

## New devices for inguinal hernia repair in elderly patients

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**Summary.** A recent meta-analysis concluded that there was a lower incidence of recurrences after mesh hernioplasty, as opposed to non-mesh open methods. Inguinal mesh 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, more or less severe and/or persistent. As a consequence it may interfere with the time required to return to work and to normal daily activities. Finally, concerning the postoperative complications and recurrences, the data presented in our study confirm the very low rate for both aspects; then, as regards the time to return to work, our good results are similar to those of other studies available in literature. In conclusion the tension-free hernia repair described, based upon the use of Prolene 3D patch<sup>®</sup>, is a safe operation, simple to be acquired, it can be performed on an out-patient basis, with a low complication rate, a low level of pain, and an excellent quality of life thereafter. The new device seems to satisfy all requisites of a feasible, reliable and effective system for repairing primary inguinal hernia, at low cost, high patient comfort, and with low risk of recurrences.

**Key words:** Devices, inguinal hernia, elderly patients

### Introduction

The variety of prosthetic materials commercially available, the new alternative ways of access and technical solutions are all indicative of the still ongoing pursuit of the ideal hernioplasty technique; the turbulent evolution of prosthetic surgery in recent years has actually resulted in a real improvement of the quality of inguinal hernia repair. Several papers of late years have drawn our attention to the problem of complications, caused by using the plug for the inguinal hernia treatment. Quite recently a new device, named "Prolene 3D patch<sup>®</sup>" (Ethicon© a Johnson & Johnson Company, Sommerville, NJ) combine the benefits offered separately by different type of prosthesis: it is a polypropylene three-dimensional system consisting of a flat onlay patch, securely linked to a diamond-shaped plug, which can be deployed through the use of an integrated looped non-absorbable suture. The purpose of this

study was to evaluate the feasibility of Trabucco's technique, for primary inguinal hernia, using a new polypropylene "plug and patch system" and the quality of the repairs in terms of reduction of postoperative discomfort in day surgery setting.

### Materials and methods

Inclusion criteria were: adult patients with primary, uncomplicated, unilateral inguinal hernia.

Exclusion criteria were: patient younger than 18 years old, irreducible hernia or recurrent hernia, morbid obesity, patients taking anticoagulant drugs, and hernia repair performed in combination with another surgical operation.

The end-points were: postoperative pain evaluation as the degree of pain determined by using a 10 cm Visual Analogue Scale (VAS) (1) (0=no pain and 10=worst possible pain), at 24h, 48h, 72h and 7, 15, 30

days after the operation, and by the number of oral analgesic drugs (Ketorolac 30 mg) taken by each patient; than the time required to return to work, to normal daily activities and the patient satisfaction determined by using a generic quality of life questionnaire (36 items Short-Form health survey [SF-36]) (2).

This questionnaire was submitted by the same surgeon at 7-10 days before and 3 months after the operation.

The patients were discharged 3-8 hour after the operation and the follow-up was carried out at 7, 15 and 30 days, and at 3 months.

The Trabucco's technique (3) (sutureless and tension-free) and a selective spinal anaesthesia were used in all patients.

Especially in elderly patients in which some misdiagnosed coagulation disorders could be disclosed, we utilized a fibrin glue (1:10 dilution) as a spray for the fixation of the mesh to the inguinal floor and to the tubercle.

The new mesh, measuring 12.5x5.5 cm, 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 4.8x2.3 cm, and small size measuring 3.5x1.9 cm.

The plug must be placed in the preperitoneal space through the deep inguinal ring or through the direct defect, while the flat onlay patch, either the Extended or Preshaped Overlay type, shall lie on the inguinal floor; pulling the suture will cause the deployment of the plug, which will expand flattened in the opposite side.

## Results

Of 56 consecutive patients 94.6% were male and the mean age was 54.5 (11.2) years (range 32-90); nine of these had an age >65 years. Postoperative pain evaluation was the following: mean VAS pain scores were 2.8 (2.1) at 24 h; 1.8 (1.8) at 72 h; 1.01 (1.6) at 7 days; 0.4 (0.8) at 15 days, and 0.03 (0.2) at 30 days.

At 24 hour, 45 patients (80.4%) had a pain score

lower than 5 (range 0.5-4) and at 72h 51 patients (91.1%) had a pain score lower than 4 (range 0-3); 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 by 66.0% (n=37) of the patients.

At 3 months follow-up, none of the patients was suffering any sort of pain discomfort at the or a persistent neuralgia.

The mean global time to return to work and to normal daily activities, including a moderate sporting activity, were 9.9 (4.6) and 14.6 (7.0) days, respectively.

Significant deficiencies in preoperative functional status appear in all SF-36 domains and three months after the operation, a statistically significant improvement was observed (mean total SF-36 score improved from 68.3 (14.3) to 92.4(5.4) ( $p<0.001$ ).

Six patients (10.7%) developed seroma that was treated by a needle single aspiration; two patients (3.6%) developed a little haematoma, and one patient (1.8%) had to be aided to empty the bladder after the operation.

There were no instances of draining sinuses, testicular atrophy, plug erosion and migration, recurrences or mortality. No statistical significant difference has been found between the groups of patients with age > 65 and < 65 years old in terms of complications and quality of life.

## Discussion

A recent meta-analysis (4) concluded that there was a lower incidence of recurrences after mesh hernioplasty, as opposed to non-mesh open methods.

Inguinal mesh 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 (5, 6), more or less severe and/or persistent. As a consequence it may interfere with the time required to return to work and to normal daily activities.

According to a further study by Bay-Nielsen et al. (7) over 1059 patients, operated for primary inguinal hernia using Lichtenstein's technique, postoperative

pain was the cause, in 50% and in 46.7% of cases respectively, preventing the resumption of normal working activity, and of heavier and more stressing activity, 1 month after the operation.

Many studies (8, 9) have also been devoted to establish the possible origin of postoperative pain: the total amount of non resorbable material used during the repair, the rigidity of the prosthesis (8), which most frequently produces pain in the sitting position, fixation to the muscle plane with the obvious risk of lesions to local nerves and improper use of excessively bulky or “sharp” plugs, which may compress or damage vascular and nervous structure within the preperitoneal space. 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 and it located within the preperitoneal space would induce an insufficient prosthetic ingrowth<sup>10</sup>, and would undergo a significant shrinkage; finally, standard plugs, being semi-rigid three-dimensional structures plenty of prosthetic material, may cause postoperative pain, as rightly suggested by Kingsnorth e Le Blanc (11).

In a multicentric study over 590 patients treated with the “plug and patch” technique, Le Blanc et al (12) are reporting 5.76% morbidity subsequent to the plug migration till the small bowel occlusion and/or a fistula formation, or a deep venous thrombosis of the plug site, or the abscess of this limited area, till the hernia recurrence (2.2%) due to “plug shrinkage”.

In the new 3D patch system, the onlay portion is not a rigid mesh but flexible, with good memory and, at the same time, well resistant; which is already an advantage as it fits quite well the groin area, thus reducing, in our view, all troubles linked to patient’s movement and his postural changes.

The plug is diamond-shaped and this ergonomic form makes the insertion easier into the deep inguinal ring or the direct defect, without the need to dissect the preperitoneal space; besides it’s hollow and this implies an overall reduction of the prosthetic material used.

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, if compared to the various non-flat type plugs; furthermore, since the two parts of the new de-

vice are joint together, the plug migration is duly prevented.

We believe that both the above aspects are reducing the amount of damages to the deep structures and the postoperative pain.

In our study postoperative pain has been experienced to a very low level.

For the majority of our patients (66.7%) there was no need to administer analgesic drugs.

In a study by Goldstein e coll.<sup>13</sup> over 155 patients, operated using “Atrium ProLite® self-forming plug and onlay patch” (Atrium Medical Corporation, Hudson, NH), the percentage of those not requiring analgesic drugs on the first day after the operation was 31% only.

Kingsnorth et al (14) also reported that both their groups of patients – one treated with Prolene Hernia System® (PHS) (Ethicon© a Johnson & Johnson Company, Sommerville, NJ) and the second with Lichtenstein patch – took analgesic drugs for an average of 6 days after operation, and the majority was keeping on taking pain relief pills till day 14th.

In a further prospective study, directed to evaluate the results using Perfix® Plug (C.R. Bard Inc. Murray Hill, NJ) for primary inguinal hernia repair, Pelissier et al (15) are reporting, at an average follow-up of 22.3 months, 8.6% of patients were still suffering postoperative pain to some extent.

Minor discomfort and/or minor postoperative pain are obviously favouring an early return to work and to normal daily activities.

With regard to the SF-36 questionnaire, we have documented unexpectedly low pre-operative 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 three months follow-up.

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, concerning the postoperative complications and recurrences, the data presented in our study confirm the very low rate for both aspects; then, as regards the time to return to work, our good results are similar to those of other studies available in literature (16).

In conclusion the tension-free hernia repair described, based upon the use of Prolene 3D patch®, is a safe operation, simple to be acquired, it can be performed on an outpatient basis, with a low complication rate, a low level of pain, and an excellent quality of life thereafter.

The new device seems to satisfy all requisites of a feasible, reliable and effective system for repairing primary inguinal hernia, at low cost, high patient comfort, and with low risk of recurrences.

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