

Fibrin sealant for mesh fixation in Lichtenstein repair: biomechanical analysis of different techniques

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Abstract

Background Mesh fixation using sealants is becoming increasingly popular in hernia surgery. Fibrin sealant is an atraumatic alternative to suture or stapler fixation and is currently the most frequently used sealant. There are currently no biomechanical data available for evaluation of the quality of adhesion achieved with fibrin sealant during Lichtenstein hernia repair.

Methods Five different suture and sealant techniques were evaluated and compared during simulated Lichtenstein hernia repair in an established, standardised biomechanical model for abdominal wall hernias.

Results Significantly greater stability was achieved with fibrin sealant fixation of meshes than with point-by-point suture fixation. Fibrin adhesion protected meshes from dislocation at least as well as suture fixation with additional running-suture closure of the hernia orifice. Fibrin mesh fixation combined with additional support from running-suture hernia closure was significantly ($P \leq 0.002$) superior to all other methods.

Conclusions On the basis of these favourable biomechanical properties, mesh fixation using fibrin sealant can be recommended for use in onlay repair of transinguinal hernias.

Keywords Hernia · Lichtenstein · Mesh fixation · Fibrin sealant · Tissucol

Introduction

The increasing use of mesh procedures in inguinal hernia surgery has led to a substantial decrease in recurrences, although it has not succeeded in stopping them completely. Surgeons and patients are currently concentrating on other post-operative measures of the quality of hernia repair.

The prevalence of post-operative pain syndromes after open and laparoscopic procedures has been reported to be as high as 30% [1], and a recent meta-analysis [2] has calculated that 12% of patients feel themselves restricted in their daily activity because of pain. For example, chronic groin pain is rated as the most important factor in patient dissatisfaction after inguinal hernia repair [3]. In assessment of outcomes for patients who report severe or very severe pain three months after groin hernia repair, Callesen et al. [4] described chronic groin pain as “the most serious problem that may affect the results of hernia surgery”.

Sutures and clips for mesh fixation are thought to be an important cause of the development of chronic inguinal pain syndrome. For this reason there has been a search for possible improved approaches toward atraumatic mesh fixation in laparoscopic hernia surgery—with the objective of reducing post-operative pain. Results from three separate, controlled studies published in the last two years [5–7] reveal that “chronic post-herniorraphy pain” is significantly reduced after laparoscopic repair procedures when fibrin sealant is used, compared with traditional staple

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fixation. In addition, use of fibrin sealant was not associated with any different risk of recurrence.

It is important to assess whether the favourable outcomes of use of fibrin sealant in laparoscopic procedures extends to open inguinal hernia surgery. Initial clinical results from mesh fixation with fibrin sealant seemed very promising [8–10], and encouraged the European Hernia Society (EHS) to initiate a study to evaluate mesh fixation with fibrin sealant in Lichtenstein repair. The TIMELI trial (TIssucol for MESH fixation in LIchtenstein hernia repair) is a prospective, randomised, controlled, patient-blinded and evaluator-blinded multicentre study currently in progress in centres across the EU (Belgium, Denmark, Germany, Spain, France, Italy, UK), co-ordinated by G. Campanelli (Milan, Italy). Recruitment began in February 2006 and will be complete in December 2006. The first results are expected in 2008 and will enable solid evaluation of the efficacy and safety of fibrin sealant, compared with sutures, for mesh fixation in open hernia repair in over 300 patients.

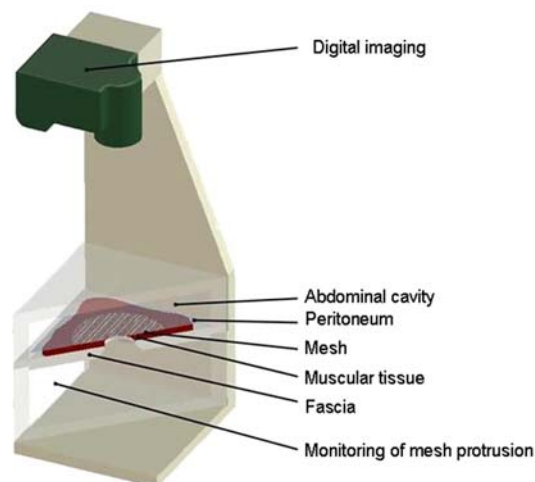
There have not yet been any biomechanical evaluations of fibrin sealant in comparison with suture techniques for mesh fixation in Lichtenstein repair. Here, we address this gap in the data by presenting results of five different suture and sealant techniques for simulated Lichtenstein hernia repair in an established, standardised biomechanical simulation model for abdominal wall hernias.

Methods

The hernia test stand

In co-operation with the Fraunhofer Institute for Production Technologies (IPT, Aachen, Germany), a stan-

Fig. 1 The hernia test stand: a standardised biomechanical model for the simulation of hernias



dardised test stand was implemented to simulate abdominal wall hernias and their reconstruction in a sublay and onlay set-up. In accordance with our previous investigations [11], abdominal peak pressures of up to 200 mmHg and abdominal wall elasticity of 20–30% at a pressure level of 150 mmHg (20 kPa) were set as physiological landmarks in the simulation.

The hernia test stand (Fig. 1) is characterised by two main components. The first is a pressure chamber that simulates the abdominal cavity. This includes a highly elastic and ultra-thin silicone sac that models the peritoneum and can be inflated by air pressure. The second main component is a standardised “abdominal wall” consisting of a specially designed silicone sheet (providing 20–30% elasticity at a pressure of 150 mmHg) combined with a “mesh layer” composed of fresh porcine muscular tissue.

By replacing the real abdominal wall with a standardised silicone membrane with comparable biomechanical properties it was possible to eliminate a major source of errors—variations in the anatomical specimen. The porcine muscular tissue (mesh layer) was fixed to the silicone sheet, which performed no relevant mechanical work but served as a gliding fixation support for the mesh. It was therefore possible to investigate the effect of variations in overlap, defect size, and mesh fixation technique in a model with otherwise static biomechanical properties.

Surgical technique simulation

The biomechanical quality of different (simulated) fixation techniques was assessed by using two meshes of different texture and elasticity. Atrium mesh (Atrium Medical Corporation, Hudson, NH, USA) was selected as an example of traditional, small-pore, polypropylene mesh; Ultrapro mesh (Ethicon Norderstedt, Germany)



was used as an example of a new, large-pore, light-weight and elastic mesh.

A 3-cm-long slit-shaped defect simulating the hernia orifice was made in the biological base, over which the meshes were anchored. Standardised abdominal wall herniorraphy simulations were always performed with a mesh overlap of at least 2 cm in all directions over the hernia orifice, giving a total implant size of 7 cm × 7 cm (Fig. 2). The techniques studied for mesh fixation utilised single 2-0 Prolene thread sutures (SS) (Fig. 3), with and without running-suture (RS) closure of the muscle defect, and sealing of the mesh to the musculature with 1 mL Tissucol/Tisseel fibrin sealant (Baxter Biosurgery, Vienna, Austria), applied as a spray. Five individual variants were evaluated:

1. Suture fixation: 4 Prolene SS at the mesh corners, always 1 cm from the mesh edge—without closure of the hernia orifice defect in the musculature.
2. Suture fixation: 6 Prolene SS at the mesh corners, always 1 cm from the mesh edge—without closure of the hernia orifice defect in the musculature.
3. Suture fixation: 4 Prolene SS at the mesh corners, always 1 cm from the mesh edge—with running Prolene 2-0 suture closure of the defect in the musculature.
4. Sealant fixation: 1 mL Tissucol/Tisseel fibrin sealant—without closure of the hernia orifice defect in the musculature.
5. Sealant fixation: 1 mL Tissucol/Tisseel fibrin sealant—with running Prolene 2-0 suture closure of the defect in the musculature.

Fig. 2 Repair of the simulated hernia with running suture for defect closure (*left*), and positioning of an onlay mesh and fixation with fibrin sealant (*middle and right*)

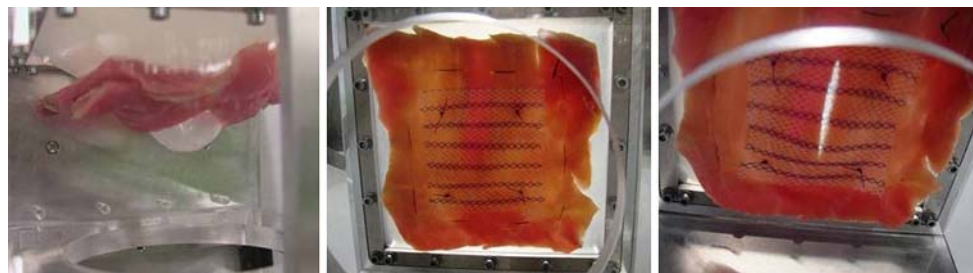
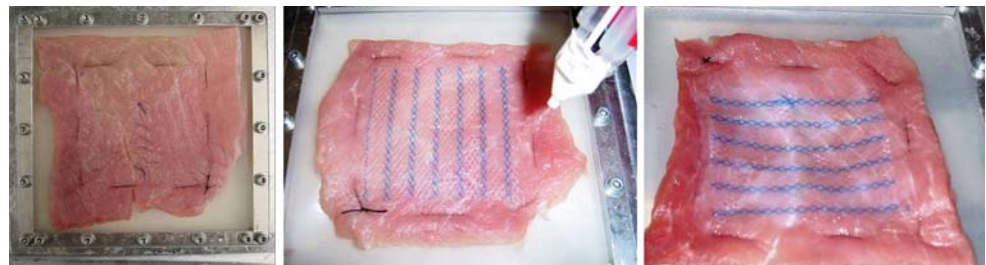


Fig. 3 Simulated hernia without repair (*left*); example shows Ultrapro mesh fixed with four single sutures in the onlay simulation at 50 mmHg (*middle*), and reopening of muscular hernia orifice at 80 mmHg (*right*)

Study endpoints and statistics

The endpoints of the simulated Lichtenstein repairs were defined to evaluate the biomechanical quality of the different fixation techniques. They included: “reopening of the hernia orifice (the muscular defect)” and “mesh dislocation”, both of which depended on the simulated abdominal pressure. Evaluations were based on ten replicate measurements for each technique. Statistical analysis of the results was based on one-way ANOVA and a post-hoc Bonferroni test, both according to a $P < 0.05$ level of significance.

Results

Reopening of the hernia orifice

The increases, per group, in simulated intra-abdominal pressure at which “reopening of the hernia orifice” occurred (irrespective of whether there was concomitant dislocation of the mesh) are summarised in Fig. 4. In single-suture mesh fixation procedures without running-suture closure of the hernia orifice (Groups 1 and 2), the first reopening of the hernia orifice was seen at 79 ± 6.6 (mean \pm SD) mmHg intra-abdominal pressure with 4 SS and at 81 ± 6.0 mmHg with 6 SS, respectively. If the meshes were secured with fibrin sealant only, however (Group 4), a substantially higher simulated intra-abdominal pressure (175 ± 11.2 mmHg) was required to provoke hernia reopening.

As expected, the highest pressures required for reopening of the hernia orifice were when the muscular defect had also been closed with a running suture. In Group 3 (suture fixation + running-suture closure), hernia reopening occurred at 188 ± 7.9 mmHg. The greatest pressure required to induce hernia reopening (196 ± 3.9 mmHg) was in Group 5 (fibrin sealant fixation + running-suture closure). It was also striking that only minimal variation (in the pressure at which hernia reopening occurred) was seen in Group 5 (Fig. 4).

Statistical analysis (one-way ANOVA and Bonferroni test) found no significant difference between reopening pressures in Groups 1 and 2 (4 and 6 SS fixation only, respectively), but a highly statistically significant improvement ($P < 0.001$) was observed for Group 4 (fibrin fixation only) compared with Groups 1 and 2. Predictably, Groups 3 and 5 (4 SS and fibrin fixation + running-suture closure) were also significantly superior to Group 4 ($P = 0.003$ and $P < 0.001$, respectively).

Fig. 4 Box and whisker plot of intra-abdominal pressures required for hernia orifice reopening after hernia repair using different mesh fixation methods. *Significant in one-way ANOVA, followed by correction for multiple comparison with the Bonferroni test (*n.s.* non-significant, $P > 0.05$)

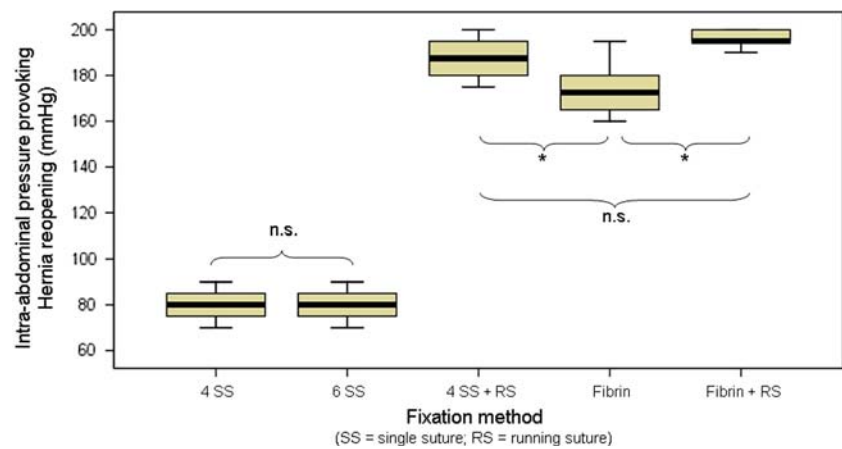
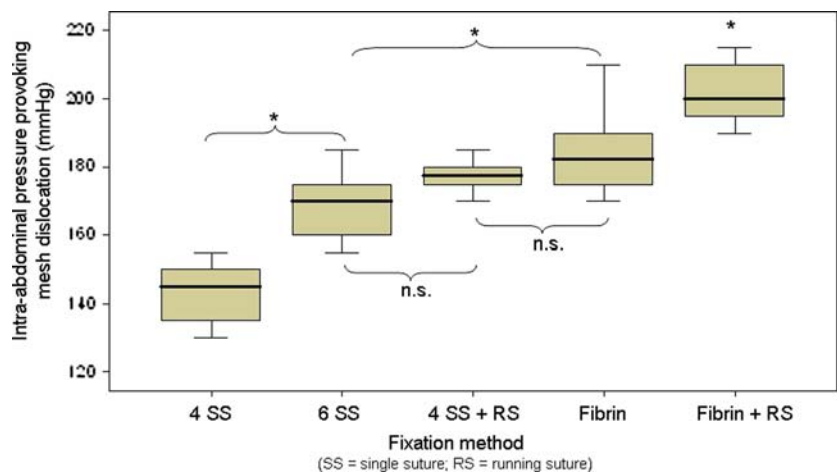


Fig. 5 Box and whisker plot of intra-abdominal pressures required for mesh dislocation after hernia repair using different mesh-fixation methods. *Significant in one-way ANOVA, followed by correction for multiple comparison with the Bonferroni test (*n.s.* non-significant, $P > 0.05$)



Mesh dislocation

The minimum simulated intra-abdominal pressure at which dislocation or tearing of meshes from the muscular base occurred, per group, are summarised in Fig. 5. The endpoint “mesh dislocation” is of greater clinical relevance for the permanent stability of a hernia preparation. In this respect, the effect of additional running-suture closure of muscular defects on the overall stability of the simulated repair was of particular interest.

The first mesh dislocation was seen at 143 ± 8.6 mmHg in Group 1 (4 SS) and at 170 ± 10.3 mmHg in Group 2 (6 SS) (Fig. 5). The pressure needed for mesh dislocation after 4 SS mesh fixation was higher if supplemented by running-suture closure of the muscular defect (178 ± 4.8 mmHg in Group 3). Dislocation pressure was 184 ± 12.2 mmHg in Group 4 (fibrin sealant only), and the highest pressure resistance (201 ± 8.4 mmHg) was seen in Group 5 (fibrin sealant + running-suture closure).

Statistical analysis showed Group 5 was the most significantly stable of all repair and fixation methods

($P \leq 0.000$ versus Group 1–3 and $P \leq 0.002$ versus Group 4). The greatest degree of scatter, but the second greatest stability, was seen for Group 4 (fibrin sealant only). It is worthy of note that the mean Group 4 dislocation pressure was significantly better than for Groups 1 and 2 (4 and 6 SS fixation only; $P \leq 0.014$). No significant differences were seen in comparisons of Groups 3 and 4 or Groups 2 and 3, and no significant differences were detected when comparing the mesh type sub-analyses.

Discussion

The Lichtenstein technique is a popular procedure used throughout the world for open inguinal hernia repair; it is currently often performed using prosthetic meshes to strengthen the inguinal canal posterior wall [12]. Recurrence is, however, a potential problem with this technique if mesh overlap around the hernia orifice is inadequate, with consequent anatomical weak points around the medial border of the inguinal canal [13, 14]. Unfortunately, the maximum medial mesh overlap is only 2 cm, and secure placement cannot therefore be guaranteed by internal abdominal pressure alone because there is no anatomical cover (external aponeurosis) in the subcutaneous direction on the external inguinal ring that can serve as ventral support for mesh prostheses. For these reasons, meshes should be properly secured using high-quality fixation methods at insertion, which remain effective until the mesh is incorporated.

We used a standardised biomechanical model—which has now been fully characterised—to evaluate the quality of different suture and sealant techniques for mesh fixation. So far there has been no description in the literature of a model for intra-abdominal pressure-dependent simulation of onlay procedures that can assess the biomechanical characteristics of hernia repairs. The available data are limited to studies on the removal of fixed meshes with monodirectional force vectors [15, 16]. The model used here has enabled the first successful simulation of the action of biomechanical forces in three dimensions.

We acknowledge a limitation of this model that, in vivo, the ventral anatomical cover is only lacking in the area of the external inguinal ring. In the arrangement we selected there is no ventral cover of any sort over the whole mesh. It therefore follows that the mechanical strength which could actually be achieved in vivo would be higher than that simulated in this study. Conclusions about whether fibrin sealant fixation of the mesh would be adequate should accordingly

assume that the in-vivo stability is higher. This excludes the possibility of false-positive results for this fixation method. In addition, to achieve a robust conclusion with regard to the use of fibrin sealant for mesh fixation, two mesh types with very different material properties and textures were deliberately selected. The fixation of the two mesh types was comparable in all test series, no significant differences were seen in comparisons of the Atrium and Ultrapro mesh.

Another important feature of our model was the use of an avital pig abdominal wall as the muscular mesh base. This enabled assessment of whether fibrin sealant, sprayed directly on to an avital tissue, would result in worse outcomes than intra-operative use of locally active clotting substrates on vital human abdominal wall tissue. In this respect, the results with fibrin sealant in our test series may be regarded as inferior to those that can be achieved in vivo. There is, in any case, certainly no risk the mechanical strength of meshes fixed with fibrin could be overestimated.

In 2003, Helbling and Schlumpf [17] reported the first results on “sutureless Lichtenstein repair” with *n*-butyl-2-cyanoacrylate glue. Routine intracorporeal use of cyanoacrylate glues has not become established in everyday surgery, however [18]. One reason for this is the known cytotoxicity of this material [19]. Another disadvantage of such synthetic sealants is that they become very hard, intraoperatively, preventing their use over the whole area of the mesh. In contrast, fibrin sealant seems to be more suitable for intracorporeal application, because it enables initial local fixation, can be applied evenly across an area, and maintains useful elasticity. This elasticity is of particular advantage in the surface fixation of modern elastic meshes. In 2001, Katkhouda et al. [20] reported mechanically adequate and biologically well-tolerated mesh fixation in a pig model investigating the laparoscopic fixation of hernia meshes with fibrin sealant compared with stapler tacks. Initial clinical findings with fibrin sealant were reported as early as 1997 by Chevrel [21], from a series of 110 scar hernia repairs performed with fibrin sealant since 1989.

Fibrin sealant is fully absorbed after approximately three weeks and is replaced by endogenous connective tissue. It must therefore be considered whether this period is adequate for mechanically stable incorporation of meshes. In simulated scar hernia repairs in pig abdominal walls, Brockman et al. [15] showed that the mechanical strength of the meshes as little as two weeks after implantation was comparable with that achieved after 6 weeks. Mesh dislocation was observed under a mean pressure of 259 (191–388) mmHg after two weeks and 291 (140–330) mmHg after six weeks. In

a model of polypropylene mesh implantation into abdominal wall defects in rats, Zieren et al. [22] observed abdominal pressures required to dislocate non-fixed meshes of 216 ± 16 mmHg in rats killed seven days post-operatively, 229 ± 14 mmHg at fourteen days and 253 ± 15 mmHg at ninety days. In the first biomechanical and histologic comparison of intra-abdominal mesh fixation with fibrin sealant or metal staples in rats, Petter-Puchner et al. [23] showed no difference between these fixation methods in animals sacrificed seventeen days post-operatively. Histologic analysis showed comparable mesh incorporation in the two groups, and that fibrin sealant was fully broken down after seventeen days to be replaced by a vital fibroblast network with vascular budding; there were no detectable fibrin residues in any animal.

Together these studies demonstrate that physiological incorporation of prosthetic meshes starts immediately after implantation. Even after a few days their mechanical strength was in the range of non-physiologically high intra-abdominal pressures. It follows that temporary fixation for one to two weeks post-operatively can be regarded as adequate. Certainly we regard this strategy as far more applicable than the possibility of permanent fixation of non-absorbable meshes with staples or clips. In our opinion the latter approach should be judged with a great deal of scepticism, bearing in mind that in hernia surgery it is adequate mesh overlap—not fixation—that protects from long-term recurrence.

Conclusions

This study was performed to evaluate the biomechanics of fibrin sealant fixation in simulated Lichtenstein hernia repair. On the basis of the following favourable biomechanical properties, we recommend the clinical use of fibrin sealant for mesh fixation in transinguinal onlay repair:

- Our data indicate that fibrin sealant alone is *superior to* pure suture fixation, and that it can be regarded as being *at least as good as* suture fixation combined with running hernia orifice closure.
- Fibrin sealant fixation of meshes results in significantly greater stability than suture fixation alone—with respect to both reopening of the hernia orifice and mesh dislocation.
- Fibrin sealant mesh fixation supported by running-suture closure of the muscular hernia orifice was significantly superior to all other methods; additional running-suture closure seems to significantly increase the stability of repairs.

Overall, fibrin sealant seems to be the current product of choice for intra-abdominal mesh fixation in Lichtenstein hernia repair, because it results in less biological stress and is associated with practical advantages compared with other fixation methods. Fibrin sealant has been approved for use in this indication in Germany.

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