New "all-in-one" device for mesh plug hernioplasty: the Trabucco repair

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New "all-in-one" device for mesh plug hernioplasty: the Trabucco repair

Although Mesh Plug Repair (MPR) represents an effective method for the treatment of groin hernia, some criticisms still concern adverse effects related to the plug (shrinkage, chronic pain, migration and erosion). Different mesh and plug devices have been proposed in the past mostly to prevent migration but none of these achieved the same popularity as the cone or flower-shaped plug. Authors hereby present a pilot study with a new tridimensional device, denominated NeT Plug and Patch, that avoids any risk of migration. Results after 12 months follow-up have demonstrated low incidence of postoperative and chronic pain, with both patients and surgeons greatly satisfied. NeT Plug and Patch has proven to achieve a simple and effective repair for primary inguinal hernias.

KEY WORDS: Mesh-plug, Plug migration, Trabucco repair

Introduction

Mesh Plug repair (MPR) is frequently used in the current approach to hernia repair [1]. Update of European Hernia Society states that MPR can be considered as an alternative treatment to Lichtenstein technique, being short and long-term results comparable (level 1A) [2]. MPR is easy to learn and gets high surgeon's satisfaction [3]. Its operative time is shorter than other techniques [4]. The chance for mesh migration/erosion with the use of plug, however, needs to be taken into account, even if considered small [2]. Only few case of plug migration have indeed been published in literature [5], but this risk could be underestimated.
Plug can shrink and shrunken plug could act as foreign body ("meshoma") thus resulting in awareness, numbness and chronic groin pain. Moreover it could migrate and erode into surrounding structures. Although some technical details can reduce this complication [6,7], the choice of a proper tridimensional device is mandatory. Hereby we present a new "all-in-one" mesh, designed in order to realize a safe and effective MPR without any risk of migration.

The Mesh

NeT Plug & Patch (Herniamesh, Chivasso, Torino, Italy) is a symmetric pre-shaped mesh, 6 cm wide and 11 cm long, knitted with a polypropylene monofilament. Being the mesh with a convenient central diverticular opening of 15 mm in diameter, located 7 cm from the tip (referring to the center of the diverticular opening), NeT Plug & Patch can be configured as a monolithic mesh, which

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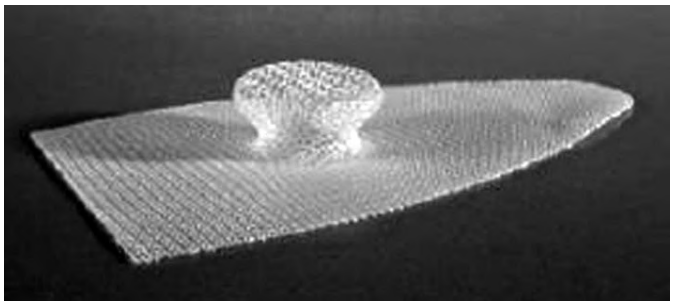

Fig. 1: NeT Plug & Patch.

means that the patch and plug are one piece, without being jointed sutures. An extruded shaped plug, which is 25 mm in diameter and 12 mm in length, in fact, has been obtained from the base, getting a soft, lightweight flat and rounded tip (Fig. 1). The hollow plug is compressible and can easily introduced into a defect also much smaller than the diameter of the plug.

Surgical Technique

NeT Plug & Patch is particularly indicated for the treatment of lateral (indirect) hernias, but it can also be used to treat a medial (direct) hernia and concurrently to prevent lateral recurrence.

An oblique (4 to 6 cm) incision is made under local or regional anesthesia. The external oblique aponeurosis is opened. The spermatic cord is mobilized and a loop is placed around the cord. The ilioinguinal and genitofemoral nerves are preserved when possible.

In lateral hernias, the highly , freely dissected, unopened sac is reduced in abdominal cavity. Then the strength of posterior wall is tested and the latter is flattened with a running suture, if necessary. A blunt dissection of the loose tissue under the aponeurosis of the external oblique muscle and the dissection of the inferior crus from the cribriform fascia prepare the space for the placement of the mesh.

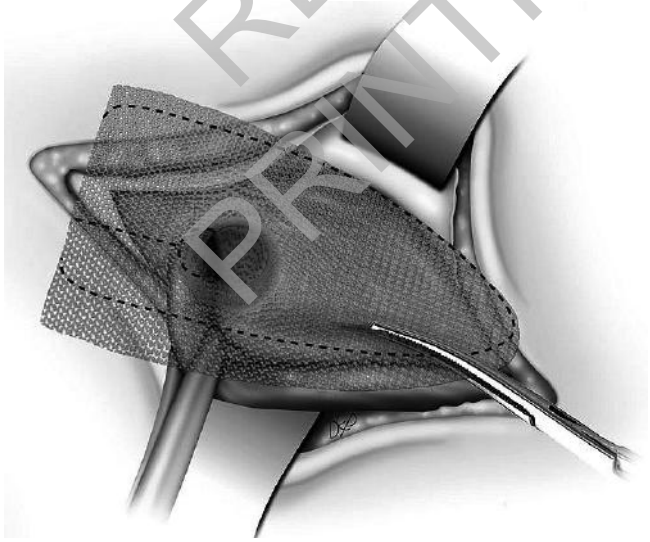

Fig. 2: NeT Plug & Patch is trimmed to adapt to the posterior wall and to permit the passage of the cord.

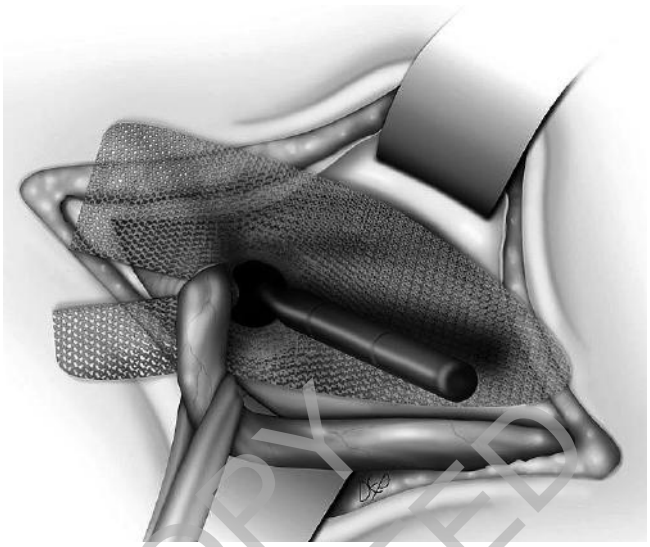

Fig. 3: The plug is positioned into the internal inguinal ring.

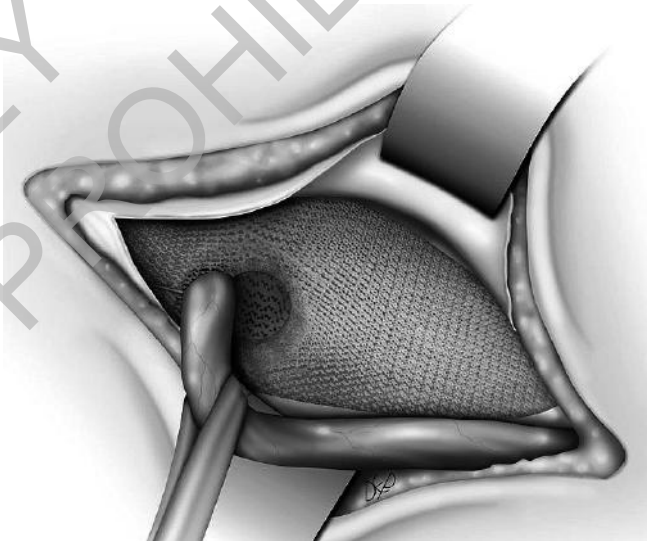

Fig. 4: NeT Plug & Patch in position.

NeT Plug & Patch is then removed from its package and the surgeon trims the mesh in the operative field to adapt it to the posterior wall of the inguinal canal, according to the position of the spermatic cord. To do this the patch is trimmed medially or posteriorly and a keyhole slit close to the plug is performed to permit the passage of the cord (Fig. 2). When the orifice is too

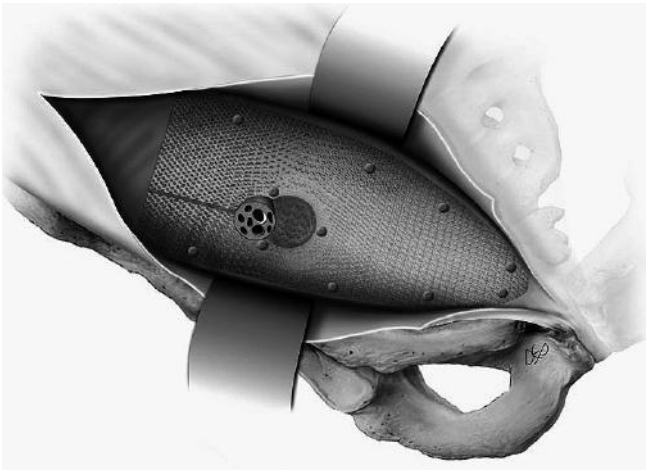

Fig. 5: Some drops of glue fix the device.

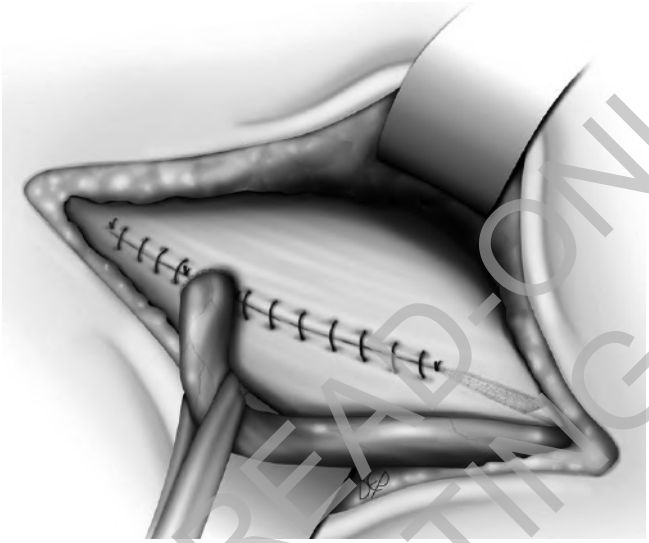

Fig. 6: NeT Plug & Patch is lying in the "inguinal box".

enlarged, a plasty of the internal ring should be previously performed. A sponge dissection can help to create a preperitoneal space for the plug. Once reduced the sac into the preperitoneal space, the surgeon positions the plug inside the internal ring by mean of his finger or a positioner in the hole of the plug (Fig. 3). The flat portion of the previously trimmed mesh is then laid on the posterior wall of the inguinal canal, overlapping the pubic tubercle by at least 1 cm. In this way a medial (direct) hernia can be prevented (Fig. 4). NeT Plug & Patch fixation is done with synthetic or fibrin glue, taking care the mesh adhere to the inguinal canal. Less than 1 ml of fibrin glue or 0.2 ml of cyanoacrylate-2 (6-8 drops) allow rapid and effective adhesion of the mesh (Fig. 5).
In medial hernias, the sac is reduced and a tension-free reinforcement of the posterior wall is performed using continuous polypropylene suture. The internal ring is explored to exclude a synchronic lateral hernia. Then NeT Plug & Patch , trimmed as above described, is laid on the posterior wall of the inguinal canal and the plug is inserted through the internal ring into the preperitoneal space to prevent an indirect recurrence. Then the mesh is fixed with the glue.
The external oblique aponeurosis is re-approximated over the mesh but below the spermatic cord with continuous absorbable suture. In this way NeT Plug & Patch is lying in a closed anatomical space (the so-called inguinal box) (Fig. 6). This favors the infiltration of the macroporous mesh by connective tissue and separates the spermatic cord from the mesh-related scar formation. The wound is finally closed with absorbable sutures for subcutaneous and skin layer in a routine fashion.

Pilot Clinical study

NeT Plug & Patch achieves the purpose of mesh hernioplasty, according to Trabucco's repair.
This device has been tested in a multicenter pilot clinical study carried out in three Centers with large experience in Trabucco's repair (FA, Azienda Ospedaliera Pugliese –Ciaccio, Catanzaro; FG, Policlinico Universitario Umberto I, Roma; SM, Azienda Ospedaliera Sant'Anna e San Sebastiano, Caserta) [8]. Between January and June 2014, 100 primary repairs for lateral hernias ((L 1-3) (EHS Classification) [9] were included in a prospective observational study. Primary endpoint was the assessment of postoperative pain; secondary endpoints were represented by chronic pain and recurrence.
The study considered also the surgeon's satisfaction, including operative time. Each surgeon had to fill in a form, specifying the slit's direction, the fixation method of the mesh, the positioning time and the overall satisfaction, using a numeric scale ranging from 0 (dissatisfaction) to 10 (maximum satisfaction).
All patients were evaluated with physical examination at 7 and 30 days, at 6 and 12 months, postoperatively. Pain was measured using a 10 cm Visual Analogue Scale (VAS), graduated from 0 (no pain) to 10 (unbearable pain). Short-term results (at 7 and 30 days) reflected postoperative pain at rest, when standing up, when climbing stairs, taking into account the use of analgesic drugs. Mid-term results (at 6 months) considered prolonged postoperative pain and early recurrence while long-term (at 12 months) evaluated chronic pain, recurrence and migration.
VAS scores for pain were assembled in 5 subgroups: 0 (no pain), 1-3 (mild pain), 4-5 (moderate pain), 6-7 (moderate pain requiring occasional use of analgesic drugs) and 8-10 (severe pain requiring frequent use of analgesic drugs).

Results

The pilot prospective study included 100 patients, 91 males and 9 females, aging from 33 to 86 years (mean 56). All hernia repairs were performed under local or epidural anesthesia. All patients were discharged within 24 hours.

Hernia type was classified as L1 in 18%, L2 in 78% and L3 in 4% of patients. In 30 patients a concomitant medial hernia was observed (M1 17%, M2 13%). Slit's direction resulted to be longitudinal or oblique in the totality of cases. In 82% of patients the mesh was fixed using cyanoacrylate (Glubran, GEM or Histoacryl, Braun); fibrin glue (Tisseel, Baxter) was the fixation method in 18% of cases. The positioning time ranged from 2 to 4 minutes.

The assessment of surgeon's satisfaction was very high (10/10) in 94% of the procedures and high (8/10) in 5% of them. Only in one case the evaluation gained 7/10 due to difficulties in reducing tissue around the cord.

Follow-up included 100% of patients at 30 days, 92% at 6 months and 88% at 12 months. Patients lost at follow-up were considered to have the same risk of recurrence of those who were examined.

Postoperative pain evaluation (VAS score) is shown in table I. Numbness (atypical sensation of tension without pain) was reported by 17% of patients at 7 days, 10% at 30 days and 0% at 6 and 12 months . Mean VAS score was 0.3 (0-4) and 0 at rest , 0.5 (0-4) and 0.1 (0-1) when standing up and 0.6 (0-4) and 0.1 (0-1) when climbing stairs at 7 and 30 days respectively; VAS score registered 0 as mean value at 6 and 12 month follow-up.

No recurrence related symptoms were observed.

TABLE I - *VAS results.*

VAS (%) at rest	**7 days**	**30 days**	**6 months**	**12 months**
0	80	8	100	100
1-3	19	2	-	-
4-5	1	-	-	-
6-7	-	-	-	-
8-10	-	-	-	-
VAS (%) when standing up				
0	67	94	100	100
1-3	31	6	-	-
4-5	2	-	-	-
6-7	-	-	-	-
8-10	-	-	-	-
VAS (%) when climbing stairs				
0	65	94	100	100
1-3	33	6	-	-
4-5	2	-	-	-
6-7	-	-	-	-
8-10	-	-	-	-

Discussion

Plug and Patch is an effective method for the treatment of groin hernia. The patch covers the posterior wall after a medial hernia is reduced into the peritoneal cavity by a running suture or reinforces a weak transversalis fascia. The plug prevents eversion of previously inverted sac of lateral hernia thus avoiding any sub-prosthetic recurrence, as it could occur when the Lichtenstein technique is performed [10]. The technique is fast and easy to learn. Although results from wide series are satisfactory, there are still some criticisms concerning adverse effects associated with the plug. It can shrink and shrunken plug could result in awareness, numbness and chronic pain. More dramatically it could migrate and erode surrounding anatomical structures (bowel, cecum, bladder). Technical details, as to fix the plug to the internal ring, to avoid the excision of the sac, to identify and repair any hole in the peritoneal sac, can reduce this risk [7]. Anyway a proper choice of the device is mandatory. Handmade plug should be avoided in favor of preshaped, light plug with proper size. Some devices have been proposed to prevent the risk of mesh migration but they require a long learning curve and their results are contrasting [11-14]. None of these in fact is so widely used as the cone or flower-shaped plug.

NeT Plug & Patch achieves all the purposes of MPR, according to Trabucco's repair (outpatient setting, suturless technique, treatment and prevention of groin hernia) [8,15]. In fact, it provides a posterior repair in the preperitoneal space (inguinal internal ring) and an anterior repair above the transversalis fascia. For this, it is indicated in the treatment of lateral and medial hernias. The technique is fast and simple. During the pilot study, NeT Plug & Patch has showed quick positioning, short learning curve and achieved high surgeon's satisfaction. Moreover it has realized great patient's compliance, displaying low VAS scores, from 0.3 to 0.6 for postoperative pain, and nil for chronic pain, during the entire follow-up. VAS score resulted sensibly lower than MPR with conic plug or PHS repair [16]. Pain showed to be lower also when the technique was compared to MPR with semiabsorbable plug [17,18].

In our opinion, NeT Plug and Patch's good results in terms of chronic pain are related to the improved manufacturing with a low profile configuration and relatively stable structure of the device, that doesn't allow any tilt or drift of the plug, as it happens with cone or dart plug [19]. Its extruded cup conforms better to the entire circumference of the internal ring and is made by a soft macroporous polypropylene. It should to be emphasized that only one patient reported foreign body sensation. The characteristics of the device and its fixation (synthetic or fibrin glue) preventes the recurrence. The "all-in-one" configuration excludes migration.

The present study is associated with some limitations. First, the patient selection was not randomized. Second,

the follow-up was limited to 12 months. If we had followed patients for a longer time, more information on long-term recurrence and course of chronic pain could have been achieved. On the other hand, since it has been demonstrated that chronic pain correlates with the rate of postoperative pain [13], we could not expect any sensible increase over time.

Riassunto

Sebbene la tecnica Mesh Plug rappresenti una procedura di indubbia efficacia nel trattamento dell'ernia inguinale, tuttora permangono dubbi in relazione alla storia naturale del plug. In particolare, il plug può andare incontro a coartazione (shrinkage) con formazione di un "meshoma" responsabile di una sintomatologia dolorosa cronica. Più raramente, il plug può migrare e provocare erosione delle strutture anatomiche circostanti. Nel passato sono stati proposti alcuni devices per cercare di risolvere il problema della migrazione; nessuno di questi, tuttavia, ha raggiunto la popolarità dei plug conici o a forma di fiore.
Il presente lavoro riporta i risultati di uno studio pilota condotto con l'impiego di un nuovo device tridimensionale, il NeT Plug & Patch. I risultati dopo 12 mesi di follow-up, hanno dimostrato una ridotta incidenza di dolore postoperatorio e cronico, senza rischio di migrazione. Inoltre è stata registrata una compliance soddisfacente sia dei pazienti che degli operatori. La protesi NeT Plug & Patch ha dimostrato di poter realizzare un'ernioplastica semplice ed efficace per la riparazione dell'ernia inguinale.

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