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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Use of fibrin glue (Tissucol®) in laparoscopic repair of abdominal wall defects: preliminary experience

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Abstract
Introduction: The aim of this study was to establish the efficacy and tolerability of human fibrin glue (Tissucol®) for the nontraumatic fixation of a composite prosthesis (Parietex®) in the laparoscopic repair of small to medium-sized incisional hernias and primary defects of the abdominal wall.
Materials and methods: From October 2003 to October 2005, 40 patients underwent laparoscopic repair at the hands of one surgeon with expertise in laparoscopic surgery; all meshes were implanted in an intraperitoneal position. Follow-up visits were scheduled for 7 days and 1, 6, and 12 months. These included assessments for pain and postoperative complications.
Results: Forty patients (24 females, 16 males) with a mean age of 50 years (range, 26–65 years) and a mean Body Mass Index (BMI) of 27 (range 25 to 30) were included in the study. Sixteen patients had incisional hernias, and 24 had primary defects. The size of the defects varied from 2 to 7 cm. Adhesiolysis was necessary in 92.5% of cases (25/40). There were no intraoperative complications or conversions. After a mean follow-up of 16 months (range, 3–24 months), no postoperative complications were observed. The mean surgical intervention time was 36 min (range, 12–40 min), with an average hospitalization time of 1 day.
Conclusions: The use of fibrin glue in the present study provided stable and uniform fixation of the prosthesis and minimized intraoperative and postoperative complications. Consequently, laparoscopic treatment of small to medium-sized abdominal defects using this approach is our therapeutic option of choice.

Key words: Incisional hernias — Abdominal wall hernia — Fibrin glue — Laparoscopy — Composite prosthesis

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Defects of the abdominal wall comprise a variety of lesions including fascial defects, epigastric hernias, inguinal and subinguinal hernias, Spigelian hernias, and incisional hernias. The formation of incisional hernias remains a common complication in abdominal surgery, with a reported incidence of 3%–20% among all laparotomy procedures [26]. This complication rate increases to 23% when infection of the laparoscopy wound occurs [26]. Such defects typically occur within the first 5 years after surgical intervention, but may develop later [16]. In the United States alone, over 90,000 patients undergo surgical intervention to correct incisional hernias each year [7].

Several techniques have been described for the repair of abdominal defects. Direct repair of tissue requires the use of sutures along the fascial margins of both sides of the defect; this technique has a recurrence rate of 31%–54% in long-term follow-up [1, 23]. Advances in prosthetic materials have revolutionized surgery of abdominal wall defects by enabling the development of tension-free repair techniques, thereby reducing the recurrence rate to less than 10% [22]. Nonetheless, the need for more extensive dissection in order to position the prosthesis contributes to an increased rate of wound infection and complications related to the wound itself [20, 30, 31]. These problems have stimulated an ongoing search for new techniques for the repair of abdominal defects.

Laparoscopic repair of abdominal defects is increasingly popular with patients and surgeons, as it reduces postoperative pain, operating and hospitalization time, wound complications, and recurrence [5, 6, 12, 15, 21]. It can also be used in patients with recurrent defects. The principal indications for laparoscopic treatment of abdominal defects include incisional hernias with a diameter from 4 to 15 cm, multiple (''Swiss-cheese'') defects, anticoagulant therapy, and pathologies treatable by laparoscopic procedures (e.g., inguinal hernia, gastroesophageal reflux disease, biliary tract disorders). It is also recommended for patients who are obese or very athletic.

In spite of the established benefits of laparoscopic repair of abdominal wall defects, the use of staples for fixation of the prosthesis is associated with pain in approximately one quarter of patients during the immediate postoperative period [6]. Importantly, pain can persist, with a reported incidence of 7.4% at 2 months, and 1%–3% at 6 months [13]. Often, this pain is caused by the entrapment of nerves, which can be resolved only by laparoscopic removal of the staple. In our experience with a series of 178 patients, this was necessary in 3 cases (1.7%) [25].

In hernia repair, the role of human fibrin glue has recently been established as a means of reducing the complications associated with stapling the prosthesis [2, 5, 17, 19]. Consequently, we have introduced human fibrin glue (Tissucol®/Tisseel®, Baxter Healthcare, Deerfield, IL, USA) to anchor the intraperitoneal prosthesis during abdominal surgery. The aim of the present study was to establish the efficacy and tolerability of Tissucol® in the fixation of a macroporous intraperitoneal prosthesis for the laparoscopic repair of incisional hernias and primary defects of the abdominal wall. To our knowledge, use of fibrin glue in primary defects of the abdominal wall has not been studied before.

Materials and methods

Our study sample comprised 40 patients who underwent laparoscopic repair of incisional hernias and primary defects of the abdominal wall from October 2003 to October 2005. Only patients with abdominal wall defects between 2 and 7 cm in size were included. Exclusion criteria were contraindications to laparoscopic procedures—i.e., severe cardiopulmonary disorders and portal hypertension. All patients were treated by a single surgeon with expertise in laparoscopic surgery; all meshes were implanted in an intraperitoneal position. Details of the operation, including duration, were noted immediately after surgery was completed. All patients received one 100 mg dose of ketoprofen to manage postoperative pain. Follow-up visits were scheduled for day 7, week 6, and months 6 and 12. Conducted by the operating surgeon, these interviews incorporated assessments for pain (quantified using a Visual Analogue Scale [range, 0–10]) and complications including gastrointestinal symptoms. Ultrasound was not included as a routine part of follow-up.

Preoperative preparation

Standard preoperative procedure included bowel preparation (Selg Esse®, Promefarm srl Milan, Italy) and short-term antibiotic prophylaxis with a third-generation cephalosporin. Patients with incarcerated incisional or primary hernias also took simethicone (Mylicon®, Warner Lambert Consumer Healthcare, Milan, Italy) the day before surgery, to reduce the volume of intestinal gas.

Materials

A new-generation polyester prosthesis was used (Parietex® composite mesh; Sofradim, Trévoux, France), which is designed to promote tissue regrowth and prevent adhesions. Fibrin glue (Tissucol®) was used to fix the prosthesis in place. Tissucol® fibrin glue (Baxter Healthcare, Deerfield, Illinois, USA), is a biodegradable biological adhesive. It is formed by the combination of human-derived fibrinogen and human-derived thrombin activated by calcium chloride, leading to the formation of a matrix of polymerized fibrin fibers. Tissucol mimics the last step of coagulation and is an adjuvant to hemostasis. In addition to its hemostatic action, Tissucol has been shown to have adhesive properties [27], and to promote wound healing [10] and fibroblast proliferation [8].

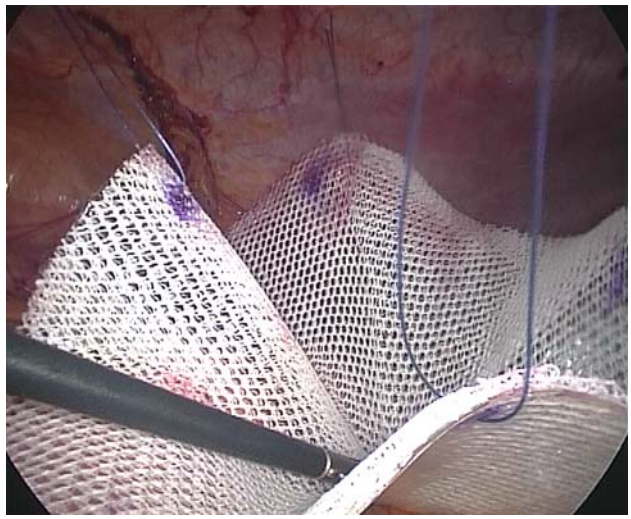

Fig. 1. Suspension of the mesh using a neddle holder and four straight transcutaneous needles.

In our series, we used 2 ml Tissucol for prostheses up to 12 cm, 3 ml for prostheses up to 15 cm or 10 × 15 cm, and 5 ml for prostheses up to 20 × 15 cm. Thrombin was diluted with sterile water from 500 to 50 IU/ml to slow polymerization to 3 minutes to allow adequate time to fix the prosthesis securely.

Surgical technique

The laparoscopic abdominal repair procedure followed at our institution is described briefly here. Pneumoperitoneum is induced using a Veress needle inserted away from both the hernia and previous scar tissue, usually just under the left subcostal. The advantage of the Veress needle is that it allows the surgeon to choose the best site, under pneumoperitoneum, to position the first trocar, in comparison with an open procedure using Hasson trocars. A 5-mm, 30° scope is introduced and another two trocars are inserted with the aid of transillumination and internal vision. We use three trocars (one 12 mm and two 5 mm) (Endopath® Ethicon Endo-surgery, Cincinnati, OH, USA) arranged in a triangular fashion converging on the defect as far away as possible, but such that the defect can be accessed with reasonable ease. Peritoneal adhesions are carefully lysed. The hernial sac is neither reduced nor treated, and is left *in situ*.

After the abdominal wall is completely cleared of adhesions and all defects have been identified along the previous scar line, the hernial defect is evaluated for the optimal size of prosthesis (the prosthesis should overlap the defect by at least 4–5 cm). Four points are marked on the angles of the prosthesis and the abdominal wall. The prosthesis is then introduced via the 12-mm trocar (by rolling it up with the collagen side toward the inside) and then unrolled with particular care to orient it such that the adhesion-prevention side is in contact with the intestinal loop.

The mesh is first suspended and temporarily affixed to the abdominal wall using a needle holder and four straight transcutaneous needles (Fig. 1) corresponding to the points marked on the prosthesis and the abdominal wall. In this way, precise placement of the prosthesis on the hernial defect is achieved, and it is easy to position the mesh on the abdominal wall before the fibrin glue begins polymerizing. Diluted fibrin glue is applied to the four points using a dedicated laparoscopic tool (Duplotip®, Baxter Healthcare, Deerfield, IL, USA) in concentric circles starting from the more external portions of the prosthesis (Fig. 2). The four points are next pulled under traction, and the prosthesis is fixed to the abdominal wall with mosquito clamps so that it is suspended on the abdominal wall. Using laparoscopic forceps,

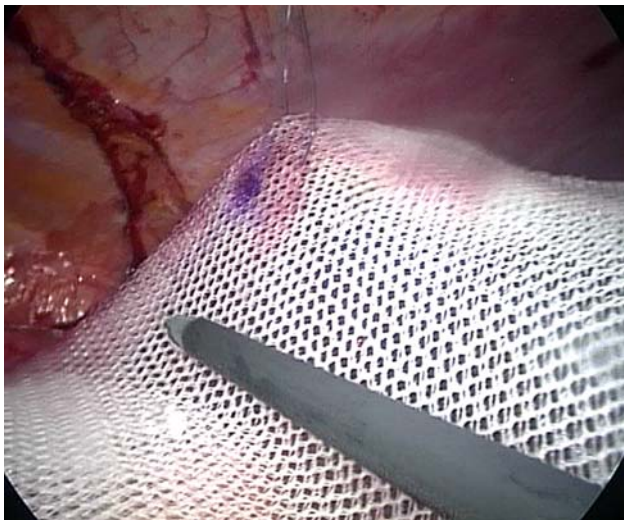

Fig. 2. Application of diluted fibrin glue.

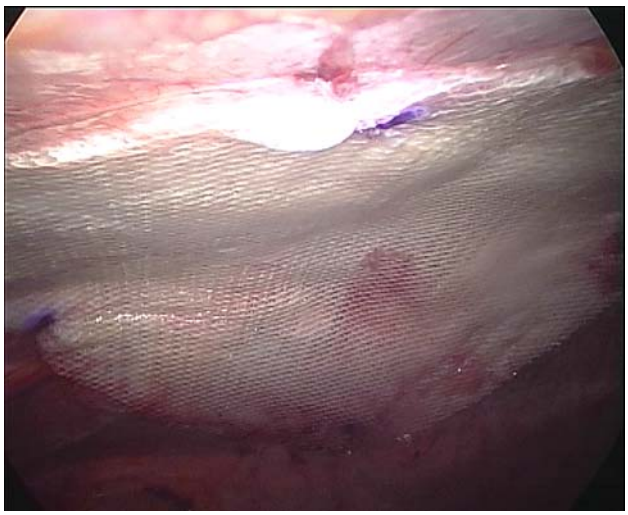

Fig. 3. Fibrin glue completely polymerized.

the prosthesis is distended and pushed toward the abdominal wall to ensure uniform fixation.

When the fibrin glue is completely polymerized (after 3 min), it has a mother-of-pearl–like sheen, at which point the four transcutaneous needles and temporary sutures are removed (Fig. 3). The trocars are withdrawn carefully and the pneumoperitoneum is released. Drainage tubes are not required; a compressive bandage is applied for 7 days.

Results

From October 2003 to October 2005, 40 patients (24 females, 16 males) with a mean age of 50 years (range, 26–65 years) and a mean BMI of 27 (range, 25–30) underwent laparoscopic repair of abdominal wall defects. Of these, 16 patients (40%) had incisional hernias, and 24 (60%) had primary defects (Table 1).

There were no intraoperative conversions or complications, including peritoneal or intestinal perforations. Excluding primary defects, adhesiolysis was carried out in 25 of 40 patients (92.5%). The mean operating time was 36 min (range, 12–40 min), and the average hospitalization time was 1 day. Drainage tubes were not required.

No intra-abdominal or abdominal wall hemorrhages or hematomas occurred; there were no seromas at the 1- or 6-week follow-up visit. Complete recovery of physical and work activities was observed at an average of 7 days, in the absence of pain-related symptoms.

After a mean follow-up of 16 months (range, 3–24 months), no postoperative complications, recurrences, or deaths had been reported. Similarly, no adverse gastrointestinal events were reported (e.g., nausea, vomiting, diarrhea, abdominal distension, abdominal colic).

Mean pain scores, as ranked by the Visual Analogue Scale (ranked from 0 = no pain, to 10 = worst pain), indicated that, in spite of analgesia, some patients experienced a low level of postoperative pain for the first 3 days following surgery, but that pain had disappeared by day 7 (Fig. 4), and did not return. There were no reports of neuralgia during follow-up.

Discussion

The role of fibrin glue in surgery is supported by a growing body of evidence that confirms that it is associated with low rates of complications combined with good tolerability and few contraindications [2–4, 14–18, 19, 29]. In our preliminary study of laparoscopic repair of abdominal wall defects, we used Tissucol® fibrin glue to fix a polyester composite mesh (Parietex®) over the hernial defect. During 16 months' follow-up, no gastrointestinal symptoms were observed (nausea, vomiting, diarrhea, abdominal distension/colic), indicating reperitonealization in the absence of adhesions. In addition, there were no complications such as intestinal obstruction or fistulization of adhesions.

Most patients who undergo traumatic fixation methods develop postoperative seromas, although these typically resolve without additional intervention. This is most evident in incisional hernias larger than 4 or 5 cm. Seromas are considered a clinically significant complication if symptomatic and persisting for more than 8 weeks. In the largest multicenter trial reported to date, clinically evident seromas persisting beyond 8 weeks occurred in 2.6% of cases [15]. Whereas the use of compression bandages for 7 days after intervention followed by an elastic bandage for 15 days reduces the incidence of seroma, it also increases the formation of adhesions between the prosthesis and the hernial sac. In our study, there was no evidence of either seroma or intraoperative hemorrhage, even at the trocar site. We attribute the absences of seroma to the use of a nontraumatic means of fixation (in this case, Tissucol®) to secure a macroporous prosthesis in conjunction with accurate hemostasis and use of a compression bandage. We ascribe the absence of intraoperative hemorrhage to careful introduction and extraction of the trocars as guided by transillumination.

Table 1. Abdominal wall defects in 30 patients undergoing laparoscopic repair by fixation of Parietex® composite mesh with Tissucol® fibrin glue

No. of patients	Site of defect	Size of defect (cm)	Size of prosthesis (cm)	Volume of Tissucol® used (ml)
3	Incisional hernia (above/below umbilical)	7 × 4	20 × 15	5
1	Incisional hernia (above/below umbilical)	6 × 3	15 × 10	3
2	Incisional hernia (McBurney's point)	5 × 4	15	3
2	Incisional hernia (above umbilical)	5–4	15	3
3	Incisional hernia (above umbilical)	3–4	12	2
3	Incisional hernia (below umbilical)	3–4	12	2
2	Incisional hernia (right infracostal)	6 × 3	15 × 10	3
14	Umbilical hernia, at least 3 recurrences	2–4	12	2
3	Spigelian hernia	3	12	2
7	Epigastric hernia	3–4	12	2

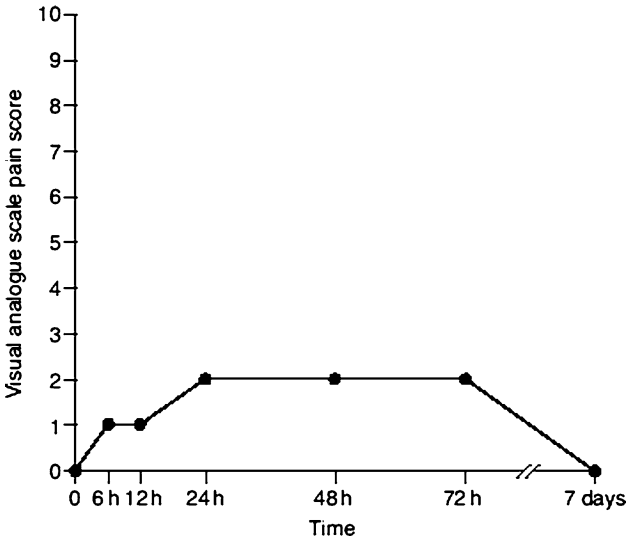

Fig. 4. Mean Visual Analogue Scale pain score (0–10) in 30 patients after laparoscopic repair of abdominal hernia with Tissucol® fibrin glue and a Parietex® composite mesh prosthesis.

Other troublesome postoperative complications include infection and pain. Infection following abdominal wall defect surgery constitutes a serious complication, although its incidence is low. From a series of studies of at least 50 patients, the overall frequency of prosthetic infection was 0.6%, and 1.1% of patients developed infection at the site of trocar insertion [7]. More commonly, patients complain of persistent pain or a painful suture. After interventions in which staples were used for fixation, postoperative pain has been reported in 25.6% of cases at 1 week [6], and persistent pain in 7.4% of cases at 2 months [13]. In our study, no patient developed infection of the prosthesis or the surgical wound, nor did any patient report painful symptoms throughout the follow-up period.

Perhaps of most importance is the long-term efficacy of abdominal wall defect repair, assessed by rate of recurrence. In a recent review of available literature on incisional hernia repair, at an average follow-up of 12 months, the overall incidence of recurrence was 4.3%, rising to 5.6% in eight studies that used only staples for fixation of the prosthesis [7].

The likelihood of recurrence is influenced by many factors. For example, the use of a mesh-type prosthesis drastically reduces the frequency of recurrences compared with suture-based techniques [24]. The method of prosthesis fixation is also key. The most widely used technique is fixation with staples and permanent transabdominal sutures [15]. Correctly positioned staples penetrate only around 2 mm below the prosthesis, and may therefore not provide adequate fixation. In our view, it is imperative that the mesh be fixed, especially during the initial period of placement of the prosthesis. Sufficient overlap of the prosthesis is also essential because it counteracts intra-abdominal forces that can dislocate the mesh. Most surgeons use an overlap of at least 3 cm; a larger overlap (e.g., 5 cm) is recommended in patients with an increased risk of recurrence, such as obese individuals or those with large defects [15, 28]. In our study, prostheses with adequate dimensions were used to ensure overlap of the defect by at least 4–5 cm. Fixation of the prosthesis on only one margin is another risk factor for defect recurrence, as is poor positioning of the prosthesis [9, 11]. In our study, fibrin glue (Tissucol®) facilitated uniform fixation and good stability of the prosthesis. Positioning was aided by the use of four transcutaneous needles at cardinal points in order to obtain optimal positioning of the prosthesis over the hernial defect, without movement, before it was adhered to the abdominal wall. Lastly, inadequate hernial diagnosis is a risk factor for recurrence. A laparoscopic approach provides the surgeon with the ability to clearly define the defect margins and identify additional defects that may not be clinically evident during the preoperative period, e.g., underlying "Swiss-cheese" defects. No evidence of recurrence was observed at 16 months in any of our patients, indicating significant benefit associated with the use of Tissucol® as part of our standard laparoscopic approach to abdominal wall repair.

With regard to economic considerations, the costs of fixation with Tissucol® are lower than those associated with metal staples (e.g., 2 ml Tissucol®, €160 versus 1 Protak® or Endoanchor®, €280). In the absence of more formal study, our preliminary experience suggests that, whereas the use of fibrin glue in preference to staples for mesh fixation confers no advantage in terms of reduced operating time, reductions in hospitalization time of up to 1 day have been observed (S.O., unpublished data, 2005).

Conclusions

The outcomes of this study indicate that laparoscopic surgery coupled with fixation of a macroporous composite prosthesis using fibrin glue is well-tolerated and effective. Based on these initial findings, we consider that Tissucol® fibrin glue constitutes an optimal approach to the repair of small to medium-sized abdominal wall defects, as it provides prosthetic stability with a low incidence of pain, hemorrhage, seroma development, or recurrence. Extended follow-up is needed to establish the long-term efficacy of this approach.

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