



Medical Group

Open Journal of Pain Medicine

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Dates: Received: 22 March, 2017; Accepted: 21 April, 2017; Published: 22 April, 2017

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Keywords: TAPP; Inguinal hernia; Polypropylene; Polyester; Mesh; Pain; Chronic pain

Research Article

Chronic Pain after Laparoscopic Inguinal Hernia Repair Depends on Mesh Implant Features: A Clinical Randomised Trial

Abstract

Chronic pain is a severe complication of mesh-based inguinal hernia repair. In this prospective, clinical, randomized, double-blind study we investigated the biocompatibility of three different meshes and their influence on chronic pain. One hundred eighty male patients with primary inguinal hernia undergoing laparoscopic transabdominal polypropylene plastic (TAPP) were randomized for using a heavyweight (108 g/m²), double-filament polypropylene mesh (Prolene, 10X15 cm, group A, n = 60), a multifilament, heavyweight variant (116 g/m²) of polypropylene mesh (Serapren, 10X15 cm, group B, n = 60), or a composite mesh (polyglactin / polypropylene) (Vypro II, 10X15 cm, group C, n = 60). Groups were compared in terms of complications, pain development and life quality (SF-36 Health Survey). Convalescence in group A lasted more time than in groups B and C: mean-term values of the visual scales for pain development were significantly higher (p<0.05), incapacity for work was 8.2 days longer, and urological adverse effects were stronger. The mean-term development of life quality was significantly lower in group A up to the 12th week. There were no significant differences between groups B and C. Beyond the 12th postinterventional week the differences were not statistically significant. Independent of the mesh implanted there was still 5% of patients suffer chronic pain 60 months later.

Introduction

The use of alloplastic materials has become the standard procedure in inguinal hernia surgery [1-6]. Hernia surgery is one of the most common visceral operations and thus of great medical and economic importance. Many publications have shown that there are advantages in the early postoperative outcome and lower recurrence rate when using techniques with mesh implantation compared with mesh-free inguinal hernia repair [1-6]. Therefore, inguinal hernia repair with mesh has become the standard in the last 20 years. Open surgery according to Lichtenstein was used most often at the earlier times, whereas minimally invasive techniques have been increasingly applied in the last decade [1-6]. Chronic pain is the most frequent long-term complication after inguinal hernia repair. Its perceived risk varies widely in the international literature. There are studies describing a higher rate of chronic pain after laparoscopic hernia repair in comparison to the open surgery and there are also studies describing it the other way round. Nevertheless, mesh associated chronic pain after hernia repair is an often described phenomenon [7-9].

Meshes cause rigidity, shrinking, chronic pain, adhesion

formation as well as inflammatory process concerning epididimidis and vas deferens [10-13]. Permanent relief of pain or discomfort and low incidence of peri- and postoperative complications and recurrence rates are the goals of successful hernia repair. In laparoscopic inguinal hernia repair the inguinal region is approached and hernia repair is performed from the interior side. Exploration and placement of staplers in the internal inguinal region during laparoscopic hernia repair may induce specific complications such as nerve entrapment, neuralgia, hematomas [14-16]. In laparoscopic procedures mainly polypropylene meshes are used due to its strength and incorporation characteristics [15,17,18]. They provoke a strong stimulus for chronic inflammatory response [16-20]. These problem has led to the development of different meshes characterized by a reduction of the polypropylene volume, an increase of the pore size and different web structures [21,22]. Also meshes with absorbable and nonabsorbable components have been produced and used (filaments of polypropylene and polyglactin) to minimize the amount of nonabsorbable foreign material. Although the complications are relatively low considering the large number of meshes being implanted, some complications are observed, including seromas, wound

discomfort and stiffness of the abdominal wall [11,15,23-25]. The impact of laparoscopic inguinal hernia repair on open radical retropubic prostatectomy is discussed and it is described that pelvic lymphadenectomy could be compromised [24-26]. However, urological affections or disorders do play a leading role in the postoperative disorders like dysuria, touchsensitivity of the testicle or ejaculation with pain [16].

The designed prospective comparative clinical trial, investigated the compatibility of three different meshes (Table 1) in patients undergoing laparoscopic transabdominal polypropylene plastic (TAPP) for primary inguinal hernia in long-term follow-up. In every case we used the same surgical technique, inserting three different meshes with different percent of polypropylene or structure. We investigated the consequences of reducing the quantity of nonabsorbable polypropylene (two pure heavy-weight polypropylene meshes, or a polypropylene-polyglactin tangle) and of different structure (double- and multifilament heavy-weight polypropylene mesh) by means of urological affections and life quality.

Methods

The study was conducted in accordance with the Declaration of Helsinki and all its amendments. Patients declared their approval of the study by signing an informed consent document.

In the years 1999-2001 one hundred eighty male patients undergoing a laparoscopic transabdominal hernia repair for primary inguinal hernia and fulfilling the criteria were included into the study. After the process of randomisation 60 patients were treated with mesh A, 60 got mesh B and 60 mesh C implanted (Figure 1). In every group 60 patients were allocated to intervention. In group A only 58 patients received the intervention. In two cases the Lichtenstein procedure had to be done because of massive peritoneal adhesions. Also one person in group B had an operation of Lichtenstein. In group C two patients received open hernia repair because of peritoneal adhesions, like in group A (Figure 1).

Inclusion criteria were: male patient, one-sided inguinal hernia, age between 35 and 75 years, BMI less than 30. The exclusion criteria were: peripheral arterial disease worse than clinical stage II b, recurrent inguinal and scrotal hernia, neurological affections or paresthesia of the genital region or the lateral region of the proximal lower extremity, polyneuropathy,

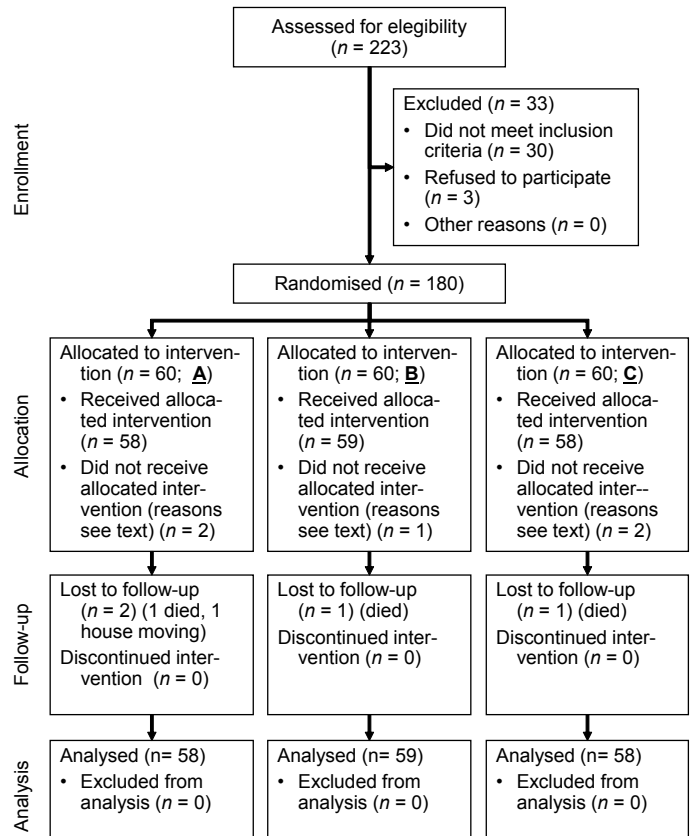


Figure 1:

disturbance of the testicular blood circulation with testicular atrophy, therapy with anticoagulative drugs, chronic back pain, intraoperative conversion to open procedures, hydrocele, epididymitis, funiculitis, femoral hernia or incarceration.

After the process of randomisation we had three groups: A: 60 (average age 61.5 years) of these were treated with a monofile, heavy-weight (108 g/m²) and double-filament polypropylene mesh. B: 60 (average age 62.3 years) got a multifilament, heavy-weight variant (116 g/m²) of polypropylene mesh being composed by multifile material implanted. C: 60 patients (average age 63.2 years) were treated with a composite-mesh made of polyglactin (PG) and polypropylene (PP) (PP 35 g/m²) (Table 1).

Randomisation

The coincidence distribution was done with prepared envelopes. The day before the operations every patient has to tear an envelope with a card inside. The name of the mesh was typed on the card. Every surgeon (two fixed teams) received a list with the name of the patient and the sort of mesh that had to be implanted. The surgeons who implanted the mesh were not included in the follow-up. Neither the patients nor the investigating doctor were informed about the type of mesh used (Table 1).

Follow-up of the patients

On the day prior to the operation a detailed physical investigation with determination of the blood routine-

Table 1: Mesh data used for TAPP.

	Unit	Prolene	Serapren	Vypro II
Material		100% PP	100% PP	50% PP/ 50% PG
Structure		double-filament	multifilament	multifilament
Absorbable		no	no	PG proportion
Number of pores	[pro 1 cm]	4.6	6	2
Pore size	[mm]	1.0 - 1.6	0.08 - 0.1	2.0 - 5.0
Thickness	[mm]	0.55	0.5	0.49
Weight	[g/m ²]	108	116	PP 35
Implant size	[cm]	15x10	15x10	15x10

(PP: Polypropylene, PG: Polyglactin)

parameters and a doppler-ultrasound investigation of the testicular vessels (arteria testicularis, plexus pampiniformis) took place. The testicle volume and the blood circulation of the testicle were likewise documented at the 1st and 3rd postoperative day by means of ultrasound. At the 1st and 3rd postoperative day as well as after the 1st, 2nd, 4th, 8th and 12th postoperative week and the 12th, 24th and 60th postoperative month on the basis of questionnaires the pain development (*visual scales*), impairment of the sexual life and duration of incapacity for work were documented. The physical conditions were checked in the 4th, 8th and 12th postoperative week and the 12th, 24th and 60th postoperative month by using the German SF-36 Health Survey Test. This test is an instrument to evaluate the influence on quality of life of different forms of therapies by measuring four components: general physical conditions, social relations, psychological conditions and functional competence. Furthermore postoperative complications were documented.

Statistical analysis

Based on our previous experience (Surg Endosc 2003;17:1105-9), our sample size calculation aimed at detecting a difference of 10 points in the SF-36 subscale on bodily pain at the 12-week follow-up. With a power of 80%, a type I error of 5%, and a standard deviation of 18, a sample size of 52 patients per groups was required. Thus, the study recruited a total of 180 patients. Data analysis have been done on an intention to treat basis (Figure 1).

All results are given as mean \pm SEM. Differences for parameters obtained at each point of time were evaluated by a 2-way ANOVA for repeated measures using SPSS software. At a level of $p < 0.05$ differences were considered significant.

The scales of SF-36 have been transformed in values of numbers between 0 and 100 to enable comparability in each group and the different groups of patients.

Endoscopic surgical procedure

All patients were treated under general anaesthesia. At the starting point the pneumoperitoneum was built up with CO₂ at 15 mm Hg. A 10 mm trocar was placed within the umbilicus and two 10 mm trocars were placed laterally. The hernia was identified and the peritoneum was dissected. We regularly separated the peritoneum far upwards into the abdominal cavity from the structures of the spermatic cord. In this way we ensured that at final closure of the peritoneum the mesh could not be raised up from its position, lying flat at the inguinal region. We paid special attention we to retrovesical dissection, so that the mesh covered the entire medical compartment without any folds, since this region is predisposed towards recurrences. Depending on the randomisation either mesh A, B or C was positioned. All the meshes had the same size (15x10 cm). We did not cut any slits in the meshes. We tried to use a minimum number of clips (Cooper's ligament, medial and lateral to the epigastric vessels; straight Endostapler, Ethicon, Norderstedt, Germany). Any application of clips between the ductus deferens and testicular vessels (the so called "triangle

of doom" with underlying external iliac vessels) and lateral to the structures of the spermatic cord and below the ileopubic tract (the so called "square of doom" with the lateral femoral cutaneous nerve) was strictly avoided. In the case of medial hernias we drew the thinned-out transversalis fascia into the abdomen and fixed it with at least two clips to the ligament of Cooper, to avoid any seroma formation. The hernial sac was always completely dissected out of the hernial canal and separated from the spermatic cord structures. The peritoneum was also closed with a resorbable suture (Ethicon, Vycryl 3/0).

The two surgeons, who carried out the operative procedure, had a long experience of laparoscopic hernia repair procedure with more than three hundred.

Results

The three groups were comparable in terms of group size and age structure, body mass index and comorbidities as well as the local findings (Table 1). The overall follow-up rate was 97.2% after 60 months (Figure 1): We lost two patients in group A after two years: one died and one did house moving. In group B one patient died after one year of follow-up and in group C we lost a patient after two years (Figure 1).

Overall we analysed 58 patients of group A, 59 patients of group B and 58 of group C.

In each group we found COPD, hypercholesterinemia and -lipidemia, arterial hypertony and coronary heart disease at comparable percentage (Table 2). In the patient group with mesh A we found in 43% a left-sided lateral hernia inguinalis, in 43% a right-sided hernia inguinalis lateralis and in 14% a right-sided hernia inguinalis medialis. In the group with mesh B there were 40% patients with a left-sided hernia inguinalis lateralis, 40% with a right-sided hernia inguinalis lateralis, 10% with a left-sided hernia inguinalis medialis and 10%

Table 2: Patient data of the three groups undergoing TAPP for one-sided, primary hernia using 3 different meshes.

	Group A (Prolene)	Group B (Serapren)	Group C (Vypro II)
Number of patients	58	59	58
Age	61.5 \pm 3.4	62.3 \pm 4.3	63.3 \pm 3.8
Sex	m	m	m
BMI (kg/m²)	24.2 \pm 2.1	25.6 \pm 1.9	25.2 \pm 2.3
Overall comorbidity	33(56.8%)	32(54.2%)	30(51.7%)
Diabetes mellitus	12(20.6%)	10(16.9%)	13(22.4%)
Hypertony	25(43.1%)	23(38.9%)	25(41.1%)
Coronary heart disease	7(12.0%)	6(10.1%)	6(10.3%)
COPD	3(5.1%)	2(3.3%)	3(5.1%)
Hypercholesterinemia	23(39.6%)	22(37.2%)	21(36.2%)
Nyhus classification			
Type II	15(25.8%)	13(22.0%)	12(20.6%)
Type IIIa	12(20.6%)	11(18.6%)	9(15.5%)
Type IIIb	13(22.4%)	9(15.2%)	8(13.7%)
Type IIIc	2(3.4%)	1(1.6%)	2(3.4%)
Type IV	3(5.1%)	2(3.3%)	1(1.7%)

with a right-sided hernia inguinalis medialis. In group C there were 35% with left-sided hernia inguinalis lateralis, 47% with right-sided hernia inguinalis medialis and 18% with right-sided hernia inguinalis lateralis. The size of the hernia was measured during the operation and the surface was calculated. In all group the surface was determined between 3 and 16 cm².

The patients spent nearly the same time in hospital (group A: 3.7 days, group B: 3.9 days, group C: 3.8 days). Average operation time was 63.9 minutes in group A, 72.6 minutes in group B and 65.3 minutes in group C. A reduction of the doppler signals in the testicular vessels at the hernia site at preoperative check was found in 8 cases over all groups. After surgical therapy the flow was improved. There were no postoperative atrophies of the testicles found. In 10 cases the pampiniform plexus was congested at the site of the hernia before the operative procedure over all groups. This congestion was relieved in all cases after surgery. In all the groups nearly the same number of complications occurred in the form of

scrotal and abdominal wall hematomas, testicular contact pain at the operated site and seroma formation on the 1st and 2nd postoperative days (Table 3). We had an overall recurrence rate of 2.3 % (two in group A, one in group B and one in group C). In all these cases we found medial recurrences caused by partial mesh migration. There were no significant differences between the individual groups as regards the frequency of recurrence.

From the first postoperative week in all groups an increase of touch-sensitiveness of the testicle at the operated side, pain with ejaculation and discomfort with urination could be documented (Table 3). These symptoms became significant different ($p < 0.05$) in the 4th and 12th postoperative week (Table 3) in group A compared to groups B and C.

Regarding the pain development measured with visual scales one could find significant ($p < 0.05$) more pain from the 1th day after the operation up to the 12th postoperative week (Figure 2) in group A. In the other groups there was no significant

Table 3: Postoperative complications after TAPP in 180 patients (meshes A, B, C).

Endpoints	Complications	Patients in A (Prolene)	Patients in B (Serapren)	S	Patients in A (Prolene)	Patients in C (Vypro II)	S	Patients in B (Serapren)	Patients in C (Vypro II)	S
1 st postop. day	Scotal hematoma	3	2	No	3	2	No	2	2	No
	Abdominal wall seroma	8	6	No	8	6	No	6	6	No
	Testicular contact pain	3	4	No	3	4	No	4	4	No
2 nd postop. day	Scotal hematoma	12	10	No	12	10	No	10	10	No
	Abdominal wall seroma	10	8	No	10	8	No	8	8	No
	Testicular contact pain	8	6	No	8	7	No	6	7	No
1 st postop. week	Scotal hematoma	12	10	No	12	10	No	10	10	No
	Abdominal wall seroma	8	7	No	8	8	No	7	8	No
	Testicular contact pain	4	4	No	4	4	No	4	4	No
	Pain with ejaculation	5	6	No	5	4	No	6	4	No
2 nd postop. week	Discomfort with urination	8	5	No	8	4	$p=0.02$	5	4	No
	Scotal hematoma	12	10	No	12	10	No	10	10	No
	Abdominal wall seroma	8	6	No	8	7	No	6	7	No
	Testicular contact pain	7	3	$p=0.02$	7	2	$p=0.02$	3	2	No
	Pain with ejaculation	10	6	$p=0.02$	10	4	$p=0.01$	6	4	No
4 th postop. week	Discomfort with urination	7	3	$p=0.02$	7	4	$p=0.03$	3	4	No
	Scotal hematoma	8	6	No	8	6	No	6	6	No
	Abdominal wall seroma	6	4	No	6	2	$p=0.02$	4	2	No
	Testicular contact pain	7	2	$p=0.02$	7	2	$p=0.02$	2	2	No
	Pain with ejaculation	12	4	$p=0.01$	12	4	$p=0.01$	4	4	No
12 th postop. week	Discomfort with urination	7	2	$p=0.02$	7	3	$p=0.02$	2	3	No
	Testicular contact pain	8	1	$p=0.01$	8	2	$p=0.02$	1	2	No
	Pain with ejaculation	12	2	$p=0.01$	12	2	$p=0.01$	2	2	No
24 th postop. month	Discomfort with urination	7	1	$p=0.02$	7	2	$p=0.02$	1	2	No
	Pain with ejaculation	2	0	No	2	1	No	0	1	No
	Discomfort with urination	2	1	No	2	1	No	1	1	No
60 th postop. month	Recurrence rate	1	0	No	1	1	No	0	1	No
	Pain with ejaculation	1	0	No	1	0	No	0	0	No
	Discomfort with urination	1	0	No	1	0	No	0	0	No
	Recurrence rate	1	1	No	1	0	No	0	1	No

difference in pain development. Also the therapy with analgetics (novalminesulfon drops) reflected the presence of higher pain in group A after the operations. The consumption of the analgetic was significantly ($p < 0.05$) higher in group A than in groups B and C up to the 4th day after TAPP (Figure 3).

Nearly the same situation could be found concerning the impairment of sexual life after TAPP through pain. The impairment of sexual life was significantly bigger in group A from the 1th week after the operation up to the 12th postoperative week compared to groups B and C (Figure 4). In group A the average duration of incapacity for work was significantly ($p = 0.02$) longer (39.1 days) than the one registered in group B (32.4 days) and group C (33.3 days).

Before surgery, the generic quality of life was prospectively measured using the Medical Outcome Study SF-36 Health Survey. In Figure 5 the development of physical function from preoperative up to the 60th postoperative month is shown. At the starting point the average physical function was nearly the same in the three groups. In the 4th postoperative week it was significantly ($p < 0.02$) lower in group C than in the two other groups. Figure 6 shows the development of pain measured with the SF-36: One day before the operation pain was nearly the same in all the groups. After the operative procedure up to the 12th postoperative week a significantly stronger pain development was again described in group A than in groups B and C.

Discussion

Nowadays the introduction of biomaterials for inguinal hernia repair has become an integral component of surgery. Mesh implants are often regarded as a standard treatment for this anatomic defect, and their routine use in surgical practice is rapidly increasing. The high number of patients getting an inguinal hernia repair (for example 770.000 patients in 2003 in the US) makes it necessary to talk about the long-term side effects, especially the development of chronic pain [6]. Not only surgeons, but also many other medical specialists and generalists are confronted with this chronic problems. On the one hand surgeons should prevent causing chronic pain by

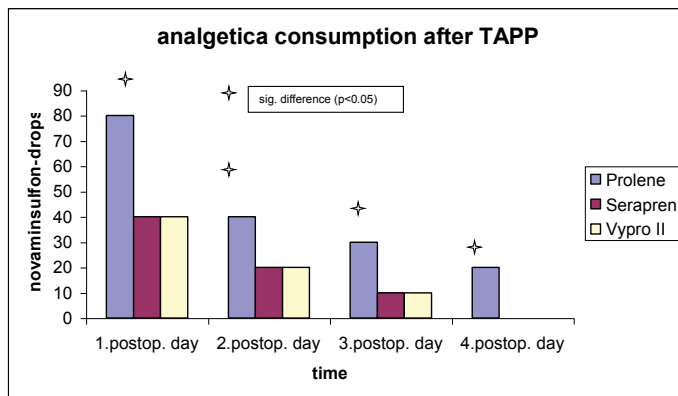


Figure 3: Consumption of novaminsulfon-drops in the three collectives.

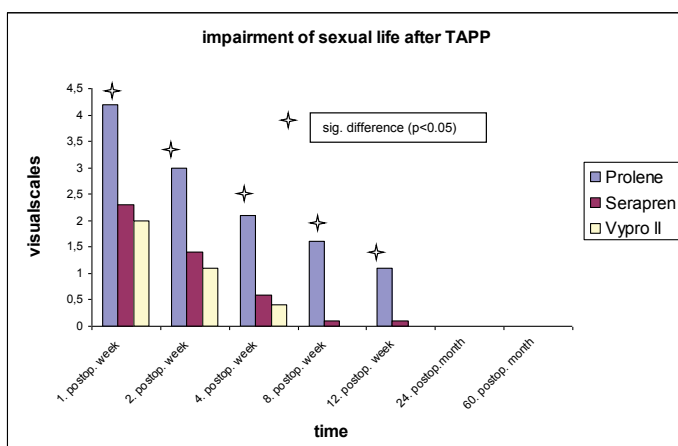


Figure 4: Impairment of sexual life in the three collectives.

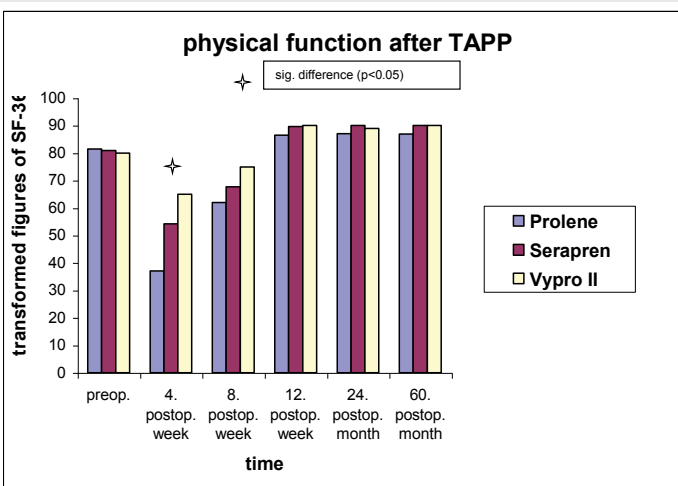


Figure 5: Physical function documented with the SF-36 in the three collectives. The scales of SF-36 have been transformed in values of numbers between 0 and 100 to enable comparability in each group and the different groups of patients.

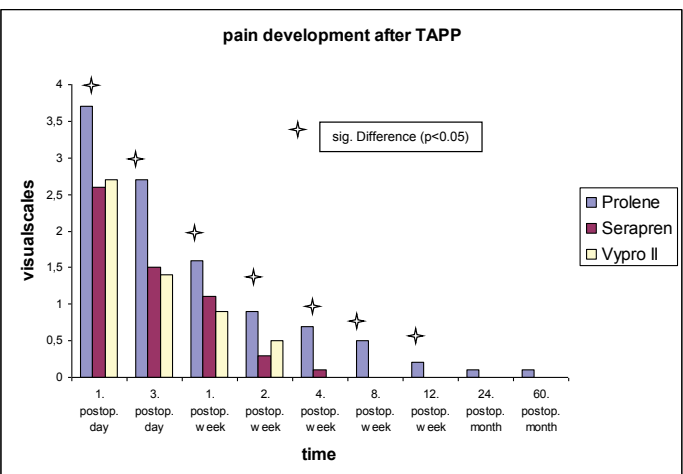


Figure 2: Pain development in the three collectives documented with visual scales.

using biocompatible materials and on the other hand it seems important to define a way how to handle the chronic pain symptoms.

Kehlet et al. describe a compromising effect on daily life for 5-10 % of the patients and pain-related sexual dysfunction, including dysejaculation occurring in about 2 % of young

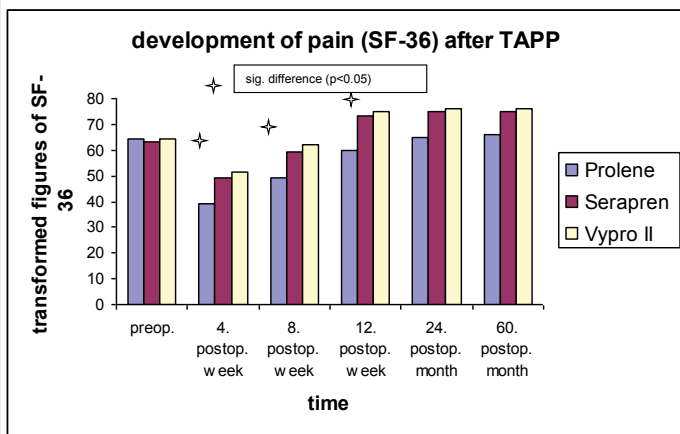


Figure 6: Development of pain documented with the SF-36 in the three collectives. The scales of SF-36 have been transformed in values of numbers between 0 and 100 to enable comparability in each group and the different groups of patients.

men. Sensory disturbances are described in many patients after inguinal hernia repair without chronic pain [16,27,28]. Kehlet considers the main issue for future research on the pathogenesis and treatment of chronic post-herniorrhaphy pain in the role of patient-related factors versus surgery [16,27,28]. Nienhuijs et al draw the conclusion that 11% of patients suffer chronic pain after mesh based inguinal hernia repair. In this study more than a quarter of patients have moderate to severe pain, mostly with a neuropathic origin. Almost one third of these patients describe limitations in daily leisure activities [2,3]. Both authors come to the conclusion that laparoscopic repair of inguinal hernia should be done with light meshes that have a reduced amount of material.

For about a century, surgical treatment of the hernial gap was based on suture repair. Now days the introduction of biomaterials for inguinal hernia repair has become the standard. This study was designed to investigate whether life quality is influenced by properties of the implanted mesh. Corresponding to the results of previous studies comparing pure polypropylene meshes and Vypro II meshes we found no differences in the recurrence rates up to 60 months after the operative procedure [21,29].

Horstmann et al. [29], examined the impact of polypropylene amount on functional outcome and quality of life after TAPP procedure using three different meshes (Prolene, Vypro II, T-mesh) in an observational setting. He drew the conclusion that comparable functional results, lower postoperative complications, and improved quality of life can be achieved by reducing the polypropylene amount in meshes used for laparoscopic hernia repair. In our randomised trial we could not find a significant difference between the heavy-weight, small-pored, smooth, multifilament polypropylene mesh and the composite mesh in postoperative complications or life quality. In terms of incidence of discomfort, chronic groin pain and sensations of numbness after prosthetic inguinal hernia repair we could only find a significant ($p < 0.05$) difference concerning the pure, heavy-weight, rigid, double-filament polypropylene mesh from the 4th up to the 12th post-interventional week. Beyond this point of time there were no significant differences

in our three groups. In the long-term follow up (60 months) no significant difference was documented. The difference was just significant in the short- and the mean-term follow up.

Schmidtbauer et al. showed that large pore-sized, low-weight polypropylene meshes composed of multifilaments (e.g., Vypro II), had better abdominal wall compliance and caused less chronic pain than large pore-sized, monofilament heavy-weight polypropylene mesh (e.g., Prolene) [25]. In contrast we did not find an advantage of the composite mesh concerning the development of functional competence and the pain development after TAPP in comparison to the heavy-weight, smooth polypropylene mesh, but there was a significant advantage in pain development and functional competence from the 4th up to the 12th postoperative week in comparison to the heavy-weight, rigid polypropylene mesh. And we could also observe an advantage of the heavy-weight, smooth polypropylene-mesh in comparison to the heavy-weight, rigid mesh concerning pain development and functional competence from the 4th up to the 12th post-interventional week in our trial. Khan et al. [24], found no difference between a light-weight and a heavy-weight polypropylene mesh in patients with laparoscopic inguinal hernia repair (TEP) concerning pain or discomfort at mean 3-month follow up. He described a significant inverse correlation between the length of time since operation and severity of pain or discomfort in the light-weight group, suggesting a faster speed of recovery with light-weight mesh.

It is quite interesting, that the differences seem to diminish in the long-term follow up. After 60 months we could not find any significant differences between the three groups. The process of incorporation of the materials seems to provoke different reactions reflecting in pain development, life quality and discomfort. But after the 12th week of operative therapy these differences are not evident anymore in our groups. Nevertheless, we found still 5% of patients suffering from chronic pain and discomfort in the long-term follow-up independent of which mesh was implanted.

There is a need for evidence-based treatment strategies for established chronic pain. Few prospective long-term follow-ups of large cohorts suggest a burn-out rate of about 50% within 5 years. Some positive results have been reported using neurectomy. But the literature on surgical treatment of chronic pain after laparoscopic inguinal hernia repair does not allow any firm recommendations [26]. Pharmacological treatment of chronic pain after hernia repair has not been established, gabapentanoids and tricyclics may play a role. Local anaesthetics may prove useful concerning the relatively limited anatomical pain area [16].

In conclusion, independent of which mesh was implanted still 5% of the patients are suffering from discomfort after five years. Chronic pain after laparoscopic inguinal hernia repair is an interdisciplinary global problem. Urological affections like dysejaculation, dysuria and touchsensitivity are the most described chronic symptoms. It is still unclear which kind of mesh is ideal for the patient but it is clear that life quality is influenced by properties of the implanted mesh. Laparoscopic

hernia approach with a light-weight mesh seems to provoke less chronic discomfort. Evidence-based strategies for established chronic pain are still missing.

Acknowledgement

This study was funded in part by German Ministry of Education and Research (CHIR-Net, grant 01GH0605).

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