

# Impact of Polypropylene Amount on Functional Outcome and Quality of Life after Inguinal Hernia Repair by the TAPP Procedure Using Pure, Mixed, and Titanium-coated Meshes

Ruediger Horstmann, MD,<sup>1</sup> Matthias Hellwig, MD,<sup>1</sup> Claus Classen, MD,<sup>1</sup>  
Susanne Röttgermann, MD,<sup>1</sup> Daniel Palmes, MD<sup>2</sup>

<sup>1</sup>Department of General Surgery, Herz-Jesu-Hospital Muenster-Hiltrup, Westfalenstr. 109, D-48165 Muenster, Germany

<sup>2</sup>Department of General Surgery, Münster University Hospital, Waldeyerstr. 1, D-48149 Muenster, Germany

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## Abstract

**Background:** Laparoscopic inguinal hernia repair requires the use of prosthetic material. This prospective, single-center study was intended to investigate the impact of the amount of polypropylene (PP) mesh used in hernia repair on functional results and quality of life.

**Methods:** For this series, 672 consecutive patients with primary inguinal hernia undergoing transabdominal preperitoneal hernia repair (TAPP) using a heavyweight PP mesh (Prolene 10 × 15 cm, 1.5 g, group I, n = 232), a mixed PP- and Polyglactin mesh (Vypro II, 10 × 15 cm, 0.53 g, group II, n = 217), or a light-weight titanized PP mesh (Ti-Mesh, 10 × 15 cm, 0.24 g, group III, n = 223) were compared in terms of postoperative complications (seroma, wound healing disorders), quality of life score (pain development, physical condition, urologic disorders), and hernia recurrence.

**Results:** During a 12-month follow-up there were no significant differences in the recurrence rate (1.3%-1.7%). Patients with a pure PP mesh (group I) showed significantly more postoperative seromas (12.1% versus 4.1%/1.8%), foreign body sensations (9.1% versus 5.5%/3.5%), and sensitivity to weather changes (5.6% versus 3.2%/2.2%) compared to groups II and III. In all groups, the quality of life score was improved postoperatively. However, among those patients in our series with few preoperative complaints, the postoperative quality of life was worsened when heavy-weight PP meshes (group I+II) were used but significantly improved when light-weight titanized PP meshes were used.

**Conclusions:** Comparable functional results, fewer postoperative complications, and improved quality of life can be achieved by reducing the amount of PP in meshes used for laparoscopic hernia repair by TAPP procedure.

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In the surgical treatment of inguinal hernia, the use of mesh is optional for the anterior approach, but with laparoscopic methods it is absolutely essential. In Ger-

many, meshes are used in roughly 50% of all repair operations, amounting to an absolute number of 80,000 to 100,000 implants per year. Worldwide, the number of mesh operations is estimated at over 1 million.<sup>1</sup> Polypropylene (PP) meshes show good mechanical stability and reasonable elasticity, and they are regarded as being slow to biodegrade.<sup>2</sup> Therefore PP meshes have become the implant most frequently used for hernia surgery.

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Correspondence to: Ruediger Horstmann, MD, Department of General Surgery, Herz-Jesu-Hospital Muenster-Hiltrup, Westfalenstr. 109, D-48165 Muenster, Germany, e-mail: chirurgie@herz-jesu-kh-ms.de

Nevertheless, the wide assortment of methods used for the repair of inguinal hernias bears witness to the continuing controversy regarding the routine use of synthetic materials, in particular in young patients. After recommendation of biomaterials for “tension-free” hernioplasties in open surgery, prospective randomized studies have shown a certain advantage of laparoscopic prosthetic repair of inguinal hernias in terms of a lower recurrence rates and earlier resumption of everyday activities.<sup>3,4</sup> However, there is still a strikingly high incidence of chronic inguinal pain and feelings of numbness, which calls for improvement.<sup>5–8</sup> It has been surmised that the inflammatory reaction to the foreign material is correlated with the amount and structure (i.e., pore size) of the synthetic material inserted.<sup>9</sup> If we assume that the maximum loading of the abdominal wall amounts to 16 N/cm, the pure PP meshes are roughly 3–8 times over-dimensional, i.e., their quantity of foreign material is too high by a corresponding factor.<sup>1,10</sup> For these reasons, synthetic composites have been developed by industry in order to minimize the amount of nonabsorbable foreign material, for example, by the use of light-weight meshes or tangles of PP and an absorbable component such as polyglactin.

In this prospective comparative study we used the same surgical technique (transabdominal pre-peritoneal hernioplasty = TAPP) in every case, using three different meshes with different PP amount (pure heavy-weight PP, a PP-polyglactin tangle, or a titanized low-weight PP). We investigated the consequences of reducing the quantity of nonabsorbable PP by means of objective criteria (recurrence rate, complication rate, etc.) and subjective criteria (quality of life).

## PATIENTS AND METHODS

### Study Design

This prospective comparative study comprised the 672 patients who, from July 1999 to December 2003, underwent laparoscopic surgery with the transabdominal pre-peritoneal technique (TAPP) for primary inguinal hernia repair. This is the standard method employed in our hospital since 1993. Only in exceptional cases (children, extensive previous abdominal operations), did we choose an anterior technique, and those patients were excluded from the study. In all consecutive operations during the period between July 1999 and December 2000 (group I, n = 232 patients) we used Prolene (Ethicon, Norderstedt, Germany) as an implant to strengthen the transversalis

fascia. This Prolene mesh consists exclusively of PP and is plaited from double-stranded monofilaments. Having a weight of 100 g/m<sup>2</sup> it is counted as one of the heavy-weight, small-mesh networks. From January 2001 to September 2002 (group II, n = 217 patients) all patients without exception were treated with a Vypro II mesh (Ethicon, Norderstedt, Germany). As a light-weight PP variant with large pores, Polyglactin 910 as an absorbable material is woven into the Vypro II mesh to make it easier to handle. After 6 weeks, resorption of the Polyglactin results in a wide-mesh (5 mm) PP network in which the amount of foreign material becomes reduced by 65% in comparison with the Prolene mesh. From October 2002 to December 2003 (group III, n = 223 patients) we used exclusively Ti-Mesh extralight (GFE, Nuremberg, Germany), a pure lightweight PP network (16 g/m<sup>2</sup>) coated with titanium. Using the so-called PACVD technique (plasma-activated chemical vapor deposition), the manufacturers have for the first time succeeded in depositing a few layers of titanium atoms on the synthetic materials so that the fibers are coated on all sides with a titanium layer of roughly 30 nm (Table 1).

### Parameters

All patients were assessed according to the following parameters:

Overall operating time, measured from entering to leaving the operating room.

Handling of the various meshes: by recording the intraoperative mesh implantation time, measured from the insertion of the mesh through the trocar to starting the peritoneal closure.

Mesh infection: diagnosed by the presence of micro-biologically demonstrated micro-organisms.

Seroma/hematoma: ultrasound examination of the inguinal region was performed in all patients before their discharge with the evaluator blinded to the type of mesh used. Seromas with a diameter >1 cm were considered to be an inflammatory reaction associated with the implant.

Increased analgesic requirements: defined as an analgesic intake of more than 1 day's duration.

Overall duration of hospital stay.

Duration of incapacity for work.

Recurrence: Follow-up 12 months after surgery was conducted by questionnaire. When answers to the questionnaire suggested a recurrence the patient was called in for a physical examination and ultrasound, performed with the evaluator blinded to the type of mesh used.

**Table 1.**  
Mesh data (Manufacturers' statements: <sup>a</sup>Ethicon, <sup>b</sup>GSE) used for laparoscopic hernia repair

	Prolene <sup>a</sup>	Vypro II <sup>a</sup>	TiMesh <sup>b</sup>
Material	100% PP	50% PP 50% Polyglactin	100% PP coated with titanium 30 nm
Structure	Double-filament	Multifilament	Monofilament
Absorbable	No	Polyglactin proportion (ca. 70 days to absorption)	No
Weight/area	100 g/m <sup>2</sup>	35 g/m <sup>2</sup>	16 g/m <sup>2</sup>
Pore size	1.0–1.6 mm	2–5 mm	<1.0 mm
Implant size	10 × 15 cm	10 × 15 cm	10 × 15 cm
Implant weight	1.5 g	0.53g (PP proportion)	0.24 g
Thickness	0.55 mm	0.49 mm	0.2 mm
Extensibility at 16 N/cm	8%	28%	No information

**Table 2.**  
Preoperative quality of life score

Parameter	Severity	Points
Pain	None	0
	On exercise	3
	At rest	6
Sensation of Pressure	Slight	0
	Severe	1
	None	2
Swelling	Slight/easily replaced	0
	Marked/severe	1
	Can be replaced	2
Urinary symptoms	None	0
	Mild	1
	Severe	2
Disorder of potency	None/occasionally	0
	Frequent	1
	Duration of symptoms (in relation to the hernia)	<6 months
	6 months to 2 years	2
	>2 years	3
		Max. 16

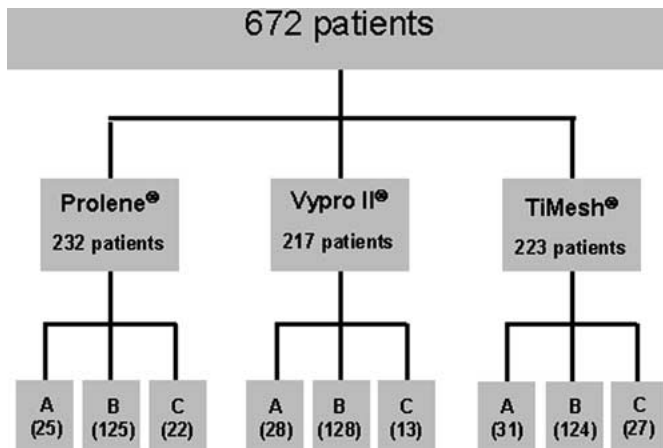
**Table 3.**  
Postoperative quality of life score

Parameter	Severity	Points
Pain	None	0
	On exercise	3
	At rest	6
Recurrence	None	0
	Evident	6
Sensitivity to weather changes	None	0
	Slight	1
	Severe	2
Sensation of foreign body	None	0
	Slight	1
Urinary Symptoms	Severe	2
	None	0
	Slight	1
Disorder of potency	Severe	2
	None/occasional	0
	Frequent	1
		Max. 19

## Quality of Life

The quality of life was assessed preoperatively and 12 months postoperatively with the help of a standardized questionnaire. The underlying score was developed by us and calculated by our medical staff. The number of points attributed to each patient is indicated in Tables 2 and 3. Preoperatively, we established six parameters: intensity of pain, sensation of pressure and swelling in the inguinal region, disorders of potency, urinary symptoms, and duration of pain (Table 2). Postoperatively, the parameters were: pain intensity, recurrence, sensitivity to weather changes, sensation of a foreign body, abnormalities of micturition, and disorders of potency (Table 3). The score consists of different parameters pre- and

postoperatively: preoperatively, the parameter “Swelling” is merely a symptom of the disease, but postoperatively it is a sign of recurrence and therefore it earns a higher score. “Sensitivity to weather changes” and Sensation of foreign body” are postoperative parameters since they point to an inflammatory reaction to a foreign body. “Pain” and “Sensation of pressure” had a pivotal meaning in the preoperative score and therefore earned a higher score. For the postoperative analysis of quality of life, in addition to scoring the group as a whole, we drew a distinction between the separate groups and even between those patients who preoperatively experienced minor impairment (preoperative 0–3 points, subgroup a), moderate impairment (preoperative 4–6 points, subgroup b), or definite impairment (preoperatively >6 points, sub-



**Figure 1.** Study groups. 672 patients undergoing consecutive TAPP were subdivided into three groups (I: Prolene mesh,  $n = 232$ , July 1999 to December 2000; II: Vypro II mesh,  $n = 217$ , January 2001 to September 2002; III: TiMesh,  $n = 223$ , October 2002 to December 2003). By reference to the quality of life score, at the time of follow-up all patients in group I-III were divided into subgroups with minimal (**A**), moderate (**B**) or severe (**C**) preoperative symptoms due to the inguinal hernia.

group c), the symptoms being caused by the hernia. In this way we established three subgroups for each main group (Fig. 1).

### Operative Technique

The principle of transabdominal preperitoneal mesh insertion for the treatment of inguinal hernias has been known since 1990.<sup>11</sup> To explain our own surgical standards, we shall deal only with certain important aspects (Fig. 2). All patients were operated under general anesthesia. In general, we implanted a mesh measuring  $10 \times 15$  cm without cutting any slits in it. For this reason 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 gave special attention to retrovesical dissection so that the mesh covered the entire medial compartment without any folds, since this region is predisposed toward recurrences. Any application of clips between the ductus deferens and testicular vessels ("triangle of doom" with the underlying external iliac vessels) and lateral to the structures of the spermatic cord and below the ileopubic tract ("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, so as to avoid any seroma formation. In general, we tried to use a minimum number of clips (Cooper's ligament, medial and lateral to the epigastric blood vessels, straight Endostapler, Ethicon, Norderstedt, Germany). The hernial sac, including any attached lipomas, was always completely dissected out of the hernial canal and separated from the spermatic cord structures. The peritoneum was closed with a continuous absorbable suture (Vicryl, Ethicon, Norderstedt, Germany). As a general rule, based on personal experience, we placed Redon drainage between the mesh and the peritoneum for 24 hours.

### Statistics

The data were summarized as mean values with standard deviations. Statistical analysis was performed by the  $\chi^2$ -test to compare discrete variables and by the  $t$ -test to compare continuous variables using SPSS 12.0 for Windows computer software (SPSS Inc., Chicago, IL). A  $P$  value of less than 0.05 was considered to indicate statistical significance.

## RESULTS

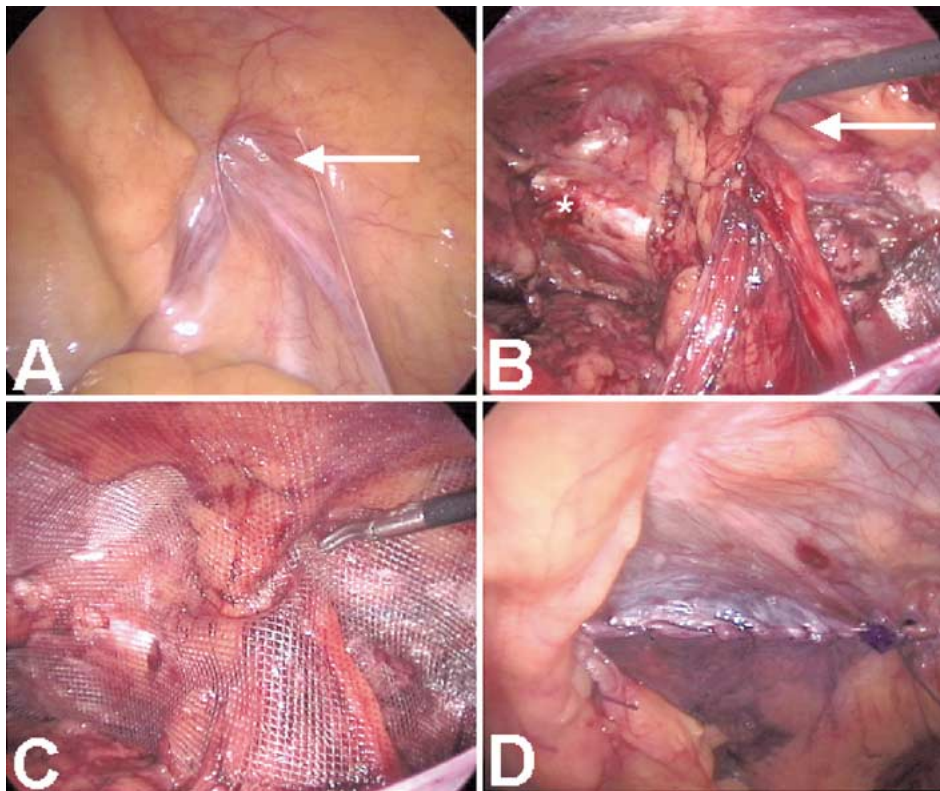
All the groups were comparable in terms of group size and age structure, sex distribution, body mass index, and comorbidities, as well as the local findings assessed by the Nyhus classification (Table 4). The overall follow-up rate was 81.2% after 12 months (group I: 84.1%, group II: 77.8%, group III: 81.6%).

### Handling of the Mesh Material

When dealing with unilateral hernias, the average operative times in the three groups ranged from 58 to 65 minutes, and that for bilateral hernias ranged from 89 to 96 minutes. The mesh placement time for the Vypro II mesh ( $3.3 \pm 0.3$  min) was significantly shorter than that for the Prolene mesh ( $4.2 \pm 1.2$  min) and the TiMesh ( $5.1 \pm 1.7$  min) (Table 5).

### Perioperative Morbidity

Perioperative morbidity was significantly increased in group I. In one patient the Prolene mesh had to be explanted because of a staphylococcal infection. At the time of discharge a seroma was demonstrable by ultrasound in 28 patients (12.1%), and in 2 patients it required mul-



**Figure 2.** Surgical steps of TAPP. **A.** Preoperative findings (arrow: indirect inguinal hernia). **B.** Representation of the spermatic cord before mesh implantation (\*os pubis). **C.** Mesh implantation (TiMesh) before closure of the peritoneum. **D.** Peritoneal suture (for details see text).

**Table 4.**

Patient data of the three groups undergoing TAPP for hernia repair using different meshes, Prolene, Vypro II, TiMesh

	Group I (Prolene)	Group II (Vypro II)	Group III (TiMesh)
Number of patients	232	217	223
Period (month/year)	07/99–12/00	01/01–09/02	10/02–12/03
Age (years)	55.0 ( $\pm$ 12.3)	57.5 ( $\pm$ 13.8)	55.3 ( $\pm$ 12.9)
Sex (male/female)	205/27	199/18	203/20
BMI (kg/m <sup>2</sup> )	25.6 ( $\pm$ 2.3)	26.4 ( $\pm$ 2.1)	25.9 ( $\pm$ 2.4)
Overall comorbidity	123 (53.0%)	102 (47.0%)	99 (44.4%)
Diabetes mellitus	47 (20.3%)	37 (17.1%)	38 (17.0%)
Heart failure	68 (29.3%)	53 (24.4%)	51 (22.9%)
Arterial hypertension	97 (41.8%)	78 (35.9%)	74 (33.2%)
COPD	19 (8.2%)	15 (6.9%)	19 (8.5%)
Nyhus classification			
Type II	73 (31.5%)	72 (33.2%)	69 (30.9%)
Type IIIa	52 (22.4%)	46 (21.2%)	55 (24.7%)
Type IIIb	56 (24.1%)	34 (15.7%)	42 (18.8%)
Type IIIc	5 (2.2%)	1 (0.5%)	3 (1.3%)
Type IV	20 (8.6%)	22 (10.1%)	23 (10.3%)
Bilateral	26 (11.2%)	42 (19.4%)	31 (13.9%)

BMI: Body Mass Index; COPD: chronic obstructive pulmonary disease.

multiple punctures because of discomfort. In these cases the diameter of the seroma was more than 3 cm. There were no significant differences in analgesic consumption, overall duration of hospital stay, and the duration of postoperative incapacity for work between the individual groups (Table 5).

### Frequency of Recurrences

After 12 months, inguinal hernias had recurred in 10 patients and were confirmed during subsequent laparoscopic repair. In all these patients we found medial recurrences caused by partial migration of the mesh. There were no significant differences between the individual groups as

**Table 5.**  
Results of TAPP using three different meshes

	Prolene	Vypro II	TiMesh
Operating time one side (min)	65 ± 22	58 ± 17	62 ± 26
Operating time both sides (min)	95 ± 29	89 ± 27	96 ± 31
Mesh placing time (min)	4.2 ± 1.2 <sup>a,b</sup>	3.3 ± 0.8 <sup>c</sup>	5.1 ± 1.7
Infection	1	0	0
Seroma/hematoma	28 <sup>a,b</sup> (12.1%)	9 (4.1%)	4 (1.8%)
Number needing puncture	2 (0.9%)	2 (0.9%)	0
Pain (analgesics >1 day)	4 (1.7%)	2 (0.9%)	1 (0.4%)
Duration of hospital stay (days)	4.4 ± 1.6	3.9 ± 1.3	3.2 ± 1.1
Incapacity for work (weeks)	3.1 ± 1.8	2.6 ± 1.7	2.5 ± 1.7
Confirmed recurrence (12 months postoperatively)	4 (1.7%)	3 (1.4%)	3 (1.3%)
Persistent pain syndrome (12 months postoperatively)	2 (0.9%)	1 (0.5%)	1 (0.4%)
Sensation of foreign body (12 months postoperatively)	21 <sup>a,b</sup> (9.1%)	12 (5.5%)	8 (3.5%)
Undue sensitivity to weather changes (12 months postoperatively)	13 <sup>a,b</sup> (5.6%)	7 (3.2%)	5 (2.2%)

<sup>a</sup>*P* < 0.05: Prolene versus Vypro II.

<sup>b</sup>*P* < 0.05: Prolene versus TiMesh.

<sup>c</sup>*P* < 0.05: Vypro II versus TiMesh.

regards the frequency of recurrence (group I: 4 recurrences; group II: 3 recurrences; group III: 3 recurrences). All recurrences were repaired laparoscopically (Table 5).

### Quality of Life

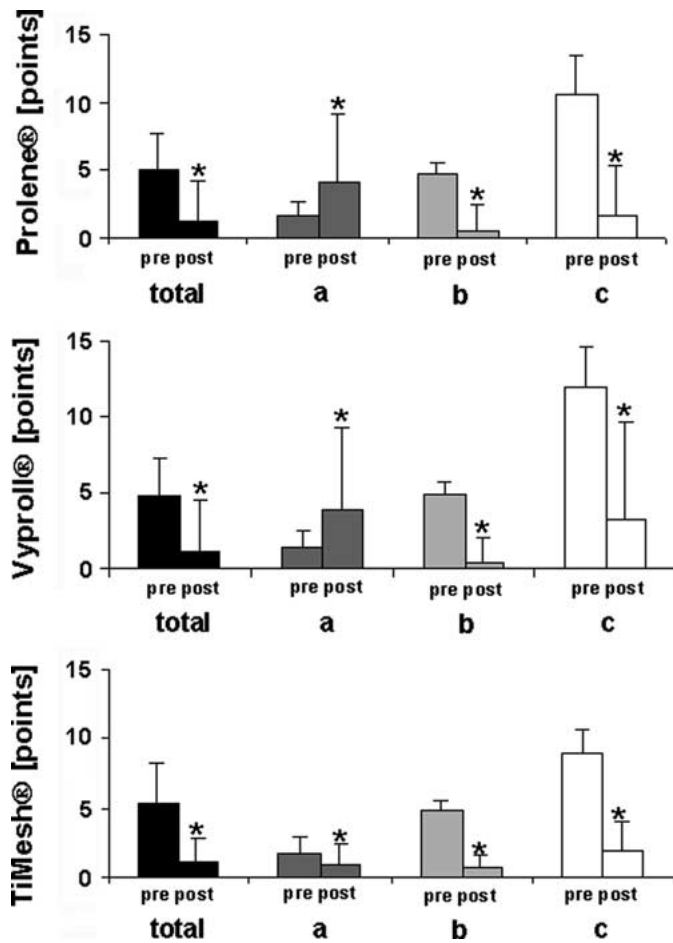
A significant improvement in the quality of life was achieved in all groups after 12 months (Fig. 3). As compared with the group as a whole, there were no significant differences in the incidence of persistent postoperative pain (Table 5). After Prolene mesh implantation there were significantly more patients who experienced sensitivity to weather changes and sensations of a foreign body compared to those patients with TiMesh and Vypro II mesh implantation. Depending on the degree of preoperative impairment of quality of life by the inguinal hernia (subgroups a-c), we found in all patients with moderate (group Ib, IIb, IIIb) and severe preoperative impairment (group Ic, IIc, IIIc) a definite improvement in quality of life 12 months postoperatively, without any significant differences between the individual groups (Fig. 3). In patients with minor symptoms preoperatively (group Ia, IIa, IIIa), only after the use of TiMesh (group IIIa) was there any significant improvement in quality of life at 12 months, whereas the use of Prolene (group Ia) or Vypro II mesh (group IIa) even led to some significant deterioration in quality of life at 12 months (Fig. 3).

## DISCUSSION

In the comparison between various competing operative procedures for the repair of primary inguinal hernia,

TAPP can now be regarded as an alternative of equal value to the anterior procedure, such as the Shouldice and Lichtenstein repairs, as measured by postoperative recurrence rates, provided TAPP is carried out by an experienced surgeon. Although no objective data concerning the surgeon volume and perioperative morbidity and recurrence after inguinal hernia repair by TAPP procedure exist, in our personal experience at least 100 TAPP procedures are necessary before becoming a surgeon becomes experienced in this surgical technique.<sup>12</sup> Thanks to the minimal trauma in gaining access to the groin region, the risk of possible nerve injury and scar formation, together with the incidence of postoperative pain syndrome is reduced compared to anterior procedures.<sup>13,14</sup> Nevertheless, the incidence of discomfort, chronic groin pain, and sensations of numbness after prosthetic inguinal hernia repair is as high as 40%; this is an unacceptable level, and in some circumstances even exceeds the preoperative subjective symptoms caused by the inguinal hernia itself.<sup>15,16</sup>

Study of the quality of life after inguinal hernia repair is therefore of particular importance, because recurrence is frequently an asymptomatic chance finding, and the reason for operation is primarily the danger of incarceration. This means that subjective sensations such as chronic pain and sensitivity to weather changes play a special role in assessing the success of the operation after inguinal hernia repair. Recent studies suggest that there is some correlation between the PP amount and structure of mesh and postoperative quality of life.<sup>17-20</sup> Schmidbauer et al. showed that large pore-sized low-weight PP-meshes composed of multifilaments, e.g.,



**Figure 3.** Quality of life related to preoperative impairment. Significant improvement in quality of life was achieved in all patients postoperatively (black columns). In patients whose preoperative impairment of quality of life by the inguinal hernia was only minor (dark gray columns), this was improved by the use of a lightweight TiMesh (group III), whereas the use of heavy-weight Prolene (group I), or Vypro II meshes (group II) led to significant impairment of the quality of life. In all patients with moderate (light gray columns) or severe preoperative impairment (white columns), the preoperative quality of life was significantly improved irrespective of the PP content of the mesh inserted (pre: preoperative; post: postoperative; \* $P < 0.05$ ).

Vypro II, had better abdominal wall compliance and caused less chronic pain than large pore-sized, monofilament heavy-weight PP meshes, e.g., Prolene.<sup>19</sup> In a recently published randomized trial comparing Prolene and Vypro II mesh in endoscopic extraperitoneal inguinal hernia repair (TEP) of recurrent unilateral hernias the Vypro II group had a significantly better score.<sup>20</sup>

In the present study we additionally investigated a titanized PP mesh containing the lowest PP amount among all meshes used for inguinal or incisional hernia repair. Up to now no long-term results concerning the recurrence rate or quality of life using the titanized PP

mesh are available except of a feasibility study.<sup>18</sup> Corresponding to the results of previous studies comparing Prolene and Vypro II meshes, we found no differences in the recurrence rates using Prolene, Vypro II, or titanized PP meshes after 12 months in our study.<sup>21</sup> In those cases where laparoscopic surgery was necessary for recurrent hernias, we found that all recurrences occurred medially. It can be postulated that the tendency of the mesh to shrink and wrinkle, possibly after an inadequate prosthetic overlap of the retrovesicular space and the use of “small-for-size” meshes, is a factor leading to recurrence after TAPP. However, because of the small number of overall recurrences in this study and the regular distribution of recurrence among all groups, no conclusions can be drawn from the pathogenesis of the recurrences or correlation with the amount of PP in the mesh.

The quality of life score after inguinal hernia operations in this study considered different mental, social, and emotional parameters pre- and postoperatively because preoperative pain is usually absent, and even physical criteria are often negligible. For this reason we have developed an assessment score for investigation of postoperative quality of life after inguinal hernia operations; this postoperative score is much simpler than the scoring systems used for gastrointestinal quality of life, as for example a SF-36 health survey like the Eypasch score (Table 3).<sup>22</sup> Whereas after TAPP the overall quality of life in the various groups was significantly improved, closer scrutiny of patients without preoperative symptoms showed improvement in their postoperative quality of life only if TiMesh was employed (subgroup III a). The use of meshes with a higher PP content (groups I and II) actually caused some deterioration in quality of life, so that patients who had been relatively free from symptoms before operation developed symptoms that advised against the use of heavy-weight PP meshes. We therefore recommend a preoperative quality of life assessment for all patients undergoing hernia repair. It can be postulated that a large amount of PP in the mesh is associated with a tendency to shrinkage, fold formation, and abacterial inflammatory reactions, which consecutively provoke foreign body sensations and sensitivity to weather changes that ultimately impair the quality of life. Experimental studies have shown that titanized meshes are associated with the smallest chronic inflammatory reaction, surface induration, and scar formation.<sup>23</sup> These findings could explain why the use of TiMesh in the present study was associated with the least subjective sensations of a foreign body and in sensitivity to weather changes.

In conclusion, comparable functional results, lower postoperative complications, and improved quality of life can be achieved by reducing the PP amount in meshes used for laparoscopic repair of hernias. In particular, patients with only minor preoperative symptoms will profit from the use of lightweight PP meshes because of the significant improvement in postoperative quality of life. However, the results of this observational study should be confirmed in controlled randomized trials including more patients and a long-term follow-up.

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