Hernia (2010) 14:617–621
DOI 10.1007/s10029-010-0723-7

ORIGINAL ARTICLE

Advantages of new materials in fascia transversalis reinforcement for inguinal hernia repair

N. Arslani · L. Patrlj · M. Kopljar · Z. Rajković · S. Altarac · D. Papeš · D. Štritof

Received: 1 June 2010 / Accepted: 16 August 2010 / Published online: 2 September 2010

Abstract
Purpose We investigated whether new absorbable materials can be used in the treatment of inguinal hernia with the same efficacy as the traditionally used polypropylene.
Methods We compared local tissue inflammation and fibrous reaction, postoperative complications (bleeding, wound haematoma, wound infection) and postoperative recovery time (time of mobilisation) in rats (Fischer strain) after implantation of a polypropylene mesh (PPM) (Prolene, Ethicon, Bracknell, UK) or a dual component fibrin mesh (DCFM) (Tachosil, Nycomed, Marlow, UK), between the muscle layer and the fascia transversalis defect. We further compared direct hernia repair methods using Lichtenstein's operation in humans after implantation of either PPM or DCFM for fascia transversalis reinforcement regarding postoperative pain and complications, time needed for patient mobilisation, and recurrence.
Results The results show that implantation of DCFM in rats resulted in milder inflammatory response and thicker fibrous tissue formation. Patients implanted with DCFM had significantly lower postoperative pain scores on a visual-analogue scale and lower analgesic use. The overall incidence of postoperative complications was significantly reduced with the use of DCFM. The incidence of recurrence after 24-month follow-up was the same in both groups.
Conclusion This study has shown that DCFM has the same short-term efficacy in hernia treatment as the standard PPM, with a reduction in postoperative pain and analgesic use, and a decrease in overall postoperative complications. In the rat model, DCFM resulted in milder inflammatory response and thicker fibrous plate than the PPM. Further biomechanical testing and longer follow-up is necessary, but initial results are promising.

Keywords Inguinal hernia · Polypropylene mesh · Tachosil · Collagen mesh · Biologic mesh

N. Arslani (✉) · Z. Rajković · S. Altarac · D. Papeš · D. Štritof
Department of Surgery and Urology, Zabok General Hospital, Bračak 8, 49210 Zabok, Croatia
e-mail: arslani.nuhi@gmail.com

L. Patrlj · M. Kopljar
Department of Surgery, Clinical Hospital Dubrava, Zagreb, Croatia

Introduction

Inguinal hernia is one of the most frequently observed conditions in today's modern surgical practice, appearing with a prevalence of 10% in the general population [1]. However, there is still disagreement concerning its treatment and etiology. The main factor in development of hernia is the insufficiency of abdominal wall structures, which leads to intermittent or permanent protrusion of internal organs or tissues [2]. Around 75% of all hernias appear in the inguinal region [3]. Operations undertaken for its treatment are considered to be one of the most commonly performed elective surgical procedures [3]. Traditionally, the structure of the highest importance when considering posterior inguinal canal wall strength is the transversalis fascia [4]. Currently used tension-free reconstruction techniques reinforce the fascia by implanting different types of meshes comprised of completely non-absorbable materials (polypropylene), mixed absorbable and non-absorbable materials (polypropylene and polygalactine) or completely absorbable materials—used mostly in infected areas. We investigated whether new absorbable

materials can be used in the treatment of inguinal hernia with the same efficacy as the traditionally used polypropylene, but with fewer postoperative complications and less pain. In this study we used TachoSil (manufactured by Nycomed, Marlow, UK) dual component fibrin mesh, used mainly for achieving an accurate haemostasis. TachoSil is a collagen-fibrin sealant patch fabricated in two layers: the outer white sponge-like layer consists of collagen, and the inner yellow layer consists of coagulation factors fibrinogen and thrombin, and riboflavin. It is made of human collagen and coagulation factors. Several randomised controlled trials have shown its efficiency in achieving haemostasis in general, thoracic and urologic surgery [5–10].

The study was divided into two parts. The aim of the first was to compare local tissue inflammation and fibrous reaction, postoperative complications (bleeding, wound haematoma, wound infection) and postoperative recovery time (time of mobilisation) in Fischer strain rats after implantation of a polypropylene mesh (PPM) (Prolene, manufactured by Ethicon, Bracknell, UK), or a dual component fibrin mesh (DCFM) prosthesis between the muscle layer and the fascia transversalis defect. The aim of the second part of the study was to compare direct hernia repair methods using Lichtenstein's operation in humans after the implantation of either PPM or DCFM for fascia transversalis reinforcement in terms of postoperative pain and complications, time needed for patient mobilisation, and recurrence.

Materials and methods

The study was conducted in two parts: the first, experimental, part was performed in the Institute for Biology of Zagreb University Medical School, and the second part, the randomised controlled clinical trial, was performed in a clinical hospital in Zagreb. The study took place between October 2006 and May 2010.

First part

The experimental study included 78 animals of 3 months of age and weighing between 300 and 350 grams each. The animals were divided into two groups: (1) 40 rats implanted with PPM, and (2) 38 rats implanted with DCFM.

For the operation, one piece (2 × 1.5 cm) of PPM or DCFM was implanted in the inguinal region of the test animal. The groin region was first shaved and disinfected with alcohol. This was followed by ether-induced anaesthesia and the procedure was performed with the animals in a supine position. An incision of 3 cm in length was made in the inguinal region, and the underlying structures were exposed. A piece of mesh material was then placed below the muscle layer, onto a 1 cm long incision in the fascia transversalis. The wound was closed with Michel clamps.

During the recovery period, the animals were kept in standard conditions and monitored for the following: (1) early bleeding and wound haematoma (in first 24 h), (2) late bleeding and wound haematoma (after 24 h), (3) wound and mesh infection, (4) early mobilisation (in first 24 h), and (5) late mobilisation (after 24 h). The occurrence of bleeding, haematoma and infection was assessed by visual examination during the first 5 days. Mobilisation was defined as a complete ability to move as prior to surgery, and was assessed during an observation period of 48 h. The animals were sacrificed after 30 days, the implanted material with the surrounding fibrous plate was excised, and tissue samples were sent to the Pathological Institute of a clinical hospital in Zagreb for macroscopic and microscopic analyses. The grade of inflammation and fibrous tissue formation were assessed microscopically by a pathologist. The inflammation was graded as mild, moderate or severe, according to the number of infiltrated cells, and the fibrous reaction was graded as thin, medium or thick, according to the diameter of the fibrous tissue of the foreign body granuloma. All procedures were performed in line with the ethical principles of the Helsinki Declaration and the laws of the Republic of Croatia.

Second part

The randomised controlled clinical study included 97 patients who were diagnosed with direct inguinal hernia and were surgically treated between October 2006 and November 2007. The duration of their condition prior to surgery was 1 to 10 years. The criterion for inclusion was hernia type M III or Mc III according to the Aachen classification. Patients were excluded if they had incarcerated or gangrenous hernia requiring emergency surgery.

Patients were divided into two groups: (1) 45 patients implanted with PPM, and (2) 52 patients implanted with DCFM.

For the operation, the skin was shaved and disinfected with antiseptic solution and iodine. The surgical procedure began by making an oblique inguinal incision, 5–6 cm cranial of inguinal ligament from the tuberculum pubicum, following Langer's lines. The aponeurosis of the external oblique muscle was exposed and dissected from internal to external inguinal ring. The ilioinguinal nerve was identified and secured. The edges of dissected aponeurosis were elevated and structures of inguinal ligament, rectus abdominis and internal oblique muscle identified. Then, by lifting the aponeurosis from the underlying muscle, a space for the prosthesis was formed. The funiculus spermaticus,

surrounded by cremasteric muscle fibres, was then mobilised from the posterior wall and rubber banded. The hernia sac was then separated from its neighbouring structures, circularly sutured and resected or simply pushed back into the preperitoneal space, depending on the size of the sac. The transverse fascia was then reinforced with Prolen 3-0 sutures in a continuous manner. The mesh was trimmed to fit the space, with a slit cut laterally to embrace the spermatic cord. The mesh was laid with the medial edge 1–2 cm medial to the pubic tubercle. The PPM was then fixed with 3-0 Prolene sutures. The DCFM mesh was not fixated with stitches.

The preoperative preparation (cefazolin 1 g i.v. prior to the skin incision), anaesthesia (general endotracheal anaesthesia), and postoperative care (changing of bandages 48 h after surgery, reduction in physical activity in the following 2 weeks) were the same in both the groups. All the patients were discharged within 2 days of surgery, except in cases of early bleeding. All the patients were followed-up once a week until the wound healed completely, and then again 1, 6, 12, and 24 months after the operation. The patients were contacted by telephone to attend control examinations.

Postoperative complications that were monitored included: urinary retention, early bleeding (within 24 h following the surgery), late bleeding (more than 24 h after the surgery), wound and mesh infection, scrotal haematoma, testicular atrophy, and chronic groin pain. Time needed for patient mobilisation (early—within 24 h, late—after 24 h), and recurrence were also monitored.

Urinary retention was defined as the lack of ability to urinate and characterised by a poor urinary stream with intermittent flow, straining, hesitancy and a sense of incomplete voiding. Postoperative pain was assessed in the first 5 days in two ways:

1. Patient's personal pain assessment by using an 11-point (from 0 to 10) visual-analogue scale (VAS). Patients were divided into three groups by VAS scores: (1) no pain or mild pain, no discomfort (scores 0–3); (2) moderate pain with discomfort (scores 4–7); and (3) severe or intolerable pain (8–10). The highest score in the first 5 postoperative days was noted.
2. Measurement of the highest dose of analgesic needed to achieve analgesia in the first 5 postoperative days. The patients were divided into five groups: (1) no analgesic was necessary, (2) parenteral Tramadol 200 mg/day was sufficient, (3) parenteral Tramadol $>$ 200 mg/day was necessary, (4) stronger analgesic Dolantin 100 mg was necessary, and (5) sufficient analgesia was not achieved.

Wound and mesh infection were assessed visually and defined by classical local and systemic clinical signs of wound infection. The appearance of scrotal haematoma was assessed by visual examination in the first 5 postoperative days. The occurrence of testicular atrophy in the postoperative period was assessed by an urologist at follow-up appointments. Patient mobilisation was defined as the patient's ability to walk 50 m without discomfort. The incidence of recurrence and chronic groin pain were evaluated during control clinical examinations over a 24-month follow-up period. Recurrence was defined as palpable hernia on inguinal canal finger examination when straining. Chronic groin pain was defined as intermittent pain in the groin area lasting for at least 3 months.

Informed consent was obtained from each patient to undergo one of the two methods mentioned. None of the patients refused to participate in the study. The ethical committee of the University of Zagreb approved the study.

Statistical analysis was conducted by a certified medical statistician using MedCalc statistical software version 10.3 (copyrighted by MedCalc Software bvba 1993–2010). The significance of differences was determined using Fischer's exact test and chi-squared test where applicable. $P < 0.05$ was considered statistically significant.

Results

Of the 78 rats, 40 (51.3%) were male. There was no statistically significant difference in gender and age between the two groups. Of 97 patients, 95 (97.9%) were male. The average age was 52.3 $\pm$ 13.9 years, with a range of between 23 and 75 years. The average duration of the condition prior to surgery was 5.5 $\pm$ 3.5 years, with a range of between 1 and 10 years. There were no statistically significant differences in gender, age or duration of condition between the two groups. None of the patients were lost during follow-up. According to the Aachen classification, 65 patients were classified as M III type of hernia, and 32 as Mc III. There were no statistically significant differences between the two groups in type of hernia (31 M III and 14 Mc III hernias in the PPM group; 34 M III and 18 Mc III hernias in the DCFM group).

Local tissue inflammation, fibrous reaction, postoperative complications, and postoperative recovery time (time of mobilisation) in the two groups of Fischer strain rats after implantation of PPM or DCFM are shown in Table 1. No adhesions were noted in either of the groups. The overall bleeding (early and late) rate was 25.0% in the PPM group compared to 0.0% in the DCFM group ($P = 0.003$), and overall complication (early and late bleeding and wound and mesh infection) rate was 30.0% in the PPM group compared to 0.0% in the DCFM group ($P = 0.0008$).

Table 1 Local tissue inflammation, fibrous reaction, postoperative complications, and postoperative time of mobilisation in the two groups of Fischer strain rats after implantation of polypropylene mesh (PPM) or dual component fibrin mesh (DCFM)

	PPM ($N = 40$)	DCFM ($N = 38$)	P
Inflammation degree N (%)			
Mild	1 (2.5)	16 (42.1)	0.0001
Moderate	26 (65.0)	18 (47.4)	0.1808
High	13 (32.5)	4 (10.5)	0.0377
Fibrous tissue diameter N (%)			
Thin	31 (77.5)	10 (26.3)	0.0001
Medium	9 (22.5)	24 (63.2)	0.0007
Thick	0 (0.0)	4 (10.5)	0.1119
Early bleeding and wound Haematoma N (%)	6 (15.0)	0 (0.0)	0.0394
Late bleeding and wound Haematoma N (%)	4 (10.0)	0 (0.0)	0.1368
Wound and mesh infection N (%)	2 (5.0)	0 (0.0)	0.4966
Early mobilisation N (%)	20 (50.0)	32 (84.2)	0.0031
Late mobilisation N (%)	20 (50.0)	6 (15.8)	0.0031

Table 2 Postoperative pain and complications, time needed for patient mobilisation, and recurrence after direct hernia repair using Lichtenstein's operation in the two groups of patients implanted with PPM or DCFM component fibrin mesh

	PPM ($N = 45$)	DCFM ($N = 52$)	P
Early mobilisation N (%)	8 (17.8)	30 (57.7)	0.0001
Late mobilisation N (%)	37 (82.2)	22 (42.3)	0.0001
Pain assessment on VAS N (%)			
Mild	8 (17.8)	49 (94.2)	0.0001
Moderate	15 (33.3)	3 (5.8)	0.0013
Severe	22 (48.9)	0 (0.0)	0.0001
Dose of analgesic needed N (%)			
None	0 (0.0)	30 (57.7)	0.0001
Tramadol 200 mg/day	9 (20.0)	22 (42.3)	0.0331
Tramadol > 200 mg/day	23 (51.1)	0 (0.0)	0.0001
Dolantin 100 mg	13 (28.9)	0 (0.0)	0.0001
Analgesia not achieved	0 (0.0)	0 (0.0)	–
Urinary retention N (%)	6 (13.3)	1 (1.9)	0.0761
Early bleeding and wound haematoma N (%)	3 (6.7)	0 (0.0)	0.1903
Late bleeding and wound haematoma N (%)	1 (2.2)	0 (0.0)	0.9504
Wound and mesh infection N (%)	1 (2.2)	0 (0.0)	0.9504
Scrotal haematoma N (%)	8 (17.8)	0 (0.0)	0.0050
Testicular atrophy N (%)	1 (2.2)	0 (0.0)	0.9504
Chronic groin pain N (%)	3 (6.7)	0 (0.0)	0.1903
Recurrence N (%)	1 (1.0)	0 (0.0)	0.4382

VAS Visual-analogue scale

Postoperative pain and complications, time needed for patient mobilisation, and recurrence after direct hernia repair using Lichtenstein's operation with the implantation of PPM or DCFM in the two groups of patients are shown in Table 2. The overall complication (urinary retention, early and late bleeding, wound and mesh infection, scrotal haematoma, testicular atrophy, and chronic groin pain) rate was 51.1% in the PPM group compared to 1.9% in the DCFM group ($P = 0.0001$). The overall recurrence rate after 24 months was 1.0% (1 patient out of 97).

Discussion

The first part of this study has shown that DCFM implanted between the muscle layer and the fascia transversalis in rats causes milder inflammatory response, and thicker fibrous tissue formation than PPM. The 30-day period was chosen because the number of infiltrated chronic inflammatory cells stabilises at that point [11]. The overall incidence of postoperative complications was significantly lower in rats implanted with DCFM than those implanted with PPM (30.0% vs 0.0%, $P = 0.0008$), although, when observed separately, there were no statistically significant differences in postoperative complications between the two groups of rats (except in the incidence of early postoperative bleeding, which was lower in rats implanted with DCFM).

Bleeding and wound haematoma (early and late) occurred in 25.0% of the rats in the PPM group compared to none in the DCFM group, which is statistically significant ($P = 0.003$). This can be partially explained by the haemostatic effect of the DCFM shown in four randomised clinical surveys where fibrin mesh was used in urologic and surgery. Also, the number of rats that reached full mobility in the first 24 h was significantly higher among the group implanted with DCFM then in the group implanted with PPM.

The second part of this study has shown that the overall number of postoperative complications is significantly higher in the group of patients implanted with PPM than in those implanted with DCFM during Lichtenstein hernia repair (23 patients, 51.1% vs 1 patient, 1.9%, $P = 0.0001$). Similar to the findings in the first part of the study, when observed separately, there are no statistically significant differences in the incidences of complications between the two groups of patients, although the incidences of all complications were higher in the group of patients implanted with PPM. The incidence of recurrence was higher in the PPM group than in the DCFM group (1 patient, 1.0%, vs none, 0.0%), and the difference was not

statistically significant. Postoperative pain was reduced significantly in DCFM group when compared to PPM, with 94.2% versus 17.8% patients describing the pain as mild. Also, 48.9% of patients in the PPM group described the pain as severe, compared to 0.0% in the DCFM group. The consumption of analgesics was significantly reduced in the DCFM group as 52.7% patients did not require any analgesics at all, compared to 0.0% in the PPM group. None of the patients in the DCFM group required Tramadol in high doses (>200 mg/day) or Dolantin, compared to 51.1 and 28.9% patients in the PPM group.

Polypropylene mesh is the mesh most widely used for inguinal hernia repair since it is non-absorbable and has high tensile strength [12, 13]. Nevertheless, many studies still question its use and biological effects. Chronic inflammation and tissue irritation have even raised some suspicions concerning polypropylene's oncogenic potential [14]. The massive, non-organised scaring in the groin area that sometimes occurs has also been suspected to cause azospermia and reduced fertility [15–17].

Biological meshes are composed of collagen matrix and become vascularised over time. This feature is of major importance, because it provides additional strength as host collagen deposits over time [18–20].

This study has shown that DCFM has the same short-term efficacy in hernia treatment as the standard PPM, with a reduction of postoperative pain and analgesic use, and a decrease in overall postoperative complications. Also, we proved in the rat model that DCFM results in milder inflammatory response and thicker fibrous plate than PPM. Further biomechanical testing and longer follow-up is necessary, but initial results are promising.

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Arslani N (2008) The effectiveness of tension free method and dual component fibrin mesh prosthesis in strengthening of transversalis fascia in rats and people. Dissertation, University of Zagreb
2. Read RC (1970) Attenuation of rectus sheath inguinal herniation. Am J Surg 120:610–614
3. Awad SS, Fagan SP (2004) Current approaches to inguinal hernia repair. Am J Surg 188(6A Suppl):9S–16S
4. Read RC (1995) The transversalis and peritoneal fasciae: a reevaluation. Lippincott, Philadelphia
5. Nordentoft T, Romer J, Sorensen M (2007) Sealing of gastrointestinal anastomoses with a fibrin glue-coated collagen patch: a safety study. J Invest Surg 20:363–369
6. Getman V, Devyatko E, Wolner E, Aharinejad S, Mueller MR (2006) Fleece bound sealing prevents pleural adhesions. Interact Cardiovasc Thorac Surg 5:243–246
7. Sagalowsky AI (2007) Editorial comment on: efficacy and safety of TachoSil as haemostatic treatment versus standard suturing in kidney tumour resection: a randomised prospective study. Eur Urol 52:1162–1163
8. Siemer S, Lahme S, Altziebler S, Machtens S, Strohmaier W, Wechsel HW, Goebell P, Schmeller N, Oberneder R, Stolzenburg JU, Becker H, Lüftenegger W, Tetens V, Van Poppel H (2007) Efficacy and safety of TachoSil as haemostatic treatment versus standard suturing in kidney tumour resection: a randomised prospective study. Eur Urol 52:1156–1163
9. Frena A, Martin F (2006) How to improve biliostasis in liver surgery. Chir Ital 58:793–795
10. Haas S (2006) The use of a surgical patch coated with human coagulation factors in surgical routine: a multicenter postauthorization surveillance. Clin Appl Thromb Hemost 12:445–450
11. Vaz M, Krebs RK, Trindade EN, Trindade MR (2009) Fibroplasia after polypropylene mesh implantation for abdominal wall hernia repair in rats. Acta Cir Bras 24:19–25
12. Amid P (1997) Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia 1:15–21
13. Korenkov M, Sauerland S, Arndt M, Bograd L, Neugebauer EA, Troidl H (2002) Randomized clinical trial of suture repair, polypropylene mesh or autodermal hernioplasty for incisional hernia. Br J Surg 89:50–56
14. Klosterhalfen B, Klinge U, Hermanns B, Schumpelick V (2000) Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. Chirurg 71:43–51
15. Shin D, Lipshultz LI, Goldstein M, Barmé GA, Fuchs EF, Nagler HM, McCallum SW, Niederberger CS, Schoor RA, Brugh VM III, Honig SC (2005) Herniorrhaphy with polypropylene mesh causing inguinal vasal obstruction: a preventable cause of obstructive azoospermia. Ann Surg 241:553–558
16. Peiper C, Junge K, Klinge U, Strehlau E, Ottinger A, Schumpelick V (2006) Is there a risk of infertility after inguinal mesh repair? Experimental studies in the pig and the rabbit. Hernia 10:7–12
17. Peiper C, Junge K, Klinge U, Strehlau E, Krones C, Ottinger A, Schumpelick V (2005) The influence of inguinal mesh repair on the spermatic cord: a pilot study in the rabbit. J Invest Surg 18:273–278
18. Badylak S, Kokini K, Tullius B, Simmons-Byrd A, Morff R (2002) Morphologic study of small intestinal submucosa as a body wall repair device. J Surg Res 103:190–202
19. Menon NG, Rodriguez ED, Byrnes CK, Girotto JA, Goldberg NH, Silverman RP (2003) Revascularization of human acellular dermis in full-thickness abdominal wall reconstruction in the rabbit model. Ann Plast Surg 50:523–527
20. Dejardin LM, Arnoczky SP, Clarke RB (1999) Use of small intestinal submucosal implants for regeneration of large fascial defects: an experimental study in dogs. Biomed Mater Res 46:203–211