Randomized clinical trial

Randomized clinical trial of self-gripping mesh *versus* sutured mesh for Lichtenstein hernia repair

L. N. Jorgensen[1], T. Sommer[3], S. Assaadzadeh[2], L. Strand[4], A. Dorfelt[5], M. Hensler[1] and J. Rosenberg[2] for the Danish Multicentre DANGRIP Study Group*

Departments of Surgery, [1]Bispebjerg Hospital and [2]Herlev Hospital, University of Copenhagen, Copenhagen, [3]Randers Hospital, Randers, [4]Frederikshavn Hospital, Frederikshavn, and [5]Nyborg Hospital, Nyborg, Denmark

Correspondence to: Professor L. N. Jorgensen, Department of Surgery K, Bispebjerg Hospital, Bispebjerg Bakke 23, DK-2400 Copenhagen NV, Denmark (e-mail: larsnjorgensen@hotmail.com)

Background: **Many patients develop discomfort after open repair of a groin hernia. It was hypothesized that suture fixation of the mesh is a cause of these symptoms.**

Methods: **This patient- and assessor-blinded randomized multicentre clinical trial compared a self-gripping mesh (Parietene Progrip®) and sutured mesh for open primary repair of uncomplicated inguinal hernia by the Lichtenstein technique. Patients were assessed before surgery, on the day of operation, and at 1 and 12 months after surgery. The primary endpoint was moderate or severe symptoms after 12 months, including a combination of chronic pain, numbness and discomfort.**

Results: **The intention-to-treat population comprised 163 patients with self-gripping mesh and 171 with sutured mesh. The 12-month prevalence of moderate or severe symptoms was 17·4 and 20·2 per cent respectively ($P = 0·573$). There were no significant differences between the groups in postoperative complications (33·7 *versus* 40·4 per cent; $P = 0·215$), rate of recurrent hernia within 1 year (1·2 per cent in both groups) or quality of life.**

Conclusion: **The avoidance of suture fixation using a self-gripping mesh was not accompanied by a reduction in chronic symptoms after inguinal hernia repair. Registration number: NCT00815698 (http://www.clinicaltrials.gov).**

*Members of the Danish Multicentre DANGRIP Study Group are co-authors and can be found under the heading Collaborators.

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Introduction

The open tension-free method for inguinal hernia repair using a mesh is the most often used technique worldwide. However, this operation may be followed by an unacceptably high rate of chronic pain, numbness and discomfort. Some 19–29 per cent of patients report chronic inguinal pain[1–3] and 11 per cent report that this pain is present during work or leisure activities[1]. Numbness in the groin may be present in 9–26 per cent of patients after open inguinal hernia repair[2,4–6]. Finally, discomfort in the groin area is a less clearly defined term, but usually describes the presence of slight pain or other sensations in the groin that the patient does not describe as 'chronic pain'. The incidence of groin discomfort may be as high as 11–27 per cent[7,8].

There are various hypotheses about what causes chronic pain, numbness and discomfort after hernia repair, but one possible mechanism is the use of sutures during surgery that may injure minor or major nerves in the operative field. A new self-gripping mesh (Parietene Progrip®; Sofradim, Trevoux, France) has been developed, making the use of sutures unnecessary for inguinal hernia mesh repair. This mesh combines the properties of Parietene Light® mesh (Sofradim) with a surface coverage of absorbable microhooks for tissue fixation to the mesh[9]. Preliminary human data from the use of this mesh have shown promising results[10–12], but there are currently no controlled data or data with long-term follow-up.

The aim of the present study was to evaluate the effect of suturing as a method of fixing the mesh in open inguinal hernia repair on groin pain, numbness and discomfort 12 months after operation.

Methods

This was a randomized multicentre trial conducted in five hospitals in Denmark. The enrolment of patients took place between November 2008 and April 2010. Patients were eligible if they met the following criteria: physically active men aged between 18 and 80 years, diagnosed with an uncomplicated unilateral inguinal hernia and eligible for open elective inguinal hernia repair using the Lichtenstein procedure. The exclusion criteria were: recurrent, scrotal, incarcerated or femoral hernia; body mass index over 30 kg/m^2; non-Danish speaking; concomitant abdominal surgery; ongoing long-term analgesic or steroid treatment; known abuse of alcohol or drugs; Child–Pugh grade C hepatic cirrhosis; or severely compromised health that was likely to affect patient compliance. The ethics committee of the Capital Region of Denmark approved the study and all patients provided written informed consent. The trial was registered at http://www.clinicaltrials.gov (NCT00815698).

Randomization and blinding

Patients were randomized during surgery just before mesh implantation. Treatment allocation was by means of computerized randomization using sealed, numbered envelopes that were opened in sequence. The block size was six. The enrolled patients were assigned to operation with either a self-gripping mesh or mesh fixation with sutures.

Patients and evaluators were blinded to the allocation for the full 12 months after operation. The surgical staff members were not allowed to communicate information about treatment allocation to patients or other staff.

Interventions

Eleven senior consultants with a wide experience of open inguinal hernia repair performed all the procedures on study patients. Each patient underwent inguinal hernia repair by the Lichtenstein technique[13]. The procedures were carried out under general or local anaesthesia according to centre preference. Hernia size and European Hernia Society classification[14] were assessed during surgery. Attention was paid to identification and preservation of nerves. Any nerve division was recorded. Large direct hernias were reduced into the abdomen with an absorbable suture. Indirect hernia sacs were either resected or reduced.

According to allocation, tension-free hernioplasty was done with either a self-gripping polypropylene 8 × 12-cm mesh with absorbable microhooks (Parietene Progrip®) or a 10 × 15-cm polypropylene mesh (Parietene Light®). The structure of the two mesh types is similar following

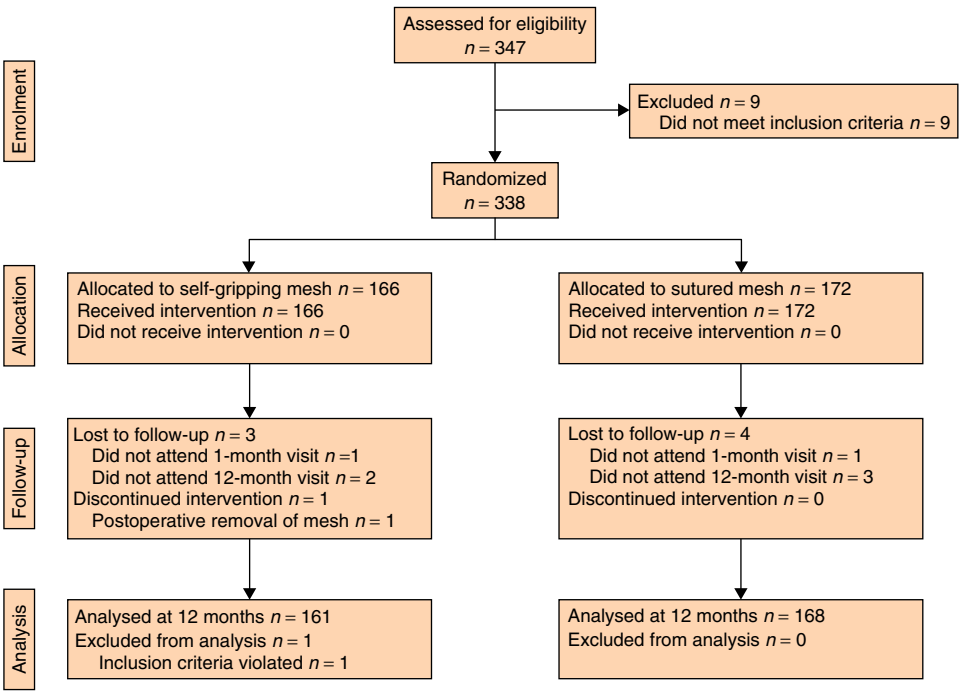

Fig. 1 CONSORT diagram for the trial

degradation of the fixation hooks of the Progrip® mesh. The density of both meshes is 40 g/m^2 after hook degradation.

In the self-gripping mesh group, the flaps of the Progrip® mesh were released and closed around the cord away from the deepest part of the wound. The mesh was carefully oriented to the final position. Fixation to the muscle plane was achieved with gentle pressure on the mesh, starting caudally and medially to the pubic bone, then laterally to the internal oblique structures. The cranial part of the mesh was placed under the external oblique aponeurosis. Finally, the mesh was pushed down to the inguinal ligament and the inner part of the external oblique aponeurosis laterally. No suture was used between the mesh and the pubic bone.

In the sutured mesh group, the Parietene Light® mesh was trimmed to an appropriate size, and placed between the conjoined tendon, the inguinal ligament, the pubic bone and the internal oblique aponeurosis[13]. The spermatic cord was passed through a slit made in the mesh. Fixation of the mesh was by a nylon suture (2/0 Prolene®; Ethicon, Norderstedt, Germany) beginning at the medial corner of the mesh that was sutured to the tendinous surface of the pubic tubercle. This suture was continued as a running suture to attach the lower edge of the mesh to the inguinal ligament up to a point just lateral to the internal ring. The excess patch on the lateral side was trimmed and the two tails of the mesh were placed laterally underneath the external oblique aponeurosis, leaving at least 5 cm of mesh lateral to the internal ring. The upper edge of the patch was sutured in place with two to three interrupted absorbable sutures (2/0 Vicryl®; Ethicon) to the rectus sheath and the internal oblique aponeurosis. Care was taken to avoid passing sutures through the internal oblique muscle in order to avoid entrapment of the intramuscular part of the iliohypogastric nerve.

The external oblique aponeurosis was closed with a running suture (2/0 Vicryl®). Local infiltration analgesia was allowed at the end of operation in patients treated

Table 1 Preoperative characteristics of men undergoing hernia repair in self-gripping mesh and sutured mesh groups

	Self-gripping mesh ($n = 163$)	Sutured mesh ($n = 171$)	P‡
Age (years)*	56·8 (40·2–65·1)	59·9 (45·8–67·5)	0·100§
Body mass index (kg/m^2)*	25·2 (23·5–27·1)	24·8 (23·1–26·7)	0·183§
ASA grade			0·459
I	123 (75·5)	123 (71·9)	
II	35 (21·5)	45 (26·3)	
III	5 (3·1)	3 (1·8)	
Smoker	48 (29·4)	47 (27·5)	0·717¶
Employment			0·055
Full time	106 (65·0)	89 (52·0)	
Part time	9 (5·5)	13 (7·6)	
None	48 (29·4)	69 (40·4)	
Physical activity level			0·924
No sport	66 (40·5)	69 (40·4)	
Leisure sport	95 (58·3)	99 (57·9)	
Professional sport	2 (1·2)	3 (1·8)	
Concomitant disease			
COPD	4 (2·5)	3 (1·8)	0·718¶
Constipation	7 (4·3)	6 (3·5)	0·782¶
Prostatism	13 (8·0)	21 (12·3)	0·210¶
Other pathology	42 (25·8)	29 (17·0)	0·061¶
Moderate to severe symptoms†	116 (71·2)	111 (64·9)	0·242
Persistent pain (VAS, mm)*	30 (4–50)	25 (2–50)	0·701§
Numbness (VAS, mm)*	0 (0–8)	0 (0–20)	0·478§
Groin discomfort (VAS, mm)*	26 (0–50)	23·5 (0–50)	0·813§
Worst pain			0·310
At leisure	38 (23·3)	39 (22·8)	
At rest	17 (10·4)	10 (5·8)	
Doing exercise	86 (52·8)	90 (52·6)	
VAS score 0 mm	22 (13·5)	32 (18·7)	
Analgesic medication	17 (10·4)	17 (9·9)	1·000

Values in parentheses are percentages unless indicated otherwise; *values are median (interquartile range). †Score for persistent pain, numbness or groin discomfort exceeding 30 mm on a visual analogue scale (VAS). ASA, American Society of Anesthesiologists physical status classification system; COPD, chronic obstructive pulmonary disease. ‡χ^2 test, except §Mann–Whitney U test and ¶Fisher's exact test.

under general anaesthesia. The skin was closed with a running nylon suture.

Postoperative analgesia comprised 400 mg ibuprofen three times daily and 1 g paracetamol four times daily for the first 3 days after surgery.

Patient assessments

Patients were assessed within 4 weeks before planned surgery, at operation, at 1 month ± 2 days and at 12 months ± 14 days.

Outcomes

The primary endpoint was a combined measure that evaluated the prevalence of symptoms considered moderate or severe[15,16]. These symptoms included moderate to severe chronic pain and/or numbness and/or groin discomfort at the 12-month visit. Using a visual analogue scale (VAS), in which 0 mm represented no symptoms and 100 mm the worst degree of symptoms, patients' scores for pain, numbness and discomfort were classified as mild (1–30 mm), moderate (31–60 mm) or severe (61–100 mm). This composite endpoint was applied to obtain a robust overall assessment of the principal chronic complaints after inguinal hernia repair. Because these complications each occur at a relatively low rate, the use of the composite endpoint provides a more powerful statistical assessment of the clinical outcome.

Secondary endpoints included: duration of surgery; length of hospital stay; overall wound complications, including haematomas and seromas larger than 10 ml, wound infection including purulent discharge from the wound, antibiotic treatment or positive culture from wound, and bruising; time to return to daily activities; pain (VAS exceeding 30 mm) at the 1-month visit; analgesic medication for groin pain at the 12-month visit; patient satisfaction, assessed by asking the patient 'Would you recommend this operation to others?'; quality of life, assessed by a questionnaire modified from Short Form 12 as described by Ware and colleagues[17]; and hernia recurrence, as confirmed by a blinded examiner or by ultrasonography.

Statistical analysis

The power calculation was based on the prevalence of at least one of the symptoms of chronic pain, numbness or groin discomfort, considered to be moderate to severe in intensity 12 months after hernia repair. Earlier studies have described such symptoms in 25 per cent of patients following Lichtenstein hernia repair with conventional suture fixation of mesh[1,2,8,18,19]. A 50 per cent reduction in prevalence was considered clinically relevant, requiring

Table 2 Perioperative outcomes

	Self-gripping mesh ($n = 163$)	Sutured mesh ($n = 171$)	P†
Anaesthesia			0·289
General	125 (76·7)	138 (80·7)	
Local	35 (21·5)	27 (15·8)	
Regional	3 (1·8)	6 (3·5)	
Skin incision (mm)*	80 (60–97)	80 (65–95)	0·957‡
Type of hernia			0·961
Indirect	107 (65·6)	110 (64·3)	
Direct	52 (31·9)	57 (33·3)	
Combined	4 (2·5)	4 (2·3)	
Largest hernia size (cm)			0·937
< 1·5	47 (28·8)	51 (29·8)	
1·5–3·0	86 (52·8)	91 (53·2)	
> 3·0	30 (18·4)	29 (17·0)	
Nerves identified (any)	157 (96·3)	160 (93·6)	0·322§
Ilioinguinal	149 (91·4)	159 (93·0)	0·684§
Iliohypogastric	118 (72·4)	122 (71·3)	0·903§
Genitofemoral	40 (24·5)	33 (19·3)	0·290§
Nerve preserved			
Yes	154 (94·5)	162 (94·7)	0·617
No	9 (5·5)	9 (5·3)	1·000
Duration of operation (min)*	29 (22–35)	30 (25–39)	< 0·001‡
Duration of admission (h)*	4 (3–6)	4 (3–6)	0·681‡

Values in parentheses are percentages unless indicated otherwise; *values are median (interquartile range). †χ^2 test, except ‡Mann–Whitney U test and §Fisher's exact test.

a total sample of 328 patients, based on 80 per cent power, a 5 per cent type I error (two-sided) and a dropout rate of 10 per cent.

Unpaired numerical data were analysed by the Mann–Whitney *U* test. Pearson's χ^2 or Fisher's exact test was used for analysis of categorical data. Two-way ANOVA for repeated measurements was applied for synchronous assessment of time and allocation. $P < 0{\cdot}050$ was considered statistically significant.

Results

During the study enrolment, 347 patients were assessed for eligibility; 338 of these were randomized to self-gripping mesh (166) or sutured mesh (172). The distribution of patients from the five participating centres was 84, 67, 67, 66 and 54. Four patients were excluded after randomization and before the 1-month visit owing to loss of follow-up (2), reoperation on day 8 with removal of the mesh because of acute pain (1) and violation of the inclusion criteria (1 patient aged 84 years). The 1-month intention-to-treat efficacy analysis comprised 334 patients, 163 with a self-gripping mesh and 171 with a sutured mesh. Five patients did not attend the 12-month visit, leaving 329 in the 12-month intention-to-treat population: 161 with a self-gripping mesh and 168 with a sutured mesh (*Fig. 1*). The respective per-protocol populations comprised 160 and 167 patients, because the type of mesh was uncertain in one patient in each group.

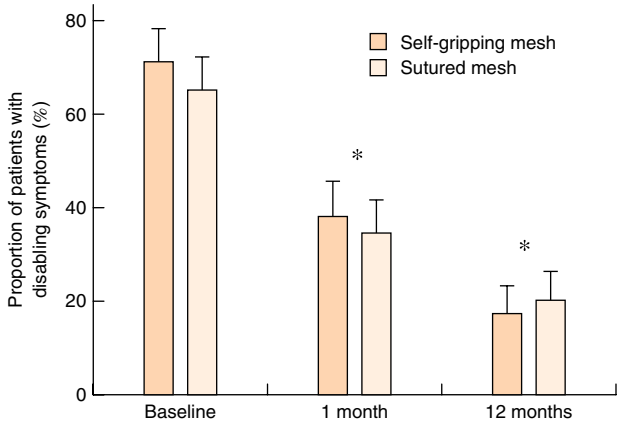

Fig. 2 Proportion of patients with moderate to severe symptoms (score for pain, numbness or groin discomfort exceeding 30 mm on visual analogue scale). Horizontal lines within boxes, boxes and error bars represent median values, interquartile range and 95 per cent confidence limits respectively. *$P < 0{\cdot}001$, levels at 1 month *versus* baseline, and levels at 12 months *versus* 1 month (ANOVA for repeated measurements). There were no significant differences between the allocation groups

No significant differences in demographic variables were demonstrated between the allocation groups (*Table 1*). There was a trend towards a higher employment rate in

Table 3 Outcomes 1 and 12 months after hernia repair

	Self-gripping	Sutured mesh	*P*‡
1-month visit	*n* = 163	n = 171	
Complications (any)	55 (33·7)	69 (40·4)	0·215
Haematoma or seroma	24 (14·7)	36 (21·1)	0·154
Wound infection	9 (5·5)	12 (7·0)	0·655
Other	6 (3·7)	6 (3·5)	1·000
Readmission, any reason	5 (3·1)	5 (2·9)	1·000
Moderate to severe symptoms†	62 (38·0)	59 (34·5)	0·569
Persistent pain (VAS > 30 mm)	21 (12·9)	17 (9·9)	0·491
Persistent pain (VAS, mm)*	0 (0–12)	0 (1–11)	0·740§
Numbness (VAS, mm)*	0 (0–20)	0 (0–29)	0·315§
Groin discomfort (VAS, mm)*	5 (0–25)	0 (0–19)	0·048§
12-month visit	*n* = 161	*n* = 168	
Readmission, any reason	7 (4·3)	17 (10·1)	0·056
Moderate to severe symptoms†	28 (17·4)	34 (20·2)	0·573
Persistent pain (VAS > 30 mm)	16 (9·9)	13 (7·7)	0·561
Persistent pain (VAS, mm)*	0 (0–0)	0 (0–0)	0·173§
Numbness (VAS, mm)*	0 (0–0)	0 (0–0)	0·178§
Groin discomfort (VAS, mm)*	0 (0–0)	0 (0–0)	0·422§
Hernia recurrence	2 (1·2)	2 (1·2)	1·000
Analgesics for groin pain	3 (1·9)	1 (0·6)	0·362
Would recommend operation to others	157 (97·5)	163 (97·0)	1·000

Values in parentheses are percentages unless indicated otherwise; *values are median (interquartile range). †Score for persistent pain, numbness or groin discomfort exceeding 30 mm on a visual analogue scale (VAS). ‡Fisher's exact test, except §Mann–Whitney *U* test.

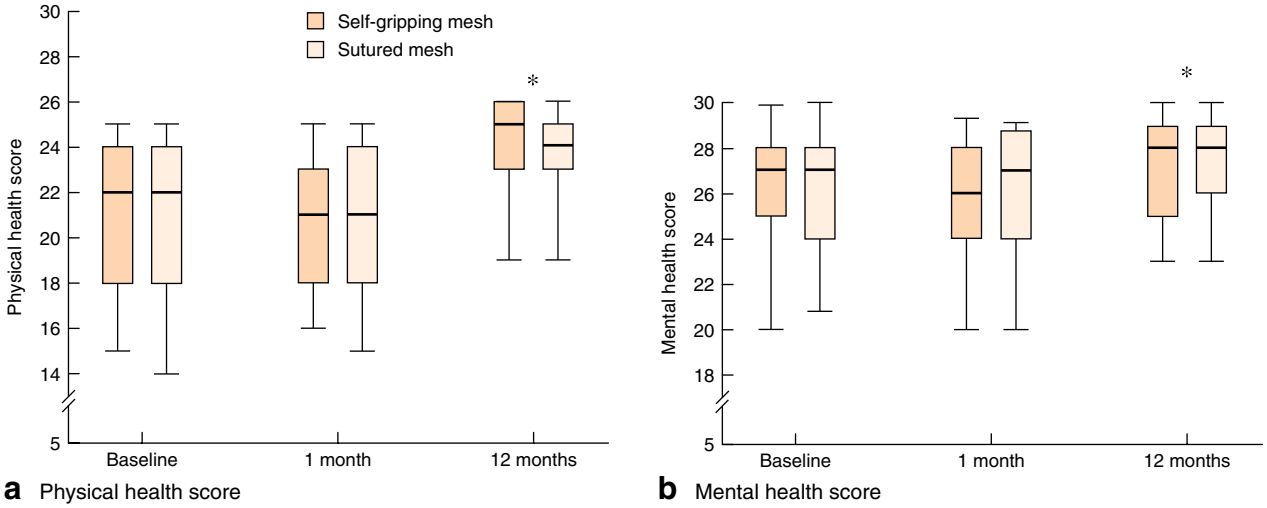

Fig. 3 Changes in **a** physical health score and **b** mental health score after hernia repair. Scores (each range 5–30) were modified after Ware and colleagues[17]. Horizontal lines within boxes, boxes and error bars represent median values, interquartile range and 95 per cent confidence limits respectively. *$P < 0{\cdot}001$ *versus* levels at baseline and 1 month (ANOVA for repeated measurements). There were no significant differences between the allocation groups

the group allocated to self-gripping mesh, but employment status was not statistically associated with the primary endpoint of the study ($P = 0{\cdot}471$).

The majority of patients had surgery under general anaesthesia (*Table 2*) and all of these received supplementary subcutaneous local anaesthesia at the end of operation. Hernia characteristics and nerve identification were comparable in the allocation groups. The median duration of surgery was 1 min shorter in patients receiving self-gripping mesh ($P < 0{\cdot}001$). Three hundred patients (89·8 per cent) left hospital the same day.

Complications were reported in 37·1 per cent of patients during the first month after surgery. Most of these were minor and wound-related, with no significant differences according to the mesh fixation technique (*Table 3*). One patient with a self-gripping mesh had the mesh removed on day 8 because of severe pain, and was excluded from the trial. The mesh was flat and the nerves could not be identified during the reoperation. Some 3·0 per cent of the patients were readmitted, usually for reasons unrelated to the hernia repair. No hernia recurrences were encountered 1 month after operation.

The rate of moderate to severe symptoms related to the hernia and the operation decreased significantly with time (*Table 3*, *Fig. 2*). Such symptoms at the 12-month visit were the primary outcome of the study, and occurred in almost one in five patients with no significant difference between the randomized groups ($P = 0{\cdot}573$). The proportion of patients reporting moderate to severe pain decreased from 11·4 per cent at 1 month to 8·8 per cent after 12 months. The allocated fixation technique was not associated with any significant change in this rate (*Table 3*). Only four patients (1·2 per cent), three after a self-gripping mesh and one after a sutured mesh procedure, used analgesics because of groin pain after 12 months.

The overall rate of hernia recurrence after 12 months was 1·2 per cent, with two recurrences in each group. Both physical and mental health scores improved significantly over time ($P < 0{\cdot}001$) without significant differences between groups ($P = 0{\cdot}318$ and $P = 0{\cdot}891$ respectively) (*Fig. 3*).

Discussion

The omission of mesh fixation with sutures and using the self-gripping Progrip® mesh did not reduce acute or chronic pain after operation. Use of self-gripping mesh was associated with a slight reduction in the duration of operation, but to a magnitude that was not clinically relevant.

The present patient- and assessor-blinded trial indicated that mesh fixation during Lichtenstein inguinal hernia repair with self-gripping mesh is feasible and safe, with an acceptable 1·2 per cent recurrence rate after 1 year in both allocation groups. The rate of moderate to severe symptoms was considerable, reaching 36·2 and 18·8 per cent after 1 and 12 months respectively. Causes of pain after open repair of groin hernia are multifactorial. Early

postoperative pain is generated by trauma to the tissue from preparation of the anterior space and handling of the hernia sac. The mesh material induces a certain inflammatory response, and anchoring the mesh to the posterior wall with sutures, tacks or staples may cause nerve entrapment and neuropathic pain. Moreover, tension due to shrinkage and adhesions between the mesh and nerves may contribute to late postoperative pain.

Several groups have studied the effect of minimalization of mesh fixation in order to reduce damage to nerves or the pubic periosteum, but the results have been inconsistent. Fixation with cyanoacrylate glue or fibrin sealant has been reported to be effective and associated with less postoperative morbidity compared with suture fixation[16,20]. However, a recent study did not detect any reduction in pain or foreign body sensation with use of a cyanacrylate glue product compared with absorbable sutures for mesh fixation in Lichtenstein hernia repair[21]. Early studies on the use of the semiabsorbable self-gripping Progrip® mesh suggested less postoperative chronic pain while maintaining a low hernia recurrence rate[9,11,22], but these studies were either small or not assessor-blind. In contrast, in a recent study Pierides and colleagues[23] could not demonstrate any reduction in pain or discomfort at the operation site secondary to use of self-gripping Progrip® mesh compared with suture fixation. The rate of chronic pain or discomfort 1 year after surgery was 35·2 per cent, compared with the more conservative 18·8 per cent pooled incidence of moderate to severe symptoms in the present trial. In agreement with most other studies, these rates are substantially higher than the reported hernia recurrence rates of 0–1·2 per cent in the two studies, emphasizing the fact that pain and discomfort rather than recurrence are the challenges of modern hernia surgery[24].

More groin discomfort was found after 1 month in the group receiving the self-gripping Progrip® mesh. There is no good explanation for this finding, which theoretically might be related to increased inflammatory reactions after implantation of the self-gripping mesh, with its many additional fibres ending in microhooks. However, no increased tissue reactions were found 2 months after implantation of self-gripping Progrip® compared with Parietene Light® mesh in an experimental study[25].

The initial hypothesis, that suturing by itself may contribute to postoperative pain after open groin hernia repair, is challenged by the present study. Pain after Lichtenstein repair may predominantly be due to dissection in the planes containing peripheral nerves and the close position of the mesh to the nerves, in contrast to the preperitoneal dissection and mesh placement in laparoscopic repair[2]. The finding of less pain with fibrin sealant[16] still, however, supports the relevance of the initial hypothesis.

A minimal reduction in operating time was demonstrated in patients allocated to the self-gripping mesh, in contrast to the findings of other studies that investigated the use of self-gripping mesh or glue[11,22,23]. This might be related to the fact that the median duration of surgery in the present trial for conventional suture fixation of the mesh was only 30 min, shorter than in most other trials[11,12,16,21,23,26].

There were some limitations of this trial. A larger study would have been required to detect a difference in the rate of chronic pain. In agreement with Campanelli and colleagues[15], the compound endpoints of moderate to severe pain, numbness or discomfort were considered clinically relevant alternatives. The timing of the study visits did not allow assessment of early postoperative symptoms. Moreover, follow-up longer than 1 year would be needed to evaluate safety in terms of the rate of hernia recurrence[27].

Collaborators

Other members of the DANGRIP Study Group and co-authors of this study are: C. Hauge (Bispebjerg University Hospital), L. M. Andersen (Randers Hospital) and F. Micheelsen (Nyborg Hospital).

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