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Research

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A New Prosthesis in Inguinal Hernia Repair: Results of a Pilot Study

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ABSTRACT

Purpose: Prosthetic reinforcement is the gold standard in inguinal hernia repair. One-third of patients complain of post – surgical pain due to irritation and inflammation caused by the mesh and methods of fixation; 4-10% of these will experience severe chronic pain. We performed a prospective single arm study for the assessment of post-operative pain after inguinal hernia repair with a new self-gripping hernia prosthesis.
Methods: From December 2011 to December 2013, 44 consecutive patients with primary oblique inguinal hernia underwent to inguinal hernia repair with Proflor™ (Insightra). All patients were preoperatively evaluated by ultrasound and the defect size was < 2 cm. Visual Analog Scale (VAS) was assessed at 7 days and 3-6 months. All patients were included in ultrasound follow up at 7 days and 3-6-12-18-24 months.
Results: No sutures or other fixation systems have been used.According to the VAS scale pain was reported in a range from 1 to 3 during the first week. No peri-operative complications occurred. 10 post-operative complications was reported: 3 hematomas (6.8%), 1 ecchymosis (2.2%), 2 seroma (4.5%), 4 hypoaesthesia (9.1%). None of total implants delivered dislodged, as confirmed bythe ultrasounds.
Conclusions: Operative and post-operative complication rates were comparable to the literature; chronic pain did not occur. The use of this new prosthesis, which through its design allows fixation without sutures, could be an alternative method to decrease chronic pain after inguinal hernia repair. We acknowledge that further studies are needed.

KEYWORDS: Inguinal hernia; Chronic pain; Self-gripping; Proflor™.

ABBREVIATIONS: VAS: Visual Analog Scale; IASP: International Association for the Study of Pain; QoL: Quality of Life.

INTRODUCTION

Hernia repair is one of the most common surgical procedures performed in the United States, with 800,000 operations each year.[1] The new prosthetic materials have significantly improved outcomes for many patients. Inguinal hernia repair historically was challenging and recurrence rates were high. To reduce the incidence of recurrence rate, Lichtenstein tension free mesh repair or similar procedures were introduced into open inguinal hernia. This showed a dramatic reduction in recurrence rates.[2] However, mesh fixation with sutures, to avoid dislocation has been reported in the literature as a cause of chronic pain and discomfort. According to the International Association for the Study of Pain (IASP) chronic groin pain was "groin pain reported by the patient at or beyond 3 months following inguinal hernia repair.[3] Post-operative pain may be incapacitating and can dramatically affect quality of life; the reported incidence of chronic pain 1 year after hernia repair varies from 0.7 to 28.7%.[4] Management of chronic groin pain constitutes a challenging issue for the clinician, often more challenging than deal-

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ing with recurrence. According to the literature, perioperative nerve damage, postoperative fibrosis, and mesh related fibrosis are the main reasons for chronic groin pain.[4,5] In attempts to reduce it, researchers have tried various surgical techniques and materials.[6,7] Therefore a novel technique for a diminished rate of post-operative chronic pain was developed. We used a new self–gripping 3-D prosthesis for inguinal hernia repair, which does not require suture point fixation.

PATIENTS AND METHODS

From December 2011 to December 2013, we performed a prospective single arm study for the assessment of post-operative pain after inguinal hernia repair with a new self-gripping mesh (Freedom Proflor™; Insightra) (Figure 1).

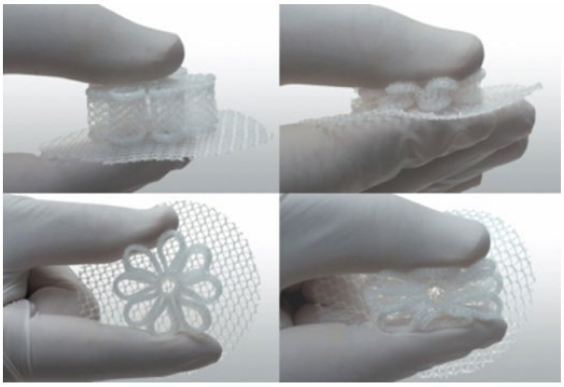

Figure 1: 3D polypropylene implant with a multi-lamellar central core with a welded pre-peritoneal disc (Freedom Proflor™; Insightra).

The study was approved bythe local ethics committee, informed consent was provided by all patients. According to Nyhus classification,[8] 44 consecutive patients with primary unilateral inguinal hernia stage I-IIIa were included. We did not included patients ASA IV-V, BMI>35 and stage IIIb or IV. Characteristics of the patients are shown in Table 1.

Total patients	N=44
Median (range)/Age (years)	51,08/(32-68)
Sex Ratio (M/F)	42/2
Median BMI (Kg/m²)/Range	27.4/(19.4-35)

Table 1: Patient characteristics.

Ultrasound scan was postoperatively performed in all patients after 7 days, 3 months and after 6 months, to detect any early recurrence, shrinkage or dislocation. Patients were invited to the outpatient setting 3, 6, 12, 18 and 24 months after surgery. The primary end point of this study was to evaluate the incidence of postoperative chronic pain defined as any pain reported by the patient beyond 3 months post surgery, according to international association of the study of pain (IASP);[3] pain intensity was categorized as mild (occasional discomfort or pain not interfering with daily activities), moderate pain (discomfort or pain occasionally interfering with daily activities) and severe pain (discomfort or pain interfering with daily activities) with long post-operative follow up at 24 months.

In agreement with Bodian CA, et al,[9] visual analog scale (VAS) was used to evaluate chronic pain in which score of 0=pain, score 1 to 3=mild pain, score 4 to 6=moderate pain, score 7 to 9=severe pain, score 10= unbearable pain.

SURGICAL TECHNIQUE

The surgical technique at the Day Surgery of the University Hospital of Rome Tor Vergata can be considered a variant of the technique proposed by Lichtenstein,[10] by the use of a self-fixing, three-dimensional implant.

Inguinal hernia repairs were performed using the new prosthesis by the same surgeons with an experience of more than five procedures to eliminate bias of a learning curve. All patients received local or locoregional anesthesia (Naropine 10%) and prophylactic antibiotic (1 × 2 g Cefazolin). In all procedures an oblique 4-7 cm incision was made overlying the inguinal canal. The external oblique aponeurosis was opened and blunt dissection was used to separate the sac from the cord. The hernia sac was ligated and resected and the pre-peritoneal space was prepared by blunt finger dissection of the tissue planes. A polypropylene implant consisting of a “flower shaped” central core with a pre-peritoneal disc was used as per the manufacturer’s instructions for use. The implant was placed with a proprietary delivery device, which compressed to flower during insertion. The implant was released and adjusted to sit in the correct anatomical space. No suture point or other method of fixation was used. The characteristics of hernia size and the dimension of implant used were reported in Table 2.

Type of hernia (Nyhus)	Number Pieces	Mesh size core (mm)	Mesh size disc (mm)
I	5	25	60
II	37	40	70
IIIa	2	40	70
Defect size (cm)			
<1,5 cm	5	25	60
1,5-3 cm	39	40	70

Table 2: Hernia size and implant use.

RESULTS

We investigated short-term (within 7 days from surgery) and long-term complications (more than 3 months after surgery) in 44 patients, with particular attention to chronic postoperative pain. The median follow-up was 17.65 months (range, 3-24). One patient was lost to follow-up after 3 months for an unrelated death.

There were 10 cases of early complications (22.7%): 3 cases of hematoma (6.8%), 1 ecchymosis (2.2%), 4 inguinal

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hypoaesthesia (9.1%), 2 seromas (4.5%), no case of infection occurred. At 1 month all early complications resolved spontaneously. All patients were followed closely on an outpatient basis and have not been necessary medical procedures invasive. Hematoma and bruising were resorbed independently, serom as were small in size, we decided the only clinical observation and these are reabsorbed independently. Mild acute post-operative pain was present in 40 patients (90.1% of the sample) with a median duration of 3 days (range 1-7 days).

According to the VAS score, pain reported during the first post-operative week ranged from 0 to 3 (Mean 1.09, SD 0.98) (Table 3). In all patients acute pain was completely resolved within 7 days after surgery with the use of 1 g of paracetamole.

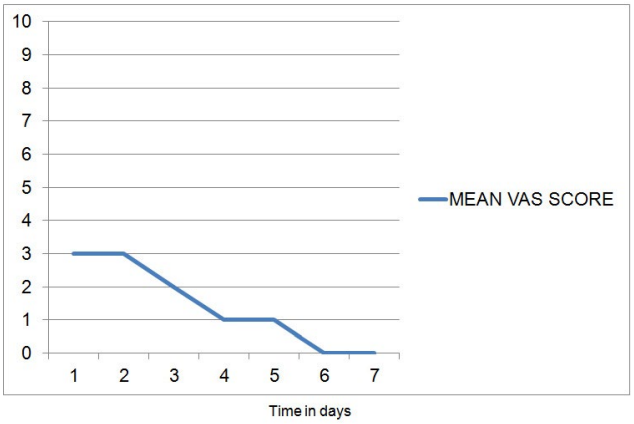

Table 3: Mean visual analog scale (VAS) pain scores in the first week after Proflor™ inguinal hernia repair.

Late complications investigated were: recurrence, testicular atrophy, and chronic postoperative pain (Table 4).

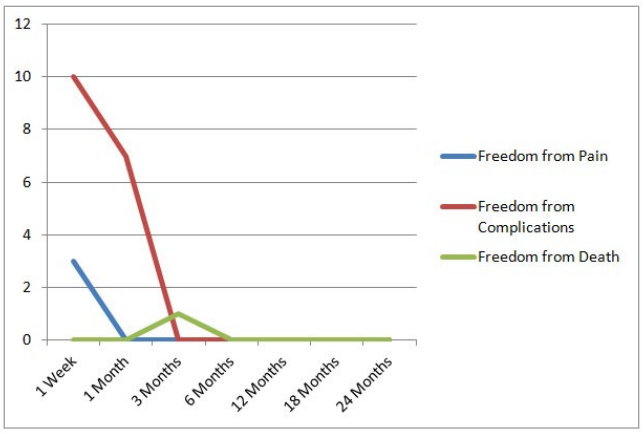

Table 4: Number of patients with adverse event during the follow-up.

All patients underwent clinical and instrumental (ultrasound and Doppler ultrasound) within 7 days, 3-6-12-18-24 months. The use of post-operative ultrasound served for the assessment of the correct positioning of the prosthesis and any dimensional changes linked to the infiltration of fibrotic, contracting scar tissue (Figures 2 and 3). No shrinkage or migration of mesh was found from the first control until 24 months. The red line in Figure 3 shows no dimensional change in the mesh core, it results 39.7 mm using an implant core of 40 mm.

The ultrasound examination showed no recurrence or testicular atrophy in any patient.

The onset of chronic post-operative pain was evaluated at 3-6-12-18-24 months after surgery through administration of the VAS score (Table 5). At the minimum follow-up of 3 months after surgery none of the patients felt pain. No cases of chronic pain were detected at follow-up of 3-6-12-18-24 months after surgery (median follow-up was 17.65 months).

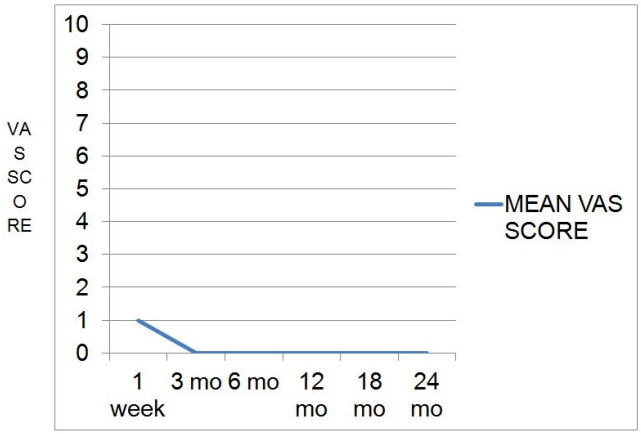

Table 5: Mean visual analog scale (VAS) pain scores in 2 years after Proflor™ inguinal hernia repair.

DISCUSSION

The evolution of prosthetic hernia repairs can be traced back to more than three decades ago;[11] the concept of tension-free hernioplasty has achieved long-term success with low recurrence, short hospitalization and decreased preoperative pain.[10] Although the Lichtenstein repair is known as a safe and easy technique with a low morbidity rate, in several publications, high rates of postoperative inguinal chronic pain have to be recognized.[12] Unfortunately the definition of chronic postoperative pain, is not clear: it can include neuralgia (e.g. from the ilioinguinal and/or genitofemoral nerve), slight to serious inguinal pain, paresthesia, and dysaesthesia.[13,14] Because of these different definitions of pain, comparison between published results is highly problematic. Furthermore, study populations are often heterogeneous, comprising of both open and laparoscopic repairs, primary and recurrent hernias, and varying lengths of follow-up assessment.[15,16] In our study, postoperative pain is conventionally divided into acute and chronic, depending on which will be resolved during the first 3 months after surgery; chronic postoperative pain defined as any pain reported by the patient beyond 3 months post surgery, according to the international association of the study of pain (IASP).[5]

In a review of Poobalan AS, et al. an incidence of chronic pain in hernia surgery from 0% to 2% was reported

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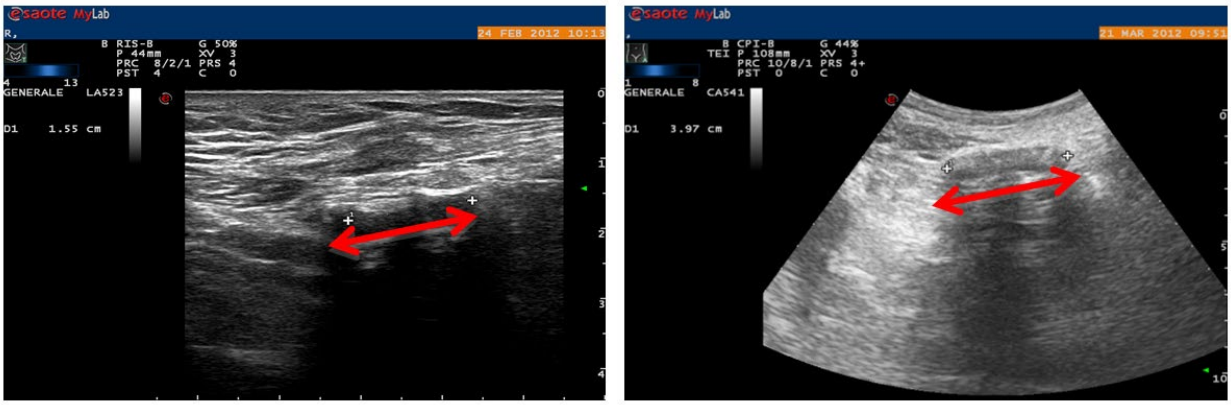

Figures 2 and 3: The ultrasound shows the correct position of the prosthesis after 6 months. The line shows the dimension of the prosthesis core: 39.7 mm.

in centers specifically dedicated to hernia surgery. Instead, in public hospitals or universities, values refer to much higher incidences (12-37%).[17] An important publication of the Danish Hernia Data Base Group reports an incidence of chronic pain at 12 months of 28.7%, with 11% considered severe disabling type of pain.[18] Other recent studies confirm an incidence of a high post-operative pain, suggesting the distinct importance of the problem: 7.6%,[3] 31%,[4] 19.7%.[5] The variability of this data is influenced by the different methods of defining pain. However, few of these studies have a long post-operative follow-up and a population large enough to give clear results.

Several risk factors have been identified to play a crucial role in the development of chronic pain, including low patient age, female sex, high preoperative and immediate postoperative pain scores, and surgery for recurrent hernia.[18] However, the long-term influence of the different surgical approaches to the groin and the presence or absence of a prosthetic mesh on long-term pain is not clear.[17]

There are many factors considered responsible for the onset of chronic postoperative pain: the experience of the surgeon, re-do surgery, damage to the nerves and the position of the mesh.[17] Many authors believe the use of prostheses and the open technique may play a role in the onset of chronic postoperative pain;[18] others exclude both of these factors;[19] still others believe that the tension-free technique is associated with a lower risk of chronic pain compared to a sutured tissue to tissue repair.[20]

Because of the variability of these findings, it is very difficult to find a common aetiology for pain. It is believed that the presence of prosthesis may contribute to the onset of pain. It has been hypothesized that, by varying the position of mesh placement, the composition of the materials or methods of fixation; we can reduce post-operative pain in inguinal hernia surgery.[21] Of course, the accuracy of dissection and damage to delicate structures may also influence the postoperative course and influence the onset of chronic pain.[5] Polypropylene flat mesh may be associated with pain and discomfort as it generates a profound inflammatory response, which results in negative, fibrotic scar formation, increased rigidity and stiffness of the abdominal wall, and shrinkage of the biomaterial with time. The search for the ideal prosthetic biomaterial has been a longstanding issue with debate over simple versus composite biomaterials and lightweight *versus* heavyweight meshes. The characteristics of the ideal prosthesis are well defined: large overlap of mesh, strong, flexible, low specific weight, biologically inert and able to be incorporated into the tissues with large pore size.

In our practice, the Proflor™ prosthesis has several characteristics of these "ideal" implants: it is made from inert non-absorbable polypropylene, is self-fixating, has a three-dimensional structure which allows a dynamic behaviour, lightweight, large pore structure; and most importantly, moving with the muscular structures through its dynamic design. This results in a different biological response to flat meshes: rapid incorporation, less inflammatory response, regeneration of tissue instead of the growth of a fibrotic scar.[22]

Several studies have shown that, at the onset of the hernia pathology, there is a degeneration of the tissues of the inguinal region, leading to weakness of the groin.[1-3]

Most of the techniques described today do not take into account the pathophysiology of inguinal region and, because they use static systems do not comply with the dynamics of the abdominal wall in the inguinal region. The implants used to repair the hernia defect have what is considered a "static behaviour" and are often fixed in various ways to the muscles, and often on top of sensory nerves. This goes against the mobility of the muscles of the groin potentially causing an intense inflammatory response that may contribute to the genesis of chronic pain after surgery. The device we used in this prospective study adapts to the movements of the inguinal region, which is quite unique. Our dynamic ultrasound studies on these patients demonstrate a complete integration of the implant into the groin tissues with apparently healthy tissue in the area where the hernia was. This appears to be in line with previous animal studies.[23]

In our sample, the incidence of chronic pain was shown

to be 0%. The difference between results in terms of chronic pain compared to data in the literature might be due precisely to the use of this new prosthesis described above. The absence of fixation, combined with a better quality of dynamic scar seems to reduce chronic pain significantly.[24] Previous pre-clinical work with the device demonstrates that being dynamic combined with the absence of additional fixation sutures, results in a reduced inflammatory response and non-fibrotic scar.[22] For this reason, all of our patients underwent clinical and instrumental (ultrasound and Doppler ultrasound) investigation within 7 days, 3-6-12-18 months and 2 years after surgery. The use of ultrasound served for the assessment of the correct positioning of the prosthesis post operatively, and over time looked for any dimensional variations implicating shrinkage (Figures 2 and 3). We found it crucial to confirm that there was no shrinkage as has been reported in most meshes. Shrinking fibrotic scars are thought to be partly responsible for the genesis of chronic post-operative pain so we feel the reduction of such scars contributed to lower pain scores in our study.

CONCLUSION

The problem of chronic pain after inguinal hernia repair can be significantly disabling[1] and is poorly accepted by the patient as a result of hernia being a benign disease. This complication may be attributed to the direct involvement of nerves trapped in sutures (neuropathic pain), or mainly a consequence of inflammatory fibrotic response to the placement of a foreign body on top of sensory nerves, or contracting upon delicate inguinal tissues. Despite the small number of patients in this study the results of the study are very encouraging. We saw, as hypothesized, a very low chronic pain score. We think in part as a result of no point fixation, and in part as result of a better integration of the prosthesis. Based on these results we are participating in a major international study that will look at 150 patient's long term with a specific goal at looking how this seeming absence of chronic pain translates into quality of life scores.

COMPETING INTERESTS

The authors declare that they have no competing interests or financial support

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DV: Manuscript preparation, interpretation of data and critical review.
PR: Acquisition data and drafting the manuscript.
GL: Acquisition data and drafting the manuscript.
FDS: Acquisition data and literature review.
GS: Acquisition and processing data.
ADM: Acquisition and processing data.
SE: Literature review and manuscript preparation.
OCB: Literature review and manuscript preparation.
All authors read and approved the final manuscript.

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