



Stapled fascial suture: ex vivo modeling and clinical implications

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Abstract

Background Recently, in the field of abdominal wall repair surgery, some minimally invasive procedures introduced the use of staplers to provide a retromuscular prosthetic repair. However, to the knowledge of the authors, there are little data in the literature about the outcomes of stapled sutures adoption for midline reconstruction. This study aims to investigate the biomechanics of stapled sutures, simple (stapled), or oversewn (hybrid), in comparison with handsewn suture. From the results obtained, we tried to draw indications for their use in a clinical context.

Methods Human cadaver fascia lata specimens, sutured (handsewn, stapled, or hybrid) or not, underwent tensile tests. The data on *strength* (maximal stress), *ultimate strain* (deformability), *Young's modulus* (rigidity), and *dissipated specific energy* (ability to absorb mechanical energy up to the breaking point) were recorded for each type of specimens and analyzed.

Results Stapled and hybrid suture showed a significantly higher *strength* (handsewn 0.83 MPa, stapled 2.10 MPa, hybrid 2.68 MPa) and a trend toward a lower *ultimate strain* as compared to manual sutures (handsewn 344%, stapled 249%, hybrid 280%). Stapled and hybrid sutures had fourfold higher *Young's modulus* as compared to handsewn sutures (handsewn 1.779 MPa, stapled 7.374 MPa, hybrid 6.964 MPa). Handsewn and hybrid sutures showed significantly higher *dissipated specific energy* (handsewn 0.99 mJ-mm³, stapled 0.73 mJ-mm³, hybrid 1.35 mJ-mm³).

Conclusion Stapled sutures can resist high loads, but are less deformable and rigid than handsewn suture. This suggests a safer employment in case of small defects or diastasis (< W1 in accord to EHS classification), where the presumed tissutal displacement is minimal.

Oversewing a stapled suture improves its efficiency, becoming crucial in case of larger defects (> W1 in accord to EHS classification) where the expected tissutal displacement is maximal. Hybrid sutures seem to be a good compromise.

Keywords Diastasis recti · Stapled repair · Tensile test · Anterior rectus sheath plication · Laparo-endoscopic · Minimally invasive

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In the field of abdominal wall repair surgery, the minimally invasive techniques are gaining an increasing interest. In

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1993, LeBlanc first described laparoscopic hernia repair with the placement of an intraperitoneal mesh that provided a shorter length of hospital stay, less surgical site infection, and a recurrence rate similar to open techniques [1]. Afterward, to avoid the related risk of mesh adhesions with the abdominal viscera, which can lead to enteric fistulae, infections, and prosthesis displacement, several techniques have been developed to combine the advantages of minimally invasive surgery with the placement of a retromuscular mesh. Trans-abdominal preperitoneal approach (TAPP), totally endoscopic sublay repair (TES), endoscopic mini/less open sublay technique (EMILOS), retrorectal sublay mesh repair, and extended-view totally extraperitoneal approach (e-TEP) combine the advantages of laparoscopic surgery, with the consolidated results of the Rives–Stoppa repair, which is still considered the gold standard in ventral hernia repair [2–8].

Recently, some minimally invasive procedures use staplers to provide a retromuscular prosthetic repair [9–13].

Staplers are widely used for gastrointestinal, vascular, and thoracic surgery [14–17].

The advantages of stapling include rapidity and reproducibility, the absence of knots, a homogeneous tension along the suture line, and the chance of employment in laparoscopic surgery [2].

On the other hand, it has been also reported that stapling failure can occur [18–23].

Oversewn stapled suture line appears to be correlated with lower complications rate, such as leakage and bleeding [24–27].

However, to the knowledge of the authors, there are a little data in the literature about the outcomes of stapled sutures adoption for midline reconstruction [28].

Even the clinical indications remain vague and are mainly based on the experience of each surgeon.

This study aims to investigate the biomechanics of stapled sutures, handsewn, or hybrid, on fascial aponeuroses, to understand their behavior under traction, their strengths, but above all their critical issues, trying to make these scientific data useful for technological improvements and in the clinical context.

Materials and methods

Design of the study and data collection

Fascia lata was harvested from human cadavers. Tensile tests were performed on four types of samples:

- Intact (unsutured) fascia lata (number of samples $n = 5$);
- Fascia lata with handsewn suture ($n = 5$);
- Fascia lata with stapled suture ($n = 6$);

- Fascia lata with hybrid suture ($n = 5$).

The primary outcomes were as follows:

1. To compare the mechanical properties of handsewn, stapled, and hybrid sutures.
2. To compare the mode of failure and the failure area of the different sutured samples.

The secondary outcomes were as follows:

1. To study whether the fiber orientation affects the tensile performance.
2. To compare the tensile behavior of unsutured fascia lata samples to sutured samples.

Features, collection, and processing of the fascia lata tissue

Cadaver fascia lata allografts were collected, processed, and cryopreserved by Treviso Tissue Bank Foundation (FBTV) following the requirements approved by the National Transplant Center. Donor selection includes serological tests for infectious diseases, and all tissues were decontaminated two times with a validated antibiotic cocktail [29].

Microbiological tests were performed following FBTV procedures. During the processing of fascia lata, adipose tissue and muscle tissue were removed. Tissues were stored at $-140\text{ }^{\circ}\text{C}$ in liquid nitrogen vapor phase and thawed before their use.

The harvested patches were characterized by a fibrous structure embedded in a matrix, with an aligned or randomized orientation of the fibers. A digital caliper was used to measure the mean thickness of the patches [30]. The average thickness of the patches was $1.24 \pm 0.29\text{ mm}$. The samples were composed of two fascia lata halves of $4 \times 4\text{ cm}$ sutured together, and samples of unsutured fascia lata measuring $8\text{ cm} \times 4\text{ cm}$. To test the sutures in physiological conditions, samples were released in a heated saline solution at $37\text{ }^{\circ}\text{C}$ before testing [31].

Fascia lata samples and types of sutures

Three different types of sutures performed by one investigator were tested (Fig. 1):

- *Handsewn* ($n = 5$): Sutures were performed in a simple running pattern with polydioxanone (PDS II 2-0, Ethicon™). Tissue bites were placed every 5 mm from the wound edge, with inter-suture spacing of 5 mm (*small bites technique*) [32].

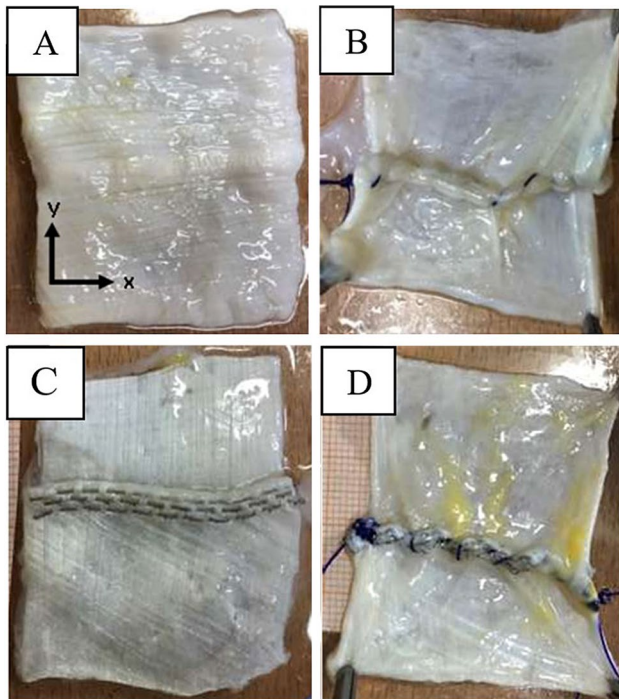
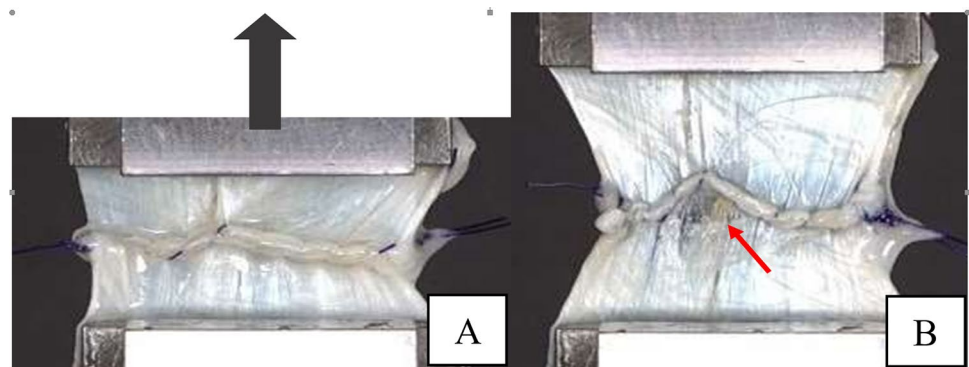


Fig. 1 **A** Intact fascia lata, (black arrows for x/y-fiber orientation); **B** handsewn suture; **C** stapled suture; **D** hybrid suture

- **Stapled** ($n=6$): A disposable endoscopic stapler was used to obtain a mechanical suture. Each suture is made of three rows of titanium staples with three different heights (Tri-Staple™ technology, Medtronic), respectively, of 3.0 mm, 3.5 mm, and 4.0 mm. The closed staples height ranges from 1.25 to 1.75 mm. Before firing across the fascial tissue, the two branches of the stapler were held in place for 15 seconds after closing and before firing, to ensure a better compression and staple formation.
- **Hybrid** ($n=5$): A stapled suture (Tri-Staple™ technology, Medtronic) was oversewn with a small bites running suture (PDS II 2-0, Ethicon™).

Fig. 2 Tensile test on a handsewn suture sample. **A** The arrow shows the direction of the applied tensile load. **B** The arrow underlines the failure event (pull-out of the suture) which led to the decrease of the force recorded



Tensile test

Tensile tests were performed with a Messphysik MIDI 10-20 Machine. A Mettler Toledo 500 N load cell was used with a tensile module. The tensile load was applied in quasi-static conditions, setting a 1 mm/s displacement speed. The total distance between the two grips was 2 cm (gauge length), and the suture was placed in the middle [Fig. 2A]. The sutures had different heights: 2.73 ± 0.48 mm in the handsewn, 2.64 ± 0.14 mm in the stapled, and 2.83 ± 0.33 mm in the hybrid suture. During tensile tests, the top patch was pulled vertically up to its breaking point (Fig. 2), and the tests were stopped when the complete breakage of the sample occurred.

Each test was recorded with a camera (SONY 4 K FDR-AX700). The first event causing a sudden decrease of the recorded force was considered as the failure.

Failure was classified according to the damaged area. The *junction failure* was defined as the slipping of one of the patches from the bordering edge, without breaking the rest of the tissue. *Tissue failure* is the breakage of the tissue distant from the suture. The area of failure was specified. The orientation of the fibers of each sample was investigated with the camera as y-oriented (parallel to the direction of the applied force), x-oriented (orthogonally to the direction of the applied force), or *randomly* oriented.

Stress (the force divided by the cross-sectional area)–strain (the displacement divided by the gauge length) curves were obtained to compare the different types of sutures and the unsutured samples. To obtain a more cautious value of the stress, the rectangular cross-sectional area was calculated considering the thickest of the two sutured patches.

To evaluate the tensile behavior of the samples, four properties obtained from the stress–strain curves were considered:

- Strength** (σ_f): The highest stress reached during the tensile test.
- Ultimate strain** (ϵ_u): The ratio of length increment to initial length along the direction of stress at the break-

ing point; it defines the deformability of a material when a force is applied.

- (c) *Young's modulus (E)*: The longitudinal stress divided by the strain, as expressed by the slope in the first linear region of the stress/strain curve; it describes the elastic property of a solid undergoing lengthwise tension.
- (d) *Dissipated specific energy (W)*: The area under the stress–strain curve up to the ultimate strain (ϵ_u); it defines the ability to absorb mechanical energy up to the breaking point, also called toughness modulus.

Statistical analysis

The force and displacement values of each sample were measured with the tensile tests. The mechanical properties (strength, ultimate strain, Young's modulus, and dissipated specific energy) were calculated from the data obtained with the tensile tests. Subsequently, mean values and the standard deviations of each considered mechanical property were computed. Student's t test was performed to verify statistically significant differences ($p < 0.05$) between the mechanical properties of the three types of samples (handsewn, stapled, and hybrid suture).

Results

Data collected from samples with a different orientation of the fibers were heterogeneous and not comparable, in accordance with Henderson et al. [33]. Samples with fibers mainly oriented parallel to the suture line (x -oriented) showed a worse tensile performance compared to samples with y -oriented fibers. To reduce the influence of fiber orientation, only the results of stress–strain curves on y -oriented fibers (intact fascia lata $n = 3$; handsewn $n = 4$; stapled $n = 3$; hybrid $n = 3$) were considered (Fig. 3).

- *Strength*. Stapled and hybrid suture showed a higher strength as compared to handsewn sutures (handsewn 0.83 MPa, stapled 2.10 MPa, hybrid 2.68 MPa) with significant difference (handsewn vs stapled $p = 0.004$; handsewn vs. hybrid $p = 0.005$); hybrid sutures presented higher strength than stapled sutures, without statistically significant difference ($p = 0.31$).
- *Ultimate strain*. A trend toward a lower strain of stapled and hybrid sutures versus handsewn was found, although non-statistically significant (handsewn 344.91%, stapled 249.16%, hybrid 280.75%).
- *Young's modulus*. Stapled and hybrid sutures were about fourfold higher as compared to handsewn sutures (handsewn 1.779 MPa, stapled 7.374 MPa, hybrid 6.964 MPa) with statistically significant difference (handsewn vs stapled $p = 0.002$; handsewn vs. hybrid $p = 0.005$); sig-

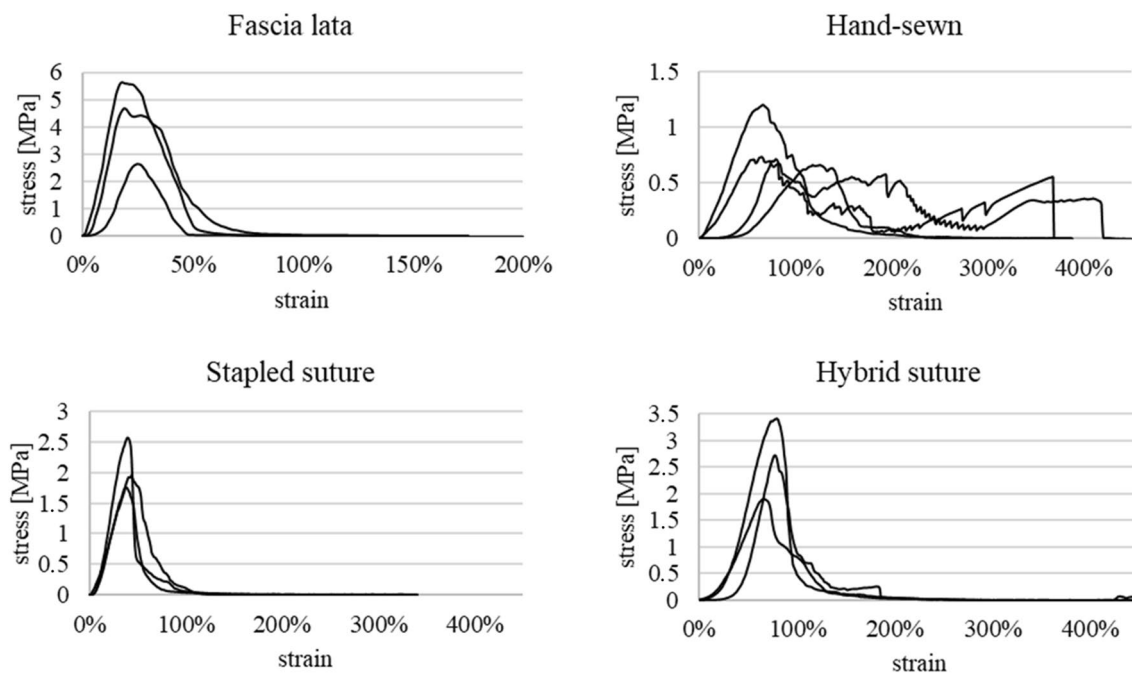


Fig. 3 Tensile test curves on samples with y -oriented fibers

nificant difference was not observed between stapled and hybrid sutures ($p=0.82$).

- *Dissipated specific energy*. Handsewn and hybrid sutures showed higher values as compared to stapled sutures (handsewn $0.99 \text{ mJ}\cdot\text{mm}^{-3}$, vs. stapled $0.73 \text{ mJ}\cdot\text{mm}^{-3}$, vs. hybrid $1.35 \text{ mJ}\cdot\text{mm}^{-3}$), with a significant difference between stapled and hybrid sutures ($p=0.02$).

The mean values of the calculated mechanical properties obtained with the three types of sutures are presented in Fig. 4.

Mode of failure and failure area

All the tested samples broke due to junction failure. A different area of failure was observed according to the different sutures. The handsewn-sutured samples broke at the end knots. In the stapled-sutured samples, the patches were uniformly pulled out along the suture line in two of three cases; the hybrid suture failed both at the end knots (two

cases) and with the complete breakage of the patch due to its pull-out in one case.

Unstured fascia lata

The highest mechanical properties were recorded on samples with y -directed fibers (strength 4.32 MPa , Young's modulus 32.33 MPa , dissipated specific energy $1.26 \text{ mJ}/\text{mm}^3$), except the ultimate strain which was higher in the samples composed of randomly oriented fibers (570.81%). During the tests on samples with fibers parallel to the tensile direction (y -oriented) the top grip of the tensile machine slipped from the specimen.

Discussion and conclusion

Stapled closure of fascial tissues has been recently adopted for laparo-endoscopic midline repair [9–13], but their use is controversial since their advantages (i.e., rapidity and

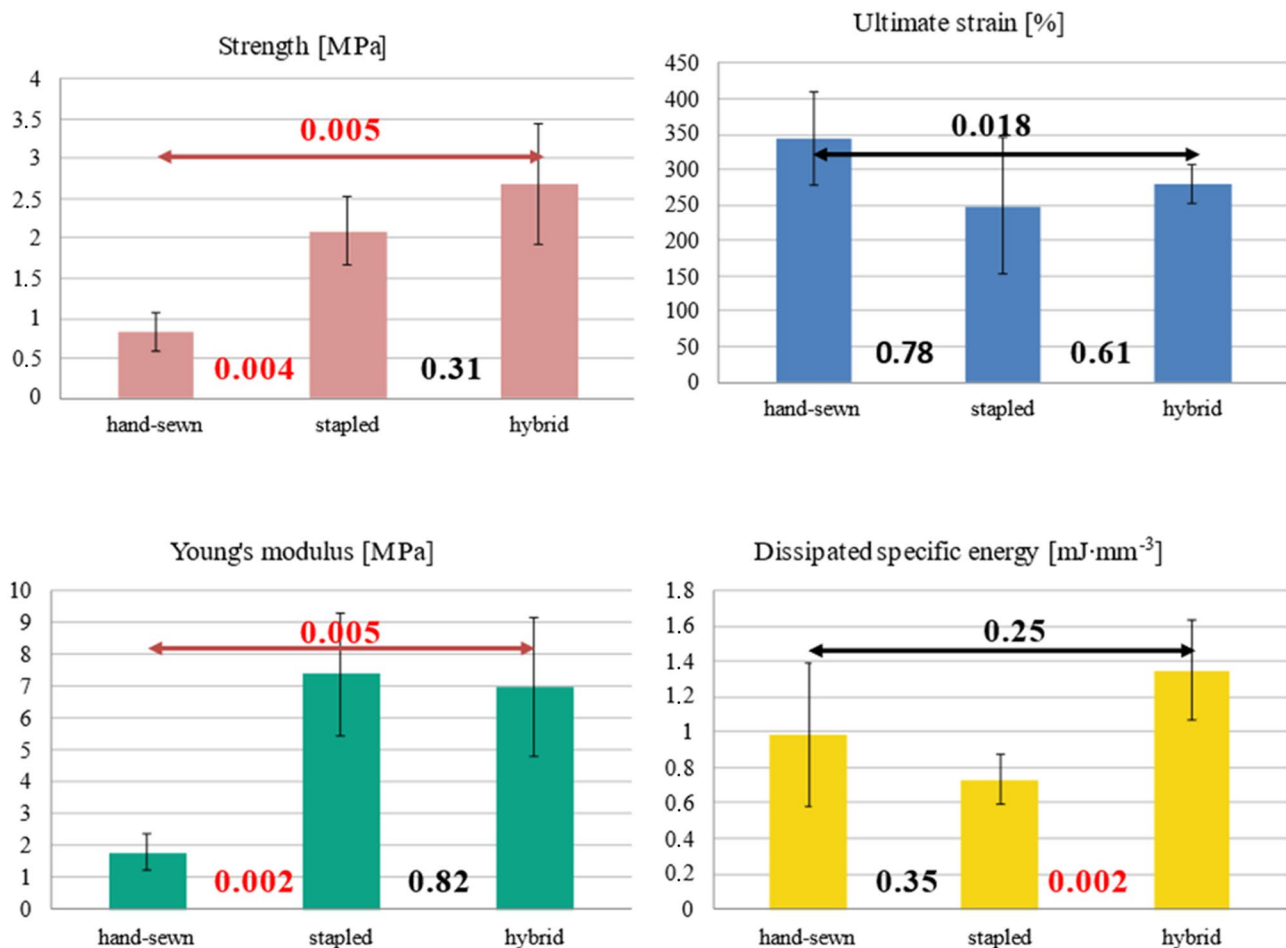


Fig. 4 Comparison between mechanical properties of handsewn, stapled, and hybrid sutures

reproducibility, absence of knots, homogeneous tension along the suture) are obscured by a lack of evidence in the literature.

Staplers are employed to join the posterior and anterior rectus sheaths together, developing the retromuscular space for mesh reinforcement (Fig. 5).

The novelty introduced is a purely technological aspect, represented by the synthesis of the anterior and posterior fascial layers through a mechanical device.

As in other fields of general surgery, where oversewn the staple suture appears to be correlated with lower complications rate, such as leakage or bleeding [24–27], the stapled

suture can be manually reinforced, either to improve its tensile resistance and to increase the plication of the rectus muscles during diastasis repair (Fig. 5D).

The higher stiffness and less vascularisation of fascial tissues as compared to other organs may further limit their use in this context [34, 35].

Furthermore, any type of suture on muscle-aponeurotic structures must resist higher forces than on other tissues [34] (e.g., bowel, vessels, or bronchus).

The stapled suture may fail due to opening of the row of staples, with possible formation of an internal hernia (Fig. 6A) or breakage of the fascial tissue along the suture line, with consequent prosthetic exposure into the abdominal cavity (Fig. 6B).

Nowadays, no data on the biomechanical properties of stapled sutures on human fasciae are available, and their use is often based on useful anecdotal experience as surgeons, without achieving the necessary mandatory level of objective evidence by studying their mechanical properties.

Tensile tests on cadaveric fascia lata specimens were performed due to their similarities with the aponeurotic sheaths of the rectus abdominis muscle.

Directly testing linea alba samples, instead of fascia lata, would not have had a greater methodological value, because in case of hernias or diastasis the midline is absent, replaced by scar tissue or deeply altered.

Furthermore, restoring the linea alba and its anatomic 3D characteristics through a surgical repair is not possible, because the neo-midline will be composed by scar tissue, with less resistance to multidirectional stresses and very different from its original structure.

Different types of mechanical testing (e.g., tensile tests, cyclic tests, fatigue tests, dynamic intermittent strain test [36–39]) should be performed to obtain a comprehensive description of the biomechanics of the studied tissue/material. The data should be consequently linked and correlated

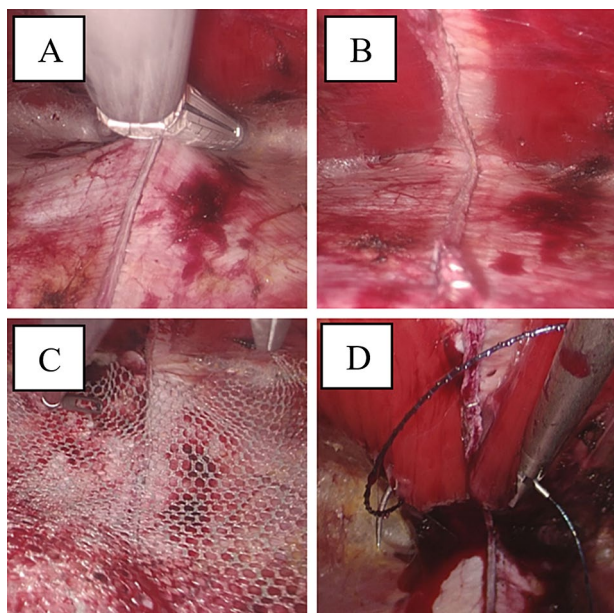


Fig. 5 **A** Endo stapler firing (during surgical operation by an author); **B** retromuscular space development; **C** sublay mesh reinforcement; **D** stapled suture oversewn

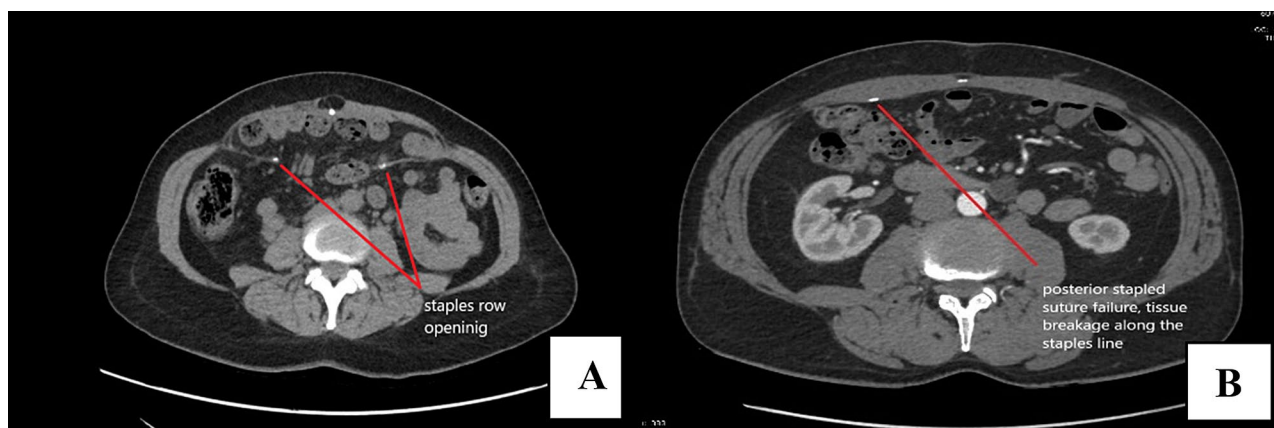


Fig. 6 **A** Posterior staples row opening and “internal” hernia formation (as observed by us); **B** posterior stapled suture failure for tissue breakage along the suture line: intraperitoneal mesh exposure

to have a complete description of the interaction between host tissue, mesh, and fixation devices.

To obtain reliable results, potentially capable of describing the physiological conditions of living tissues, we performed mechanical tests immediately after removing the samples from the heated saline solution at 37 °C as previously described by other authors [33].

The tensile tests lasted 50 s on average and the samples resulted hydrated.

Furthermore, we used human fascia lata samples, similar to the rectus sheaths and already used in ventral hernia surgery [40–44].

Primary endpoints

Tensile tests on sutured samples

This study suggests that stapled and hybrid sutures have better rigidity (Young's modulus) and strength performances than handsewn sutures, implying that stapled sutures, alone or oversewn, can resist high tensile forces per cross-sectional tissue area. Indeed, the absence of knots and a balanced load along the staplers' rows make stapled sutures more stable as compared to handsewn sutures [2, 35].

However, stapled and hybrid sutures have lower ultimate strain values, showing less deformability than handsewn sutures.

Thus, less efficiency is expected for mechanical sutures in case of high tissue displacements or when a more deformable behavior is needed as in case of large midline defects closure (e.g., W2 in accord to EHS classification).

Handsewn sutures, both handsewn and oversewn, absorb higher mechanical energy up to the breaking point, thus assuming characteristics more similar to intact and non-sutured tissue, whereas stapled sutures showed to be less tough.

An hybrid suture, as compared to a stapled suture, gains in terms of overall strength, ultimate strain, Young's modulus, and dissipated specific energy, suggesting the need for hybrid sutures in case of larger fascial defects or higher tension expected along the suture line.

Mode of failure and failure area

In handsewn sutures, end knots represent an area of weakness under tensile stress [45].

Stapled sutures show a uniform failure mode along the suture line, where the load is equally distributed without different weakness zones. Each entry bite of the staples represents itself a single weakness area, one equal to the other, and uniformly distributed along the suture, where the

force lines act up to the breaking point in an "all or nothing" model.

Hybrid sutures show an intermediate failure behavior between handsewn and stapled sutures, probably due to interaction between handsewn and stapled sutures in the breaking event.

Secondary endpoints

Fibers orientation

The secondary endpoint investigated shows that fibers orientation with respect to the applied force influences the tensile performance of the sutures. Thus, comparing samples with different fibers orientation was not possible, as reported by previous investigators [33, 36]. Fasciae with fibers oriented parallel the applied force show better results in terms of overall stress, ultimate strain, Young's modulus, and dissipated specific energy.

Intact vs. sutured fascia lata

Results show that intact samples of fascia lata present higher resistance (4.32 MPa). Comparing these data to the results obtained with sutured samples, it is possible to conclude that a suture nearly halves (stapled 2.09 MPa and hybrid 2.68 MPa) or decreases fivefold (handsewn, 0.83 MPa) the strength of the tissue when loaded with a tensile force.

Drawing clinical indications from an *ex vivo* model will always be debated, but at the same time we are encouraged from previous studies demonstrating the potential to be useful for adoption of surgical novelties [46, 47].

The advantage of this model is the chance to control single variables (tissue thickness, staples height, stapling technique, handsewn suture technique) affecting the expected results.

The small sample size and the difficulty to apply the experimental results to surgical practice are the limitations of our study.

Moreover, the rectus sheath and linea alba fibers are anisotropic [34] and distributed to resist multidirectional forces, as opposed to the unidirectional force applied in experimental conditions.

However, the experiments were conducted in a standardized fashion obtaining consistent results for each type of suture.

In conclusion, the ideal suture should be resistant to high loads (strength), high deformable (ultimate strain), and stiff (Young's modulus), able to absorb high energy (toughness).

These properties are not yet available in only one suture, and choosing which one to use should be a balance between pros and cons.

Stapled sutures can resist high loads but, by contrast, are less deformable than handsewn sutures.

This suggests a safer employment in case of small defects or diastasis (< W1 in accord to EHS classification), where the presumed tissue displacement is minimal.

Oversewing a stapled suture improves its deformability, becoming crucial in case of larger defects (> W1 in accord to EHS classification) where the presumed tissue displacement is maximal (e.g., in stout male patients, thick lateral muscles, elevated BMI).

A careful preoperative patient assessment (patient selection, imaging, preoperative botulin toxin A injection) coupled with intraoperative precautions (correct stapling technique, right staples height choice, oversewn reinforcement) can be helpful in controlling intra- and post-operative complications, such as staples opening, suture failure, intraperitoneal mesh exposure, and recurrences.

Further larger studies, including in vivo models, will be needed to confirm our results and to pave the way to develop staplers dedicated to this type of surgery.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00464-022-09304-9>.

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Author contributions The corresponding authors confirm that each author named in the by-line qualify by having participated actively and sufficiently in the study.

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Declarations

Disclosures Enrico Lauro, Ilaria Corridori, Lorenzo Luciani, Alberto Di Leo, Alberto Sartori, Jacopo Andreuccetti, Diletta Trojan, Giovanni Scudo, Antonella Motta, and Nicola M. Pugno have no conflict of interest or financial ties to disclose.

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