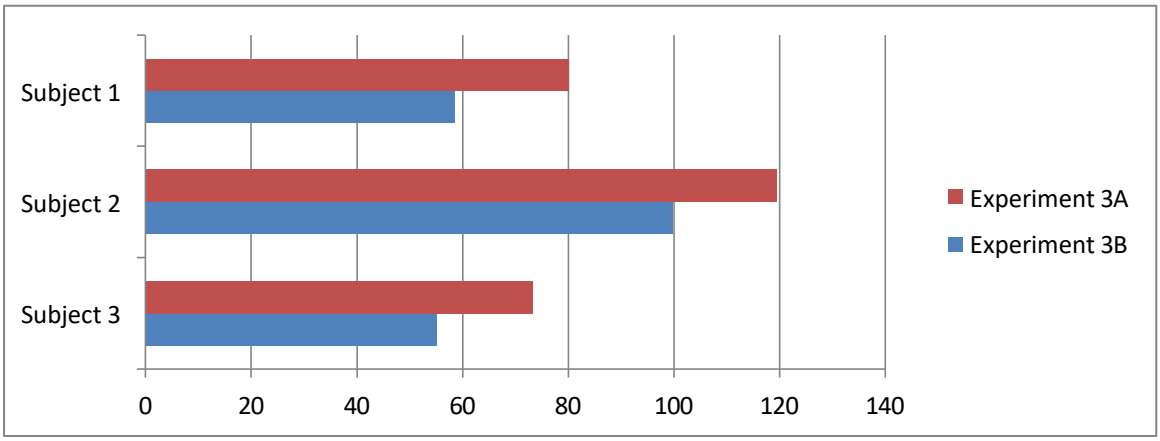
Table 6: Overall percentage change (%) of the time needed for completing each set of experiment for cumulated result of Day 1 and 2



Graph 1: Comparison between the average time required to complete experiment 1A and 1B obtained from Day 1 and Day 2



Graph 2: Comparison between the average time required to complete experiment 2A and 2B obtained from Day 1 and Day 2



Graph 3: Comparison between the average time required to complete experiment 3A and 3B obtained from Day 1 and Day 2

As indicated in table 6, graph 1, 2 and 3, all trials showed that shorter time was needed to complete the task with the use of DFSA device, indicating its effectiveness. The average time required by individual subject at each experiment was illustrated by the graph 1, 2 and 3 where the blue bars indicated the experiments with the use of the DFSA device, while the red bars indicated the experiments with the use of a typical needle holder as assistance. The three graphs offered easy visualization of the difference in time used by the subjects with the use of different assistive forceps. The shorter blue bars found in each graph illustrated the less average time required for all the subjects in performing knot tying on a tissue, suturing and knot tying between two tissues, and continuous suturing with the help of a DFSA device, in replacement of the typical needle holder as assistance, echoing with the three experimental hypothesis.

According to table 6, the average time used by the subjects in using the DFSA device instead of a typical needle holder for knot tying on a tissue had been reduced for a range of 7% to 18%, while that for suturing and knot tying between two tissues was reduced for a range of 7% to 23%. The most significant reduction was found at the continuous suturing, where all the subjects demonstrated a more than 16% reduction in time with the use of DFSA, while the largest reduction was closed to 27%.

(b) Working area for suturing or knot tying

Regarding the motion analysis, only the video from the one out of thirty trials were selected. The video of the shortest duration of each experiment was selected for analysis with the software, Kinovea for motion tracking and analysis. The trajectory of the main suturing forceps held by the dominant hand was indicated by the blue color in figures 39,40 and 41, while the trajectory of the assistive forces held by the non-dominant hand was colored in red.

The trajectory formed by the main suturing forceps with the use of a typical needle holder as assistance was visually much denser and occupying a larger grid area, as compared to the trajectory formed with the use of a DFSA device.

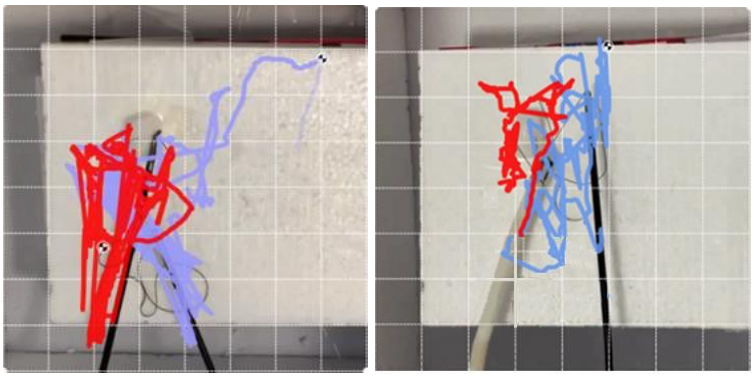


Figure 39. (Left) Motion tracking of the trajectory of the two typical needle holder during tying a knot on a tissue (Experiment 1)

(Right) Motion tracking of the trajectory of the a typical needle holder and the DFSA device as assistance during tying a knot on a tissue (Experiment 1)

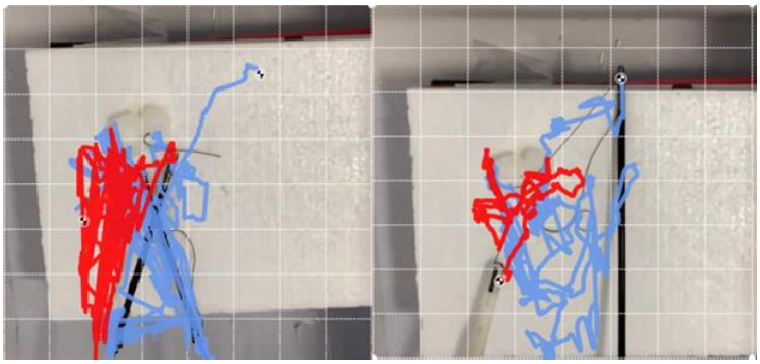


Figure 40. (Left) Motion tracking of the trajectory of the two typical needle holders during suturing and tying a knot between two tissues (Experiment 2)

(Right) Motion tracking of the trajectory of the a typical needle holder and the DFSA device as assistance during suturing and tying a knot between two tissues (Experiment 2)

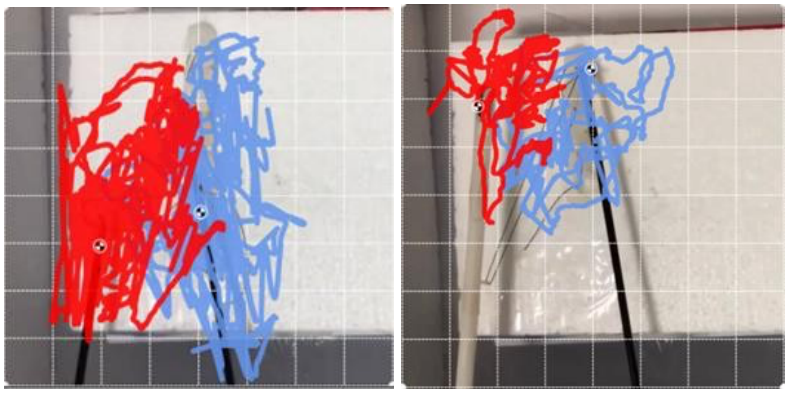


Figure 41. (Left) Motion tracking of the trajectory of the two typical needle holder during continuous suturing (Experiment 3)

(Right) Motion tracking of the trajectory of the a typical needle holder and the DFSA device as assistance during continuous suturing (Experiment 3)

In order to obtain a numerical comparison, the motion data was uploaded to Matlab to calculate the total distance traveled and the workspace occupied by each of the forceps in the experiments.

Motion data was collected from Kinovea and uploaded to Matlab for further analysis. The following algorithm was applied at Matlab:

```
rng('default')
plot(X,Y,'.')
xlim([-30 30])
ylim([-30 30])
k = boundary(X,Y);
hold on;
plot(X(k),Y(k));
A = polyarea(X(k), Y(k));
```

The boundary of the workspace of forceps and motion analysis in the three experiments were shown below;

All the difference in distance travelled and workspace difference were calculated with the following equation;

Distance travelled in experimental set up – Distance travelled in control set up

Workspace in experimental set up – Workspace in control set up.

(a) Experiment 1

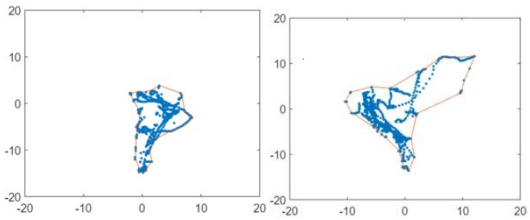


Figure 42. (Left) Boundary of workspace occupied by the typical needle holder as assistive forceps for knot tying of one tissue (Experiment 1A).

(Right) Boundary of workspace occupied by the main suturing forceps for knot tying of one tissue (Experiment 1A)

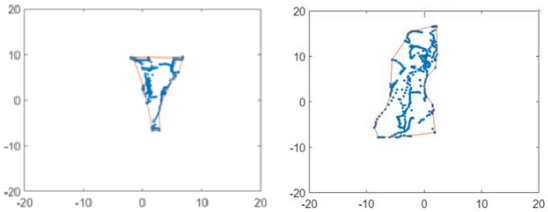


Figure 43. (Left) Boundary of workspace occupied by the DFSA device as assistive forceps for knot tying of one tissue (Experiment 1B).

(Right) Boundary of workspace occupied by the main suturing forceps for knot tying of one tissue (Experiment 1B)

	Knot tying on tissue			
	with typical needle holder		with DFSA	
Type of forceps	Assistive	Main	Assistive	Main
Total distance travelled (cm)	394.30	324.53	268.94	126.29
Difference in distance travelled (cm)			-125.36 (-32%)	-198.23 (-61%)
Workspace (cm^2)	95.95	210.07	67.05	170.06
Workspace difference (cm^2)			-28.9 (-30%)	-40.1 (-19%)

Table 7. Motion analysis for Experiment 1

(b) Experiment 2

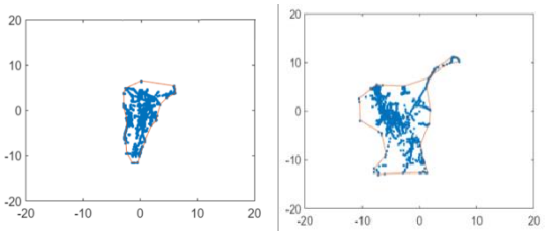


Figure 44. (Left) Boundary of workspace occupied by the typical needle holder as assistive forceps for knot tying between two tissue (Experiment 2A).

(Right) Boundary of workspace occupied by the main suturing forceps for knot tying between two tissue (Experiment 2A)

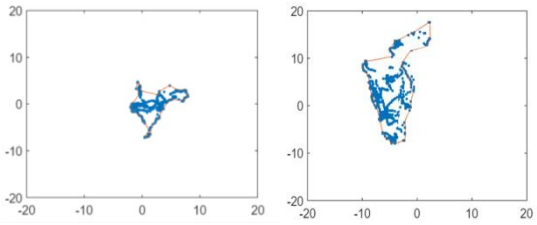


Figure 45. (Left) Boundary of workspace occupied by the DFSA device as assistive forceps for knot tying between two tissue (Experiment 2B).

(Right) Boundary of workspace occupied by the main suturing forceps for knot tying between two tissue (Experiment 2B)

	Suturing and knot tying between 2 tissues			
	with typical needle holder		with DFSA	
Type of forceps	Assistive	Main	Assistive	Main
Total distance travelled (cm)	574.60	467.51	337.08	118.42
Difference in distance travelled (cm)			-237.53 (-41%)	-349.09 (-75%)
Workspace (cm^2)	87.14	176.98	42.06	175.06
Workspace difference (cm^2)			-45.09 (-52%)	-0.92 (-0.5%)

Table 8. Motion analysis for Experiment 2

(c) Experiment 3

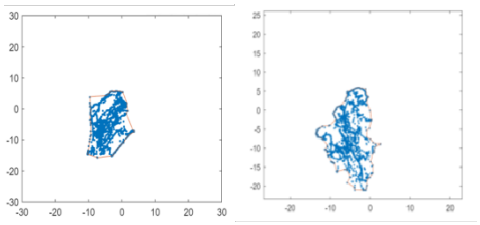


Figure 46. (Left) Boundary of workspace occupied by the typical needle holder as assistive forceps for continuous suturing (Experiment 3A).

(Right) Boundary of workspace occupied by the main suturing forceps for continuous suturing (Experiment 3A)

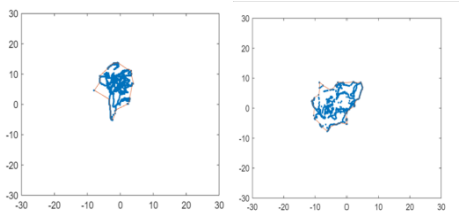


Figure 47. (Left) Boundary of workspace occupied by the DFSA device as assistive forceps for continuous suturing (Experiment 3B).

(Right) Boundary of workspace occupied by the main suturing forceps for continuous suturing (Experiment 3B)

	Continuous suturing			
	with typical needle holder		with DFSA	
Type of forceps	Assistive	Main	Assistive	Main
Total distance travelled (cm)	3713.01	3659.13	2356.54	2056.76
Difference in distance travelled (cm)			-1356.47 (-37%)	-1602.37 (-44%)
Workspace (cm^2)	215.80	229.16	121.07	163.83
Workspace difference (cm^2)			-94.73 (-44%)	-65.33 (-29%)

Table 9. Motion analysis for Experiment 3

Figures 42, 43, 44, 45, 46 and 47 offered a clear visualization of the trajectory of the main suturing forceps and the assistive forceps separately in each of the experiment. The motion figure formed with the use of a typical needle holder was found again to be visually dense, in compared with the use of the DFSA device. The relatively high density of path revealed more movement required by the two forceps in experiment 1A, 2A, and 3A than the two forceps in experiment 1B, 2B, and 3B. This was consistent to the numerical result about the total distance travelled by the forceps. According to the table 7, 8, and 9, the total distance travelled by the DFSA forceps was 32% to 41% less than that by a typical needle holder in the three sets of experiments. And, the total distance travelled by the main suturing forceps with the use of the DFSA device as assistance shortened by 44% in continuous suturing, and decreased more than half in knot tying on a tissue and suturing and knot tying between two tissues.

On top of the consideration on the total distance travelled by the forceps, their respective workspaces were measured. The figures 42, 43, 44, 45, 46 and 47 showed the boundary of the trajectory, and the corresponding workspace was calculated accordingly and displayed at the tables 7, 8 and 9. For suturing and knot tying between two tissues, the use of DFSA occupied less than 52% of the workspace of the typical needle holder, despite the workspace difference for the main suturing forceps was minimal. As for the suturing on a tissue, both the DFSA forceps and the main suturing forceps occupied a much smaller workspace than the task with the typical needle holder. The reduction in workspace was 30% and 19% respectively for the assistive and main suturing forceps. An even greater reduction was found for the continuous suturing task where the DFSA forceps occupied 44% less than the typical needle holder, and the main suturing forceps required nearly 30% less space with the use of a DFSA forces instead of a typical needle holder.

Other than the percentage change, the numerical change in the total distance travelled and workspace required by the assistive and main suturing forceps in continuous suturing worth notice. The DFSA device traveled around 1350cm less and occupied around 95cm^2 less than a typical needle holder. And, with the use of the DFSA device, the main suturing forceps also travelled around 1600cm less and occupied 65cm^2 less.

(c) Comments from the experimenters

A review session was also conducted on day 2 with the subjects after the completion of tasks. They revealed higher preference towards utilization of DFSA device as the hook could minimize their need of dropping and picking up the needle, and picking up the needle with the needle holder in a right position. They also reported the utilization of the sliding hook to pull the strand was easier than using the needle holder. However, two of the subjects mentioned about the delicacy of the controlling part of the hook. Strengthening of the controlling part could allow more efficient manipulation of the hook in suturing and knot tying.

(E) Discussion

Numerous researches were introduced in the past years on improving the design of single-handed suturing devices. However, there was still limitation of the single-handed suturing devices that it had to rely on an additional forceps for knot tying, because knot tying of tissue required the directional movement of the devices such that tip and the end of the thread could be pulled towards opposite direction. Though some suturing devices with pre-tied knots were invented in the recent years, the loading force of the knot and the reusability of the instrument remained a concern. The use of assistive device in knot tying seemed to be inevitable for tying a knot with optimal loading force controllable by the surgeon, while the DFSA device was one of a feasible prototype.

The experimental result consistently showed that the use of DFSA device instead of a typical needle holder as assistance for suturing and knot tying had significantly reduced the time needed for the procedures. This could be due to the relatively easy manipulation of thread with the sliding hook and the minimization of time needed for dropping and picking up of the needle. The most significant reduction in time was offered by the use of the DFSA device in compared to the use of the typical assistive needle holder in the continuous suturing task. Continuous suturing required frequent dropping of needle to free the two forceps to handle the suture line after each puncture, and the pulling of long thread required intermittent grasping by the two forceps. However, this could be largely resolved by the use of the DFSA device which provided the sliding hook feature to pull the thread by simply manipulating the hook handle with the index finger, allowing the reduction in time use up to 27%. With the use of the DFSA device, the operation time could be lessened, minimizing the risk of patient's complications, and surgeon's risk of errors due to fatigue.

The device facilitated surgeon in thread management with minimal locomotion of the device, which served exceptional benefit in the confined workspace for laparoscopic surgeries. Conventionally, the surgeon used two typical needle holders to grasp the thread intermittently to haul the thread away from the suture site such that the end of the thread could be closed to the suture site for knot tying. The pulling motion often occupied a lot of workspace and was time-consuming. However, with the DFSA device, simply by sliding the hook backward, the thread on the hook was dragged away from the puncture site, while the body and tip of the DFSA device could be kept relatively stationery. Moreover, the experimental result showed that the reduction in instrument's movement was not only found for the assistive forceps, but

also the main suturing forceps. This allowed the manipulation of the needle and thread within the camera viewing field, lowering the risk of injury to the surrounding tissues or organ.

Rather than staying stationery, the DFSA device could be used to perform other functions. Since the hook sliding feature of the DFSA device allowed the manipulation of thread independent form the tip of the device, the tip of the DFSA device was free for other functions such as holding the tissue static for suturing and removing tissues from the suture site for better vision.

Furthermore, the constant dragging force formed with the DFSA device on the thread helped reduced the chance of thread twisting. The confined workspace, the frequency dropping and re-picking of needle, and the inherent memory of shape of the suture line often resulted in thread twisting. The unwanted knot could be hardly untwisted with the laparoscopic instruments, and worse still, the knot fastened at the middle of the suture could lead to huge frustration since the complete suture had to be removed. The type of materials and the size of the suture line could both affect the tendency of twisting. For example, PDS had strong shape memory and the thin thread like 3.0 or 4.0 vicryl were prone to twisting, however, these sutures were frequently used in the laparoscopic surgeries. The DFSA device could help solve the twisting problem by holding the thread straight, with the dragging force maintained between the hook and the body tissue, as well as the force between the hook and the main suturing needle holder, forming a triangle among the three. This lessened the risk of twisting or obstructing field of view by the thread.

Last but not least, the simple principle of DFSA device might require little time for the surgeon to master the skills of using the device. In the experiment of this project, the three experimenters had no prior experience in using laparoscopic devices, but they could generally master the skills of using the DFSA device after 30 minutes practice, let alone the surgeons.

(F) Limitation and improvement

As acknowledging the effectiveness and efficiency of the DFSA device, the following concern of analysis of experiment and limitation of the design were raised.

Though the favoring results of time and working area, the analysis of workspace calculation was limited to 2-dimensional, lacking the analysis of depth. Nevertheless, the DFSA forceps was designed to be operating in a 3-dimensional body cavity, thus the depth of workspace should also be considered. It was also suggested to further evaluate the hook's load tolerance and dragging force to ensure a safe application on patients.

Regarding the design, there are several areas that can be considered,

First, the scale of this DFSA device was not ready for commercial production. It was up-scaled to twice of the planned size for better illustration of idea and accommodating the limited resolution of available 3D printer. For practical use, the main instrument body of DFSA device should be down-scaled to have the diameter as 5mm, yet possibly results in the hook feature being too small. If the diameter of the device body was to be kept at 10mm, the hook would be large enough to catch and manipulate the suture thread easily. However, the blades of the device should be scaled down to allow fine manipulation of tissues.

Second, the controlling handle of sliding hooking could be further modified to be more ergonomics to allow efficient manipulation of sliding hook. It was also anticipated that the utilization of tougher materials could also improve the manipulation of the sliding hook such that sufficient dragging force could be generated by pulling the hook, without breaking the feature.

Third, the angle of rotation of the tip of the current design was not adjustable. A controlling wheel connecting the inner stem of the device could be added to the handle of the device for controlling the rotational motion of the tip. And, the teeth of the blades should be refined to provide higher friction and grasping force.

With the improvement on the design and more testing on its function and effectiveness, the DFSA device was anticipated to effectively facilitate the suturing and knot tying procedure and could be highly applicable to laparoscopic surgeries. In view of the advancement in robotics surgery, despite a rigid sliding hook would be hard to be

accommodated at the flexible body of the robotic arm, the concept of having a hook for thread management could be explored.

(G) Conclusion

The superior advantages of minimally invasive surgery made it to be increasingly common to be an operative treatment for a great variety of diseases. In the minimally invasive surgery, suturing was one of the main techniques essentially required to be mastered by the surgeon, but it was complicated and often time-consuming, thus a literature review upon the current laparoscopic suturing device was done, and several common issues were identified, including, the limited tip angulation and depth of penetration by the device and the difficult management of the long suturing thread during knot tying and suturing. Due to the fact that single-hand suturing device allowing intracorporeal knot tying was found to have superior advantages over other kinds of suturing device, a assistance device, named Dual-function suture assistance, was suggested accordingly to assist in knot tying and suturing. The DFSA device was experimentally proven to shorten the time and reduce the workspace required for suturing and knot tying. Having the needle solely handled by one hand, and the thread managed by the sliding hook, the tip of the DFSA device could be free for other purpose like holding up a tissue. And the constant dragging force maintained among the thread, the hook and the tissue could minimize the risk of thread twisting. However, more testing had to be conducted and the design could be further modified before the application to clinical setting. As the utilization of DFSA device was easy and involved little training, it was anticipated that this design could be widely accepted in laparoscopic surgery, or further incorporated into the robotics surgery.

Appendix 1 - Experimental result – data

(A) Experiment I: Tying a knot on a tissue

Experiment 1A-D1

	Trials	Time required (s)
Subject 1	1	52
	2	54
	3	51
	4	52
	5	48
Subject 2	1	68
	2	60
	3	66
	4	60
	5	55
Subject 3	1	46
	2	48
	3	48
	4	39
	5	41

Experiment 1B-D1

	Trials	Time required (s)
Subject 1	1	44
	2	50
	3	43
	4	36
	5	36
Subject 2	1	60
	2	58
	3	46
	4	71
	5	52
Subject 3	1	41
	2	34
	3	34
	4	39
	5	42

The time required to complete Day 1 Experiment I: Tying a knot on a tissue

Experiment 1A-D2

	Trials	Time required (s)
Subject 1	1	49
	2	42
	3	51
	4	44
	5	47
Subject 2	1	70
	2	62
	3	52
	4	54
	5	53
Subject 3	1	45
	2	45
	3	38
	4	40
	5	38

Experiment 1B-D2

	Trials	Time required (s)
Subject 1	1	42
	2	38
	3	36
	4	37
	5	36
Subject 2	1	62
	2	59
	3	45
	4	50
	5	51
Subject 3	1	42
	2	38
	3	34
	4	33
	5	35

The time required to complete Day 2 Experiment I: Tying a knot on a tissue

(B) Experiment II: Suturing and knot tying between two tissues

Experiment 2A-D1

	Trials	Time required (s)
Subject 1	1	48
	2	45
	3	48
	4	41
	5	43
Subject 2	1	52
	2	54
	3	46
	4	56
	5	48
Subject 3	1	38
	2	35
	3	30
	4	35
	5	32

Experiment 2B-D1

	Trials	Time required (s)
Subject 1	1	45
	2	35
	3	27
	4	34
	5	31
Subject 2	1	51
	2	42
	3	48
	4	42
	5	40
Subject 3	1	32
	2	34
	3	33
	4	32
	5	27

The time required to complete Day 1 Experiment II: Suturing and knot tying between two tissues

Experiment 2A-D2

	Trials	Time required (s)
Subject 1	1	54
	2	47
	3	50
	4	54
	5	47
Subject 2	1	48
	2	49
	3	52
	4	43
	5	44
Subject 3	1	35
	2	33
	3	30
	4	39
	5	32

Experiment 2B-D2

	Trials	Time required (s)
Subject 1	1	40
	2	39
	3	37
	4	37
	5	38
Subject 2	1	48
	2	40
	3	43
	4	39
	5	39
Subject 3	1	33
	2	27
	3	33
	4	31
	5	32

The time required to complete Day 2 Experiment II: Suturing and knot tying between two tissues

(C) Experiment III: Continuous suturing

Experiment 3A-D1

	Trials	Time required (s)
Subject 1	1	91
	2	89
	3	76
	4	84
	5	67
Subject 2	1	132
	2	116
	3	103
	4	107
	5	110
Subject 3	1	80
	2	73
	3	69
	4	77
	5	67

Experiment 3B-D1

	Trials	Time required (s)
Subject 1	1	79
	2	55
	3	59
	4	51
	5	57
Subject 2	1	97
	2	99
	3	91
	4	97
	5	89
Subject 3	1	55
	2	51
	3	55
	4	57
	5	55

The time required to complete Day 1 Experiment III: Continuous suturing

Experiment 3A-D2

	Trials	Time required (s)
Subject 1	1	82
	2	75
	3	89
	4	65
	5	83
Subject 2	1	134
	2	130
	3	115
	4	128
	5	121
Subject 3	1	80
	2	73
	3	69
	4	77
	5	67

Experiment 3B-D2

	Trials	Time required (s)
Subject 1	1	68
	2	54
	3	62
	4	50
	5	51
Subject 2	1	125
	2	105
	3	102
	4	96
	5	98
Subject 3	1	60
	2	49
	3	58
	4	55
	5	56

The time required to complete Day 2 Experiment III: Continuous suturing

Appendix 2: Data analysis

	Subject / Part	1	2	3
Experiment I	1A	51.4	61.8	44.4
	1B	41.8	57.4	38
	Time difference	**-9.6**	**-4.4**	**-6.4**
	Percentage change	**-18.7**	**-7.1**	**-14.4**
Experiment II	2A	45	51.2	34
	2B	34.4	44.6	31.6
	Time difference	**-10.6**	**-6.6**	**-2.4**
	Percentage change	**-23.6**	**-12.9**	**-7.1**
Experiment III	3A	81.4	113.6	73.2
	3B	60.2	94.6	54.6
	Time difference	**-21.2**	**-19**	**-18.6**
	Percentage change	**-26**	**-16.7**	**-25.4**

Average time required (s) by individual subject in each experiment at Day 1

	Subject / Part	1	2	3
Experiment I	1A	46.6	58.2	41.2
	1B	37.8	53.4	36.4
	Time difference	**-8.8**	**-4.8**	**-4.8**
	Percentage change	**-18.9**	**-8.2**	**-11.7**
Experiment II	2A	49.6	47.2	41.8
	2B	38.2	41.8	31.2
	Time difference	**-11.4**	**-5.4**	**-2.6**
	Percentage change	**-23**	**-11.4**	**-7.7**
Experiment III	3A	78.8	125.6	73.2
	3B	57	105.2	55.6
	Time difference	**-21.8**	**-20.4**	**-17.6**
	Percentage change	**-27.7**	**-16.2**	**-24**

Average time required (s) by individual subject in each experiment at Day 2

Subject / Experiment	1	2	3
I	-0.2	-1.1	2.7
II	0.6	1.5	-0.6
III	-1.7	0.5	1.4

Comparison of the percentage difference of the time needed for completing each set of experiment at Day 1 and Day 2

	Subject / Part	1	2	3
Experiment I	1A	49	60	42.8
	1B	39.8	55.4	37.2

	Time difference	**-9.2**	**-4.6**	**-5.6**
Experiment II	2A	47.3	49.2	37.9
	2B	36.3	43.2	31.4
	Time difference	**-11**	**-6**	**-2.5**
Experiment III	3A	80.1	119.6	73.2
	3B	58.6	99.9	55.1
	Time difference	**-19.6**	**-19.7**	**-18.1**

Average time required (s) in each experiment for the cumulative result obtained from Day 1 and Day 2

Reference

Benson, S. P. (2012). *U.S. Patent No. 8,241,307*. Washington, DC: U.S. Patent and Trademark Office.

Breslin, T., Hart, C. C., Wachli, S., Hoke, A., Poulsen, N., Palermo, M., ... & Garces, A. (2020). *U.S. Patent No. 10,535,281*. Washington, DC: U.S. Patent and Trademark Office.

Calland, J. F., Tanaka, K., Foley, E., Bovbjerg, V. E., Markey, D. W., Blome, S., ... & Jones, R. S. (2001). Outpatient laparoscopic cholecystectomy: patient outcomes after implementation of a clinical pathway. *Annals of surgery*, *233*(5), 704.

Dorsey, J. H., Sharp, H. T., Chovan, J. D., & Holtz, P. M. (1995). Laparoscopic knot strength: a comparison with conventional knots. *Obstetrics & Gynecology*, *86*(4), 536-540.

El-Shazly, M. A., Moon, D. A., & Eden, C. G. (2007). Laparoscopic pyeloplasty: status and review of literature. *Journal of endourology*, *21*(7), 673-678.

Gallagher, A. G., McClure, N., McGuigan, J., Ritchie, K., & Sheehy, N. P. (1998). An ergonomic analysis of the fulcrum effect in the acquisition of endoscopic skills. *Endoscopy*, *30*(07), 617-620.

Assute Europe Suture Chirurgiche. (2016). *Endo 260* [Brochure]. https://www.assuteurope.com/catalog/Endo_360_Brochure_en.pdf

Gawande, A. A., Zinner, M. J., Studdert, D. M., & Brennan, T. A. (2003). Analysis of errors reported by surgeons at three teaching hospitals. *Surgery*, *133*(6), 614-621.

Göpel, T., Härtl, F., Schneider, A., Buss, M., & Feussner, H. (2011). Automation of a suturing device for minimally invasive surgery. *Surgical endoscopy*, *25*(7), 2100-2104.

Gorski, S., Taylor, S. V., & McGinley, K. B. (2020). U.S. Patent Application No. 16/565,065.

Hart, S. (2012). The benefits of automated suturing devices in gynecologic endoscopic surgeries: the Endo Stitch and SILS Stitch. *Surgical technology international*, *22*, 159-164.

Lee, Y. H., Kim, M. J., Chong, G. O., Hong, D. G., & Lee, Y. S. (2015). "YS knot: a new technique for a tension-controlled slip knot using a trocar," Obstetrics & Gynecology Science, vol. 58, no. 2, pp. 171–174.

Lim, S., Ghosh, S., Niklewski, P., & Roy, S. (2017). Laparoscopic suturing as a barrier to broader adoption of laparoscopic surgery. *JSLS: Journal of the Society of Laparoendoscopic Surgeons*, *21*(3).

Murphy, D.L. (1995). A new method of laparoscopic instrument knot tying. *Surgical Technology International*, *4*, 199–202.

Nagai, H., & Araki, S. (1999). Semiautomatic suturing device (Maniceps®) for laparoscopic surgery. *Surgical endoscopy*, *13*(2), 191-193.

Omar, S. K., (2008), Role of extracorporeal knots in laparoscopic surgery.

Risucci, D., Geiss, A., Gellman, L., Pinard, B., & Rosser, J. (2001). Surgeon-specific factors in the acquisition of laparoscopic surgical skills. *The American Journal of Surgery*, *181*(4), 289-293.

Scatizzi, M., Kröning, K. C., Borrelli, A., Andan, G., Lenzi, E., & Feroci, F. (2010). Extracorporeal versus intracorporeal anastomosis after laparoscopic right colectomy for cancer: a case–control study. *World journal of surgery*, *34*(12), 2902-2908.

Smit, S. (2010, May 18). Covidien Launches SILS™ Stitch Suturing Device for Advanced Laparoscopic Surgery. Retrieved December 05, 2020, from https://www.businesswire.com/news/home/20100518005863/en/Covidien-Launches-SILS%E2%84%A2-Stitch-Suturing-Device-Advanced

Tu, F. C., Wu, W. Y., Lin, H. H., & Hsiao, S. M. (2012). Laparoscopic intracorporeal knot tying using a novel device. *Surgical endoscopy*, *26*(3), 872-876.

Tu, F. C. (2017). *U.S. Patent No. 9,826,974*. Washington, DC: U.S. Patent and Trademark Office.

Wadlund, D. L. (2006). Laparoscopy: risks, benefits and complications. *Nursing Clinics*, *41*(2), 219-229.

Weizman, N. F., Maurer, R., Einarsson, J. I., Vitonis, A. F., & Cohen, S. L. (2015). Survey on barriers to adoption of laparoscopic surgery. *Journal of surgical education*, *72*(5), 985-994.

Woodard Jr, J. A., & Lesko, J. R. (2014). *U.S. Patent No. 8,702,732*. Washington, DC: U.S. Patent and Trademark Office.

Woodard Jr, J. A., Shelton IV, F. E., Lesko, J. R., & Baxter III, C. O. (2015). U.S. Patent No. 9,168,037. Washington, DC: U.S. Patent and Trademark Office.

Xu, A. A., Zhu, J. F., & Su, Y. (2015). Towards a better knot: Using mechanics methods to evaluate three knot-tying techniques in laparo-endoscopic single-site surgery. *Journal of minimal access surgery*, *11*(4), 241.

Y. H. Lee, M. J. Kim, G. O. Chong, D. G. Hong, J. & Lee, Y. S. (2015). “YS knot: a new technique for a tension-controlled slip knot using a trocar,” Obstetrics & Gynecology Science, vol. 58, no. 2, pp. 171–174

Yoho, R. A., O’Neil, D. A., & Romaine, J. J. (2015). Duration of General Anesthesia and Surgical Outcome.

COVIDIEN. (2008). EndoStitch: Suturing Instrument Intracorporeal Knot Tying Manual. Norwalk, CT.

Fernandes, T., Oliveira, M. I., Castro, R., Araújo, B., Viamonte, B., Cunha, R. (2014). "Bowel wall thickening at CT: simplifying the diagnosis". Insights into Imaging. 5 (2): 195–208.

Nandita, P., Rishma, D.P., Hrishikesh, D.P. (2012). Textbook of Hysteroscopy. JP Medical Ltd. pp. 135