World Journal of Surgery

Published Online: 12 May 2006

World J Surg (2006) 30: 1055–1062
DOI: 10.1007/s00268-005-0602-z

Feasibility of Primary Inguinal Hernia Repair with a New Mesh

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Abstract

Background: The purpose of this study was to evaluate the feasibility of primary inguinal repair with open tension-free and sutureless technique using a new polypropylene "patch and plug system" (Prolene 3D patch), and the quality of the treatment in terms of reduction of postoperative discomfort.

Methods: Fifty-six consecutive patients, mean age 54.5 ± 11.2 years, with primary unilateral uncomplicated inguinal hernia, were treated in a day-surgery setting. Collected data included: pain scores at 24 hours, 72 hours, and 7, 15, and 30 days after operation, analgesic medications, return to work and to heavy house and/or moderate sporting activities, and quality of life as measured by Short Form 36 health survey questionnaire (SF-36) before the operation and at 6 months follow-up.

Results: Postoperative pain was low: the mean visual analog scale (VAS) scores were 2.8 at 24 h, 1.8 at 72 h, and 0.9, 0.3, and 0.04 at 7, 15, and 30 days, respectively. Analgesic drugs were not used by 66.0% (n = 37) of the patients. The mean global time to return to work and to heavy activities was 9.9 ± 4.6 and 14.6 ± 7.0, days, respectively. Patient satisfaction showed a significant improvement in all SF-36 domain scores at 6 months follow-up ($P < 0.001$). There were no major complications, recurrences, or mortality.

Conclusions: The new mesh seems to satisfy all requirements of a feasible, reliable, and effective device for repairing primary inguinal hernia with high patient comfort.

Several scientific papers in recent years have drawn attention to the problem of complications caused by using a plug for the inguinal hernia repair operations. In fact, cases of plug migration into the bladder,[1] scrotal sac,[2,3] bowel,[2,4,5] and iliac vessels[6,7] have been documented. In our opinion, although such complications are rare, they are not negligible because of their clinical importance. Some surgeons who support use of the plug for the tension-free technique, tend to fix it at the internal inguinal ring pillar by means of a single stitch.

In addition to the problem of migration, the plug is a three-dimensional semi-rigid structure,[8] and unacceptable rates of persistent pain have been reported in up to 8% of patients treated with it.[2,9] Recently a new device, the "Prolene 3D patch" (Ethicon, a Johnson & Johnson Company. Somerville,NJ), has been put on the market. It is designed to combine the benefits offered separately by onlay and inlay meshes.

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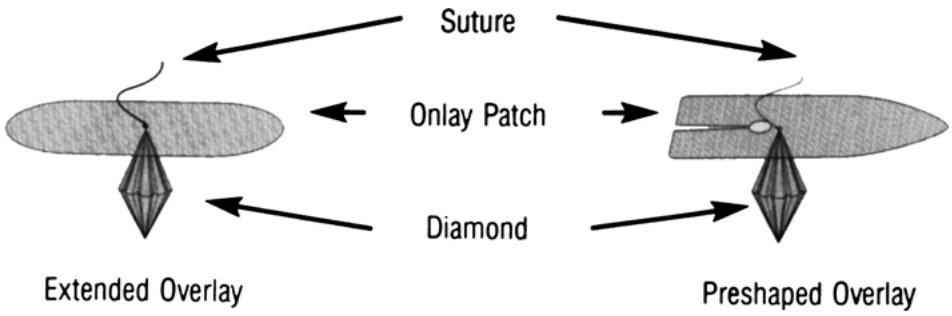

Figure 1. "Prolene 3D Patch": Extended Overlay type for specific anatomic conformation and for women's hernia, Preshaped Overlay type for men's indirect hernia. (By Ethicon Products with permission of Johnson & Johnson Medical Spa.)

The aim of the present study was twofold: to evaluate the feasibility of primary inguinal hernia repair with open Trabucco's technique[10] using the new polypropylene 3D patch and to evaluate the quality of the treatment protocol in the day-surgery setting.

MATERIALS AND METHODS

This study was carried out in a single surgical unit, and the operations were all performed by the same surgeon (L. F.). Between October 2003 and February 2005, 56 consecutive patients with primary monolateral uncomplicated reducible inguinal hernia, agreed to participate in the study. The follow-up for each patient lasted at least 6 months, and the database of this study was complete by August 2005. After Ethical Committee approval and written informed consent were obtained, we enrolled all 56 patients. Inclusion criteria were: age > 18 years, primary unilateral uncomplicated inguinal hernia. Exclusion criteria were as follows: irreducible hernia or recurrent hernia, morbid obesity (*i.e.,* Body Mass Index (BMI) > 40), patients taking anticoagulant drugs within 2 weeks of the intervention, and hernia repair performed in combination with another surgical operation. The Prolene 3D patch is a polypropylene mesh consisting of a flat onlay patch that is securely linked to a diamond-shaped plug, which can be deployed through the use of an integrated looped nonabsorbable suture (Fig. 1). The patch measures 12.5 × 5.5 cm, and it is available in two types: the Extended Overlay type which is lozenge-shaped and mainly used for, but not limited to, direct hernia and women's hernia, and the Preshaped Overlay type, with its opening and hole specific for men's spermatic cord. The plug is hollow and available in two sizes: medium size measuring 4.8 × 2.3 cm, and small size, measuring 3.5 × 1.9 cm. The plug must be placed in the preperitoneal space through the deep inguinal ring or through the direct defect, while the onlay patch, either the Extended or Preshaped Overlay type, shall lie on the inguinal floor; pulling the suture will cause flattening of the plug in the opposite side. Variables recorded were sex, age, weight, BMI, coexisting diseases, occupational status, the American Society of Anaesthesiologists preoperative assessment score (ASA); other variables were hernia site and hernia type according to the Gilbert classification as modified by Rutkow and Robbins[11] (Table 1). The first end-point was postoperative pain evaluation: the degree of pain was determined by using a 10-cm visual analog scale (VAS)[12] on which 0 = no pain and 10 = worst possible pain, at 24 hours, 72 hours, and on postoperative day 7, 15, and 30, and by counting the number of oral analgesic drugs (Ketorolac 30 mg) taken by each patient. In fact all outpatients had a prescription for analgesic drugs to be taken as required and they duly recorded analgesic use on a paper to be given back to the surgeon. The other end-points were the time required to return to work, the time required to return to heavy house and/or moderate sporting activities, and the patient satisfaction determined from a generic quality of life questionnaire (the so-called 36 items Short-Form health survey [SF-36]).[13,14] The SF-36 defines eight domains of health status: Physical Function (PF), Physical Role limitations (RP), Bodily Pain (BP), General Health perception (GH), Vitality (VT), Social Function (SF), Mental Health (MH), and Emotional Role limitation (RE). The number of questions contributing to each

Table 1.
Gilbert's hernia classification (modified by Rutkow and Robbins)

Type	Description
I	Indirect hernia, internal ring not enlarged
II	Indirect hernia, internal ring enlarged (no more than 4 cm; passable for the tip of one finger)
III	Indirect or scrotal hernia, insufficient internal ring (more than 4 cm; passable for two or more fingers)
IV	Direct hernia, large defect
V	Direct hernia, small defect
VI	Combined direct/indirect hernia ("pantaloon hernia")
VII	Femoral hernia

domain varies from 2 to 10. Response values for each question range from 1 to 6. All domain scales are standardized from 0 to 100, with higher scores signifying better health status. This questionnaire was administered by an external observer (*i.e.,* a surgical fellow) at 7–10 days before the operation, during the first access for the day-surgery procedure, and 6 months after the operation. Patients with no perioperative complications were discharged within 8 hours after the operation. Patients were encouraged to resume their normal behavior and return to work; no restrictions were imposed, except for those related to physical discomfort at the surgical site. The same external observer carried out interviews with the patients and performed physical examination at 7, 15, and 30 days, and at 6 months postoperation.

Surgical Technique

Trabucco's technique and the Prolene 3D path were used in all cases. All patients underwent selective spinal anesthesia[15]; using sterile technique, a 27-gauge, 3.5-inch Whitacre spinal needle was introduced by means of an introducer at the L2–L3 interspace using a midline approach for selective unilateral anesthesia. The patient remained positioned in the lateral decubitus position with the operative side facing downward until a satisfactory block was obtained, as verified by the pin-prick test and Bromage score. A total of 11.25 mg of 0.75% hyperbaric bupivacaine was administered as a single injection. As a standard procedure, before cutting the skin we always administered short-term antibiotic prophylaxis with teicoplanina (400 mg) i.v. After hernia sac dissection, the diamond-shaped plug of appropriate size was inserted through the internal ring (indirect hernia) or through the direct defect and overlapped by the transversalis fascia, sutured with a cosmetic 2–0 polypropylene suture. Plug insertion was made easier by means of a Klemmer clamp.

When we used the Preshaped Overlay type the patch was carefully laid on the flattened inguinal floor, with its hole surrounding the spermatic cord under the aponeurosis of the external oblique muscle. The medial end of the patch was placed on the dissected pubic tubercle with 1–2 cm overlapping. Once it was in place, we held the device in position and pulled on the free end of the looped suture to flatten the diamond-shaped plug so that it would fill the defect and lie flat below the transversalis fascia layer. The Extended Overlay type device was not limited to the treatment of women's inguinal hernias; it was also used for men's specific anatomic conformation. When it was used for men, to make an opening for the spermatic cord, we performed a transversal section on the medial side of the patch, opposite the deep inguinal ring; both patch tails were sutured around the spermatic cord with one stitch. The external oblique aponeurosis was then closed below the spermatic cord, remaining in the subcutaneous space.

Statistical Analysis

All data were expressed by mean, standard deviation (SD), median, and range. One-way analysis of variance and a paired *t*-test were applied, respectively, to compare differences among groups and changes in the SF-36 scales recorded preoperatively and at follow-up. The two-tailed significance level was 0.05. Analysis of SF-36 scores was carried out with Windows-based Excel software, according to guidelines developed by Ware and Sherbourne.[13]

RESULTS

Patient characteristics are summarized in Table 2. In terms of hernia site, 64.3% of patients had right-sided hernia and 35.7% left-sided. The hernia type classification according to Gilbert/Rutkow-Robbins was as follows: 10.7% of patients had type II hernias, 51.8% type III, 19.6% type IV, and 17.9% type VI; type I and type VII hernias were not found in this study. Postoperative mean VAS pain scores were 2.8 (1.9) with a median of 2.8 at 24 hours; 1.8 (1.6) with a median of 1.5 at 72 hours; 0.9 (1.4) with a median of 0.3 at 7 days; 0.3 (0.7) with a median of 0.0 at 15 days, and 0.04 (0.2) with a median of 0.0 at 30 days (Fig. 2). At 24 hours forty-five patients (80.4%) had a pain score lower than 5 (range: 0.5–4), and at 72 hours 51 patients (91.1%) had a pain score lower than 4 (range: 0–3); only five patients had a pain score higher than 5 at 24 hours postoperative time, and only one had such a high score at 72 hours and at 7 days. No pain was reported by 76.8% (n = 43) of patients at 15 days and by 96.4% (n = 54) at 30 days. Analgesic drugs were not used in 66.0% (n = 37) of the patients; 3.6% (n = 2) used 4 pills, 5.4% (n = 3) used 2 pills, and 25.0% (n = 14) used one pill in the postoperative period. No i.v. drugs were administered for pain alleviation. At 6 months follow-up, none of the patients suffered any sort of pain, either as localized discomfort in the inguinal area or as persistent neuralgia. The mean global time to return to work (retired patients were excluded) was 9.9 (4.6) days; more spe-

Table 2.
Clinical details of the 56 hernia patients treated with Prolene 3D patch

Characteristics	Data
Total = 56	Number (%)
Male	53 (94.6)
Occupational activity type	
Predominantly sedentary	12 (21.4)
Always on feet	19 (33.9)
Very labor intensive	9 (16.1)
Retired	16 (28.6)
Coexistent diseases	
Hypertension	8 (14.3)
Ischemic cardiopathy	1 (1.8)
Diabetes mellitus	2 (3.6)
Hyperthyroidism	1 (1.8)
Parkinson's disease	1 (1.8)
No coexistent disease	40 (71.4)
ASA score	
I	41 (73.2)
II	12 (21.4)
III	3 (5.4)
IV	0 (0)
Total = 56	Mean (SD)
Age (years)	54.5 (11.2)
Weight (kg)	73.9 (7.3)
Body mass index	25.4 (2.1)

cifically, patients with sedentary occupations returned to work within an average of 8.3 (2.3) days, with a median of 8 days; those whose work required them to be on their feet work returned within 9.1 (4.7) days, with a median of 10 days; and patients with work classified as very labor-intensive returned to work within an average of 13.8 (4.6) days, with a median of 15 days. Statistically significant differences were observed among the three groups of patients with regard to return to work ($P < 0.01$). The mean global time to return to heavy house activities and/or moderate sporting activity was 14.6 (7.0) days: patients with sedentary occupations returned within an average of 14.8 (7.1) days, with a median of 14.5 days; those whose work required that they stand for long periods returned within 15.4 (7.3) days, with a median of 14 days; and patients with very intensive work returned within 19.6 (6.4) days, with a median of 20 days. Retired patients returned to household activities within 10.8 (5.1) days, with a median of 10 days. Statistically significant differences were documented among the four groups of patients with regard to this parameter as well ($P < 0.02$). The data relating to oral analgesics intake, time to return to work, and time to return to heavy activities are summarized in Table 3. The SF-36 results are presented in Table 4. Significant deficiencies in preoperative functional status appear in all SF-36 domains; particularly, the

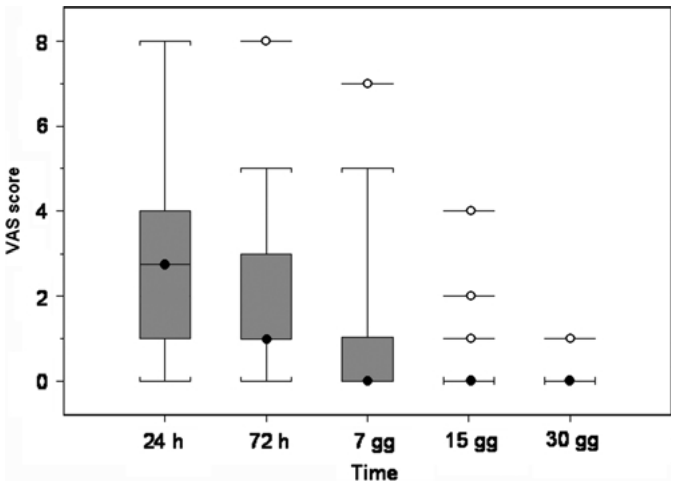

Figure 2. Box-plot of postoperative pain evaluation at different times. The ends of whiskers indicate the minimum and maximum visual analog score values, unless outliers (empty point). The upper and lower hinges indicate the 75th and the 25th percentile, respectively. The black point in the horizontal line in the box represents the median value.

mean scale scores of the Physical Function (PF), Role Physical (RP), and Bodily Pain (BP) were 76.5 (16.9), 54.0 (36.2), and 67.1 (23.0), respectively; note that the RP score was somewhat lower than the other two. Six months after the operation, a statistically significant improvement was observed in all domain scores ($P < 0.001$). The PF domain improved from 76.5 (16.9) to 97.1 (4.3); RP, from 54.0 (36.2) to 95.5 (10.8); and BP, from 67.1 (23.0) to 97.4 (5.2). At 6 months follow-up, the mean total SF-36 score improved from 68.5 (13.9) (median 68.1) to 90.8 (5.7) (median 91); statistically significant differences were evident between pre and postoperative values ($P < 0.001$). Two patients (3.5%) developed seroma that was treated by a single needle aspiration; no patients developed significant hematoma requiring evacuation or aspiration; one patient (1.8%) had to be aided to empty the bladder after the operation. There were no instances of draining sinuses, testicular problems, long-term pain, plug erosion and migration, or recurrences. No major complications related to the operation or to anesthesia were observed, and no mortality occurred.

DISCUSSION

The use of mesh in hernia repair has been increasing over the last 10 years, going from 15% to 80% of all hernia repairs. A recent meta-analysis[16] concluded that there was a lower incidence of recurrence after mesh hernioplasty, as opposed to non-mesh open methods.

Table 3.
Number of days required to return to work, to heavy activities, and number of pain pills used in patients treated with Prolene 3D patch

Time to return to work (n = 40)		
Mean ± SD, days (range)	9.9 ± 4.6 (2–20)	CI 95%
Median, days	10	8.4–11.3
Time to return to heavy activities (n = 56)		
Mean ± SD, days (range)	14.6 ± 7.0 (3–30)	CI 95%
Median, days	14	12.7–16.5
Number of pain pills used (n = 56)		
Mean ± SD (range)	0.5 ± 0.9 (0–4)	CI 95%
Median	0	0.3–0.7

n = number of patients; CI: confidence interval.

Table 4.
Mean scores of the different SF-36 scales measured preoperatively and at follow up

Scales		Baseline	Six months after operation	d.f.	*P* Value
Physical function	(PF)	76.5 (16.9)	97.1 (4.3)	55	< 0.001
Role physical	(RP)	54 (36.2)	95.5 (10.8)	55	< 0.001
Bodily pain	(BP)	67.1 (23.0)	97.4 (5.2)	55	< 0.001
General health	(GH)	67.1 (15.9)	78.8 (12.7)	55	< 0.001
Vitality	(VT)	68.8 (4.2)	81.8 (13.0)	55	< 0.001
Social functioning	(SF)	76.1 (18.4)	93.3 (9.2)	55	< 0.001
Role emotional	(RE)	74.4 (33.0)	97.0 (9.6)	55	< 0.001
Mental health	(MH)	72.1 (15.7)	85.7 (10.0)	55	< 0.001

Values in parentheses are standard deviations.

Inguinal patch and plug hernioplasties have been performed using prostheses of different sizes and shapes, either sutured or not to the tissues.

However, hernia repair using mesh is sometimes associated with postoperative pain,[17,18] more or less severe and/or persistent. Many studies[19,20] have been devoted to establishing the possible origin of postoperative pain. At least four factors appear to be the key:

1. Fixation to the muscle plane with the obvious risk of lesions to local nerves.
2. Rigidity of the mesh, which most frequently produces pain when the patient is in the sitting position.[19,21]
3. The total amount of non absorbable material used during the repair.[21–23]
4. Improper use of excessively bulky or ''sharp'' plugs, which may compress or damage vascular and nervous structure within the preperitoneal space, or may even migrate far from the internal inguinal ring.

Four aspects of the procedure have been criticized when using the plug:

1. The plug would not form a reliable ''barrier,'' in that the repair of the posterior wall of the inguinal canal is not ''bidimensional'' as it should be.
2. The plug located within the preperitoneal space would induce an insufficient prosthetic ingrowth.[9,22]
3. In the long run the plug would undergo a significant shrinkage, greater than the flat patch; in practice the plug could become a ''foreign body,'' and hence be subject to infection formation.[1,22]
4. Standard plugs, being semi-rigid three-dimensional structures made mostly of non absorbable material, may cause postoperative pain, as rightly suggested by Kingsnorth and Le Blanc.[8]

As far as we know, there is consistent lack of information about the use of the Prolene 3D patch; therefore we performed the present study to evaluate the effectiveness of this new prosthesis, using the open technique for primary inguinal hernia repair. In the ''new patch and plug system,'' the onlay portion is not a rigid mesh but a soft and lightweight polypropylene mesh with a good memory and, at the same time, good resistance; these two features give the prosthesis an advantage as it fits quite well the groin area, thus reducing, in our view, all problems linked to patient movement and postural changes. The plug is diamond-shaped and this ergonomic form makes insertion into the deep inguinal ring or the direct defect easier, and obviates the need to dissect the preperitoneal

space; in addition, the structure is hollow, and this implies an overall reduction in the amount of implantable polypropylene.[21] The plug, once inserted, is flattened by pulling the looped suture; therefore the deep repair becomes ''bidimensional'' and more subject to tissue ingrowth by fibroblasts as compared to the various ''non-flat type'' plugs; furthermore, because the two parts of the new device are joined together, plug migration is prevented. In fact in a multicentric study of over 590 patients treated with the ''plug and patch'' technique, Le Blanc *et al.*[2] reported 5.76% morbidity subsequent to plug migration to the small bowel, where it caused occlusion and/or fistula formation. Sometimes plug migration left behind a deep venous thrombosis at the plug site or an abscess in this limited area. In some cases complications led ultimately to hernia recurrence due to ''plug shrinkage'' (2.2%).

We believe that two characteristics of the plug and patch system: its lightness and flexibility as well as its resistance reduce the extent of damage to the deep structures and the degree of postoperative pain. The plug is available in two sizes, small and medium, and it is therefore easily adaptable to the defect size, another factor contributing to reduced trauma due to dissection. Prosthesis crumpling and rotation are prevented by the ''sandwich effect'' obtained through the transversalis fascia, after the plug is tightened and flattened by the surgeon pulling on the looped suture. The non-fixation of the patch to the surrounding tissue will avoid entrapment of the ilioinguinal and iliohypogastric nerves, which otherwise would cause difficult-to-treat postoperative neuralgia.[24–26] Postoperative pain may interfere with quality of life. For example, Page *et al.*[27] reported an incidence of 53.9% patients with moderate pain, 1.5% with severe pain even at rest, and 6.2% with pain when moving. Bay-Nielsen *et al.,*[28] using Lichtenstein's surgical technique, reported that postoperative pain prevented return to work in 50% of their patients and to resumption of heavy activity in 46.7% of their cases up to 1 month after operation. In a prospective study designed to evaluate the Perfix Plug (C. R. Bard, Inc. Murray Hill, NJ) for primary inguinal hernia repair, Pelissier *et al.*[29] reported, at an average follow-up of 22.3 months, that 8.6% of patients were still suffering some degree of postoperative pain. According to Palot *et al.,*[30] 4.5% of patients were suffering moderate postoperative pain, and in two cases the plug had to be removed. In our study postoperative pain, determined by VAS, has been at a very low level. For most of our patients (66.0%), there was no need to take analgesic drugs; at 72 hours, the majority of patients achieved a VAS maximum score of 3, which was progressively lower, reaching zero score between day 7 and day 15. In another study, Goldstein *et al.*[31] using the ''Atrium ProLite self-forming plug and onlay patch'' (Atrium Medical Corporation, Hudson, NH), reported that only 31% of their patients did not require analgesic drugs on the first postoperative day. Kingsnorth *et al.*[32] also reported that two groups of patients—one treated with Prolene Hernia System® (PHS) (Ethicon, a Johnson & Johnson Company. Somerville, NJ) and a second treated with the Lichtenstein patch—took analgesic drugs for an average of 6 days after operation, and most of them continued taking pain relief medication until day 14. In a recent multicentric prospective study of 115 patients (58 Lichtenstein and 57 laparoscopic hernia repairs) treated with Gluca-mesh (Brennen Medical. St. Paul, MN), Barrat *et al.*[33] documented that 92.1% of inpatients took analgesic drugs postoperatively, 64.3% of them up until the time of discharge; after 15 days pain relief medication was still being used by 4.3% of patients, whereas, after 90 days only 2.7% needed analgesics for pain relief. In our study, 19 patients required pain relief drugs: 14 received a single pill up to postoperative day 1, three patients up to postoperative day 2 ,and two patients up to postoperative day 4; thereafter none of the patients required pain relief drugs. Minor discomfort and/or low postoperative pain obviously favors an early return to work and to heavy house activities, including moderate sporting activity. Nevertheless, patients with a more stressing physical daily activity may tend to delay resumption of their occupations because of an unconscious fear of hernia recurrence, the source of their preoperative discomfort. Kingsnorth *et al.,*[32] comparing the results obtained with PHS versus the Lichtenstein patch, reported a median of 14 and 19 days, respectively, to return to work after operation. Goldstein *et al.*[31] reported that their patients were resuming normal daily activities within 22.3 (1.3) days, on average, with a median of 21 days; patients with sedentary occupations returned to work within an average of 9.8 (2.8) days, with a median of 7 days. In other studies[29,30] regarding the Perfix® plug and patch, the return to normal activity and work took somewhat longer, between 2 and 4 weeks. Callesen and Kehlet[34] observed that the average convalescence was 2 to 3 weeks, indicating that this is a reasonable period for taking time off from work for medical reasons.[35] In their view, an earlier return to activity is unlikely to be achieved by better pain control. With regard to the SF-36 questionnaire, we have documented unexpectedly low preoperative values in all eight domains; this means that inguinal hernia may become really invalidating. As expected, all SF-36 quality of life domain values improved at 6 months follow-up. It has

to be emphasized that PF, RP, and BP domains, all linked to pain perception, showed significant improvement after the operation. These excellent scores were likely attributable to the mesh flexibility and, above all, to the plug type not requiring dissection for its insertion, and becoming completely flat at the end of the operation.

Finally, the data presented in our study confirm a very low rate of both postoperative complications and recurrences. As regards the time to return to work, our good results are similar to those of other studies available in literature. The limitation of this study is the short term follow-up. Indeed, long-term follow-up outcome studies are needed.

CONCLUSIONS

The tension-free and sutureless hernia repair technique described, based on the use of the Prolene 3D patch, is a safe operation, simple to perform, and it can be done on an outpatient basis with a low complication rate, a low level of pain, and an excellent quality of life thereafter. All the results obtained so far are more than encouraging: the new mesh seems to satisfy all the requirements of a feasible, reliable, and effective system for repairing primary inguinal hernia at low cost, with high patient comfort and no recurrences.

ACKNOWLEDGMENTS

The paper was not financially supported and no financial relationships exist between the authors. No conflict of interest exists, and this work has not been presented elsewhere.

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