



Suture-Tool: A Mechanical Needle Driver for Standardized Wound Closure

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Abstract

Introduction A laparotomy is commonly required to gain abdominal access. A safe standardized access and closure technique is warranted to minimize abdominal wall complications like wound infections, burst abdomen and incisional hernias. Stitches are recommended to be small and placed tightly, obtaining a suture length-to-incision length (SL/WL) ratio of $\geq 4:1$. This can be time-consuming and difficult to achieve especially following long trying surgical procedures. The aim was to develop and evaluate a new mechanical suture device for standardized wound closure.

Methods A mechanical suture device (Suture-tool) was developed in collaboration between a medical technology engineer team with the aim to achieve a standardized suture line of high quality that could be performed speedy and safe. Ten surgeons closed an incision in an animal tissue model after a standardized introduction of the instrument comparing the device to conventional needle driver suturing (NDS) using the 4:1 technique. Outcome measures were SL/WL ratio, number of stitches and suture time.

Results In total, 80 suture lines were evaluated. SL/WL ratio of ≥ 4 was achieved in 95% using the Suture-tool and 30% using NDS ($p < 0,001$). Number of stitches was similar. Suture time was 30% shorter using the Suture-tool compared to NDS (2 min 54 s vs. 4 min 5 s; $p < 0,001$).

Conclusions The mechanical needle driver seems to be a promising device to perform a speedy standardized high-quality suture line for fascial closure.

Introduction

Surgical procedures of the abdominal cavity commonly require open surgical access. These patients have a risk of abdominal wall complications such as wound infection, burst abdomen and incisional hernia formation. Incisional

hernia is a frequent long-term problem with an incidence between 10 and 69% depending on the type of surgery, type of incision, length of surgery, comorbidities, method of follow-up and patient characteristics [1, 2]. In patients undergoing elective open abdominal surgery through a midline laparotomy, an incisional hernia was seen in around 12% after 1 year and the incidence increases gradually to > 20% after 3 years [3]. Many factors for the development of an incisional hernia are patient dependent, but the surgical technique when opening and closing the abdomen at laparotomy is another important risk factor for wound complications. A midline laparotomy should always be kept strict to the midline without entering the muscular compartments that would create weak areas. The closure

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technique is also a factor that can be influenced. It is recommended that the suture length-to-wound length (SL/WL) ratio is ≥ 4 and that the ratio is acquired with small stitches put tightly [4]. This might be time-consuming and difficult to achieve following long and trying surgical procedures.

A device for producing a “mechanical” suture line has previously been used for laparoscopic surgery, especially to perform a fundoplication (Endo Stitch™ Suturing Device, Medtronic, Minneapolis, Minnesota, USA). There is, however to our knowledge, no available suturing device for standardized closure of the abdominal wall aponeurosis. The aim of this study was to develop and evaluate a suture device for standardized abdominal wound closure.

Materials and method

Mechanical needle driver—Suture-tool

Suture-tool was developed in collaboration with an engineer team. It is a hand-held “sewing machine” using a

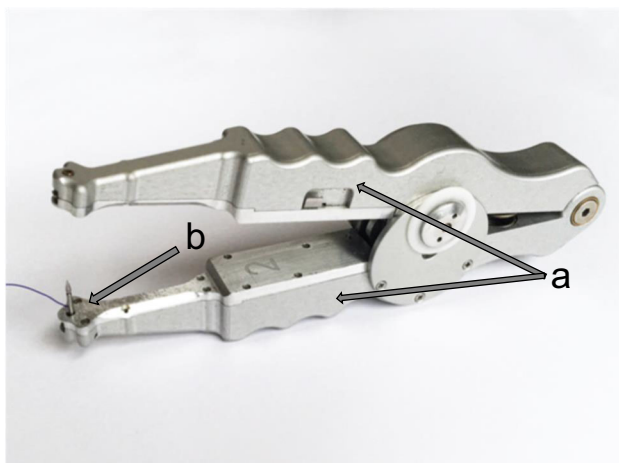


Fig. 1 Suture-tool is hand-held and hand-powered and consists of two jaws (a). Each jaw has a distally placed hole that locks the needle (b). While compressing the device the needle is automatically transferred from one jaw to the other. The needle is double ended with a centrally attached thread

double pointed needle with a centrally attached thread (Fig. 1). Suture-tool has a guide that facilitates correct stitch placement. Jaws are compressed to pass the needle through the tissue, and thereafter, the needle is automatically picked up by the opposing jaw. Hereafter, Suture-tool is let open releasing the tissue. The sequence is repeated on the other side of the incision, and thus, a complete stitch is performed according to Fig. 2.

Abdominal wall model

The model used prepared fascia from elk abdominal wall mounted in a wooden box. Elk fascia resembles human abdominal wall midline aponeurosis. A 12-cm-long incision was prepared in the fascia (Fig. 3).

Suture-tool suturing

Surgeons were introduced to Suture-tool and the technique of suturing by watching an instruction film. Suturing was practiced and participants were licensed to participate in the study when 10 stitches were made with ease.

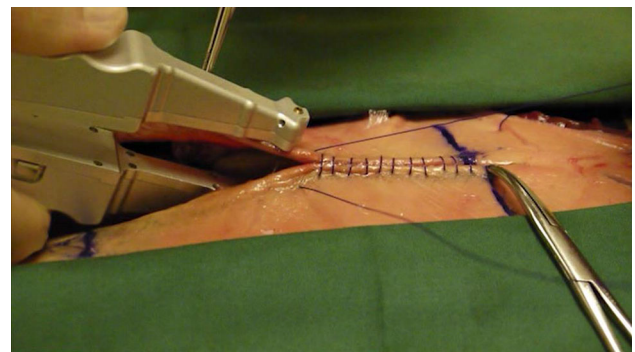


Fig. 3 Device suturing in the animal tissue model. Start and endpoints of the suturing course marked with blue ink. Start knot is replaced by fixating the thread with a clamp not to include tying time in the test

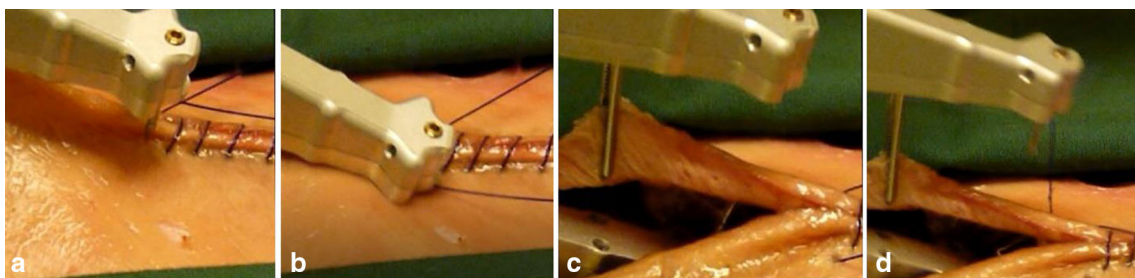


Fig. 2 Suture-tool technique with straight needle. **a** Device positioned for an “over-stitch.” **b** Device compressed and needle passed through tissue. **c** Device opened and positioned for an “under-stitch.” **d** Needle transferred to upper jaw completing a whole stitch

Needle driver suturing, NDS

A needle driver (Mayo-Hegar 16 cm, Stille AB, Sweden) and a 36-mm-semicurved CT-1 1/2 circle taper-point PDS II needle (Ethicon, Sommerville, NJ, USA) was used to produce the manual suturing. The NDS sequence is described in Fig. 4.

Test protocol

The surgeons were recorded for subspecialty, years as licensed surgeon, gender and handedness. The suture was 70 cm long for both techniques. Sutures were anchored at start and finish with clamps. Participants were instructed to aim for a SL/WL ratio of ≥ 4 . Number of practiced closures with Suture-tool was recorded. The test included closing 8 incisions alternating between Suture-tool and NDS. Number of stitches, remaining suture length and suturing time were registered.

Surgeon’s evaluation of the instrument

A questionnaire was constructed including 11 questions on construction and handling of the Suture-tool using visual analog scales for evaluation by test participants according to Fig. 5.

Ethical consideration

The regional ethical review committee was contacted for ethical approval. No approval was needed to use elk fascia.

Statistics

Differences between Suture-tool suturing and NDS regarding number of stitches, SL/WL ratio, suturing time were tested using Mann–Whitney’s *U* test. To assess differences in the proportion of SL/WL ratio between device suturing and NDS, the Fisher’s exact test was used. Statistical significance was considered for *p* values < 0.05 . Statistical analyses were performed in Stata 14 (StataCorp).

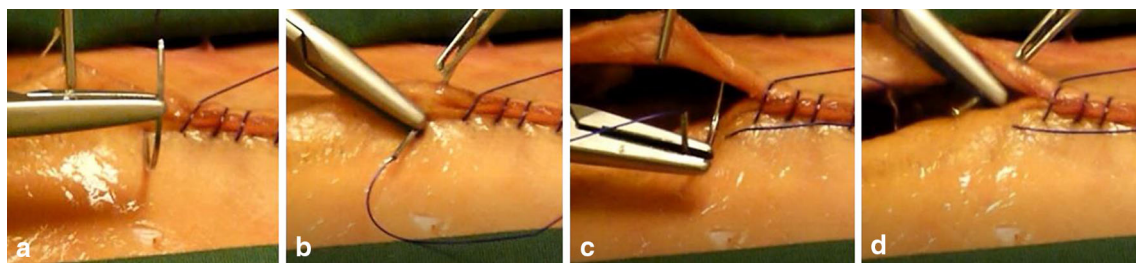
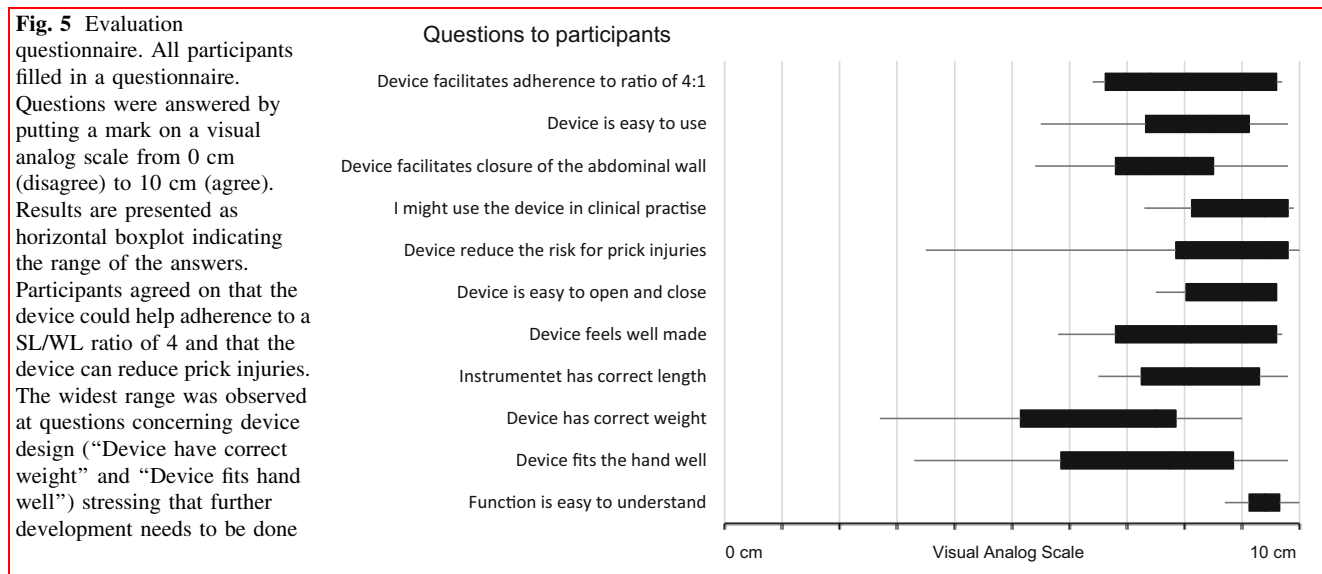


Fig. 4 NDS suturing technique with curved needle. **a** Needle grasped by the needle driver and positioned for an “over-stitch.” **b** Needle passed through the tissue supported by the forceps (**b**). Needle

grasped by the needle driver and repositioned for an “under-stitch” (**c**). Needle passed through the second tissue supported by the forceps completing the whole stitch



2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.)

Results

Characteristics of participants

Ten surgeons participated and had a median experience as “licensed” surgeons of 9 (1–25) years and were sub-specialized as general ($n = 4$), vascular ($n = 3$) or colorectal surgeons ($n = 3$). All were right-handed. Three were females. They used in median 4 (3–8) incision closures for practice with Suture-tool.

Suturing test

In total, 80 incision closures were completed, 40 using each technique. Variables including number of stitches and length of suture used, comparing Suture-tool to NDS, are reported in Table 1. Median SL/WL ratio was 4.5 using the Suture-tool and 3.8 using NDS ($p < 0,001$). A SL/WL ratio of ≥ 4 was reached in 95% of suture lines using the Suture-tool versus 30% using NDS ($p < 0.001$). Suturing time was 2 min 54 s using the Suture-tool and 4 min 5 s using NDS ($p < 0.001$) (Fig. 6).

Evaluation of suture-tool

The evaluation of the instrument by the participants was overall positive according to Fig. 5. The median VAS score was above 8 cm in 8 of 11 domains. The highest score was achieved for “Function is easy to understand” (VAS 9.4 cm). The lowest score was seen for instrument design “Device has correct weight” (VAS 6.5 cm) and “Device fits the hand well” (VAS 7.2 cm)

Discussion

Incisional hernia imposes a large economic and social burden globally. It is of increasing interest to prevent rather than repairing incisional hernias. This can be achieved by

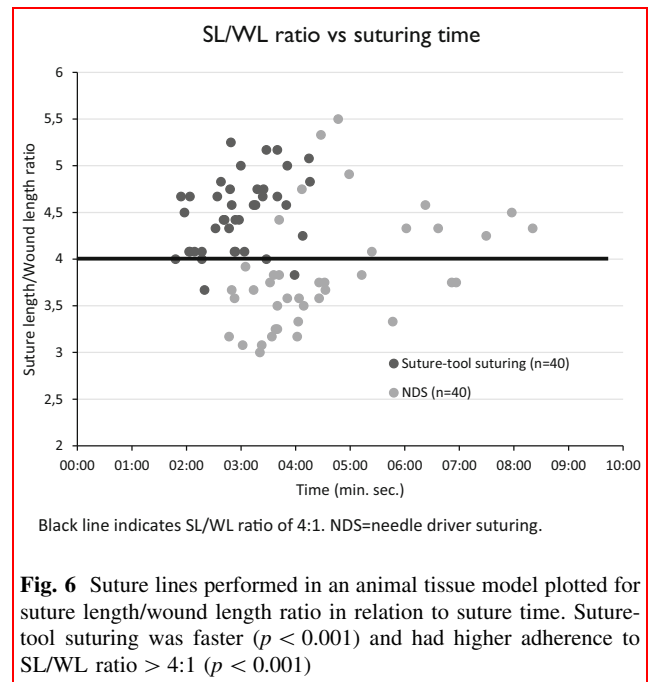


Fig. 6 Suture lines performed in an animal tissue model plotted for suture length/wound length ratio in relation to suture time. Suture-tool suturing was faster ($p < 0.001$) and had higher adherence to SL/WL ratio $> 4:1$ ($p < 0.001$)

intraoperative actions for quality of both wound incision and suture technique. This study demonstrates that the Suture-tool substantially facilitates a speedy performance of a standardized abdominal wall closure achieving a high frequency of SL/WL ratio of ≥ 4 compared to NDS.

A surgical technique with SL/WL ratio of ≥ 4 deployed with small stitches put tightly is the recommended method and can be used in all patients [4]. Disadvantages are longer time for closure, technique is user dependent, and optimal ratio can be challenging to achieve, especially when incision is long and at emergency surgery, but also for concentration difficulties after long operations.

A strength of the study is that surgeons of various experience participated in the testing showing the same high performance. A limitation is that it was performed on a prepared fascia where the suturing process was not affected by other abdominal wall structures like skin and subcutaneous fat. The traction of the thread by the assistant was not standardized which could also influence the thread length used. This is though in accordance with a conventional clinical situation.

Table 1 Suture variables comparing Suture-tool suturing to conventional needle driver suturing (NDS)

	Suture-tool suturing ($n = 40$)	NDS ($n = 40$)	p values
Suture time min. sec.; median (range)	2 m 54 s (1 m 48 s–4 m 16 s)	4 m 5 s (2 m 47 s–8 m 21 s)	$p < 0.001$
SL/WL ratio median (range)	4.5 (3.7–5.3)	3.8 (3–5.5)	$p < 0.001$
SL/WL ratio ≥ 4 %	95% (38/40)	30% (12/40)	$p < 0.001$
Number of stitches median (range)	25 (21–35)	26 (21–35)	$p = 0.125$
Length of suture centimeter: median (range)	54.4 (44–63)	45 (36–66)	$p < 0.001$

Prophylactic mesh augmentation (PMA) has been advocated in patients with high risk of developing an incisional hernia, for instance patients undergoing aortic aneurysm surgery, obese patients and patients undergoing colorectal surgery. Several studies have shown reduced incisional hernia formation with PMA [5]. The disadvantages of PMA are the risk of mesh infection, longer operating time and that mesh implantation requires specific surgical skills.

The questionnaire used to evaluate the instrument was useful in identifying ergonomic details that could be improved. Suture-tool is redesigned and made lighter and slimmer.

Suture-tool is a promising device to perform a speedy standardized high-quality suture line for fascial closure. Further studies are needed to evaluate the device in the clinical setting. We plan a comparative Suture-tool to NDS study in the autopsy setting to assess whether findings can be repeated in humans. Results from these studies will provide scientific grounds for a clinical study.

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Compliance with ethical standards

Conflict of interest GB is CEO and founder of Suturion AB; AM has no disclosures.

Statement of animal rights The regional ethical review committee was contacted, and no ethical approval was needed to use elk fascia from a local distributor.

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