

Research Article

A More than 5 Year Experience with a Self Fixating Mesh for Lichtenstein Hernioplasty

Molegraaf MJ*, Swank DJ, and Lange JF

Department of General Surgery, Groene Hart Ziekenhuis, The Netherlands

*Corresponding author

M.J. Molegraaf, Groene Hart Ziekenhuis, Bleulandweg 10, 2803 HH Gouda, The Netherlands, Tel: 31-(0)-640371747; Email: mjmolegraaf@gmail.com

Submitted: 13 February 2017

Accepted: 06 March 2017

Published: 10 March 2017

Copyright

© 2017 Molegraaf et al.

OPEN ACCESS

Keywords

- Inguinal hernia
- Self fixating mesh
- Lichtenstein
- Chronic pain
- Recurrence

Abstract

Purpose: Aim was to evaluate the long term effects of a self adhering mesh not needing traumatic fixation devices on the incidence of chronic postoperative inguinal pain (CPIP) and recurrence rate after inguinal hernioplasty according to Lichtenstein.

Methods: Two groups of fifty consecutive patients, operated in 2008 with the self fixating mesh (R/Progrid, Covidien USA) or with a suture fixating polypropylene mesh, were selected from a population of adult males with primary unilateral inguinal hernia. All patients were sent a SF-36 questionnaire and VAS score in December 2010. Three years later they were interviewed about recurrence and CPIP.

Results: 41 study patients and 42 control patients were available for both points of follow-up. After a median follow up 30 months incidence of CPIP was 14.6% in the self fixating mesh group and 23.8% in the suturing mesh group. After a median follow-up of 67 months this was reduced to 4.8% respectively 9.8% (NS). At 30 months CPIP affected daily life in 1 patient in the self fixating group (2.4%) and 3 patients in the suturing group (7.1%) (NS). After 67 months this was reduced to 0% respectively 2.4% (NS). Severe pain (VAS >70) was only seen in the suturing mesh group. Two recurrences were detected in the self fixating mesh group and one in the sutured mesh group (NS). Operating time was significant shorter for the self fixating mesh ($p=0.000$).

Conclusion: The finding presented here reflects the longest experience to date with the self fixating Progrid mesh for inguinal hernioplasty. Although the self fixating mesh appears not to reduce CPIP, it is efficient with no more recurrences and significantly reduced operating time.

INTRODUCTION

The open Lichtenstein and endoscopic inguinal hernia techniques are still recommended as the best evidence-based options for the repair of a symptomatic primary unilateral inguinal hernia, providing the surgeon is sufficiently experienced in the specific procedure [1]. In recent years chronic postoperative inguinal pain after her-nioplasty (CPIP) gained much attention. CPIP has been defined as pain lasting more than three months after surgery [2]. The reported frequency of CPIP varies widely because of different definitions used. In 2000, Poobalan et al reviewed the literature of CPIP and found incidences ranging from 0% to 63% [3]. A similar range was reported by Aasvang and Kehlet in an update [4]. The overall incidence of moderate to severe CPIP is estimated to be around 10-12% [1,5,6]. Since surgical repair of groin hernias is one of the most commonly performed operations in the Western world and CPIP is especially effecting young otherwise healthy males, CPIP must be considered a major health problem [5]. The etiology of CPIP is multifactorial among which is the surgical repair technique [1,5-7]. This includes aspects like type of mesh used, its structure and interaction with tissue, method of fixation of the prosthetic

material and handling of the cutaneous nerves [5,7,8]. The use of non-absorbable sutures for mesh fixation has been cited as an important etiologic factor because of tension at anchor sites, additional foreign body reaction and entrapment of muscle and nerve fibers [6,9,10]. A solution for this problem might be a self-fixating mesh (Parietene ProGrip®; Covidien): a polypropylene mesh with a one-sided coating of polylactic acid fibre hooks anchoring the mesh on to the tissue rendering additional fixating devices unnecessary. A number of clinical studies including clinical trials have been published to date comparing this particular mesh to the classic PPL mesh [11]. Preliminary results have shown shorter operative times and lower incidences of CPIP. However, there is a lack of data about recurrence and chronic pain results in extended follow-up. The present study aims to report the long term differences in prevalence of CPIP and recurrence between a sutured mesh and a self fixating mesh. It is presumed that a self fixating mesh induces less CPIP and sensory loss without enhancing recurrence rate.

MATERIAL AND METHODS

In the department of general surgery of the Groene Hart

Hospital, Gouda, The Netherlands, two groups of fifty patients, operated in 2008 with the self fixating mesh (R/ProGrip, Covidien USA) or with a suture fixating poly-propylene mesh (R/Prolene, Ethicon, USA), were consecutively selected from a population of adult male patients with primary unilateral inguinal hernia, operated by two surgeons, performing the self fixating mesh-technique and by six other surgeons, performing the suture fixating mesh technique. Exclusion criteria for both groups were incarcerated inguinal hernia, ASA >3, coexisting chronic groin pain and being incapacitate. The self-adhesive ProGrip mesh was introduced in the department in 2007.

All operations were performed by a surgeon or by a trainee under supervision. Operations were performed under spinal or general anaesthesia in day care setting. Tension-free hernioplasty was performed with a 6×11 cm Prolene mesh or 12×8 cm Parietene ProGrip Mesh. The hernioplasty was accomplished according to the open tension-free repair of Lichtenstein. The incision, dissection of the sac in relation to the type of hernia, dissection of the anterior inguinal floor and closure of the wound with absorbable sutures were similar in all patients. The ilioinguinal, genitofemoral (genital branch) and iliohypogastric nerves were identified and preserved if possible in each case. In case of damage to the nerve or interfering with mesh or sutures the nerve was excised. Indirect hernia sacs were inverted or in case of a large sac transfixed at the base and excised. Direct sacs were inverted with absorbable sutures.

The Parietene ProGrip Mesh [manufactured by Sofradim Production, Trévoux, France (Group Covi-dien)] is a monofilament mesh composed of polypropylene and resorbable polyactid acid (PLA) micro hooks for tissue gripping. Mesh fixation by the micro hooks to the underlying groin tissue is achieved instantly after exerting light pressure on the mesh. After the company the PLA micro hooks will be completely resorbed after 15 months and only the low-weight (40 g/m²) monofilament polypropylene (PP) will be left in situ. The mesh has an oval shape with a self-gripping flap to be placed around the spermatic cord at the internal ring. The flap can be opened and reclosed facilitating corrections during mesh placement. There is a right and left sided version for optimal fitting of the mesh to the anatomical area.

In the suturing group the mesh was positioned against the posterior wall of the inguinal canal and sutured to the aponeurotic tissue over the pubic bone with a non-absorbable monofilament suture overlapping the pubic bone by 1.0 to 1.5cm (avoiding the pubic periost). With a running PDS 2.0 suture the lower edge of the mesh was fixed to the inguinal ligament. Then the mesh was incised to create two tails which were placed around the spermatic cord in order to create a prosthetic internal ring. Both tails were overlapping each other with a single non-absorbable monofilament suture. Interrupted sutures were used to fixate the upper edge of the mesh to the conjoint tendon.

The ProGrip mesh was placed tension free over the posterior wall of the inguinal canal overlapping the pubic bone and inguinal ligament by 1cm. The self gripping flap was closed loosely around the spermatic cord as described by Chastan [25]. Fixation was achieved by applying light pressure on the mesh. No fixating suture(s) were applied.

Finally a local anaesthetic (50mg chirocaine soluted in 10ml NaCl) was administered into the wound in both groups of patients. Operating time was scored starting from skin incision to completion of skin closure.

The primary outcome of the study was the prevalence of CPIP with pain defined as a VAS score >10 [14]. Chronic pain was regarded as mild (VAS 10–30), moderate (VAS 31–60) or severe (VAS 70–100) [14]. Secondary outcomes included wound complications, operating time and recurrence rate.

After informed consent patients from both groups were sent a SF-36 questionnaire and VAS score in December 2010 to assess the degree of CPIP and interference with activities of daily living. Three years later, January 2014, a telephone call was made and patients were asked about recurrence of the hernia and the existence of CPIP or sensory loss in the operated groin area and whether the pain interfered with social activities and work. In the case of CPIP they were asked to grade their present groin pain on a visual analogue scale. Data about medical history, peri- and postoperative complications and operation details were collected from the clinical database.

STATISTICAL ANALYSIS

The statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) for Windows, version 9'01 (SPSS, Chicago, Illinois, USA). All tests were two sided and P <0.05 was considered significant. Dichotomous categorical data were compared using Pearson's Chi-squared test or Fisher's exact test for smaller groups. Continuous data were expressed as median (range) and compared with the Mann-Whitney U test.

RESULTS

Within the group of 100 patients 83 patients (n=41 self fixating mesh; n=42 suturing mesh) were available for long term follow-up (mean 67 months). Demographic details of patients and hernia types are shown in Table (1). There was no significant difference in response rate and characteristics between the two groups.

The median duration of operation was 37 min for the self-fixating and 47 min for the sutured mesh (p <0.001, Mann-Whitney U test, (Table 2). No perioperative complications were observed. Three post-operative complications occurred, all in the suturing mesh group (not significant, NS): one postoperative haematoma, one seroma and one infection (epididymitis). At the end of the study (median FU 67 months) two recurrences were detected in the self fixating group and one in the suturing group (NS).

At the first cross sectional analyses in December 2010 (median follow up 30 months, range 26-35, (Table 3) CPIP defined as VAS >10 mm was reported by 14.6% patients in the self fixating mesh group and by 23.8% patients in the suturing mesh group (OR 0.55, CI 0.179-1.681). CPIP affected daily life in 2.4% of the self fixating group and 7.1% of the suturing group (NS).

At the second cross-sectional analyses in January 2014 (median follow up 67 months, range 63-72, (Table 4) CPIP was reported by 4.8% respectively 9.8% (OR 0.59, CI 0.145-2.008) and affecting daily life in 0% respectively 2.4% (NS).

Table 1: Patient and hernia characteristics.

	Suturing Mesh N=41	Self fixating Mesh N=42
Age**	66 (24-89)	68 (21-89)
Sex ratio (F:M)	0:41	0:42
Body mass index (kg/m2)**	24.8 (18.2-31.0)	25.0 (20.2-30.4)
Type of work*		
Sedentary	13 (31.7)	11 (26.2)
Physical	11 (26.8)	12 (28.6)
Unemployed/retired	17 (41.4)	19 (45.2)
Side of hernia*		
Left	24 (58.5)	23 (54.8)
Right	17 (41.5)	19 (45.2)
Type of hernia*:		
Direct	12 (29.3)	10 (23.8)
Indirect	26 (63.4)	28 (66.7)
Combined	3 (7.3)	4 (9.5)
Operator*:		
Resident	35 (85.4)	38 (90.5)
Surgeon	6 (14.6)	4 (9.5)
Anaesthesia*:		
General	13 (28.6)	12 (31.7)
Spinal	28 (71.4)	30 (68.3)
Follow up ** (months)	67 (63-72)	67 (64-72)

*values in parentheses are percentages ;**Values are median (range)

Table 2: Results.

	Suturing Mesh N=41	Self fixating Mesh N=42	P
Operating time**	47 (34-87)	37 (17-97)	0.000 ¥
Neurectomie *	3 (7.3)	6 (14.3)	0.483\$
Complications*:			
Recurrence	1 (2.4)	2 (4.2)	0.616 \$
Haematoma	1 (2.4)	0	0.517 \$
Seroma	1 (2.4)	0	0.517 \$
Wound infection	1 (2.4)	0	0.517 \$
Testicular atrophy	0	0	
Prevalence of CPIP (%)			
median FU 30 months*	10 (23.8)	6 (14.6)	0.312§
median FU 67 months*	4 (9.8)	2 (4.8)	0.353§
Interference with daily ac- tivities (%)			
median FU 30 months*	3 (7.1)	1 (2.4)	0.317§
median FU 67 months*	1 (2.4)	0	0.517 \$
Sensory loss	25 (61)	15 (36.6)	0.037§

*values in parentheses are percentages;**Values are median (range); ¥ Mann-Whitney U test; \$ Fisher's Exact Test; § Pearson χ^2 test.

In those patients who reported CPIP, pain intensity was mostly classified as mild pain (VAS 10-30, (Table 3,4). Severe pain (VAS >70) was only seen in the sutured mesh group. Two patients in this group were referred to a pain team. Sensory loss was reported by 15 (36.6%) patients in the self fixating group and 25 (61%) patients in the suturing mesh group (P0.0367).

DISCUSSION

Our data indicate that a self fixating Progrid mesh not

needing additional suturing is safe and effective also after long term follow-up of 67 months. Compared to a sutured mesh there were no significant differences in incidence of CPIP (2% resp 4%) and recurrences (4.2% resp 2.4%). Furthermore the self fixating mesh is easy to perform reflected in significant reduced operating times. It was expected that this self fixating mesh bypassing traumatic fixation devices would lead to a reduction in CPIP compared to meshes traumatically fixated with sutures or staples. This hypothesis was based on the assumption that a traumatic fixation of a mesh would reduce the risk of compression and entrapment of muscle and nerve fibers leading to less muscle ischaemia and neuroma formation [6,12]. Indeed removal of sutures can be an effective treatment in patients with pain [13]. Further on despite Lichtenstein being a tension-free method, fixation devices will still cause tension at anchor sites [9]. Finally no fixation device means less foreign material and possibly a reduction of the foreign body reaction. This foreign body reaction is known to cause inflammatory damage to surrounding tissues and nerves and may induce a surplus of scar tissue leading to stiffness of the abdominal wall and a foreign body sensation [10,14,15]. When using the Parietene Progrid mesh the need for traumatic fixation devices is bypassed by small absorbable micro hooks on the surface of the mesh. Chastan was the first to report the initial promising clinical experience with this self fixating mesh [16]. Since his publication a number of prospective studies and randomized controlled trials have compared the self fixating mesh with a sutured mesh in Lichtenstein hernioplasty. Some studies suggested that the incidence of CPIP was significantly reduced by using this mesh [17-19], while other studies did not confirm that [20-24]. The absence of a significant reduction of CPIP when using a self fixating mesh may have several explanations. First the onset of CPIP is multi-factorial and not only caused by surgical related factors, but is also influenced by patient related factors. Patient risk factors for the onset of CPIP include young age, obesity, preoperative pain and pre-existing pain syndrome [6,7,25]. Surgical risk factors do not only include type of mesh fixation, but also the repair technique itself, inadvertent nerve injury, postoperative infection, hernia recurrence and type of prosthetic material [26-28]. It was argued that the reduction in foreign material by the absence of fixation devices would reduce the sometimes harmful effects of the foreign body reaction. However there is still the mesh causing this immune response. Thereafter it may have been too simplistic to suppose that the main difference between the meshes was the absence or presence of permanent sutures. The composition of the self fixating mesh is different in that it has polylactic acid micro hooks on its surface. The inflammatory response to these micro hooks may differ from the response to polypropylene and sutures, affecting the extent of scar tissue formation and the probability of chronic nerve irritation. Further on establishing the anterior space as well as addressing the hernia sac should cause the same measure of trauma to the tissue irrespective of mesh attachment strategy. The results of the Progrid mesh are in line with studies comparing another way of a traumatic fixation with fibrin sealant and glue fixation. A recent meta-analysis showed that there was no significant reduction in CPIP using glue or fibrin sealant compared to sutures or staples [29]. Apparently the surgical trauma to the groin itself plays a crucial role in the development of CPIP. When performing a pre peritoneal inguinal hernioplasty

Table 3: VAS score first cross-sectional analyses, median follow-up 30 months, OR for CPIP 0,55 (CI 0.179-1.681).

	Chronic pain				median VAS	range
	<10	10-30	31-70	>70		
Self fixating mesh	35	5	1	0	0	0-40
Suturing mesh	31	7	2	1	5	0-80

Table 4: VAS score second cross-sectional analyses, median follow-up 67 months, OR for CPIP 0,54 (CI 0.145-2.008),

	Chronic pain				median VAS	range
	<10	10-30	31-70	>70		
Self fixating mesh	40	2	0	0	0	0-20
Suturing mesh	38	2	1	0	15	0-40

there remains the risk of injuring the inguinal nerves by other ways than fixation devices, e.g. by transection (neurectomy), by blunt or sharp dissection, diathermic heat or entrapment of the inguinal nerves by the mesh itself.

Recurrence rate was the same for both groups after a long term of 67 months suggesting the micro hooks provide satisfactory mesh fixation or at least equivalent to sutures. This is in accordance with median-term follow-up studies [20,30,31]. Some even report no recurrent cases after 24 months with the use of the Progrid mesh [16,31]. The difference may be due to our extended follow-up of 67 months or due to the fact that most patients were operated by supervised residents instead of surgeons.

Duration of surgery with the self fixating mesh was significantly shorter. This must be due to the lack of requirement for sutures to secure the Progrid mesh and is consistent with other studies [18,31]. This is an important benefit of the Progrid mesh. Currently, the self fixating mesh costs 2.5 times more than the comparable mesh of only polypropylene, but these increased costs are compensated by the reduced utilization of the operating room.

There are important limitations to the underlying study. Causes of CPIP are multifactorial. The number of patients included in this study is insufficient to show all important differences. Other drawbacks of the current study is that it was cross-sectional, not randomized and the analysis of the questionnaire was not blinded. In conclusion, the finding presented here reflects the longest experience to date with the self fixating Progrid mesh for inguinal hernioplasty. The self fixating mesh appears safe and efficient with no more recurrences and significantly reduced operating time.

ACKNOWLEDGMENT

The authors thank Coen Baeten, surgeon, for his inspiration and support. The authors declare no conflict of interest.

REFERENCES

1. Collaboration EUHT. Repair of groin hernia with synthetic mesh: meta-analysis of randomized controlled trials. *Ann Surg.* 2002; 235: 322-332.
2. Classification of chronic pain. Descriptions of chronic pain syndromes and definitions of pain terms. Prepared by the International

Association for the Study of Pain, Subcommittee on Taxonomy. *Pain Supplement.* 1986; 3: S1-226.

3. Poobalan AS, Bruce J, King PM, Chambers WA, Krukowski ZH, Smith WC. Chronic pain and quality of life following open inguinal hernia repair. *Br J Surg.* 2001; 88: 1122-1126.
4. Aasvang E, Kehlet H. Chronic postoperative pain: the case of inguinal herniorrhaphy. *Br J Anaesth.* 2005; 95: 69-76.
5. Nienhuijs S, Staal E, Strobbe L, Rosman C, Groenewoud H, Bleichrodt R. Chronic pain after mesh repair of inguinal hernia: a systematic review. *Am J Surg.* 2007; 194: 394-400.
6. Nienhuijs SW, Rosman C, Strobbe LJ, Wolff A, Bleichrodt RP. An overview of the features influencing pain after inguinal hernia repair. *Int J Surg.* 2008; 6: 351-356.
7. Poobalan AS, Bruce J, Smith WC, King PM, Krukowski ZH, Chambers WA. A review of chronic pain after inguinal herniorrhaphy. *Clin J Pain.* 2003; 19: 48-54.
8. Wijsmuller AR, van Veen RN, Bosch JL, Lange JF, Kleinrensink GJ, Jeekel J, et al. Nerve management during open hernia repair. *Br J Surg.* 2007; 94: 17-22.
9. Paajanen H. Do absorbable mesh sutures cause less chronic pain than nonabsorbable sutures after Lich-tenstein inguinal herniorrhaphy? *Hernia: the journal of hernias and abdominal wall surgery.* 2002; 6: 26-28.
10. Miller JP, Acar F, Kaimaktchiev VB, Gultekin SH, Burchiel KJ. Pathology of ilioinguinal neuropathy produced by mesh entrapment: case report and literature review. *Hernia.* 2008; 12: 213-216.
11. Fang Z, Zhou J, Ren F, Liu D. Self-gripping mesh versus sutured mesh in open inguinal hernia repair: system review and meta-analysis. *Am J Surg.* 2014; 207: 773-781.
12. Loos MJ, Scheltinga MR, Roumen RM. Tailored neurectomy for treatment of postherniorrhaphy inguinal neuralgia. *Surgery.* 2010; 147: 275-281.
13. Silen W. Chronic pain and quality of life following open inguinal hernia repair. *Br J Surg.* 2002; 89:123.
14. Amid PK. Radiologic images of meshoma: a new phenomenon causing chronic pain after prosthetic re-pair of abdominal wall hernias. *Arch Surg.* 2004; 139: 1297-1298.
15. Brown CN, Finch JG. Which mesh for hernia repair? *Ann R Coll Surg Engl.* 2010; 92: 272-278.
16. Chastan P. Tension-free open hernia repair using an innovative self-gripping semi-resorbable mesh. *Hernia. J Minim Access Surg.* 2009; 13: 137-142.

17. Kapischke M, Schulze H, Caliebe A. Self-fixating mesh for the Lichtenstein procedure--a prestudy. *Langenbeck's Arch Surg.* 2010; 395: 317-322.
18. Kingsnorth A, Gingell-Littlejohn M, Nienhuijs S, Schule S, Appel P, Ziprin P, et al. Randomized controlled multicenter international clinical trial of self-gripping Parietex ProGrip polyester mesh versus lightweight polypropylene mesh in open inguinal hernia repair: interim results at 3 months. *Hernia. J Hernias Abdominal Wall Surg.* 2012; 16: 287-294.
19. Quyn AJ, Weatherhead KM, Daniel T. Chronic pain after open inguinal hernia surgery: suture fixation versus self-adhesive mesh repair. *Langenbeck's Arch Surg.* 2012; 397: 1215-1218.
20. Bruna Esteban M, Cantos Pallares M, Artigues Sanchez De Rojas E. [Use of adhesive mesh in hernioplasty compared to the conventional technique. Results of a randomised prospective study]. *Cirugia espanola.* 2010; 88: 253-258.
21. Anadol AZ, Akin M, Kurukahvecioglu O, Tezel E, Ersoy E. A prospective comparative study of the efficiency of conventional Lichtenstein versus self-adhesive mesh repair for inguinal hernia. *Surg Today.* 2011; 41: 1498-1503.
22. Paajanen H, Kossi J, Silvasti S, Hulmi T, Hakala T. Randomized clinical trial of tissue glue versus absorbable sutures for mesh fixation in local anaesthetic Lichtenstein hernia repair. *Br J Surg.* 2011; 98: 1245-1251.
23. Pierides G, Scheinin T, Remes V, Hermunen K, Vironen J. Randomized comparison of self-fixating and sutured mesh in open inguinal hernia repair. *Br J Surg.* 2012; 99: 630-636.
24. Jorgensen LN, Sommer T, Assaadzadeh S, Strand L, Dorfelt A, Hensler M, et al. Randomized clinical trial of self-gripping mesh versus sutured mesh for Lichtenstein hernia repair. *Br J Surg.* 2013; 100: 474-481.
25. Aasvang EK, Gmaehle E, Hansen JB, Gmaehle B, Forman JL, Schwarz J, et al. Predictive risk factors for persistent postherniotomy pain. *Anesthesiology.* 2010; 112: 957-969.
26. Franneby U, Sandblom G, Nordin P, Nyren O, Gunnarsson U. Risk factors for long-term pain after hernia surgery. *Ann Surg.* 2006; 244: 212-219.
27. Kehlet H, Rathmell JP. Persistent postsurgical pain: the path forward through better design of clinical studies. *Anesthesiology.* 2010; 112: 514-515.
28. Sajid MS, Leaver C, Baig MK, Sains P. Systematic review and meta-analysis of the use of lightweight versus heavyweight mesh in open inguinal hernia repair. *Br J Surg.* 2012; 99: 29-37.
29. Ladwa N, Sajid MS, Sains P, Baig MK. Suture mesh fixation versus glue mesh fixation in open inguinal hernia repair: a systematic review and meta-analysis. *Int J Surg.* 2013; 11: 128-135.
30. Pedano N, Pastor C, Arredondo J, Poveda I, Ruiz J, Monton S, et al. Open tension-free hernioplasty using a novel lightweight self-gripping mesh: medium-term experience from two institutions. *Langenbeck's Arch Surg.* 2012; 397: 291-295.
31. Chatzimavroudis G, Papaziogas B, Koutelidakis I, Galanis I, Atmatzidis S, Christopoulos P, et al. Lichtenstein technique for inguinal hernia repair using polypropylene mesh fixed with sutures vs. self-fixating polypropylene mesh: a prospective randomized comparative study. *Hernia.* 2014; 18: 193-198.

Cite this article

Molegraaf MJ, Swank DJ, Lange JF (2017) A More than 5 Year Experience with a Self Fixating Mesh for Lichtenstein Hernioplasty. *JSM Pain Manag* 2(1): 1005.