Four-year follow-up in 33 patients after inguinal hernioplasty using the NeT Plug & Patch device

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AIM: *To prove that the Net Plug & Patch is a valid device for the surgical treatment of inguinal hernia.*
MATERIAL OF STUDY: *The authors of a previous study decided to continue the follow-up for a further three years on 33 patients who had had hernia repair surgery using the three-dimensional NeT Plug & Patch device at their Hernia Center.*
RESULTS: *All of the patients involved took part and the follow-up appointments were scheduled as follows: clinical examination at two years; telephone contact at three years and telephone contact and questionnaire at four years. No symptoms were observed at the second, third and fourth year follow-up time-points. There were no cases of recurrence.*
DISCUSSION: *The Lichtenstein technique is currently considered the gold standard. However, many surgeons now prefer to use the MPR (Mesh Plug Repair) technique, despite the potential complications of using a plug. The technique had a short learning curve with no complications associated directly with the plug used such as migration or possible erosion of the adjacent hollow abdominal organs or blood vessels.*
CONCLUSIONS: *the NeT Plug & Patch device thus proved to be comfortable, safe and efficacious in inguinal repair surgery using the MPR technique.*

KEY WORDS: Mesh Plug Repair (MPR), Plug migration, Trabucco repair.

Introduction

According to the European Hernia Society, the MPR technique can be considered a valid alternative to the Lichtenstein technique and, indeed, the short- and long-term results are similar (level 1A)[3]. The MPR technique is characterised by a short learning curve and high operator satisfaction [4]. The average duration of surgery using this approach is shorter than for other techniques [5].

Although they are considered rare, complications associated with plug migration/erosion should be taken into due consideration [3]. Very few cases of plug migration have actually been reported in literature [6,17,18]; however, this possibility may have been underestimated.

Material and Method

In this study, which was conducted on 33 patients, the Authors used an "all-in-one" device developed so that surgery using the MPR technique can be performed safely, efficaciously and without any risk of migration. The NeT Plug & Patch is a symmetrical preformed device that is 6 cm wide and 11 cm long and made of polypropylene monofilament mesh; it has a central 15-mm diameter extruded portion, located 7 cm from the tip. The NeT Plug & Patch mesh is a device whose plug

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is obtained by extruding the mesh of the flat patch to form a joinless plug (with no gluing or seams) (Fig. 1). The hollow plug can be compressed and easily introduced into defects even far smaller than the diameter of the plug.

In addition to use to treat indirect hernias, the Net Plug & Patch device can also be used for direct (medial) hernia repair, whilst simultaneously preventing lateral recurrences. Access to the aponeurosis of the external oblique muscle is achieved by making a groin incision (inguinotomy) approximately 5 centimetres long; once the external oblique aponeurosis has been opened, the surgeon identifies the spermatic cord, which is mobilised and retracted, before identifying and, where possible, preserving, the ilioinguinal and genitofemoral nerves. Once the hernia sac has been prepared (for indirect hernias) it is sunk into the abdomen and if necessary reinforcement posterior wall repair is performed using 2/0 resorbable suture; the surgeon then creates a pocket under the external oblique aponeurosis to house the device (Fig. 3). The Net Plug & Patch device is then prepared by making a medial or posterior cut to allow the passage of the spermatic cord (Fig. 2). The device is positioned on the posterior wall of the inguinal canal, making sure that about 1 cm of the flat pointed part is

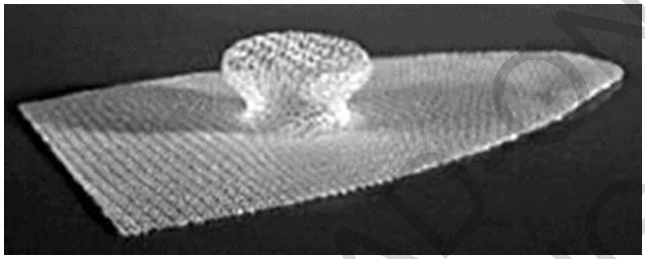

Fig. 1: The NeT Plug & Patch device.

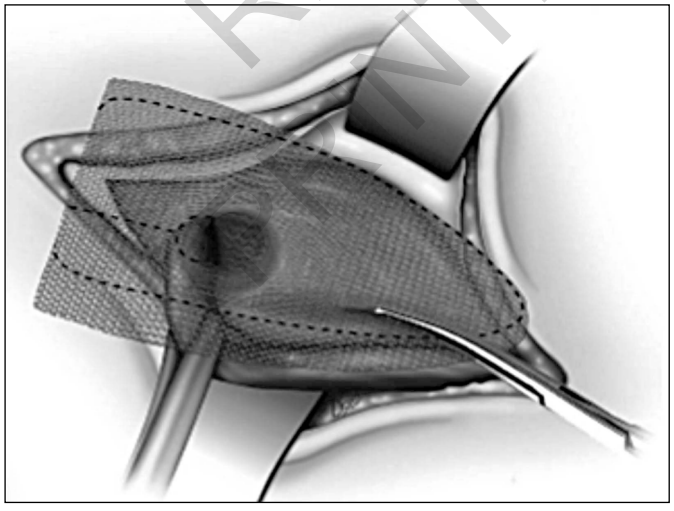

Fig. 2: The NeT Plug & Patch device is prepared for adaptation to the posterior wall and to allow the passage of the spermatic cord.

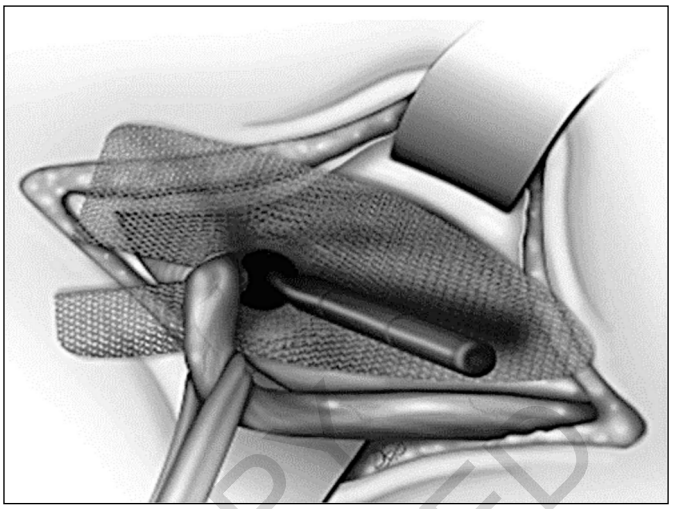

Fig. 3: The plug is positioned inside the deep inguinal ring.

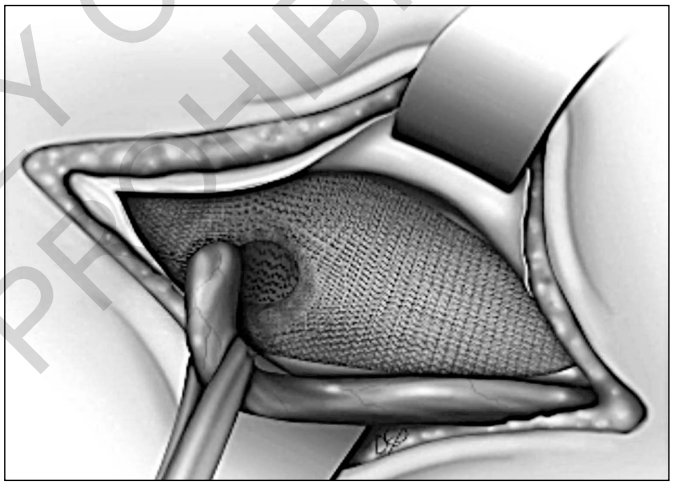

Fig. 4: The NeT Plug & Patch device in its final position.

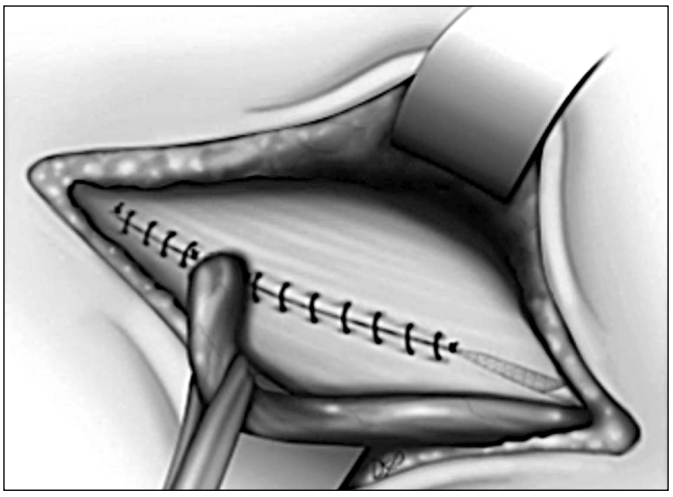

Fig. 5: NeT Plug & Patch in the "inguinal box".

positioned over the pubic tubercle without the need for permanent fixation (Fig. 4). For medial (direct) hernias, the sac is reduced and the posterior wall is reinforced with "tobacco-pouch" sutures using a resorbable material. In these cases, the deep inguinal ring must be explored to rule out the concomitant presence of an indirect hernia and the previously prepared device is positioned on the posterior wall of the inguinal canal, inserting the plug into the deep inguinal ring in the preperitoneal space. Lastly, the surgeon reconstructs the external oblique aponeurosis above the device with running stitches using resorbable material. The procedure ends with the layered closure of the surgical wound.

The NeT Plug & Patch device was used to perform hernia repair surgery using the Trabucco technique in a multicentre pilot study conducted at three centres with extensive experience in the Trabucco technique, with a one-year follow-up period. This study initially evaluated postoperative pain and, subsequently, chronic pain and any recurrence; the degree of surgeon satisfaction and duration of surgery were also assessed. Each surgeon was administered a questionnaire concerning the type of incision, the method of device fixation, positioning time and the degree of overall satisfaction. The patients attended follow-up appointments 7 days, 30 days, 6 months and 1 year after the procedure. Pain was rated using a 0 to 10 point visual analogue scale (VAS, where 0 = no pain and 10 = unbearable pain) at various time-points and in various situations during the day (at 7 and 30 days: at rest, when standing, when moving, on the stairs; at 6 months: chronic postoperative pain and short-term recurrence; at 12 months: chronic pain, recurrence and migration). The VAS scores for pain were split into 5 sub-groups: 0 (no pain), 1-3 (mild pain), 4-5 (moderate pain), 6-7 (moderate pain requiring occasional use of analgesics) and 8-10 (intense pain requiring frequent use of analgesics) [7].

Results

The 33 patients who had previously had hernia repair surgery were asked to come back to the Hernia Center Day Surgery Unit, of P.O. "S. Giovanni Bosco" in Naples for a long-term assessment. The group of patients, formed of 31 males and 2 females between 33 and 86 years of age (mean 53 years), was followed up for a total of 4 years. All procedures had been performed under epidural anaesthesia or using a laryngeal mask. All patients were discharged the same day; the types of hernia treated were: L1: 21%; L2: 76%; L3: 3%; 10 patients had a concomitant direct hernia (M1: 18%; M2: 12%) [16] (Table I). The surgical incision consisted in a groin incision in all cases. The mean duration of device posi-

TABLE I - *Patients participating in 48-month follow-up.*

	L1	L2	L3	M1	M2	Recurrence
Patients: 33 (M:31, F:2)	21% (7)	76% (25)	3% (1)	18% (6)	12% (4)	0% (0)

Age between 33 and 84 years (53)

TABLE II - *Vas Score.*

Vas (%) at rest	7 days	30 days	6 months	12 months	24 months	36 months	48 months
0	80	98	100	100	100	100	100
1-3	19	2	-	-	-	-	-
4-5	1	–	-	-	-	-	-
6-7	-	–	-	-	-	-	-
8-10	-	-	-	-	-	-	-
Vas (%) When Standing							
0	67	94	100	100	100	100	100
1-3	31	6	-	-	-	-	-
4-5	2	-	-	-	-	-	-
6-7	-	-	-	-	-	-	-
8-10	-	-	-	-	-	-	-
Vas (%) On The Stairs							
0	65	94	100	100	100	100	100
1-3	33	6	-	-	-	-	-
4-5	2	-	-	-	-	-	-
6-7	-	-	-	-	-	-	-
8-10	-	-	-	-	-	-	-

tioning was 2-4 minutes (3 on average) and the surgeon satisfaction assessment was excellent (10/10) in 94% of procedures, high (8/10) in 5% and good (7/10) in just one case, due to anatomical problems. All of the patients involved took part and the follow-up appointments were scheduled as follows: clinical examination at two years; telephone contact at three years and telephone contact and questionnaire at four years. Table II shows the results of the postoperative pain assessment using the VAS linked to the results obtained in the 12 months of the first study. No symptoms were observed at the second, third and fourth year follow-up time-points. There were no cases of recurrence.

Discussion and Comments

It is, in any case, imperative to choose a suitable device, avoiding manual plug preparation and preferring a suitably-sized preformed device. A number of devices have been proposed for preventing the risk of migration, but they involve a longer learning curve and have yielded discordant results [10,13]. The NeT Plug & Patch device satisfies all the criteria of the MPR technique (ambulatory procedure, sutureless technique, treatment and prevention of inguinal hernia) [7,14]. Indeed, it allows the posterior repair of the preperitoneal space (deep inguinal ring) and anterior repair above the transversalis fascia. This makes it ideal for the treatment of lateral and medial hernias. The NeT Plug & Patch device also proved to be rapid to position (with a short learning curve and excellent surgeon satisfaction), as well as being very comfortable for the patient, as it was allocated very low VAS scores, from 0.3 to 0.6 for postoperative pain and zero for chronic pain, for the entire duration of the follow-up period. This study showed that the good results in terms of chronic pain can be attributed to the structure and shape of the device, which prevents plug tilting or displacement [15] and its special shape adapts better to the inner circumference of the deep inguinal ring. It should be pointed out that just one patient reported a foreign-body sensation. This study therefore allows us to state that the results that were obtained for the 12-month short-term follow-up period are positively confirmed.

Conclusions

The NeT Plug & Patch proved to be a valid device for the surgical treatment of inguinal hernia. The patch adequately covered the posterior wall after hernia sac reduction and the plug prevented recurrence. The technique had a short learning curve with no complications associated directly with the plug, such as migration or possible erosion of the adjacent hollow abdominal organs or blood vessels [3,17,18].

Riassunto

Il rischio di sviluppare la patologia erniaria inguinale è del 27%-43% per gli uomini e 3%-6% per le donne nella popolazione mondiale [1]. Tra le tecniche chirurgiche di riparazione del difetto erniario che prevedono l'utilizzo di devices protesici, la tecnica di Lichtenstein viene tutt'oggi considerata il gold standard. Molti chirurghi attualmente preferiscono la tecnica MPR (Mesh Plug Repair) nonostante le complicanze che possono derivare dall'utilizzo del plug. Quest'ultimo, infatti, può restringersi con conseguente formazione di "meshoma" ed eventuale sintomatologia dolorosa cronica o, addirittura, migrare provocando erosione nelle strutture anatomiche circostanti [3,17,18]. Già in passato sono stati sviluppati dispositivi di forme diverse, ma senza portare alla completa risoluzione del problema. Il presente lavoro riparte dai risultati di un follow-up di 12 mesi condotto su 100 pazienti sottoposti ad intervento chirurgico di ernioplastica utilizzando il dispositivo tridimensionale NeT Plug & Patch (Herniamesh®, Chivasso, Torino, Italy) [8]. Lo studio mostrava risultati incoraggianti che, a nostro avviso, andavano però supportati con un follow-up a più lungo termine. Gli autori hanno deciso pertanto di proseguire il follow-up per ulteriori tre anni sui 33 pazienti sottoposti a intervento chirurgico presso il loro Hernia Center. I risultati a seguito di 48 mesi di follow-up hanno evidenziato una ridotta intensità di dolore e la protesi NeT Plug & Patch si è pertanto confermata essere confortevole, sicura ed efficace negli interventi di ernioplastica inguinale secondo la tecnica MPR.

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