

The Open New Simplified Totally Extra-Peritoneal (ONSTEP) Inguinal Hernia Repair: Initial Experience with a Novel Technique

A. Marinis, I. Psimitis

Abstract

Introduction – Aim: The Open New Simplified Totally Extra-Peritoneal (ONSTEP) inguinal hernia repair involves placing the greater part of a pre-shaped mesh in the preperitoneal space covering all hernia defects and the rest of it in the inguinal canal. Its advantages over the existing techniques include shorter operative time, faster learning curve, less postoperative pain, speedier return to normal activities, better cosmetic result and a lower recurrence rate. The purpose of this study is to present our initial experience of this novel method.

Patients – Methods: Adult patients underwent inguinal hernia repair with the ONSTEP procedure. Patients were followed up for one year for pain, wound complications and recurrence. The pre-shaped mesh used for repairing the hernia defect was the Polysoft™ hernia patch.

Results: During a 1.5-year period (between the 1st January 2013 and the 30th June 2014) thirty three (33) patients underwent inguinal hernia repair with the ONSTEP procedure. The mean operative time was 33.28 (\pm 11.69) minutes, the time to discharge was 24h for all patients and the return to normal activity was between three and seven days. The overall wound complication rate was minimal and the overall recurrence rate was zero. No patient experienced residual or chronic pain at six months. Three patients had mild discomfort related to the memory ring; however, the pain subsided and did not necessitate its removal. The cosmetic result was very good immediately postoperatively, as well as at one and six months. All patients were very satisfied owing to minimal discomfort, good cosmetic result, no chronic pain and speedy return to normal activity.

Conclusions: ONSTEP repair of inguinal hernia is a new technique which is fast to learn and perform, with a low complication rate and minimal recurrence rate. The overall cosmetic result and patient satisfaction is excellent. It is a safe alternative to other open and laparoscopic techniques.

Key words *Inguinal hernia repair; ONSTEP hernia repair; recurrence; chronic pain*

Introduction

Inguinal hernia repair has undergone several changes during the last decades, with the abandoning of older tension techniques and the introduction of newer tension-free procedures via open or laparoscopic approaches. The most known and widely used open repair methods are the Lichtenstein, the Stoppa and Nyhus and the Rutkow (mesh & plug) techniques. Newer open methods include the TIPP (transinguinal preperitoneal repair), with a dif-

ficult learning curve but shorter operative time and less postoperative pain than the aforementioned methods, and the ONSTEP procedure. The laparoscopic techniques place the mesh preperitoneally either through the abdominal cavity (TAPP) or totally extraperitoneally (TEP), both of which are associated with steep learning curves and prolonged operative time.

The ideal hernia repair should be safe to perform, quick to learn, have fewer wound complications and postoperative pain, produce good cosmetic results and be associated with minimal recurrence rates and affordable cost. This study is the presentation of our early experience with the novel method of Open New Simplified Totally Extra-Peritoneal (ONSTEP) inguinal hernia repair as performed by two surgeons in the same institution, focusing on operative time, chronic pain, recurrence rate, cosmetic results and patient satisfaction.

A. Marinis, I. Psimitis
First Department of Surgery, Tzaneion General Hospital, Zanni & 1 Afentouli STRs, 18536, Piraeus, Greece

Corresponding author: Athanasios Marinis, MD, PhD,
General Surgeon, First Department of Surgery, Tzaneion General Hospital, Zanni & 1 Afentouli STRs, 18536, Piraeus, Greece
e-mail: drmarinis@gmail.com

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Patients – Methods

Thirty three adult patients underwent inguinal hernia repair at our institution between the 1st January 2013 and the 30th June 2014 using the ONSTEP procedure, 26 under general anaesthesia and 5 under regional anaesthesia.

Mesh characteristics

The Polysoft™ hernia patch (Davol Inc., Cranston, Rhode Island, USA) was used for repair of the inguinal defect. This is a self-expandable, non-absorbable mesh consisting of polypropylene monofilaments knitted together to form a strong, porous mesh. This mesh has an interrupted memory recoil “ring” around its edge consisting of extruded monofilament polyethylene terephthalate (PET) polymer, which facilitates placement. The mesh is available in two sizes (14cm x 7.5 cm and 16cm x 9.5cm) and is pre-shaped to cover all potential hernia defects (Figure 1).

Surgical technique

A 3-4 cm horizontal incision is made at a level of two fingers above the pubic symphysis and two fingers laterally of the transumbilical midline (Figure 2). The location of the incision is such as to avoid damage to both the branches of the iliohypogastric nerve and the genital branch of the genitofemoral nerve. Cutting through the subcutaneous tissue, we usually ligate the superficial epigastric vein and through the Scarpa’s fascia expose the anterior surface of the external oblique aponeurosis. Horizontal incision of this aponeurosis without opening the underlying internal oblique aponeurosis is critical to develop the safe plane of dissection (Figure 3). The space between these two aponeurotic fasciae is developed bluntly by sweeping digitally all loose

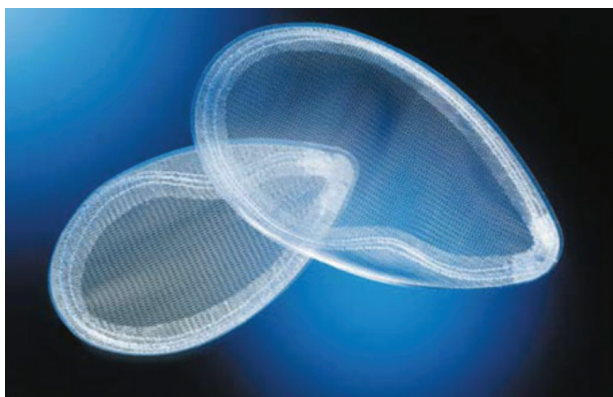


Figure 1. The PolySoft™ hernia patch (“With kind permission of Springer Science+Business Media.: Hernia, The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions, 17(3), 2013:357-364, Lourenço A, da Costa RS, Figure 1”)

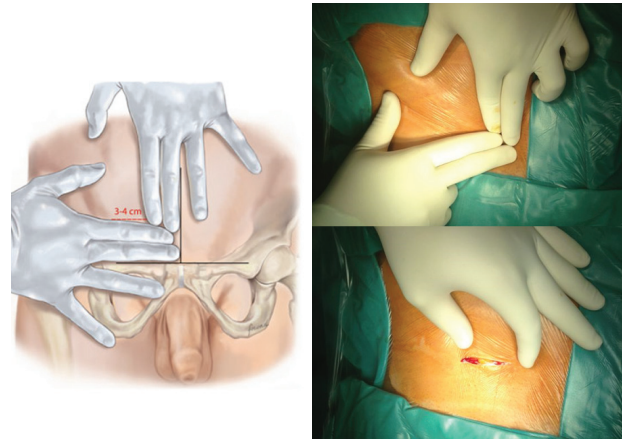


Figure 2. The landmarks for placing the incision for the ONSTEP inguinal hernia repair. Schematic illustration (“With kind permission of Springer Science+Business Media.: Hernia, The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions, 17(3), 2013:357-364, Lourenço A, da Costa RS, Figure 2a”) and operative photos (authors)

connective tissue laterally and cranially from the anterior superior iliac spine down to the Poupart’s ligament and medially to the pubic symphysis.

Identification and digitally encirclement of the spermatic

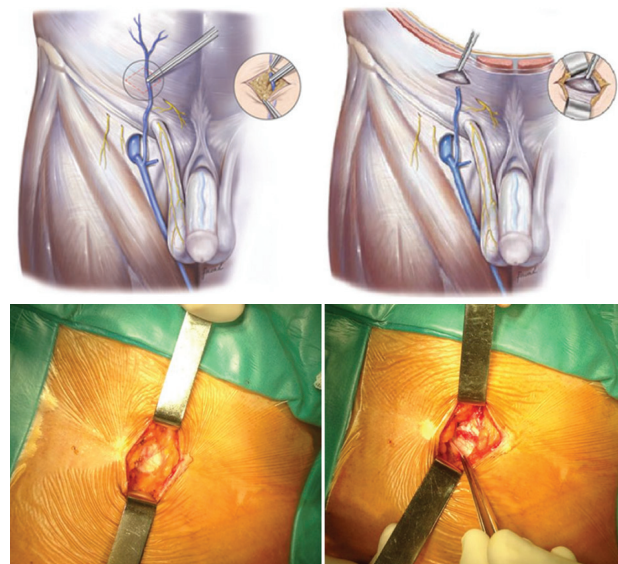


Figure 3. Cutting through the subcutaneous tissue, we usually ligate the superficial epigastric vein and through the Scarpa’s fascia expose the anterior surface of the external oblique aponeurosis. Horizontal incision of this aponeurosis without opening the underlying internal oblique aponeurosis is critical to develop the safe plane of dissection. Schematic illustration (“With kind permission of Springer Science+Business Media.: Hernia, The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions, 17(3), 2013:357-364, Lourenço A, da Costa RS, Figure 2b and c”) and operative photos (authors)

cord is followed by exploring for an indirect hernia sac. The transversalis fascia is explored for any direct inguinal hernia (followed by dissection and reduction of sac and contents in the peritoneal cavity). At the level of the pubic bone, a finger is probed through the fascia into the space of Retzius, where the characteristic yellow/orange preperitoneal fat is identified. A 20cm x 20cm sterile gauze is inserted and guided over the finger in the space of Retzius behind the pubic bone and laterally, dissecting the appropriate space for insertion of the mesh (Figure 4).

A horizontal slit between the interrupted ends of the recoil ring of the mesh is made down to the apex of the curved notch, without cutting any part of the recoil ring. The tails of the patch are placed around the spermatic cord with the curved end of the mesh oriented medially and the pre-shaped curved notch caudally. The tails of the patch are then sutured together with three sutures. The gauze is removed and the medial curved end of the mesh grasped between two fingers and inserted down to the space of Retzius behind the pubic bone (Figure 5). After ensuring that the mesh is smoothly covering all the pubic bone and laterally any hernia defects without wrinkles, the lateral tails are advanced laterally under the external oblique aponeurosis up to the level of superior iliac spine. If we observe slight wrinkling of the mesh at its lower part, we insert a suture between the mesh and the inguinal ligament. Finally, the external oblique aponeurosis is sutured with a continuous suture, and the Scarpa's fascia and skin according to the surgeon's preference (Figure 6).

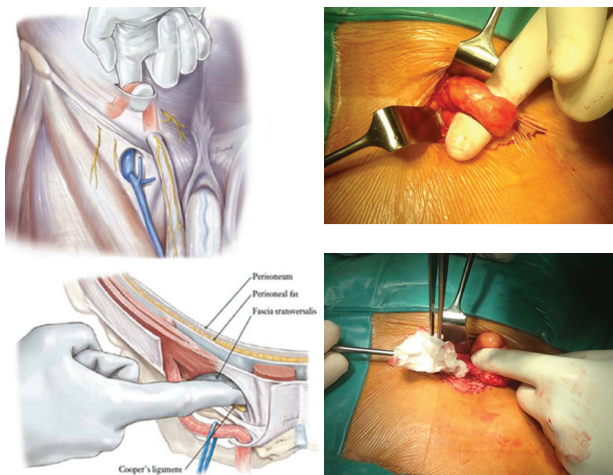


Figure 4. After encircling the spermatic cord, the finger is probed through the fascia where a sterile gauze is inserted and guided over the finger in the space of Retzius behind the pubic bone. Schematic illustration ("With kind permission of Springer Science+Business Media: Hernia, The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions, 17(3), 2013:357-364, Lourenço A, da Costa RS, Figure 2h and i") and operative photos (authors)

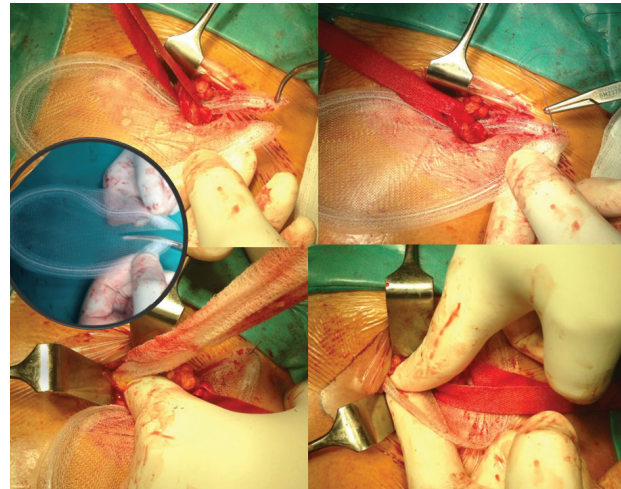


Figure 5. A horizontal slit between the interrupted ends of the recoil ring of the mesh is made down to the apex of the curved notch (small photo) and the tails of the patch are placed around the spermatic cord. The tails of the patch are then sutured together with three sutures. The gauze is subsequently removed and the medial curved end of the mesh grasped between two fingers and inserted down to the space of Retzius behind the pubic bone

Study end points and Follow up

The following variables were recorded: Operative time (minutes); postoperative pain (using the visual analogue scale) as assessed the afternoon of the day of surgery, next morning, 10 days postoperatively (when sutures are removed), and at six months and one year; return to normal activity (days); wound complications (seromas, haematomas, infection); recurrence; cosmetic result; and finally, patient satisfaction.

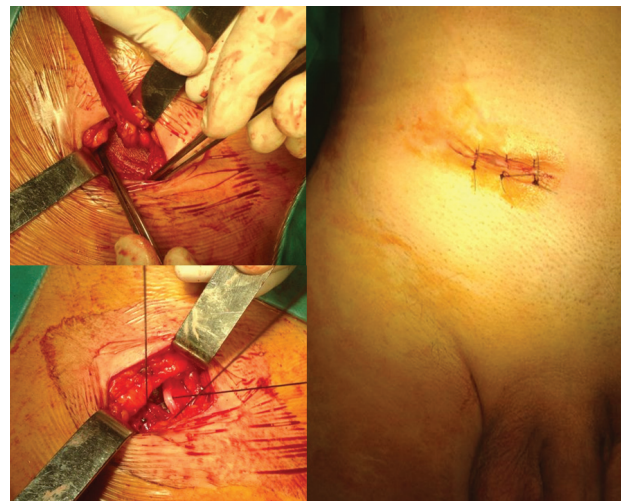


Figure 6. After ensuring that the mesh is placed properly, the external oblique aponeurosis and the skin are sutured appropriately

Results

Patient clinical characteristics are shown in Table 1. No anaesthetic complications or operative deaths were reported.

Operative time

Operative data are summarized in Table 2. The mean operative time (\pm standard deviation) was 33.28 (\pm 11.69) minutes.

Postoperative pain and wound complications (Table 3)

Postoperative pain was evaluated with the VAS scale: no pain (0), minimal discomfort (1-3), moderate pain (4-7) and severe pain (8-10). In the afternoon of the same day of surgery, pain was minimal to slightly moderate 4 (\pm 1); on 1st postoperative day patients reported only slight discomfort 1,81 (\pm 1,17); on 10th postoperative day and at six months and one year, all patients reported no residual or chronic pain at all. Three patients had mild discomfort related to the memory ring; however, the discomfort subsided and did not necessitate its removal.

No patient experienced any wound complication, such as seroma, haematoma or surgical site infection.

Table 1. ONSTEP hernia repair – Patient characteristics

Patient characteristics	Values
Total number of patients	33
Male/female	33/0
Mean age (\pm SD); years	60,56 (\pm 15,19)
Age range	33-82
Type of hernia	
Direct	17
Indirect	22
Bilateral hernias	1

Table 2. ONSTEP hernia repair – Operative data

Characteristic	Value
Mean operative time (\pm SD); minutes	33,28 (\pm 11,69)
Only direct hernia	33,28
Only indirect hernia	33,21
Direct & Indirect hernias	33,28
Duration of surgery (range, minutes)	18-70
Method of anesthesia	
General	26
Regional	7

Table 3. ONSTEP hernia repair – Postoperative pain, wound complications and recurrence

Characteristic	Value
Postoperative pain (mean \pm SD)	
Day of surgery (VAS score)	4 (\pm 1)
1 st postoperative day (VAS score)	1,81 (\pm 1,17)
10 th postoperative day (VAS score)	0
6 months (VAS score)	0
1 year (VAS score)	0
Wound complications (seroma, haematoma, surgical site infection)	0
Mild discomfort related to memory ring	3
Recurrence (number of patients)	0

All patients were discharged on the 1st postoperative day (mainly due to the absence of the setting of a one-day clinic). They returned to normal activity within 3 to 7 days.

Recurrence (Table 3)

During the follow-up period, no evidence of recurrence was reported.

Cosmetic result and patient satisfaction

The cosmetic result of this operation is excellent without any oedema of the inguinal hernia or haematoma at the base of the penis in the early (Figure 7) and late postoperative period (Figure 8). All patients were very satisfied due to minimal discomfort, good cosmetic result, no chronic pain and fast return to normal activity.



Figure 7. Cosmetic result of the incision in the early postoperative period (1st and 10th postoperative days)

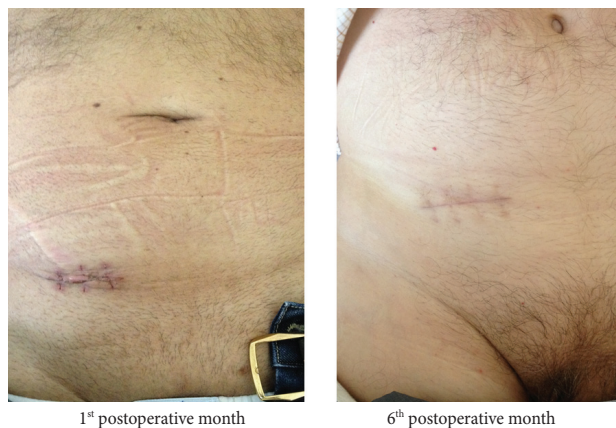


Figure 8. Cosmetic result of the incision in the late postoperative period (1st and 6th postoperative months)

Discussion

This is the first Greek study of the novel method of inguinal hernia repair called ONSTEP procedure. The early experience of using this technique has been very good and the preliminary results show that it is a safe, reproducible, quick to learn technique, with minimal postoperative pain, almost no postoperative morbidity, no mortality, excellent cosmetic results and very low, if at all, recurrence rate. However, the small group of patients as well as the wide range of time follow-up during this 1.5 year study period necessitates the extraction of more solid conclusions from a larger prospective study, which will follow this preliminary report.

Our results reflect those reported in the only two studies published in the English literature to date. The first study is that of its inventors from Portugal [1]. They published a large series of 693 patients and concluded that this is a safe and reliable technique with a short learning curve and a short operative time (approximately 17 min). Patients were discharged on the same day and returned to normal daily activities approximately after six days. The overall complication rate was small (1%), as was the overall recurrence rate (0.6%). Postoperative pain at 1-year follow up was zero. The other study was conducted in Denmark [2] and reported initial experience from 80 patients undergoing the ONSTEP procedure. The authors conclude that it is a safe technique producing results better than the Lichtenstein inguinal hernia repair: less postoperative pain, faster return to normal activity and no perioperative complications.

Based on our initial experience using this novel technique, we conclude that it is safe, and easy to learn and teach. It is associated with mild pain on the day of surgery, which subsides 24hrs later, and has excellent cosmetic results and patient satisfaction with no recurrences. The limitations of our study are its small number of patients and the diverse range of the follow-up period. From our little experience, we should mention some disadvantages of this method: a

difficult step of the procedure is finding and encircling the spermatic cord, which is due to the small incision located more cranially and horizontally than the classic inguinal incision. Perhaps, alternating the horizontal incision to a small incision parallel to the inguinal ligament would solve this problem and offer the advantage of converting to a Lichtenstein procedure (lengthening the incision) should the surgeon encounter a difficult situation. Another disadvantage of this method is the obligatory disruption of the medial portion of the transversalis fascia even if it is intact. However, this is in favour of placing half of the mesh pre-peritoneally, covering all hernia defects and potentially lowering the recurrence rate. Finally, large direct inguinal hernias can present a gap between the edge of the mesh and the distorted posterior wall of the inguinal canal; suturing the superior and inferior edges of the mesh to healthy tissue and Poupart's ligament could possibly solve this issue.

In conclusion, the ONSTEP technique for inguinal hernia repair is a safe method, with a small learning curve, mild postoperative pain during the first 24 hrs and without perioperative and postoperative morbidity. The cosmetic results are superb and all patients are very satisfied. Recurrence rates and mortality in our study were zero. Further study and randomized trials comparing this method with other open and laparoscopic procedures should be performed in order to draw safer conclusions.

Ethical Approval

The Ethical and Scientific Committees of Tzaneion General Hospital have provided authors ethical approval for this clinical study.

Declaration of conflicting interests

Both surgeons (AM and IP) were supported by Bard to receive education in the two centres (Portugal and Denmark). However, no grants or personal fees have been received from the commercial sector.

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References

1. Lourenço A, da Costa RS. The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions. *Hernia* 2013; 17:357-64
2. Andresen K, Burcharth J, Rosenberg J. The Initial Experience of Introducing the Onstep Technique for Inguinal Hernia Repair in a General Surgical Department. *Scand J Surg* 2014 Apr 22. [Epub ahead of print] PubMed PMID: 24756905.

Η Επέμβαση ONSTEP για την Αποκατάσταση της Βουβωνοκήλης: Αρχική Εμπειρία με τη Νέα Τεχνική

A. Μαρίνης, I. Ψημίτης

Περίληψη

Εισαγωγή - Σκοπός: Η νέα τεχνική αποκατάστασης της βουβωνοκήλης που ονομάζεται Open New Simplified Totally Extra-Peritoneal (ONSTEP) περιλαμβάνει την τοποθέτηση ενός προσχηματισμένου πλέγματος κυρίως στον προ-περιτοναϊκό χώρο, καλύπτοντας όλα τα κηλικά στόμια. Τα πλεονεκτήματά της σε σύγκριση με τις υπάρχουσες τεχνικές αφορούν στον μικρότερο χειρουργικό χρόνο, τη μικρότερη καμπύλη εκμάθησης, το λιγότερο μετεγχειρητικό πόνο, την ταχύτερη επαναφορά στη φυσιολογική δραστηριότητα, το καλύτερο κοσμητικό αποτέλεσμα και τη μικρότερη πιθανότητα υποτροπής. Ο σκοπός αυτής της μελέτης ήταν να καταγραφεί η αρχική εμπειρία από την νέα αυτή τεχνική.

Ασθενείς - Μέθοδος: Μελετήθηκαν ενήλικες ασθενείς που υποβλήθηκαν σε αποκατάσταση της βουβωνοκήλης με την τεχνική ONSTEP. Οι ασθενείς παρακολούθησαν για 1 έτος σχετικά με τον μετεγχειρητικό πόνο, τις επιπλοκές από το τραύμα και την υποτροπή. Το πλέγμα Polysoft™ ήταν το προσχηματισμένο πλέγμα που χρησιμοποιήθηκε για την αποκατάσταση του ελλείματος της κήλης.

Αποτελέσματα: Σε διάστημα 1,5 έτους (Ιανουάριος 2013 – Ιούνιος 2014) τριάντα τρεις (33) ασθενείς με βουβωνοκήλη υποβλήθηκαν στην τεχνική ONSTEP. Ο μέσος χειρουργικός χρόνος ήταν 33,28 (\pm 11,69) λεπτά, ο χρόνος παραμονής στο νοσοκομείο 24 ώρες για όλους τους ασθενείς, οι οποίοι επανήλθαν στη φυσιολογική τους δραστηριότητα σε 3 έως 7 ημέρες. Δεν παρατηρήθηκαν επιπλοκές από το τραύμα, ενώ μέχρι σήμερα δεν παρατηρήθηκαν υποτροπές. Κανένας ασθενής δεν παραπονέθηκε για υπολειμματικό ή χρόνιο πόνο στους 6 μήνες. Τρεις ασθενείς ανέφεραν ήπια ενόχληση στο σημείο της τομής που σχετιζόταν με τον δακτύλιο μνήμης του πλέγματος, η οποία παρήλθε χωρίς την ανάγκη αφαίρεσής του. Το αισθητικό – κοσμητικό αποτέλεσμα ήταν ιδιαίτερα ικανοποιητικό τόσο άμεσα μετεγχειρητικά, όσο κι αργότερα. Όλοι οι ασθενείς ήταν ιδιαίτερα ικανοποιημένοι από την επέμβαση λόγω της ελάχιστης ενόχλησης και πόνου, του καλού αισθητικού αποτελέσματος, της απουσίας χρόνιου πόνου και της ταχύτερης επανόδου στη φυσιολογική δραστηριότητα.

Συμπεράσματα: Η επέμβαση αποκατάστασης της βουβωνοκήλης ONSTEP είναι μια τεχνική που μαθαίνεται κι εφαρμόζεται γρήγορα, με λίγες επιπλοκές κι ελάχιστη πιθανότητα υποτροπής. Το συνολικό αισθητικό αποτέλεσμα και η ικανοποίηση των ασθενών είναι άριστα. Αποτελεί ασφαλή εναλλακτική τεχνική σε σύγκριση με τις άλλες ανοικτές και λαπαροσκοπικές επεμβάσεις.

Λέξεις κλειδιά: Αποκατάσταση βουβωνοκήλης, τεχνική ONSTEP, υποτροπή, χρόνιος πόνος