UNIVERSIDADE DA BEIRA INTERIOR

Ciências da Saúde

Development of a new technique for Inguinal Hernia Repair and evaluation of the results of its use

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Medicine
(3rd cycle of studies)

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To my daughter

To my wife

To my parents

Acknowledgments

First of all, to my esteemed advisor Prof. Luís Silveira, a person I hold in high regard for his intellectual and scientific abilities associated with his simplicity. I extend my thanks for his availability and commitment to monitoring me on this project, with the ease and difficulties inherent to my age and professional experience. To Prof. Joaquim Viana to whom I am connected to by bonds of friendship rooted in respect for his honesty and scientific quality and who played a fundamental role in encouraging me to begin this doctorate.

I must thank Prof. Martinez de Oliveira for his friendly support and for the organization of the multi-thematic meetings that greatly enriched the training of its participants.

Two institutions have made a mark on my professional life, Sousa Martins Hospital – Local Healthcare Unit Guarda, EPE and the Faculty of Healthcare Sciences at the Beira Interior University. I began my activity as an intern in the first, having since become Senior Graduate Assistant and Chief of General Surgery Department. In the second I have developed a teaching activity since its beginnings.

To all my colleagues and friends who have helped me over the years with their availability, teachings and criticism, I could not fail to mention the names of Dr. António Lourenço and Dr. Joaquim Barbosa who left a lasting impression on my first years of activity.

To my dear friend, Dr Rui Soares da Costa, my partner and companion on great part of this adventure in the development of a technique and a product.

I cannot fail to mention my father-in-law, Prof. António Martinho, who left a profound mark in my life with his teachings and incentive, always guided by ethics and scientific rigor, which characterized him.

Last but not least, I thank my wife and daughter for their unconditional support and to whom I penalized with many absences for professional reasons.

To all, my sincere thanks.

Thank you.

Resumo

O presente trabalho, tem como objetivo descrever e comprovar a eficácia duma nova técnica cirúrgica para a cura da hérnia inguinal, inicialmente designada "OPEN-TEP" e posteriormente apelidada de Open New Simplified Totally Extra-Peritoneal ("ONSTEP"). Esta técnica baseia-se em princípios que são: reparação posterior, sem tensão, e com mínima disseção.

O tratamento da hérnia inguinal é o procedimento mais comum da cirurgia geral, calculando-se entre 20 a 25 milhões operações realizadas anualmente, em todo o mundo.

O tratamento cirúrgico moderno começou com Bassini, sendo de referir que as soluções cirúrgicas chamadas genericamente herniorrafias evoluíram com o contributo de MacVay, Shouldice e outros. Desde sempre os seus críticos apontaram o elevado número de recidivas e dor, associando-os com a utilização de tecidos "doentes" na reparação, o aumento de tensão, e/ou a sutura entre planos anatómicos diferentes.

O aparecimento e a generalização dos materiais de prótese abriram um novo capítulo no tratamento da hérnia inguinal.

Lichenstein e a sua técnica são um grande marco na história da cura da hérnia, tendo-se registado uma grande redução da taxa de recidiva, mas mantendo taxas de dor crónica consideradas elevadas. Esta técnica continua a ser o *gold-standard*.

Após Lichenstein, a principal questão colocada acerca de uma técnica cirúrgica de tratamento da hérnia deixou de ser a recidiva para passar a ser a dor crónica consequente.

A cirurgia vídeo assistida tornou possível explorar abordagens posteriores, referindo-se a Totally Extra Peritoneal "TEP" e a Transabdominal Preperitoneal "TAAP" que permitem a colocação de uma prótese em localização pré-peritoneal.

Estas técnicas necessariamente vídeo assistidas apresentam bons resultados quando executadas por cirurgiões experientes. Habitualmente considera-se que são necessários mais de 50 procedimentos como aprendizagem para se atingir autonomia. Outros pontos fracos apontados estão associados com os custos relacionados com a utilização de equipamento específico e relacionado com o tempo médio de execução.

Técnicas como a Transinguinal Preperitoneal "TIPP" e a "ONSTEP", têm como objetivo realizar uma reparação posterior, pré-peritoneal, por via anterior não necessitando de equipamentos específicos para ser realizadas.

Esta dissertação incorpora a descrição desta técnica que foi desenvolvida, originalmente, pelo seu autor, bem como a comprovação da sua eficácia exposta em dois trabalhos já publicados.

O primeiro, trata-se de um estudo maioritariamente prospetivo, em que são avaliados dados referentes ao ato operatório, ao pós operatório imediato, e as revisões ao mês e ao ano. Foram avaliados 693 procedimentos consecutivos operados pelos autores. Os critérios de exclusão foram idade inferior a 18 anos e procedimentos de urgência. Os principais achados desse trabalho foram a ausência de dor crónica, o baixo nível de complicações (precoces e tardias) e o baixo tempo de execução.

As maiores celeridade e simplicidade na execução do tratamento da hérnia inguinal com a técnica "ONSTEP", permite prever redução de custos, até pela sua boa adaptação ao ambulatório.

No segundo trabalho, realizou-se um estudo retrospetivo em que foram avaliados os resultados à distância de três a cinco anos de seguimento. Os principais achados desse trabalho foram a ausência de dor crónica, mantendo-se a recidiva num baixo valor.

Paralelamente a estes estudos, com a experiência acumulada, foi desenvolvida uma nova prótese, que pensamos mais adaptada a esta técnica, que deu origem a um pedido de registo de patente e posterior venda da mesma a uma companhia, líder mundial em próteses para correção de hérnias, CRBard-Davol®. O novo produto já se encontra em comercialização, estando o seu lançamento a progredir conforme política da companhia.

Esta nova prótese incorpora melhorias tais como a substituição do anel de memória, anteriormente rígido e não reabsorvível, por um outro de reabsorção lenta e semirrígido, utilização de polipropileno de baixa densidade e alta porosidade, incremento das dimensões, existência de uma bolsa para facilitar o seu posicionamento e uma área que pode ser ajustada ao doente de acordo com a preferência do cirurgião.

Palavras chave: hérnia inguinal, ONSTEP, ONFLEX, POLYSOFT

Abstract

The aim of this project is to describe a new surgical technique to treat inguinal hernias. This was first known as OPEN-TEP and was subsequently named ONSTEP. This technique is based upon several principles such as: posterior repair, tension free and minimal dissection.

This project includes the description of the technique, originally developed by the author, as well as two studies, which have already been published that evaluate the immediate and the long-term results.

The first study is mainly a prospective one, in which various surgical approach-related data are analysed, at three time points: immediately after surgery and one month and one year after the procedure.

The second study is a retrospective one in which post-surgical results are analysed after three and five years of follow-up.

During the implementation of these studies and with the experience gathered, a new mesh which is better adapted to the ONSTEP technique was developed and this was the basis for the registration of a new patent and subsequent sale to the world leader company in meshes for treatment of hernias – CRBard-Davol®. This product is already on the international market and its launch is evolving in accordance with the company's policy.

Key-words: inguinal hernia, ONSTEP, ONFLEX, POLYSOFT

Index

1.Introduction

1.1. Inguinal hernias: types and consequences

All abdominal hernias are due to two main factors: a weakness of the abdominal wall and/or an increased abdominal pressure.

Inguinal hernias can be classified as indirect, direct and femoral, according to the place of herniation relatively to the surrounding structures. Indirect hernias protrude through the deep inguinal ring, laterally to the inferior epigastric vessels. Direct hernias protrude medially to the inferior epigastric vessels, in the Hesselbach's triangle. Femoral hernias protrude through the femoral ring.

Inguinal hernias are five times more common than femoral hernias. The prevalence of inguinal hernias increased whit age. The lifetime risk of inguinal hernia is 27 % in men and 3 % in women. In males, the incidence of inguinal hernias has a bimodal distribution, with a first peak in the first year of life and a second one after 40 years age. In spite of these incidence aspects, the social dimension and the economic burden of inguinal hernias are often underestimated.

Inguinal hernias can be classified into congenital and acquired. Congenital hernias can be regarded as a development abnormality. In a normal development, in the third trimester, testes should descend from the intra-abdominal space indo the scrotum. If the peritoneum fails to close it will result in a patent *processus vaginalis*, which will predispose to an indirect inguinal hernia. The risk will depend on the presence of other risk factors. (1)

The presumed causes of groin herniation comprise coughing, chronic obstructive pulmonary disease, obesity (although is more difficult to diagnose inguinal hernias in obese patients), straining (constipation and prostatism), pregnancy, low birthweight (<1500g), family history of hernia, Valsalva's maneuver, ascites, upright position, congenital connective tissue disorders, previous incision in the lower right quadrant, cigarette smoking, physical exertion, among others.

These causes are also risk factors for inguinal hernias, and it is really important to try to manage them in order to decrease the incidence of this surgical situation. In fact, effective solutions are needed at an appropriate cost to help solving this problem, which is an issue of public health.

In contrast with femoral hernias, which are more common in women due to anatomic reasons, a wider and lower pelvis, inguinal hernia repairs are more frequently carried out in men: 90 % have been reported in men and only 10 % in women. (2) In fact, inguinal hernia procedure is

the most commonly surgical operation performed all over the world, in general surgery. It is estimated that this procedure reaches 20 to 25 million per year.

Until now it has never been a technique that has clearly been considered superior to the others.

Despite all the classifications there are two main groups and approaches to the treatment of inguinal hernias: for those who advocate techniques of defect repair, the classification is fundamental, being not so important for those who use repair techniques of all the inguinal region.

All general surgeons should be able to treat inguinal hernias using quality and cost-controlled techniques.

1.2. Classical surgical treatments of inguinal hernias

The modern history of the treatment of inguinal hernia begins with Bassini (1844-1924), an Italian surgeon who never published his studies but whose work was luckily made known to the world by one of his pupils.

Bassini advocated a surgical technique based on dissection and treatment of the hernia sac and the suture of the "conjoint tendon" to the iliopubic ligament reinforcing the *transversalis fascia* and calibrating the external inguinal orifice. Following of this evolution, many others names emerged, among which those of McVay and Shouldice cannot fail to be mentioned. (3)

Numerous techniques were developed, which are generically known as herniorrhaphies, since in all of them, besides the treatment of the hernia sac, a suture is performed between anatomical structures.

Criticism of herniorrhaphies arose based on the fact that anatomical structures are used, which are often weakened and subjected to tight sutures, increasing the risk of ischemia, and, sometimes different anatomical planes conditioning a high level of recurrences and post-operative or chronic pain.

Treatment of inguinal hernia in adults has undergone a real revolution, with the appearance of mesh material in the market, which allows the design of new technical solutions thus reducing tension on tissues and better repair of hernia defects.

Lichtenstein is a name that will remain in history as the first technique to use mesh material. It is a solution that causes no tension and has established itself as the gold standard to this day. (4)

In the search for the ideal solution for a cure for inguinal hernia, several techniques were developed. Some involve an endoscopic approach such as the Totally Extraperitoneal (TEP) and Transabdominal Preperitoneal (TAPP) techniques, which make a posterior repair with the use of fixation of the mesh. Others make use of the anterior approach with posterior repair, such as the Transinguinal Preperitoneal (TIPP) approach, criticised for the need of posterior dissection without direct visualisation, associated whit the risk of bleeding from epigastric vessel damage.

In order to validate a technical surgery some conditions are necessary such as ensuring its non-inferiority in relation to others, its added value and its reproducibility. Furthermore, originality presupposes a change in the philosophy of the treatment of hernias, a break with something that was, until then, regarded as fundamental.

1.3. Towards novel surgical treatments of inguinal hernias

In the Open New Simplified Totally Extraperitoneal (ONSTEP) technique, a disruption of the "transversalis fascia" is regarded as the best option to obtain easy and safe access to the pre-peritoneal space, thereby allowing to feel and visualize the structures, as well as the placement of the mesh, which will repair all real and potential defects in the inguinal region.

Bassini and McVay techniques were replaced with new techniques since both promoted great tension and were associated with a significant rate of recurrence, while using diseased tissues for the repair of hernial defects.

It was with interest that I used Shouldice's technique, it is particularly interesting due to its anatomical handling and by support the principle that hernia repair was associated with the repair of the *transversalis fascia*. This is a very interesting approach, but which only allowed the repair of direct and indirect inguinal hernias and not femoral hernias. However, an increase in tension persists with poor reproducibility of results from the Shouldice Clinic practice.

The advent of repairs with mesh material, by allowing the avoidance of tension between structures, was a new hope, which evolved with the improvement of surgical techniques and with the development of new meshes.

In terms of surgical technique, the great step forward was Lichtenstein's technique, which, as aforementioned, is still today considered the gold standard. It is worth noting, in favour of this technique, its reproducibility and consistent results in relation to hernia recurrence as well as the possibility of being performed with various types of anaesthetic techniques - local, loco-

regional and general. However, a factor against this technique is the appearance of chronic pain, which is very frequently reported in the literature.

Variants, said to be evolutions of the Lichtenstein technique such as the Rutkow Robbins technique have proven not to be compliant with its objectives. One good idea was to add a cone to the previous repair, a plug, which would be a posterior repair as this would be deployed in a dynamic way. However, it proved to be inaccurate since the previously mentioned plug was never deployed, and the procedure has never been a posterior repair, since the plug always converted itself into a cylinder of surplus mesh material.

Faced with a challenge that was launched with the conviction of the superiority of posterior repair, a new concept emerged, the repair of the wall – the myopectineal orifice - and not of the hernia defect.

Two great paths emerged: the endoscopic approach and the anterior approach.

The laparoscopic approach began with the placement of a plug in the hernia orifice, which was greatly disputed and quickly abandoned. The techniques known as TEP and TAPP asserted themselves on the basis of the change in their philosophy and the improvement of results. However, their performance has limitations, namely the low number of surgeons with training in video-assisted surgery, the extended learning curve, the need for general anaesthesia, the need for equipment, the association with elevated costs and poor reproducibility.

The anterior approach followed, in most cases, an approach through the hernial defect as a way of reaching the pre-peritoneal space, which was performed with its blind dissection, without direct visualisation of the structures. The absence of visualisation during the surgical act led many surgeons to fear lesion of the epigastric vessels, a report complication.

One of the authors who best conceptualized this approach was Edouard Pélessier who created and designed a polypropylene mesh with non-absorbable memory ring called PolySoft®. It was with this mesh that I began a new technique in 2005, initially called OPEN-TEP.

With the beginning of collaboration, that still remains, with Dr. Rui Soares da Costa, the idea of creating a mesh that was better adapted to the technique arose, and which we called ONSTEP came to reality. The beginning of a partnership and collaboration with Dr. Rui Soares da Costa allowed the gain of “critical mass” and a logistic reinforcement to embark upon a new phase of the project.

Along with the development and diffusion of the technique, the idea of choosing a new mesh which would be better adapted and would allow us to overcome some of the limitations of PolySoft® (namely residual pain or the sensation of being able to feel the mesh, in slender patients) emerged. The main changes planned for the new mesh were: the alteration of the memory ring which was now reabsorbable and softer, the use of polypropylene of low density

and high porosity, the increase in dimensions, the creation of an area that could be cut and adapted to the patient according to the surgeon's preference and the existence of a pocket which facilitates the positioning of the mesh.

During the development of this new mesh, OnFlex®, we relied upon the collaboration of companies specialised in industrial design and conducted experimentation on corpses at the Surgical School of Paris.

The world launch of OnFlex® took place in May 2015 at the First World Conference on Hernias held in Milan.

2. Objectives

The general objectives of the work that led to this dissertation were to develop and evaluate a new technique for inguinal hernia repair and to create a new mesh adapted to the technique.

The individual objectives were:

1) To evaluate the application of the ONSTEP technique in a large number of cases, by evaluating the duration of surgery, the length of time until discharge and time taken to return to work or normal daily activities as well as immediate or late post-operative complications.

2) To evaluate the long term results of the technique (between 3 and 5 years), by quantifying the incidence of recurrence, chronic pain and the level of patient satisfaction.

3) To develop a new mesh that might overcome some of the limitations of PolySoft®.

3. Methods

3.1. Ethical Aspects

The study protocols were approved by the Ethics Committee of the Guarda Local Health Unit. All patients were informed about the use of the new technique and all provided written consent. The model used was submitted and approved by the aforementioned committee.

3.2. Population and Sample

The casuistry described in the research of this dissertation included patients operated at Guarda Local Healthcare Unit by the author or by Dr. Rui Soares da Costa, Director of Ambulatory Surgery at S. João Hospital Centre, Porto. Study I was carried out between 2005 and 2011 and study II was carried out between 2009 and 2011. All consecutive patients over 18 years of age were included, without refusals being expressed by any patient. Patients operated in an emergency context were excluded.

3.3.Study Outcomes

In the first study, apart from the description of the ONSTEP technique for inguinal hernia repair, essential for its diffusion, the surgical procedure was characterised in relation to its duration, duration of hospitalization, post-operative complications (both immediate and late), return to work / daily activities, recurrences and pain. Surgery duration was evaluated in minutes and duration of hospitalisation in hours.

The term “residual pain” was used to describe pain or discomfort felt by some more slender patients due to the sensation of foreign body, provoked by the rigidity of the memory ring.

Data relating to the surgical procedures and immediate postoperative were obtained from records of clinical files. These records were complemented by results of the follow-up made by consultation at the end of one month and by consultation or telephone contact at the end of first year.

All patients who reported any type of complaint after one year, related or not to the surgical procedure, were reviewed in a face to face consultation.

The second study sought to re-evaluate patients submitted to surgical treatment for inguinal hernia with the ONSTEP technique over a time period of three to five years.

The existence of recurrence, the existence or not of residual pain, as well as the degree of patient satisfaction were recorded, the latter by ascribing scores ranging between 1 and 5, with 1 being “not satisfied” and 5 being “totally satisfied”.

Data collection was carried out by telephone interview. All patients who presented any type of complaint were summoned for a face to face consultation.

The development of the mesh include its design and incorporation of new profile with high porosity and low density, as well as slow reabsorbable material.

Following the elaboration of various prototypes, one was selected and tested in corpses.

3.4. Statistical Analysis

The two studies presented (with n1=693 and n2=314) can be regarded as an Intervention Study - Phase II clinical trial (5), though for practical reasons, there was no control group. Instead our results with the ONSTEP prosthesis were compared with published results obtained by others with the current techniques.

Ideally, patients for the intervention group must be recruited randomly in order to prevent bias. In the two studies here presented all consecutive patients (satisfying the above-mentioned inclusion/exclusion criteria) were included. While randomization means that each member of a population has an equal chance of being chosen, in both studies all consecutive patients have been included, and not chosen, meaning that all participants had in fact the same chance, namely, a chance equal to 1.

In accordance with the CONSORT Statement for reporting trials (6), effect sizes and confidence intervals are provided in the results section (v.g., duration of surgery and duration of hospitalization, pain and degree of patient satisfaction, post-operative complications and recurrences, reported in absolute and relative values, together with the relevant 95 % confidence intervals).

4. Results

4.1. Description of the ONSTEP Technique

Technical aspects of the ONSTEP technique for Inguinal Hernia Techniquer using the PolySoft® Hernia Mesh with interrupted memory ring will now be described.

The most relevant elements of the ONSTEP technique for inguinal hernia repair are the following ones:

- The ONSTEP Inguinal Hernia Repair Technique offers the advantages of an anterior approach:
    - The anterior anatomy is familiar to many surgeons and therefore assists in a shorter learning curve.
    - The technique allows good visualisation of the inguinal canal and pre-peritoneal space.
    - Loco-regional, general and local anaesthesia with sedation are possible.
- The ONSTEP Inguinal Hernia Repair technique may offer advantages over other open anterior approaches, by providing:
    - A simple and concise 12 step technique.
    - An incision located in an area that avoids major nerve structures to minimise risk of chronic pain.
    - A technique designed to have a short operating time (17 +/- 6 min).

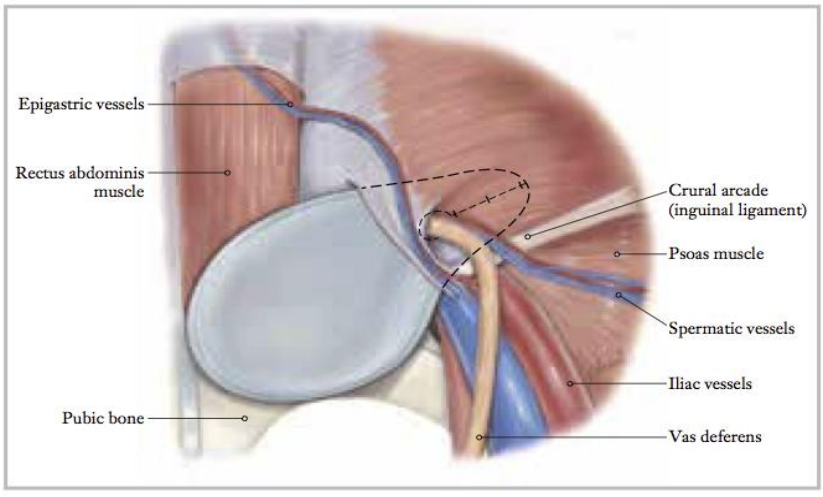

Figure 1 - Posterior view of the technique

- The ONSTEP Inguinal Hernia Repair technique is a minimally invasive, tension free repair that can be completed through a small 3-4 cm incision and requires no fixation due to type and extent of dissection in combination with the implant. It is a part pre-peritoneal, part intramuscular repair performed through an open anterior approach.
- The PolySoft® Hernia Patch has an oval anatomical shape that fits with the anatomical structures. The size of the implant must be selected to allow sufficient overlap of the hernia defect.
- Tissue ingrowth into the polypropylene mesh and pre-peritoneal placement allows a strong repair. Once the patch is placed, the interrupted “memory recoil ring” helps ensure the patch will spring open and maintain its shape.
- The PolySoft® Hernia Patch is made of soft polypropylene mesh, surrounded by an interrupted non-absorbable memory ring made of a PET polymer designed for tailoring the implant to the patient’s anatomical needs.

Summary of the 12 steps:

1. Selection of the incision site;
2. Identification and cauterisation of the superficial epigastric vein;
3. Dissection to the level of the internal oblique aponeurosis;
4. Development of the plane between the Internal and external oblique aponeurosis;
5. Identification and isolation of the spermatic cord;
6. Entry to the space of Retzius;
7. Insertion of large gauze;
8. Reduction of hernia sac;
9. Preparation of the POLYSOFT® Hernia Patch;
10. Removal of gauze;
11. Placement of the POLYSOFT® Hernia Patch;
12. Closure of Incision site.

1. **Selection of the incision site:**

- Draw two straight lines, superior and lateral from the midpoint of the pubic symphysis;
- Place the index and middle fingers against each line;
- Mark an incision line from the intersection point of the index fingers, resulting in a 4cm horizontal and lateral line.

Note: The location of the incision line can also be identified by measuring 4 cm cranially and then 4cm laterally from the midpoint of the pubic symphysis.

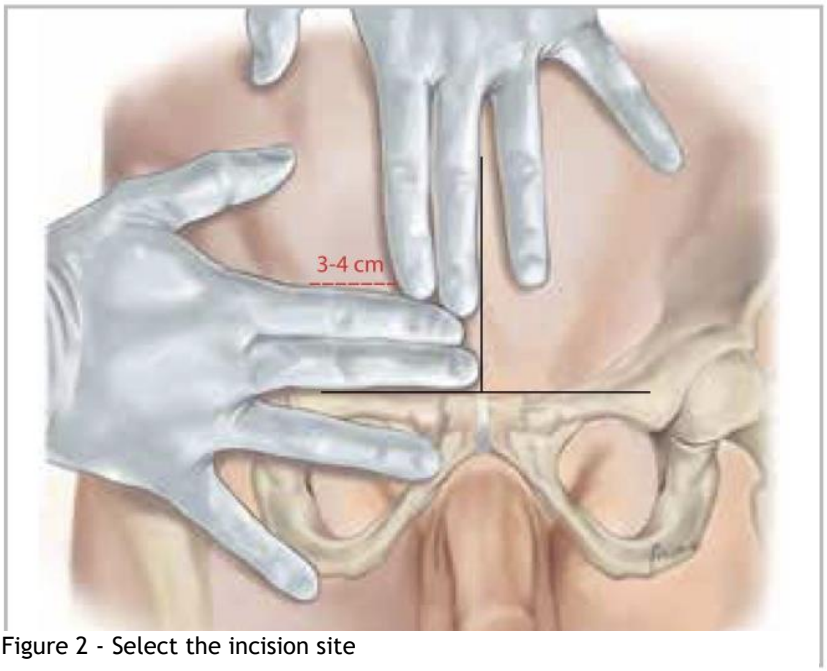

Figure 2 - Select the incision site

2. Identification and Cauterization of the Superficial Epigastric Vein:

- Incise the marked skin down to the level of the subcutaneous tissue;
- Identify and cauterize the Superficial Epigastric Vein.

Note: The superficial epigastric vein, if present, should be in the medial portion of the 3-4 cm incision line. A deviation from this point suggests the incision line may be too medial.

The superficial epigastric vein is present in the majority of patients, but may be absent in around 18 % of patients.

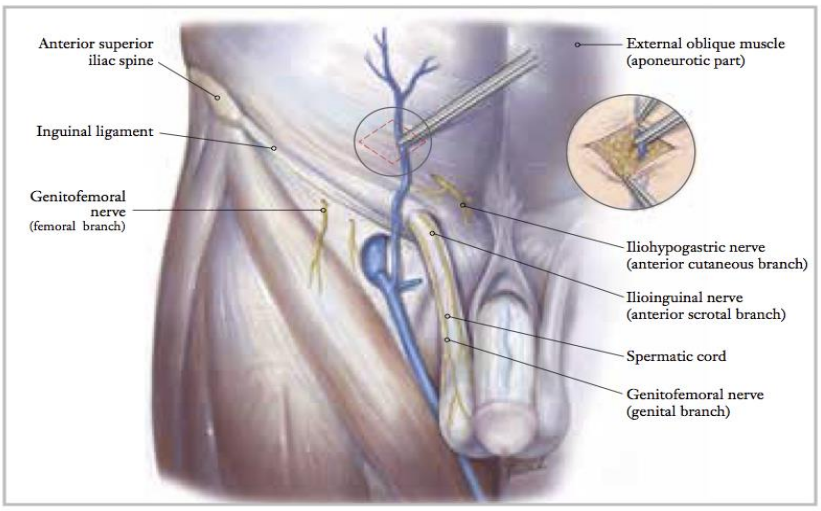

Figure 3 - Identification and cauterization of the superficial epigastric vein

3. **Dissection to the level of the Internal Oblique Aponeurosis:**

- Continue sharp dissection of Scarpa's fascia and subcutaneous fat, to reach the external oblique aponeurosis;
- Carefully begin dissection of the external oblique aponeurosis (laterally to the rectus sheath) with diathermy, exposing the underlying internal oblique aponeurosis. Take care not to dissect the anterior surface of the internal oblique aponeurosis;
- Complete dissection of the external oblique aponeurosis with diathermy.

Note: It is important to confirm that the correct tissue plane is properly identified which is evidenced by the visualisation of the avascular and white fibrous anterior surface of the internal oblique aponeurosis.

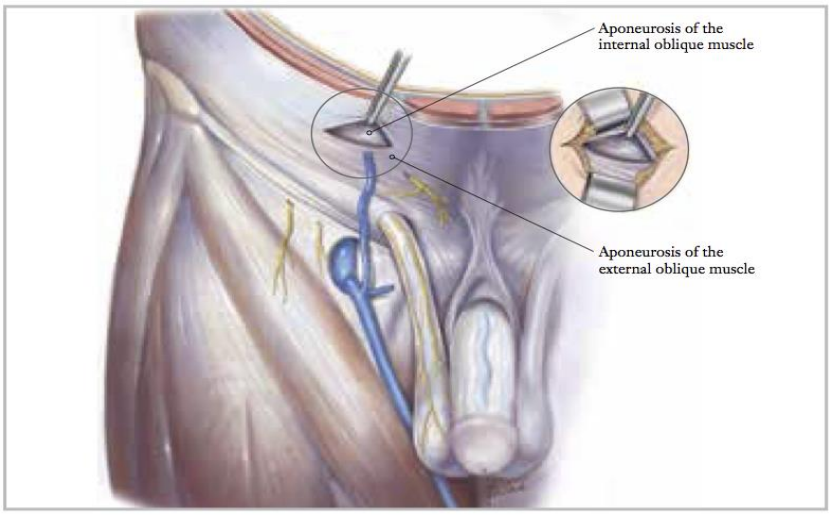

Figure 4 - Dissection to the level of the internal oblique aponeurosis

4. **Development of the plane between the Internal and External Oblique Muscles:**

- Digitally dissect the space between the external and internal oblique aponeurosis, sweeping laterally and cranially up the superior iliac spine, to create a dissected tissue plane that will subsequently accommodate the placement of the lateral tails of the POLYSOFT® Hernia Patch;

- Continue the sweeping motion medially down the inguinal ligament to the pubic bone, to complete this dissection, and gain access to the posterior wall of the inguinal canal.

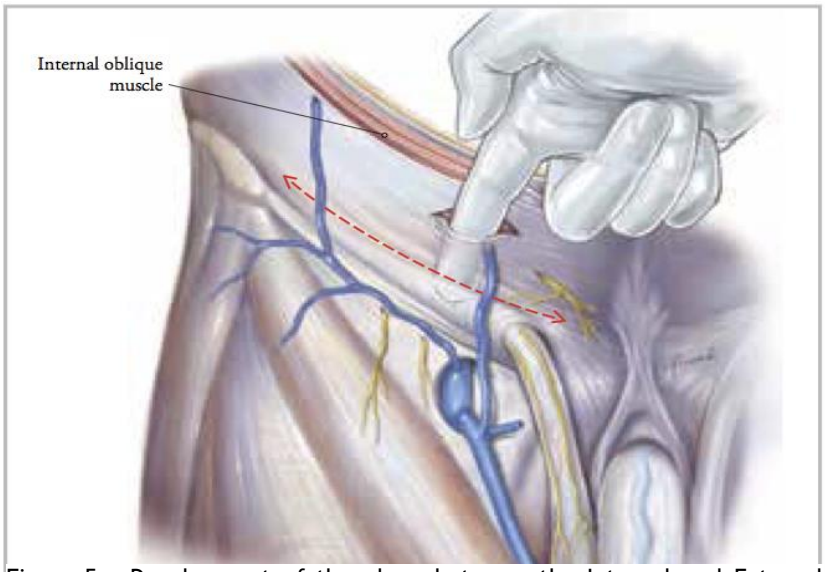

Figure 5 - Development of the plane between the Internal and External Oblique Aponeurosis

5. Identification and Isolation of the Spermatic cord:

- Identify and mobilise the spermatic cord structures by sweeping medial to lateral with an upward facing probing finger;
- Once the cord has been mobilised from the posterior wall of the external oblique aponeurosis, elevate the cord up and out of the incision site and isolate with a surgical loop.

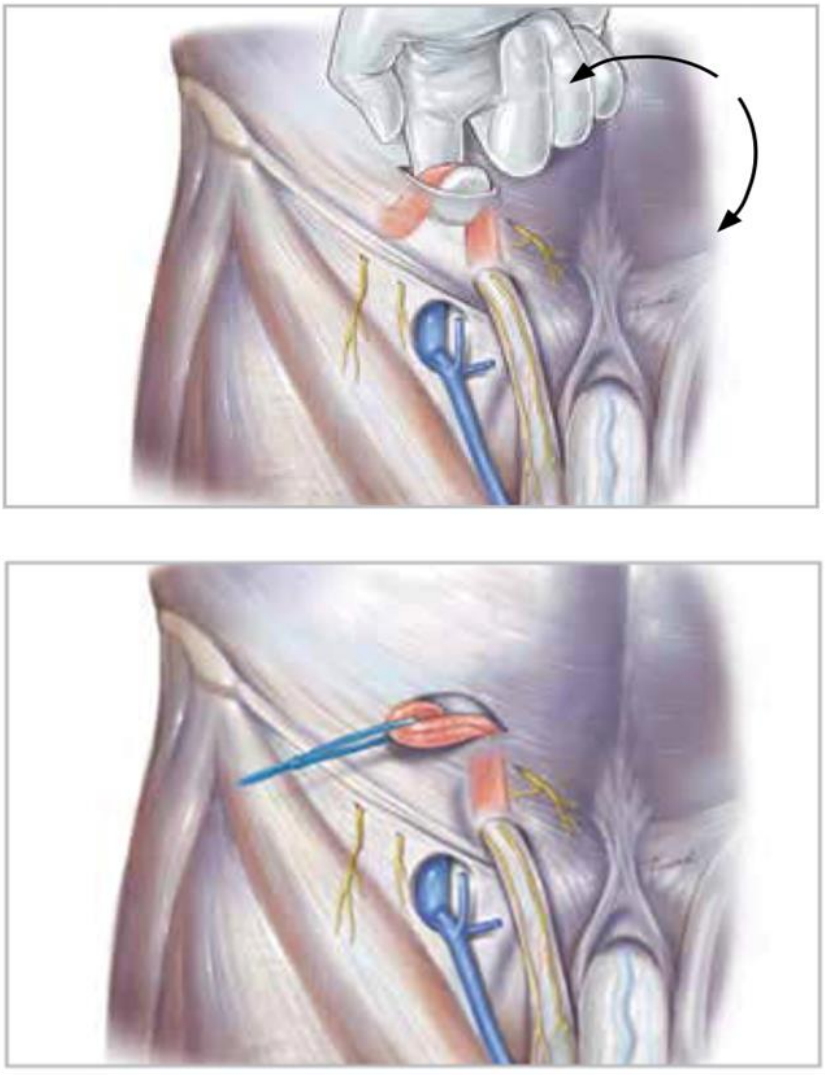

Figure 6 - Identification and Isolation of the Spermatic cord

6. Entry to Space of Retzius:

- Digitally explore the transversalis fascia down to the pubic bone and obliquely enter the space of Retzius, through spreading the fibers of the transversalis fascia.

Note: This can be done by either digitally dissecting through the fascia, or with the use of an appropriate surgical instrument to gently spread the fibres before digitally penetrating through the transversalis fascia.

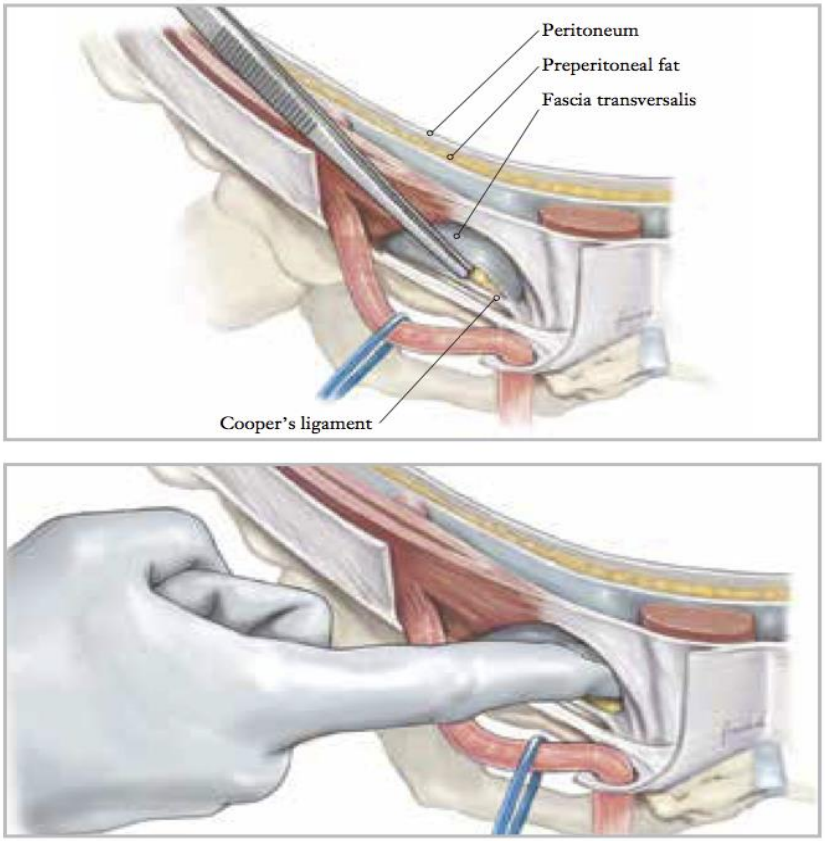

Figure 7 - Entry to Space of Retzius

7. Insertion of large gauze:

- Using blunt forceps, guide a large (20x20 cm) moist sterile gauze, down the index finger, into the retropubic space (space of Retzius), maintaining the position of the index finger protecting the epigastric veins behind the pubic bone;
- The index finger will act as a support for the posterior wall of the inguinal canal, preventing the transversalis fascia from entering the space of Retzius, when the gauze is pushed into this space.

Note: No digital dissection of the preperitoneal space or the space of Retzius is performed during the ONSTEP technique. All blunt dissection is completed by the gauze, when place in the space of Retzius.

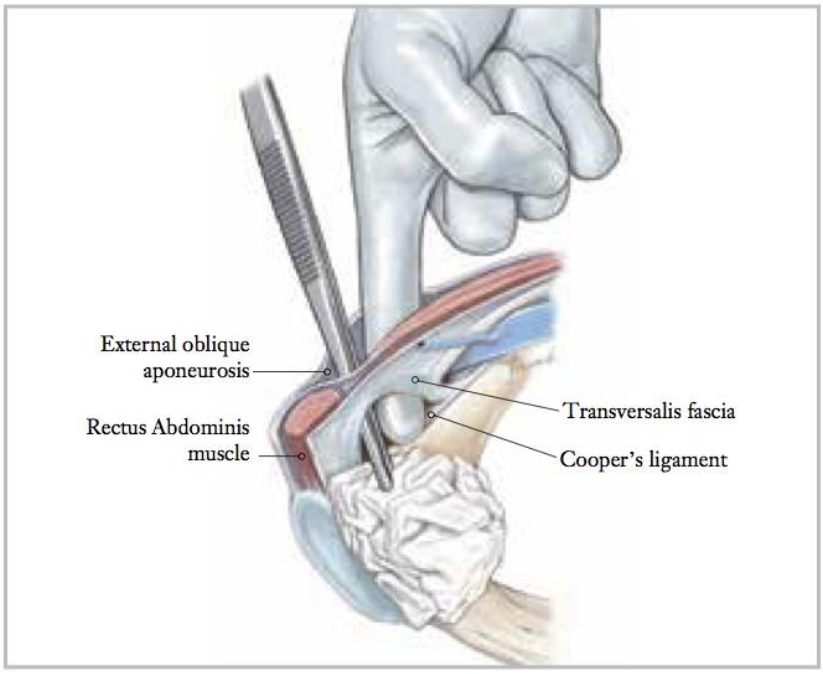

Figure 8 - Insertion of large gauze

8. Reduction of hernia sac:

- If an indirect hernia is identified, reduce the sac and contents and ligate/remove the excess sac as appropriate, according to general surgical practice;
- If a direct hernia is identified, it will be repaired with the placement of the POLYSOFT® Hernia Patch. In the case of a direct hernia, always ensure that there is no indirect hernia present.

Note: Hernia sacs should always be well dissected, to ensure they can be properly reduced, prior to the placement of the POLYSOFT® Hernia Patch.

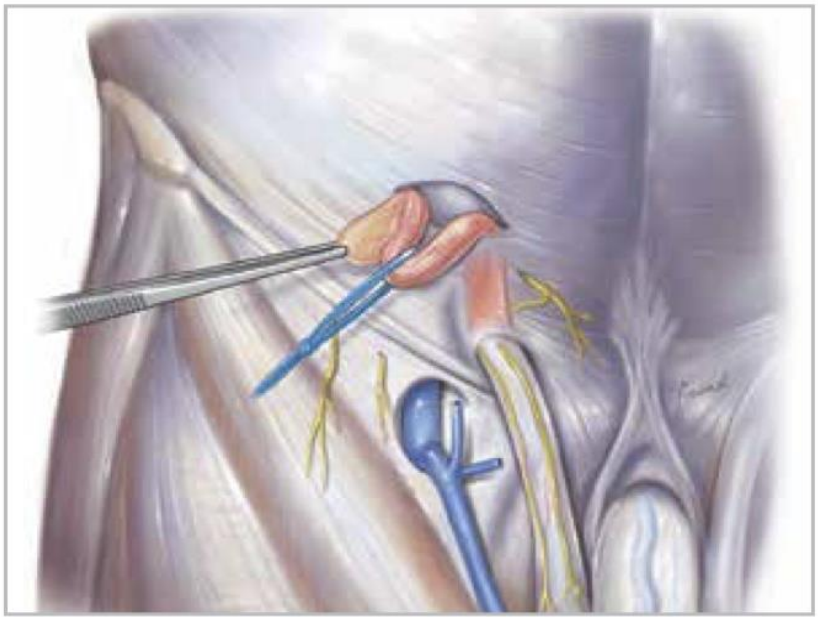

Figure 9 - Reduction of the hernia sac

9. Preparation of the POLYSOFT® Hernia Patch:

- Cut an axial slit in the prosthetic patch between the interrupted ends of the memory recoil ring, down to the apex of the curved notch of the patch. **Do not cut the recoil ring;**
- Place the inferior tail of the POLYSOFT® Hernia Patch under the spermatic cord, so that the tails are pointing lateral.

Note: The curved notch of the POLYSOFT® Hernia Patch is always placed under the spermatic cord.

Do not place the POLYSOFT® Hernia Patch directly on the skin at any time during the procedure.

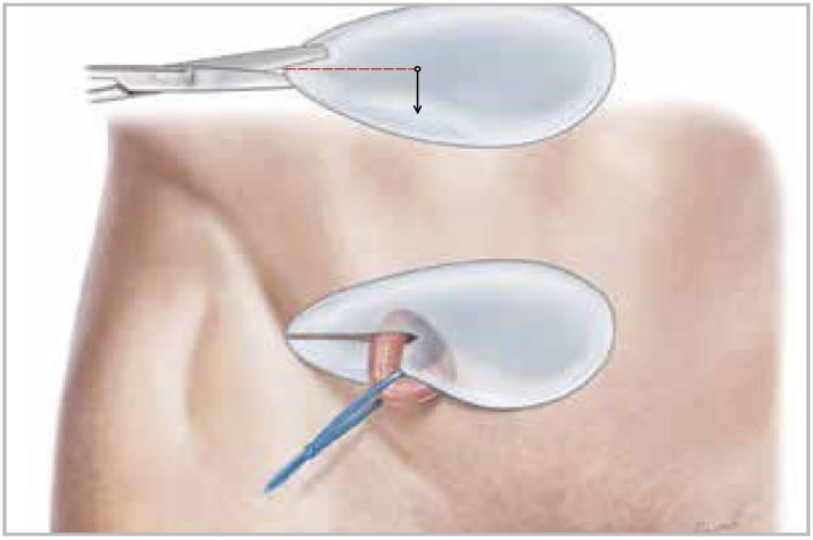

Figure 10 - Preparation of the POLYSOFT® Hernia Patch

- Place three non-absorbable interrupted sutures into the POLYSOFT® Hernia Patch to join the prosthetic tails together.
    - The first suture is placed to close the outer margin of the POLYSOFT® Hernia Patch;
    - The second suture is placed in the midpoint of the slit made in the POLYSOFT® Hernia Patch;
    - The third suture is placed adjacent to the spermatic cord. Appropriate space must be left to ensure good perforation of the cord.

Note: Take care that the three sutures are placed to ensure the opening around the spermatic cord is not too tight or too wide.

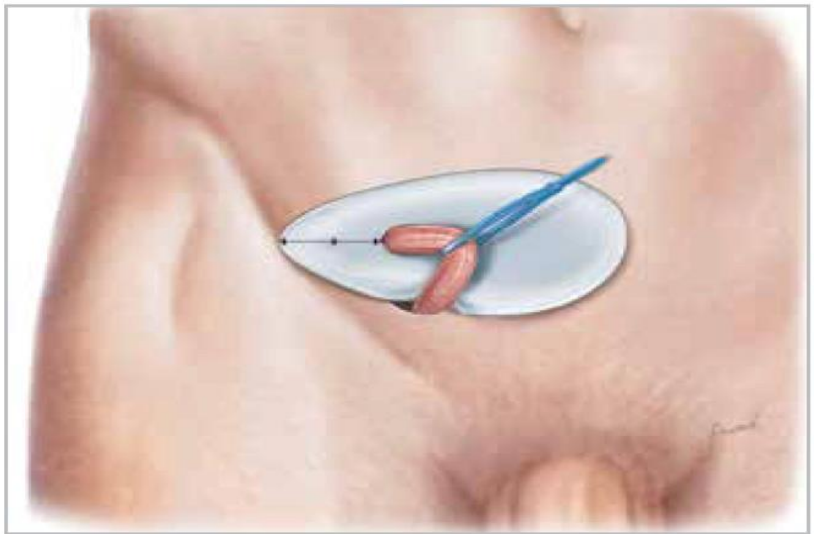

Figure 11 - Preparation of the POLYSOFT® Hernia Patch

10. Removal of Gauze:

- Remove the sterile gauze from the operative site and return to the scrub nurse.

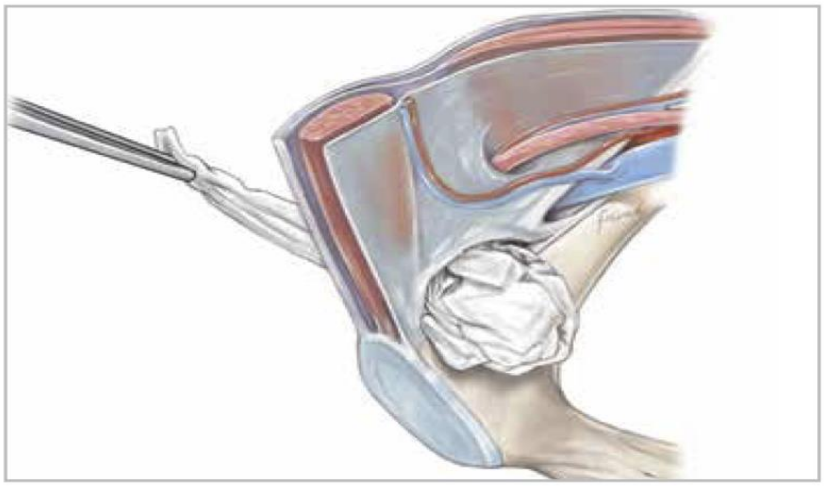

Figure 12 - Removal of the gauze

11. Placement of the POLYSOFT® Hernia Patch:

- Grasp the medial apex of the POLYSOFT® Hernia Patch with two index fingers (one finger on top of the patch and one placed underneath the patch). Insert into the incision and push the mesh down into the space of Retzius under the pubic bone, leaving the tails of the patch outside the incision;
- Digitally explore the POLYSOFT® Hernia Patch ensuring that it is fully deployed under the pubic bone, in the space of Retzius;

Note: If the POLYSOFT® Hernia Patch does not fully deploy within the space of Retzius, further blunt dissection may be required. Remove the POLYSOFT® Hernia Patch from this space and perform additional blunt dissection.

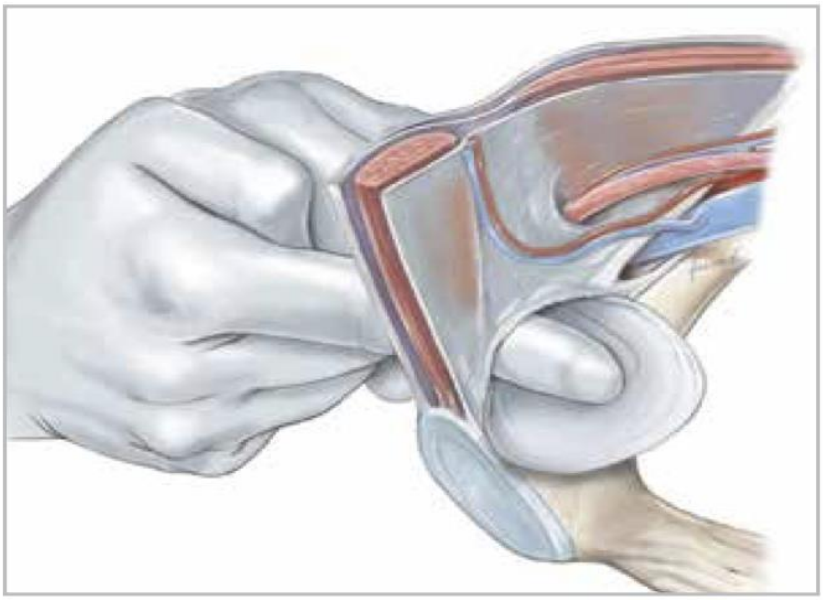

Figure 13 - Placement of the POLYSOFT Hernia Patch

- Insert the lateral tails of the POLYSOFT® Hernia Patch into the previously dissected space between the external and internal oblique aponeurosis, and digitally explore and smoothen the POLYSOFT® Hernia Patch to ensure proper placement without tension.

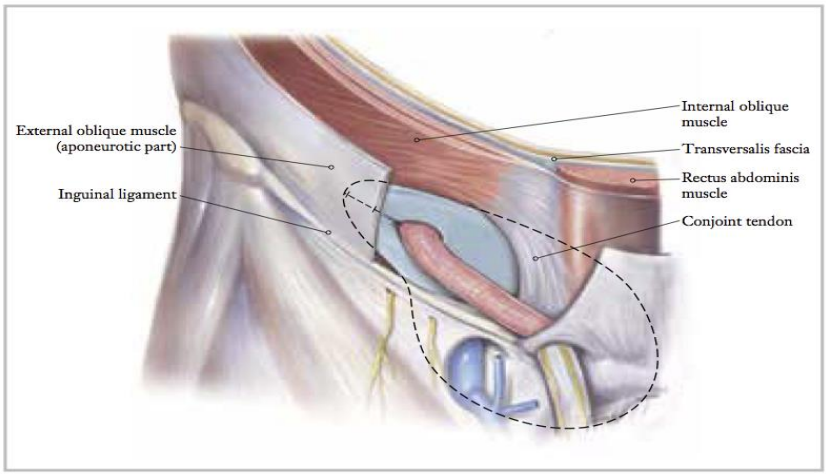

Figure 14 - Placement of the POLYSOFT® Hernia Patch

12. Closure of incision site:

- Close the external oblique aponeurosis with a suture type and a technique of choice. There is no need to close Scarpa's Fascia;
- Inject local anaesthetic of choice as appropriate;
- Close the skin with a suture or clips of your choice as appropriate.

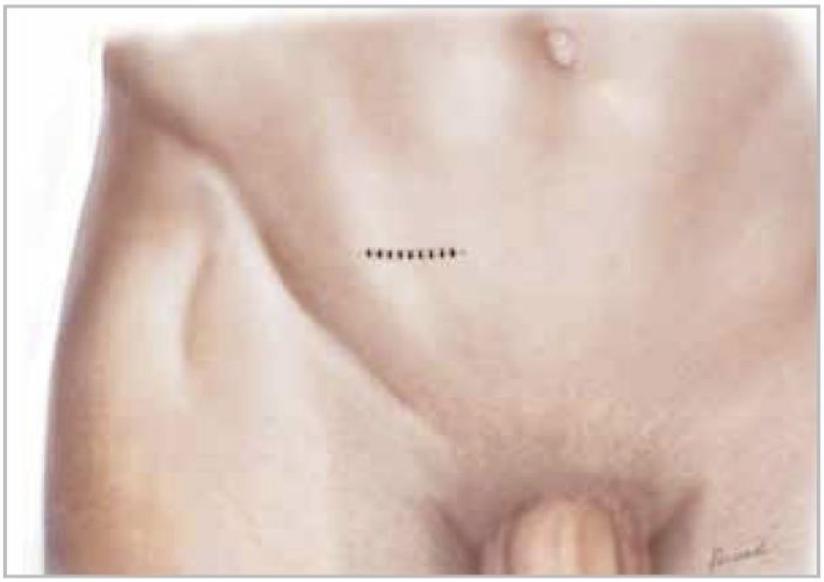

Figure 15 - Closure of incision site

4.2. Article I

"The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions"

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ORIGINAL ARTICLE

The ONSTEP inguinal hernia repair technique: initial clinical experience of 693 patients, in two institutions

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Abstract
Purpose Experience with a novel hernioplasty procedure—the ONSTEP approach—for inguinal hernia repair in a large series of patients performed by two surgeons at two institutions is described, focusing in particular on the duration of surgery, the time taken to return to normal activities, chronic pain, complication and recurrence rates.
Methods Adult patients underwent inguinal hernia repair using the ONSTEP approach. The hernia defect was repaired using a PolySoft^{TM} hernia patch. Patients were followed up for 1 year for pain, complications and recurrences.
Results A total of 693 patients underwent ONSTEP inguinal hernia repair. The mean duration of surgery (±SD) was 17 ± 6 min; the time to discharge from hospital was less than 24 h in all patients; and the mean time to return to normal daily activities was 6.1 ± 3.0 days. The overall complication rate was 1.0 % and the overall recurrence rate was 0.6 %. Residual pain was present in 4 patients at 6 months and was cured by removal of the memory ring in 3 patients and disappeared spontaneously in one case, so that there was no case of chronic pain at 1 year.
Conclusions The ONSTEP inguinal hernia repair technique described is simple, quick to perform, produces consistent results and is associated with very low overall complication, chronic pain and recurrence rates. It may offer an alternative to both Lichtenstein and laparoscopic inguinal hernia repair.

Keywords Inguinal hernia repair · Open hernia repair · ONSTEP hernia repair · Chronic pain · Recurrence · Complications

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Introduction

The two main approaches to inguinal hernia repair are open repair, which currently involves opening the abdominal wall and repairing the hernia defect by suturing or using a surgical mesh, and laparoscopic repair, which is a minimal-access technique that allows the hernia defect to be repaired without opening the abdominal wall (Table 1) [1]. Most patients with inguinal hernia undergo open repair using the Lichtenstein procedure [2]. However, this procedure causes chronic post-operative pain in a large proportion (15–40 %) of patients [3]. Another open technique, known as transinguinal preperitoneal (TIPP) repair, has recently been introduced. In this technique, a surgical mesh is placed in the preperitoneal space through the hernia orifice without the need to enter the peritoneal cavity [4]. This technique is associated with a shorter operation time and less post-operative pain than Lichtenstein repair [5], but it is more difficult to learn.

In laparoscopic surgery, small incisions are made for the laparoscope and operating instruments, and a surgical mesh is used to close the hernia defect. The main approaches to

Table 1 Current approaches to hernia repair [1, 4]

Type of repair	Example
Open repair	
Simple suturing	Bassini method
Open flat mesh	Lichtenstein method
AAA	
Open preperitoneal mesh	Stoppa and Nyhus method
Open plug and mesh repair	Rutkow method
Open transinguinal preperitoneal mesh (TIPP)	Pélissier method
Laparoscopic repair	
Hernia accessed through the peritoneal cavity	TAPP repair preperitoneal
Hernia accessed via the preperitoneal plane without entering the peritoneal cavity plane	TEP repair

TAPP transabdominal preperitoneal, *TEP* totally extraperitoneal, *TIPP* transinguinal preperitoneal

laparoscopic inguinal hernia repair are transabdominal preperitoneal (TAPP) repair, in which the hernia is accessed through the peritoneal cavity, and totally extraperitoneal (TEP) repair, in which the hernia is accessed via the preperitoneal plane without entering the peritoneal cavity [1]. These laparoscopic procedures are associated with a reduced rate of post-operative pain compared with open Lichtenstein repair [6–9]. However, they take longer to learn (typically 100 patients) and are more expensive to perform [10–14].

The TEP approach to hernia repair was first reported in 1993 [15, 16]. The procedure involves placement of a surgical mesh in the preperitoneal space, thus sealing the hernia from outside the peritoneum without the need to enter the peritoneal cavity. TEP repair is technically more difficult and thus takes longer to learn and longer to perform than Lichtenstein repair [17, 18]. However, as it preserves the integrity of the peritoneum, it is associated with minimal risk of damage to intra-abdominal organs [13] and a reduced likelihood of severe acute and chronic pain [19–21].

The ideal hernia repair technique should be reliable and quick to learn, cause minimal complications and post-operative pain, produce good cosmetic results, be associated with a quick return to normal daily activities, a minimal risk of recurrence and acceptable costs. This paper reports experience with a novel hernioplasty procedure—ONSTEP repair—for inguinal hernias, performed by two surgeons at two institutions in a large series of patients. This report focuses in particular on the duration of surgery, the absence of chronic pain, the time taken to return to normal activities, and complication and recurrence rates.

Patients and methods

Study population

Adult patients (≥18 years of age) underwent inguinal hernia repair at Hospital de Sousa Martins, ULS da Guarda or Centro Hospitalar de São João, Porto, Portugal between 1st February 2005 and 31st July 2011 using the ONSTEP approach.

PolySoft™ hernia patch

Patients underwent ONSTEP repair of the hernia defect under local (plus sedation), locoregional or general anaesthesia using a PolySoft™ hernia patch (Davol Inc., Cranston, Rhode Island, USA). This is a self-expanding, non-absorbable, sterile mesh consisting of polypropylene monofilaments knitted together to form a strong, porous support material. The patch contains an interrupted memory recoil 'ring' around its edge consisting of extruded monofilament polyethylene terephthalate (PET) polymer (Fig. 1). This patented ring adds stability to the patch and facilitates placement. The patch is available in two sizes (14 cm × 7.5 cm and 16 cm × 9.5 cm) and is shaped so that it can cover all potential hernia defects.

Surgical technique

Incision and entry into the surgical operative tissue plane

The hernia repair was performed by two different surgeons (one at each centre). A 4-cm horizontal incision line was measured and marked. The incision site was identified by two straight lines being drawn superior and lateral to the midpoint of the pubic symphysis; the index and middle fingers were then placed against each line. The intersection point of the index fingers marked the medial edge of the incision line (Fig. 2a). Determination of the correct

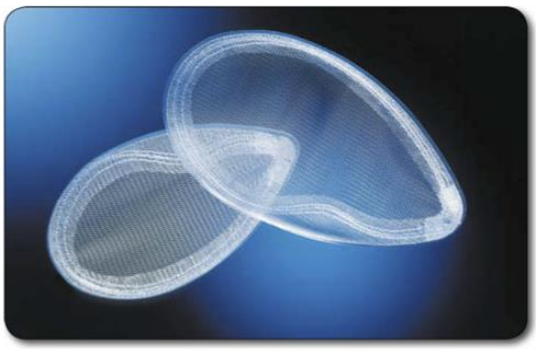

Fig. 1 The PolySoft™ hernia patch

incision site ensures that the correct tissue plane is created for optimal visualization and prosthetic placement and that the superficial anterior branches of the iliohypogastric nerve and the femoral branch of the genitofemoral nerve are avoided and spared from injury. The marked skin line was incised down to the level of the subcutaneous tissue. If necessary, the superficial epigastric vein was cauterised (Fig. 2b) as the subcutaneous tissue was dissected to the width of the skin incision exposing the anterior surface of Scarpa's fascia.

Using cautery, Scarpa's fascia was dissected to expose the anterior surface of the external oblique aponeurosis. Dissection of the external oblique aponeurosis was then started conservatively to create a small tissue window to expose the underlying internal oblique aponeurosis (Fig. 2c).

Dissection of the operative tissue plane

The space between the external oblique aponeurosis and the underlying tissues was dissected digitally by sweeping laterally and cranially up to the superior iliac spine to create a dissected tissue plane that would subsequently accommodate the lateral hernia prosthetic tails (Fig. 2d). The space between the internal and external oblique aponeurosis was then dissected medially by sweeping with the probing finger facing upwards, until the spermatic cord was identified. The cord was elevated out of the incision site (Fig. 2e) while exploring for the presence of an indirect hernia sac. If an indirect hernia sac was identified, the sac contents were reduced and the excess sac ligated or removed as appropriate. If a direct hernia was identified, the sac and contents were reduced into the abdominal cavity following careful dissection of the hernia sac, and the spermatic cord was explored to ensure no indirect hernia sac was present.

The transversalis fascia was explored digitally down to the pubic bone and the probing finger plunged obliquely down through the fascia spreading the fascial fibres (2f). The tissue on the underside of the pectin structure of the pubic bone was explored and dissected digitally to complete dissection of the transversalis fascia. The space of Retzius was then entered and the distinctive yellow/orange preperitoneal fat in this area was exposed. A 20 cm × 20 cm sterile gauze was inserted into the incision and digitally guided down towards the pubic bone to bluntly dissect the space required for insertion of the hernia patch in the Retzius space (Fig. 2g).

Insertion of the hernia patch

An axial slit was cut into the patch between the interrupted ends of the memory recoil ring, down to the apex of the curved notch of the patch, taking care not to cut the recoil ring. The tails of the patch were placed around the elevated spermatic cord with the curved edge of the patch orientated medially (Fig. 2h). The tails of the patch were then joined together using three interrupted sutures: one adjacent to the spermatic cord, one at the end of the lateral tails of the patch, and one at the mid-point of the slit (Fig. 2i). The gauze was then removed (Fig. 2j). The medial apex end of the patch was grasped on the periphery between two fingers (Fig. 2k), and the patch was inserted into the incision and pushed obliquely down into the space of Retzius under the pubic bone leaving the tails of the patch outside the incision (Fig. 2l). The patch was smoothed using the fingers so that it was fully deployed under the pubic bone in the space of Retzius (covering all potential defect sites) with no wrinkles or buckles. If wrinkling or buckling is observed, this is an indication that the dissected space is too small for the patch and further dissection is required. The lateral tails of the patch were then inserted into the previously dissected space between the external oblique aponeurosis and the tissues below it (Fig. 2m), and smoothed out with the fingers to ensure correct placement.

Closing the incision

The type of suture and technique used for closing the external oblique aponeurosis should be at the discretion of the surgeon. There is no need to close Scarpia's fascia. If appropriate, local anaesthetic can be injected and the skin closed with sutures or clips. Finally, the operative site should be cleaned and a sterile dressing applied. The final positioning of the mesh in relation to the different hernia site structures is shown schematically in Fig. 3.

Follow-up

Patients attended a follow-up visit between 1 and 2 months after surgery and a further follow-up visit 1 year after surgery.

Results

Patients and surgical data

A total of 693 patients underwent ONSTEP hernia repair and were followed up for 1 year. Of the 693 procedures, 577 were performed at the Hospital de Sousa Martins and 116 were performed at the Hospital de São João. Patient characteristics and surgical data are summarized in Tables 2 and 3. No anaesthetic complications and no surgical deaths were reported.

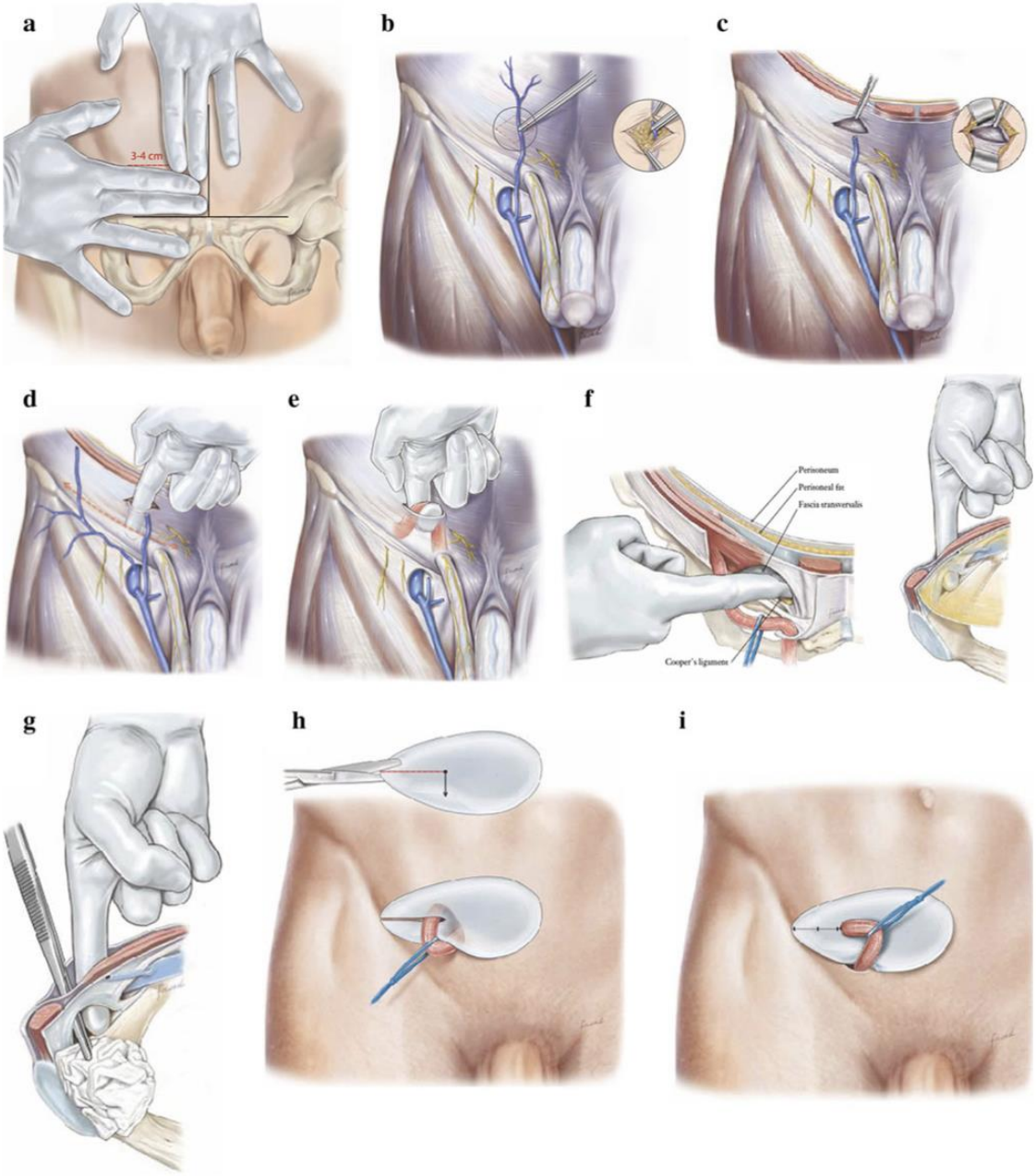

Fig. 2 **a** Identification of incision site, **b** Identification and cauterization of the superficial epigastric vein (if present), **c** Dissection to the level of the internal oblique aponeurosis, **d** Development of the plane between the internal and external oblique muscles, **e** Identification and isolation of the spermatic cord, **f** Entry to the space of retzius, **g** Insertion of large gauze, **h** Preparation of the PolySoft™ Hernia patch, **i** Closure of the prosthetic tails, **j** Removal of large gauze, **k** Placement of the PolySoft™ hernia patch into a preperitoneal position, **l** Final position of the medial portion of the prosthesis; placed in the space of Retzius behind the pubic bone covering all potential defect sites. **m** Final position of the lateral tails of the prosthesis; placed intramuscular between the external and internal oblique muscles

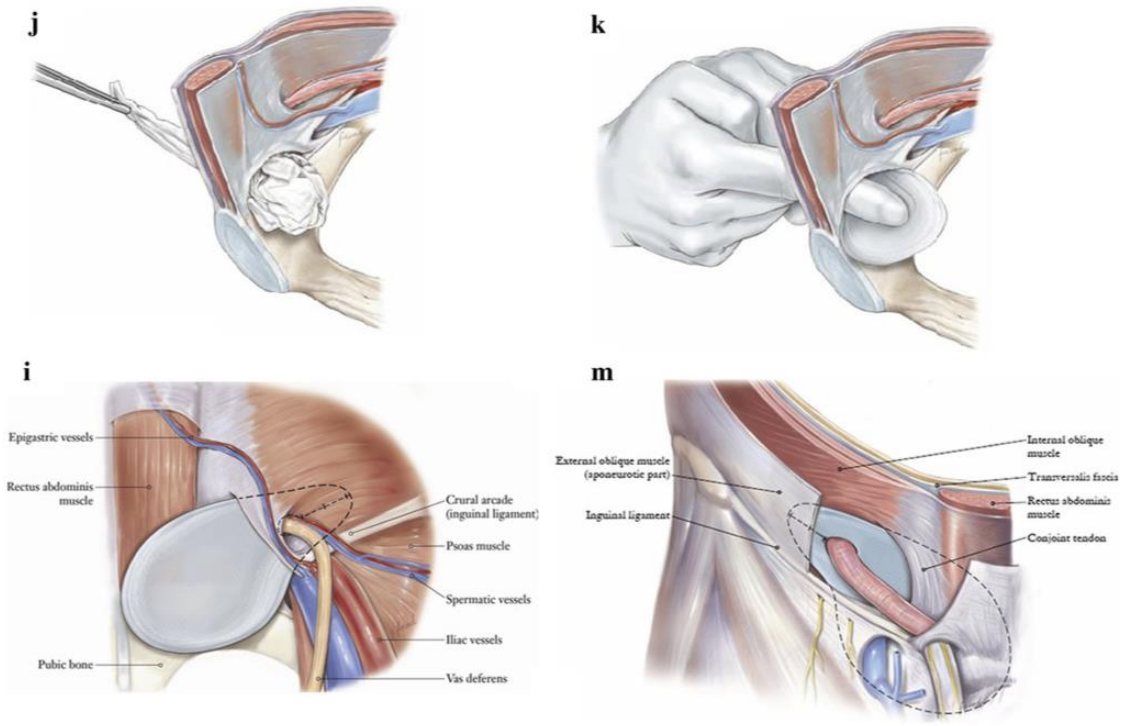

Fig. 2 continued

Complications

Of the 693 patients, only seven experienced complications, giving an overall complication rate at 1 year of 1.0 %. Five patients (0.7 %) experienced early (within 1 week of surgery) complications, including seroma, haematoma and wound infection. The only late (at 6 months) complication was residual pain in four patients (Table 4). This pain resulted in a further surgical procedure in three patients and was found to be caused by the memory recoil ring around the edge of the mesh. Removal of the ring under local anaesthetic was effective in relieving the pain and was completed through a small 3–4 cm incision, at the lateral tip of the mesh. Both ends of the memory ring were cut to facilitate complete ring removal and these patients were without any complaints at the 12 month follow-up. The fourth patient with residual pain refused further surgery, and the pain had become negligible at a 1 year consultation.

Recurrence

Four patients experienced hernia recurrence, all within the first 2 months after surgery, giving an overall recurrence rate of 0.6 %. Three of the recurrences were in female patients (3/114, 2.6 %) and one was in a male patient (1/579, 0.2 %; Table 4). In two patients (both female), the hernia recurred medially to the mesh; in one patient (male), the hernia recurred below the mesh; and in one patient (female), the recurring hernia was femoral. There were no recurrences in the patients that had undergone previous surgery to repair an inguinal hernia.

Discussion

This is the first report of the novel ONSTEP procedure for inguinal hernia repair in a large series of patients. All patients were followed up for 12 months, and there were no cases of chronic pain at the 12-month follow-up which is remarkable compared to other surgical techniques. Experience with this technique at the two Portuguese institutions suggests that it is a simple and reliable procedure for inguinal hernia repair, with a predictable short learning curve and a short duration of surgery (approximately 17 min). Most of the surgical procedure can be performed with good visibility of the different anatomical structures. The only point in the procedure when dissection is performed with minimal visibility is when developing the retropubic space using surgical gauze. However, it should

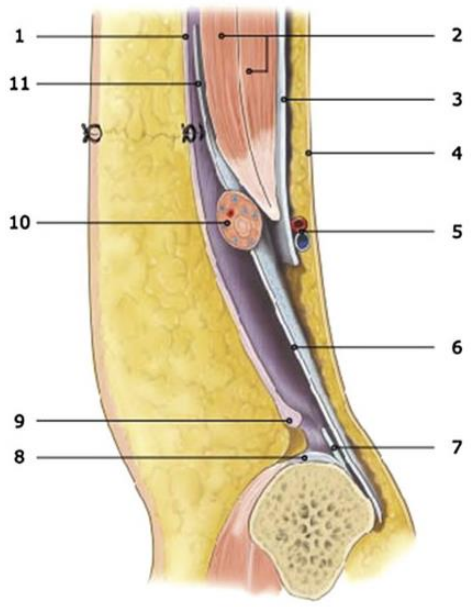

Fig. 3 Schematic diagram showing a sagittal section through the hernia repair site and final positioning of the mesh in the ONSTEP procedure: *1* external oblique aponeurosis, *2* internal oblique and transverse muscles, *3* fascia transversalis (posterior to the mesh), *4* parietal peritoneum, *5* epigastric vessels, *6* distal portion of mesh in preperitoneal position, *7* reminescent fascia transversalis, *8* Cooper's ligament, *9* crural arcade, *10* spermatic cord, *11* cephalic portion of mesh positioned below the oblique external aponeurosis

Table 2 ONSTEP Hernia repair—patient characteristics for 693 patients

Patient characteristics	Value (*n*) (%) Patients
Total number of patients	693
Male/female	579/114 (82 %/18 %)
Mean age (±SD; years)	60.6 ± 7.5
AAA	
Age range (years)	18–86
Type of hernia	
Direct hernia	254 (37 %)
Indirect hernia	429 (62 %)
Femoral hernia	10 (1 %)
Previous hernioplasty	76 (11 %)

be emphasized that there were no complications in relation to this step of the procedure. Patients treated at our centres were able to leave hospital within 24 h of surgery and return to their normal daily activities within a relatively short period of time (approximately 6 days). In addition, the overall complication rate was low (1.0 %), as was the overall recurrence rate (0.6 %).

Table 3 ONSTEP hernia repair—surgical data for 693 patients

Characteristic	Value (time) Patients
Mean duration of surgery (±SD; min)	17 ± 6
Duration of surgery (range in min)	12–32
Time to discharge (range in hours)	2–23
Mean time to return to daily activities (±SD; days)	6.1 ± 3.0
Time to return to daily activities (range in days)	3–10

Table 4 Early (within 1 week) and late (6 months) complications during ONSTEP inguinal hernia repair in 693 adult patients

Complication	Number of patients (%)
Early complications (within 1 week)	
Seroma	3 (0.4 %)
Haematoma	2 (0.3 %)
Wound infection	3 (0.4 %)
Late complications (6 months)	
Residual pain	4 (0.6 %)
Recurrence (all within 2 months)	
Overall	4 (0.6 %)
Females	3/114 (2.6 %)
Males	1/579 (0.2 %)

There is only one other report of open TEP hernia repair [22]. In this study, 106 patients underwent open TEP inguinal hernia repair. The mean length of surgery was 32.6 ± 10.5 min, which was almost double the mean length of surgery in our series (17 ± 6 min), and the rate of early complications was 11.3 %, which was higher than the rate of 0.7 % achieved in our series of patients. However, as in our patients, the overall recurrence rate was low (1.9 % compared with 0.6 % in our patients). The authors of this study concluded that open TEP inguinal hernia repair is a safe, effective and convenient technique with few post-operative complications.

Our experience suggests that the results achieved with ONSTEP inguinal hernia repair are comparable to those achieved with laparoscopic TEP in terms of recurrence rates. In the literature, recurrence rates for laparoscopic TEP range from 0 % to around 9 % [13, 17, 23–29].

Possible complications with any preperitoneal mesh repair include haematomas, seromas, residual and/or chronic pain and wound and mesh infection. In our experience, however, the complication rate associated with ONSTEP surgery was low (1.0 % overall). In our patients, the most common complications were seroma or haematoma formation and wound infection; no cases of mesh infection occurred.

The procedure described in this paper may also provide the added benefit of reduced post-operative pain compared with Lichtenstein procedure, since the incidence of residual pain was low (0.6 % at 6 months) and similar to that observed with laparoscopic TEP. The residual pain that was present in 4 patients at 6 months was cured by removal of the memory ring in 3 patients and disappeared spontaneously in one case, so that notably there was no case of chronic pain at 1 year in this series.

Conclusions

The novel ONSTEP procedure for inguinal hernia repair using the PolySoft™ hernia patch that has been described is both simple and reliable and is associated with very low overall complication and recurrence rates, as well as low levels of pain (0 % at 1 year). The Polysoft™ hernia patch has proved to be an appropriate mesh for this procedure. However, the extended lateral recoil ring in the mesh was responsible for the few complications (residual pain) observed and resulted in reoperation in three patients. In view of this, use of a different prosthesis may help to improve outcomes with the ONSTEP technique. The ONSTEP procedure may offer a valuable alternative to open Lichtenstein and laparoscopic inguinal hernia repair. Long-term follow-up has to be awaited, as well as randomised trials comparing this technique with more established repairs, such as the Lichtenstein technique.

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Conflict of interest None.

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4.3. Article II

"Long-Term Follow-Up of a Large Series of Patients Following ONSTEP Inguinal Hernia Repair"

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Research Article Open Access

Long-Term Follow-Up of a Large Series of Patients Following ONSTEP Inguinal Hernia Repair

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Abstract

Purpose: Long-term (3-5 years) results following inguinal hernia repair in a large series of patients using a novel technique-the ONSTEP approach-are presented. In particular, the recurrence rate, long-term complications and patient satisfaction with the procedure are discussed.

Methods: Adult patients underwent ONSTEP inguinal hernia repair using a PolySoft™ hernia patch. All procedures were performed by one of two surgeons. Patients were followed up for 3-5 years for recurrences and complications, including chronic and residual pain. Patients were also asked to rate their satisfaction with the procedure.

Results: Data were available from 398 hernia repair procedures in 314 patients at the 3-5-year follow-up. The overall recurrence rate was 2.0% (8/398). Additionally, there were 14 cases (3.5%; 14/398) of residual pain and 5 cases (1.3%; 5/398) of wound infection. No patients experienced chronic pain and there were no cases of mesh infection. Patient satisfaction with the ONSTEP procedure was high, with 94.9% of patients rating it as excellent, very good or good.

Conclusions: ONSTEP inguinal hernia repair produced consistent results in the long term, and was associated with a low recurrence rate, only minor complications and no chronic pain. The procedure offers an alternative approach to both Lichtenstein and laparoscopic repair.

Keywords Inguinal hernia repair; Open hernia repair; ONSTEP hernia repair; Chronic pain; Residual pain; Recurrence

Introduction

The ideal surgical technique for inguinal hernia repair is still open to debate. Current options are open repair, which involves opening the abdominal wall and repairing the hernia with sutures or a surgical mesh, and laparoscopic repair, in which the hernia defect is repaired through small incisions with a surgical mesh without the need to open the abdominal wall [1]. Lichtenstein repair [2] is the most commonly used open procedure, despite the fact that it causes chronic post-operative pain in a large proportion (15-40%) of patients [3]. Laparoscopic procedures are associated with a reduced rate of post-operative pain compared to open repair [4-7], but they take longer to learn and are more expensive to perform [8-12].

The two main approaches to laparoscopic inguinal hernia repair are the transabdominal preperitoneal (TAPP) approach, where the hernia is repaired via the peritoneal cavity, and the totally extraperitoneal (TEP) approach, where the hernia is repaired via the preperitoneal plane without entering the peritoneal cavity [1]. As the TEP approach does not involve entering the peritoneal cavity, it is less likely to cause damage to the intra-abdominal organs [11] and less likely to cause acute or chronic pain than open repair [13-15].

A novel technique for inguinal hernia repair has been developed at the Hospitals Sousa Martins and São João in Portugal. This technique, known as ONSTEP repair, is an open variation of totally extraperitoneal laparoscopic repair, and involves the placement of a hernia patch in the preperitoneal space during open surgery [16]. The procedure was used in 693 surgeries in 609 hernia patients at the authors' institutions, and data at 1-year follow-up showed that it produced consistent results with low overall complication and recurrence rates [16]. The present study follows on from the previous 1-year study, reporting long-term (3-5 years) results after ONSTEP inguinal hernia repair in a large series of patients. In particular, it focuses on complications, such as chronic and residual pain, the hernia recurrence rate, and patient satisfaction with the procedure. It involves 450 patients (535 procedures) of the 609 patients (693 procedures) of the initial study, for whom the 3-5 year follow-up was available.

Patients and Methods

Study population and ethics

Adult patients (≥ 18 years of age) underwent ONSTEP inguinal hernia repair at one of two institutions in Portugal: the Sousa Martins Hospital, Guarda, and the São João Hospital, Porto. All procedures were performed by the two authors over a 5-year period (2007-2011).

Citation: Lourenço A, da Costa RS (2016) Long-Term Follow-Up of a Large Series of Patients Following ONSTEP Inguinal Hernia Repair. J Clin Trials 6: 256. doi:10.4172/2167-0870.1000256

All patients were rated as American Society of Anaesthesiologists (ASA) grade I, II or III. The study was approved by the Ethics Committee of the Unit of Healthcare of Guarda.

Surgical technique

ONSTEP inguinal hernia repair was performed under local (plus sedation), locoregional or general anaesthesia using a PolySoft™ hernia patch (Davol Inc., Cranston, Rhode Island, USA). This is a self-expanding, non-absorbable sterile mesh consisting of polypropylene monofilaments knitted together to form a strong, porous support material. An interrupted memory recoil 'ring' consisting of extruded monofilament polyethylene terephthalate (PET) polymer runs around the edge of the patch to add stability and facilitate placement. The patch is shaped to cover all potential hernia defects and is available in two sizes (Figure 1).

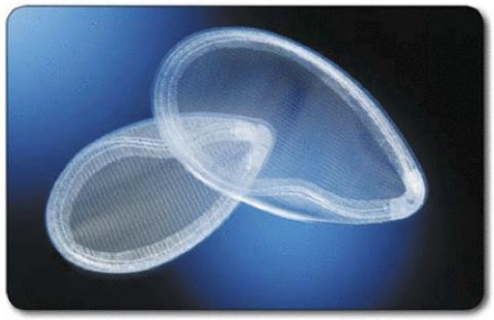

Figure 1: The PolySoft™ hernia patch.

The ONSTEP inguinal hernia repair procedure has been described in detail previously [16]. Briefly, a 4 cm horizontal incision was made in the lower abdomen, and dissection to the level of the internal oblique aponeurosis was performed, followed by development of the operative tissue plane under the external oblique aponeurosis, in order to allow the disruption of the fascia transversalis. Blunt dissection with gauze was then used to create space for insertion of the hernia patch into a part intramuscular part preperitoneal position in the space of Retzius behind the pubic bone (Figure 2).This is a sutureless and tension-free technique which avoids nerve lesions for the nerve exposure to dissection and entrapment is reduced to a minimum. In women, the technique was modified slightly to allow the hernia patch to be placed completely in the preperitoneal space: the preperitoneal dissection was extended laterally, the round ligament lifted and parietalised, and the hernia patch placed completely in the preperitoneal space covering the internal ring from the inside and posteriorly. In all cases, the skin incision was closed using the surgeon's preferred technique. All procedures were performed on an ambulatory basis.

Follow-up

Patients attended a follow-up visit between 1 and 2 months after surgery, and further follow-up consultation at 1 year. A telephone contact was done by doctors of both Hospitals at 3-5 years after surgery. The patients were asked for any complaints and answered the same protocol used for the evaluation of the results of the first year (Figure 3). If the patients mentioned any complaint they were asked to come to a consultation so that a correct evaluation could be done and a new protocol was filled (Figure 4). Complications, including chronic and residual pain, were noted, as was hernia recurrence. Chronic pain, defined a priori as any pain above 0 on a visual analogue scale (VAS) at or beyond 3 months postoperatively [17], was measured on a VAS scale of 0 to 10, where 0 = no pain, 1-2 = mild pain, 3-5 = moderate pain, 6-8 = severe pain and 9-10 = intolerable pain. Residual pain, defined as pain or discomfort due to the sensation of a foreign body and caused by the pointed distal margin of the ring of the hernia patch, was measured on a similar scale. In addition, patients were asked to rate their satisfaction with the ONSTEP procedure on a scale of 1 to 5, where 1 = poor, 2 = reasonable, 3 = good, 4 = very good and 5 = excellent.

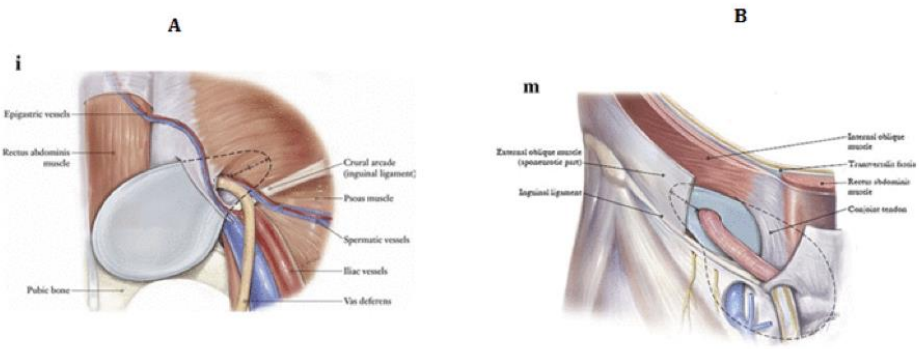

Figure 2: Preperitoneal position of the PolySoft™ hernia patch in the space of Retzius behind the pubic bone, (A) medial view, (B) lateral view.

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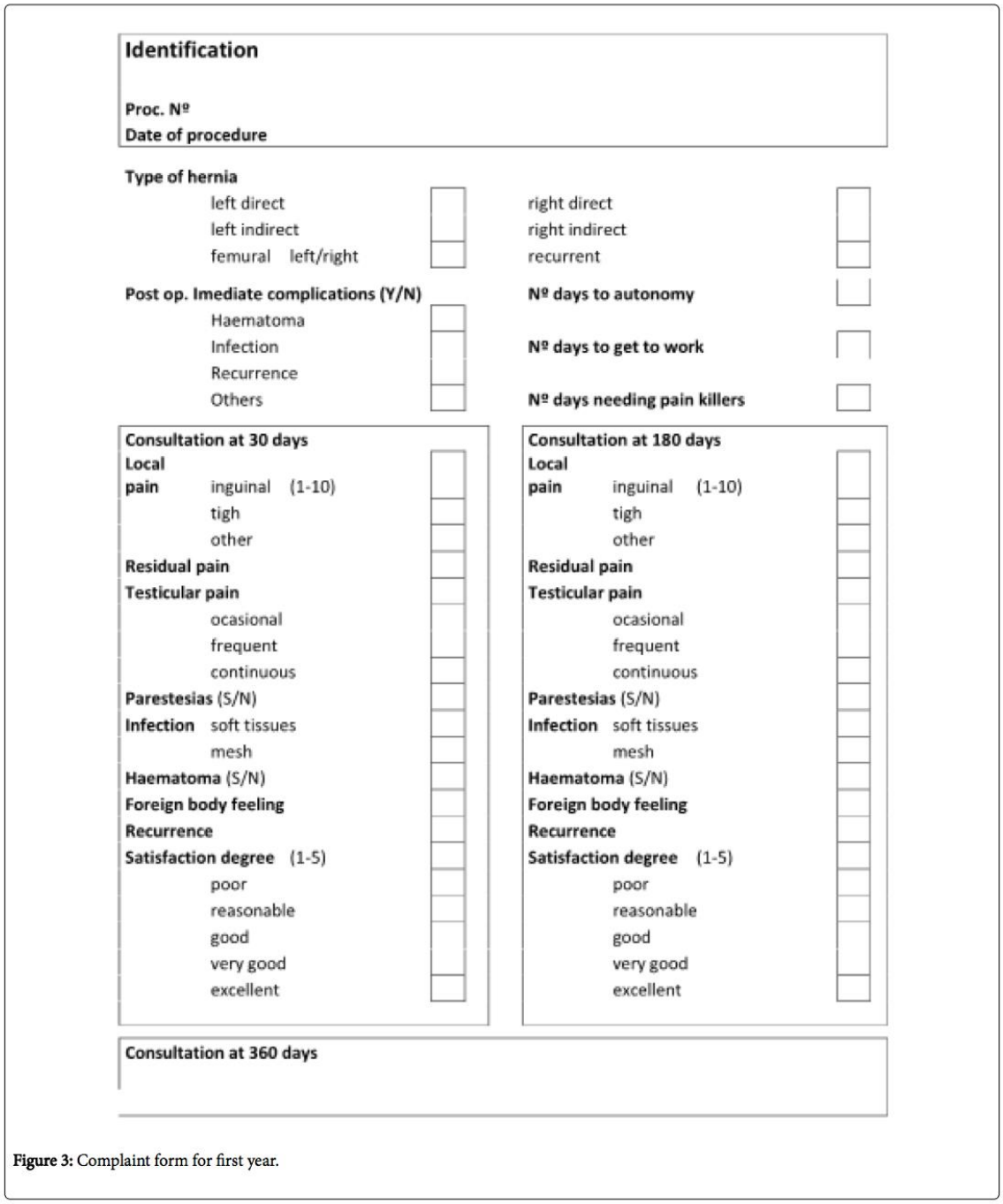

Identification

Proc. Nº
Date of procedure

Type of hernia

left direct	☐	right direct	☐
left indirect	☐	right indirect	☐
femural left/right	☐	recurrent	☐

Post op. Imediate complications (Y/N)

Haematoma	☐	**Nº days to autonomy**	☐
Infection	☐	**Nº days to get to work**	☐
Recurrence	☐		
Others	☐	**Nº days needing pain killers**	☐

Consultation at 30 days		**Consultation at 180 days**	
Local pain inguinal (1-10)	☐	**Local pain** inguinal (1-10)	☐
tigh	☐	tigh	☐
other	☐	other	☐
Residual pain	☐	**Residual pain**	☐
Testicular pain	☐	**Testicular pain**	☐
ocasional	☐	ocasional	☐
frequent	☐	frequent	☐
continuous	☐	continuous	☐
Parestesias (S/N)	☐	**Parestesias** (S/N)	☐
Infection soft tissues	☐	**Infection** soft tissues	☐
mesh	☐	mesh	☐
Haematoma (S/N)	☐	**Haematoma** (S/N)	☐
Foreign body feeling	☐	**Foreign body feeling**	☐
Recurrence	☐	**Recurrence**	☐
Satisfaction degree (1-5)	☐	**Satisfaction degree** (1-5)	☐
poor	☐	poor	☐
reasonable	☐	reasonable	☐
good	☐	good	☐
very good	☐	very good	☐
excellent	☐	excellent	☐

Consultation at 360 days

Figure 3: Complaint form for first year.

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Retrospective evaluation of 3-5 years follow-up for patients with inguinal hernia submitted to ONSTEP procedure with Polysoft mesh

All patients are contacted by phone and evaluated at a consultation if there is any complaint that might be correlated to previous surgery

Name _____ **Proc. Nº** _____

Age ☐ **Sex** M ☐ F ☐

Date of procedure ...../...../.....

Evaluation date ...../...../.....

Type of hernia

left direct		☐	right direct	☐
left indirect		☐	right indirect	☐
femural	Left / right	☐	recurrent	☐

Pain evaluation (0 a 10)

Nonexistent (0)	☐
Light (1-3)	☐
Moderate (4-6)	☐
Severe (7-9)	☐
Intolerable (10)	☐

Evidence of recurrence (Y/N) ☐

Satisfaction degree (1 to 5) ☐

Notes _____

_____

_____

Figure 4: New protocol after rectification of complaint.

Results

Patients and surgical data

From the initial population of 609 patients (693 surgeries) that were evaluated in the study already published in Hernia (2013) it was decided to exclude the years of 2005 and 2006 for difficulties on communication with the patients. A total of 450 patients underwent 535 ONSTEP hernia repair procedures (bilateral repair was counted as two procedures). Data from the 1-year follow-up have already been reported [16]. Data from the 3-5-year follow-up were available from 314 patients (69.8%) and 398 procedures (74.4%). The majority of procedures (68.2%) involved unilateral repair. Patient characteristics and surgical data are summarised in table 1. A total of 114 patients were impossible to contact mostly because of the emigration that arouse Portugal since the economic crisis of 2009 and 22 patients have died for other reasons non concerning the hernia repair procedure they were submitted (Table 1). No anesthetic complications and no surgical deaths were reported. All patients were discharged within 2-23 hours of surgery.

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Recurrence

At the 3-5-year follow-up, from 398 procedures, eight patients (five women, three men) had experienced hernia recurrence, giving an overall long-term recurrence rate of 2.0% (95% Confidence Interval: 0.6% to 3.4%) and a recurrence rate of 0.9% for men (3/348).

Characteristic	Value
Total number of patients undergoing surgery	450
Total number of hernia repair procedures	535
Long-term follow-up	
Number of patients who had died[a]	22
Number of patients who were uncontactable	114
Number of patients with follow-up data, n (%)	314 (69.8%)
Male/female, n (%)	270/44 (86.0%/14.0%)
Mean age (± SD; years) AAA	59.33 (± 7.0)
Age range (years)	18-86
Number of hernia repair procedures (male/female)[b]	398 (348/50)
Type of hernia repair, n (%)	
Bilateral	84 (26.8%)
Unilateral	214 (68.2%)
Femoral	16 (5.1%)
Time to discharge (range in hours)	2-23

Table 1: Characteristics and surgical data for 314 patients undergoing 398 ONSTEP hernia repair procedures. [a]In all cases, the cause of death was unrelated to the hernia repair procedure; [b]Bilateral hernia repair was counted as two procedures.

Complication	Number of procedures (%)
Chronic pain	0 (0.0%)
Residual pain	14 (3.5%)
Wound infection	5 (1.3%)
Ring removal	6 (1.5%)
Recurrence	8 (2.0%)

Table 2: Long-term complications following 398 ONSTEP hernia repair procedures.

Complications

All the complications were found and solved in the first year after surgery. At long-term follow-up, there were no cases of chronic pain, 14 cases (3.5%) of residual pain (95% Confidence Interval: 1.7% to 5.3%) and 5 cases (1.3%) of wound infection were found (95% Confidence Interval: 0.2% to 2.4%) (Table 2). There were no cases of mesh infection. Six patients with residual pain (1.5%) had undergone removal of the memory recoil ring around the edge of the mesh to relieve the pain. The remaining eight patients with residual pain did not require further treatment.

The residual pain, more common in skinner patients, results from the stiffness or kinking of the memory recoil ring and can be diminished with a good deployment of the mesh that can be obtained with the right dissection in the external/lateral part very easily. The ring removal should be done by a very short incision focused on the tip, under local anesthesia, never before the fourth month after surgery, and solves the pain immediately after the removal of the ring. There is no need of removing the patch, only the recoil ring. The new ONFLEX mesh, already available, avoids this problem.

Patient satisfaction

Patient satisfaction with the ONSTEP hernia repair procedure was high, with 81.5% of patients rating the repair as 'excellent' and 11.5% rating it as 'very good'. Overall, 94.9% of patients rated the procedure as excellent, very good or good (Figure 5).

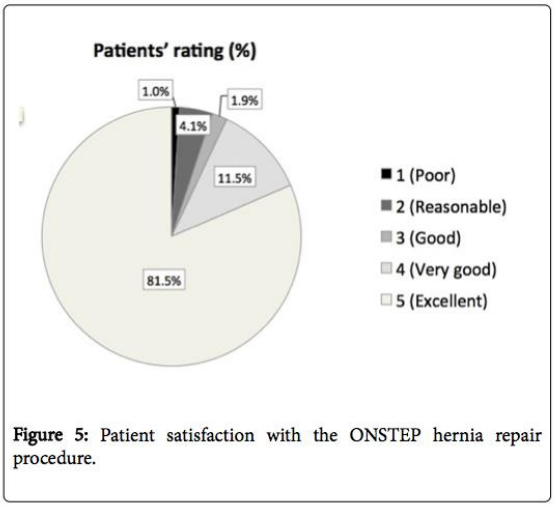

Figure 5: Patient satisfaction with the ONSTEP hernia repair procedure.

Discussion

This study shows that the novel ONSTEP procedure for inguinal hernia repair produces consistent results in the long-term, with a low recurrence rate, only minor complications and no cases of chronic pain. In a previous series of 693 surgeries in 609 patients followed up for 1 year [16], we showed that the procedure was simple and reliable, and was associated with very low complication and recurrence rates (1.0% and 0.6%, respectively) at this time. In addition, there were no cases of chronic pain and only a few cases of residual pain (0.6% of patients at 6 months, no cases at 1 year). These results were maintained in the current study, if the longer term (3-5 years) is taken into account, with a recurrence rate of 2.0%, no cases of chronic pain and only a few cases (3.5%) of residual pain. The current study also showed that patient satisfaction with the ONSTEP procedure was high, with 95% of patients rating the procedure as excellent, very good or good.

Chronic pain is a serious long-term complication after mesh repair of inguinal hernia. A pooled proportion meta-analysis in a systematic review showed that the incidence of chronic pain after such surgery is

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11% [18]. Thus, the lack of any cases of chronic pain in our series of patients should be taken in consideration. In the systematic review, chronic pain was less likely with use of a lightweight high porosity mesh than with use of a heavyweight low porosity mesh (odds ratio 0.61; 95% confidence interval 0.43-0.88). This was attributed to a reduced inflammatory response, reduced scar tissue and greater movement of the abdominal wall with the lightweight mesh. Thus, the 0% incidence of chronic pain in the current study may have been due to the small amount of dissection, the avoidance of nerve dissection, use of a tension-free technique and the lightweight properties of the PolySoft mesh.

Other possible long-term complications with preperitoneal mesh repair include residual pain, and wound or mesh infection. In our series of patients, the most common complications were residual pain and wound infection; no cases of mesh infection were observed. As in our previous report [16], some cases of residual pain (6/14; 42.9%) were cured by removal of the memory recoil ring from the hernia patch, while the pain resolved with no further intervention in the remaining eight patients with residual pain. With the new patch equipped with a reabsorbable memory-ring the problem of residual pain might be solved.

Clinical experience with the ONSTEP technique has also been reported outside of the authors' institutions in a study of 80 patients undergoing inguinal hernia repair by one of four surgeons in the general surgical department at a Danish hospital [19]. In this study, patients were followed up for a median of 4 months (range 1-13 months). The results showed that 80.3% of patients had no substantial pain-related impairment of daily function, 94.8% were asymptomatic, and 95.5% reported no pain or pain that was easily ignored. All complications were managed conservatively and/or with watchful waiting. It was concluded that the ONSTEP approach is a safe technique for inguinal hernia repair, with no serious postoperative complications and a level of postoperative pain equal to or less than that observed with Lichtenstein repair. The results from the above study [18] were not as promising as those achieved in our series of patients, but this may have been due to the fact that many of the ONSTEP procedures in the Danish study were used for teaching the technique. In addition, a fixed follow-up date was used, thus patients were assessed anywhere between 1 and 13 months after surgery, giving a mix of short- and longer-term results [19,20].

Finally, the recurrence rate in our study was comparable to the recurrence rates reported in the literature for laparoscopic TEP, which range from 0% to around 9% [11, 21-28]. Comparison with our 1 year follow-up study indicates that the rate of recurrence decreases with time.

Conclusions

ONSTEP inguinal hernia repair produced consistent results in the long term and was associated with a low recurrence rate and only minor complications, including low levels of residual pain and no evidence of chronic pain. The ONSTEP procedure may offer an alternative approach to both Lichtenstein and laparoscopic inguinal hernia repair. The results from two randomised trials comparing the ONSTEP technique with these procedures are awaited.

Acknowledgements

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Conflict of Interest

Author declares no conflict of interest.

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4.4. Further information regarding ONSTEP

It was with the polypropylene mesh with non-absorbable memory ring called PolySoft® that I began the new technique in 2005, initially called OPEN-TEP, and currently called ONSTEP. It was presented as a poster at the National Congress of Surgery and later as a presentation at the EHS congress in Berlin.

With the beginning of collaboration that still remains with Dr. Rui Soares da Costa, the idea of creating a mesh better adapted to the technique arose which we called ONSTEP. The beginning of a partnership and collaboration with Dr. Rui Soares da Costa allowed for the gain of "critical mass" and a logistic reinforcement to embark upon a new phase of the project.

To validate a surgical technique, it must be reproducible.

After national presentation of this technique as posters at two SPC congresses to promote its diffusion, a presentation at the Berlin Congress 2009 was done.

I was able to rely on the support of CRBard-Davol® and I began functions as company`s Iberian consultant for the treatment of inguinal hernia.

The first training session was held in UCMA directed by Dr. Ramon Gutierrez, an excellent professor in the treatment of ambulatory hernia, followed by visits with training sessions in Seville, San Sebastián, Badajoz, Zamora and Valencia.

At national level, I was visited by colleagues from many hospitals, reflecting a growing number of requests.

An improved structure of the technique to facilitate the teaching and training resulted in a technical guide and a 3D animation. This was followed by the development of a new mesh, which was believed to be better adapted to the ONSTEP technique in the follow up of acquired experience.

With the registration of the national patent application of European design and technique (in the United States of America) and its transaction to CRBard-Davol®, a new phase of the project was begun. We became world consultants of the company, which allowed us to develop a new mesh. This was presented worldwide in Milan in May 2015 during the First World Conference on Hernias where we were honoured to have been invited to perform a surgical demonstration, transmitted live.

A training centre at European level was headquartered in Porto, UCA S. João Hospital.

Our programme consists of receiving guests, usually four senior surgeons accompanied by delegates of the company having a presentation of the technique and results on the arriving

day. The next day, at the operating theatre, each one of the guests has later the opportunity to assist in the surgery of inguinal hernia and operate another with our help. Time is available later for discussion and future possible collaborations outlined.

This programme has allowed the training of approximately 150 surgeons across Europe and provided them with the same standard of training.

The aims of the training were to disseminate and teach the technique and to create new training centres. Some which should be mentioned for their dimension is the centre in Copenhagen, of Dr. Jacob Rosenberg, and the one in Berlin, of Dr. Ralph Laurent.

We have also been invited to visit some centres for better implementation of the technique and consolidation of previous training. Some examples include San Sebastián Hospital, Virgem de Macarena Hospital in Seville, Zamora Hospital, Herlev Copenhagen Hospital and Luxemburg Hospital among others, both national and foreign.

It was with great interest that we became aware of the publication of various articles about the use of the ONSTEP technique. It is an added value to verify the reproducibility of the results.

4.5. Patent

In order to improve the quality of the results of the ONSTEP technique we developed a mesh, which incorporated some advances, namely in terms of materials and a new design.

A mesh in polypropylene was created with tried and tested material in a low density, high porosity version. This allowed for a better adaptation of the anatomical region providing the patient with more comfort and which facilitates integration.

The inclusion of a memory ring for better placement and positioning without fixation was now in a slow re-absorbable material and less rigid than the POLYSOFT. Its objective was to avoid cases of residual pain and avert the need for its removal in some of the more slender patients.

The cavity at its most medial part facilitates the introduction and deployment of the mesh in the pre-peritoneal space.

The increase of dimensions in the medial half reinforces the quality of the repair.

The inclusion of an area that may be cut according to the physician's preference allows for a better adaptation in accordance to the user's choice.

The new ONFLEX is the result of the adaptation of the registered patent to industrial production.

Link to patent access:

- https://patents.google.com/patent/US20140379007?oq=Augusto+louren%C3%A7o
- https://patents.google.com/patent/US20140012395?oq=Augusto+louren%C3%A7o
- https://patents.google.com/patent/WO2013048272A1/en?oq=Augusto+louren%C3%A7o+hernia
- https://patents.google.com/patent/EP2760370A1/en?oq=Augusto+louren%C3%A7o+hernia

5. Discussion

Ideally, the technique for inguinal hernia repair should be reliable, replicable (with a rapid learning curve) and should imply the minimum of post-operative complications, such as post-operative pain and a recurrence rate. It should have good aesthetic results and the return to normal daily activities should be rapid. The costs of the technique must be considered and these should be acceptable.

Before the introduction of the use of meshes in techniques for inguinal hernia repair, the recurrence rate was the most important outcome to evaluate. Taking into account that this reduced significantly with the use of a mesh, at this time the most important outcome is post-operative pain, either immediate or chronic. (7)

According to a 2012 Cochrane Review, which compared Lichtenstein's with other pre-peritoneal techniques, chronic pain is the main differentiator among the various techniques not to mention the advantages of minimal dissection and tension free repair.

The ONSTEP technique is completely tension free as the patch is placed in an anatomical space without any kind of fixation and it's positioning is ensured in part by the memory ring. It is important to mention the association between chronic pain and fixation, widely cited in literature and which I had the opportunity to ascertain. (8)

From the description of the technique we can easily conclude that dissection is minimal and one of the breaking points with the past is the disruption of the transversalis fascia for a better and easier access to the pre-peritoneal space. The disruption of the transversalis fascia allows easy rapid access with the possibility of direct visualisation of the pre-peritoneal space, which increases the safety of the procedure. (9)

One of the difficulties in the diffusion of this technique involves the anatomy associated with this approach, which requires experienced surgeons so that they are comfortable with the dissection of the implicated structures.

Comparing open repair with endoscopic (TAPP and TEP) techniques, these are associated with lower rates of post-operative pain when compared with an open approach. However, they involves a long learning period (between 50-100 procedures), higher risk of complications associated with prosthesis as well as increased associated costs. The TEP technique, as it does not involve entry through the peritoneal cavity, is responsible for less organic damage and less immediate and chronic pain than the open approach.

A comparative study of ONSTEP with endoscopic is underway. It is expected that in terms of pain at 6 months, the rate of chronic pain with TAPP will be 8% while with ONSTEP it will be 0%

(although the figure calculated for this study will be 4%) and that at the end of the year, the values for TAPP and ONSTEP will be 6 % and 2 % respectively. (7)

It should be mentioned that Lichtenstein's technique presents a higher rate of post-operative pain and chronic pain, between 15-40 %, than the ONSTEP technique.

In studies I and II, chronic pain corresponds to any pain above 0 on the VAS scale at the end of three months or more post-surgery and that residual pain corresponds to any pain or discomfort due to the sensation of a foreign body.

In study I, with a sample of 693 procedures submitted to inguinal hernia repair with the ONSTEP technique with the use of the POLYSOFT® Hernia Patch, the global rate of complications was 1 %. The rate of immediate complications after one week was 0.7 %. The documented complications were: seroma, hematoma and wound infection. The rate of late complications (after 6 months) was 1.1 %, corresponding to residual pain in four patients, of which 3 were re-operated and the removal of the memory ring efficient in pain relief. In study II, the rate of residual pain was 3.5 %, being 1.5 % of patients were re-operated and, the removal of the memory ring again efficient. It can be concluded that this residual pain, which is more common in very slender patients, is possibly a result of the rigidity of the memory ring. This complication may be reduced with the use of the ONFLEX mesh, taking into account that the memory ring is semi-rigid and re-absorbable and that it is a polypropylene mesh of less density and higher porosity compared to the POLYSOFT used when conducting this study.

The long-term recurrence rate, which was studied in study II, showed an increase in comparison with study I (2.0 % versus 0.6 %, respectively) a result which appears to be quite acceptable, considering that the sample of study II corresponds to a part of the sample in study I. Therefore, it is reasonable that the recurrence rate increases in a long term analysis, 3 to 5 years, as verified in study II. It is also important to mention that in study I, 11 % of the cases operated were recurrences.

In both of the studies and in all the studies performed to this moment using ONSTEP no cases of chronic pain were documented (10) (11) (12) (13) (14). In a comparative study of ONSTEP and Lichtenstein´s it was verified that with later two cases of chronic pain were described which were incapacitating for normal daily life activities. No such case was described with ONSTEP. Although the values are not statistically relevant, what is truly relevant is the non existence of chronic pain associated with the ONSTEP technique. This absence of chronic pain may possibly be associated with minimal dissection and using a tension free technique as well as with a low density mesh which is the case of POLYSOFT, used in studies I and II.

In this comparative study of ONSTEP and Lichtenstein, it was concluded that there was no significant difference in terms of post-operative pain, complications, and the time to return to normal daily activities. It was verified that the duration of surgery with ONSTEP was lower than with Lichtenstein, which was 32 % longer. This study has as limitations the fact that surgeons

are less familiar with ONSTEP than with Lichtenstein's technique, still finding themselves on a learning curve, which might lead to the undervaluation of ONSTEP. This fact could explain that the rate of recurrence was slightly higher with ONSTEP in relation to Lichtenstein (4.8 % and 4 % respectively), not statistically significant. The frequency of damage of nerve structures was higher with the use of the Lichtenstein technique, as well as the rate of complications albeit without statistical significance. (10) (12)

The duration of surgery, 17±6 minutes in study I, with a trend towards decreasing, is important for two reasons. Firstly, it allows the reduction of costs per patient and increases the number of patients operated. Secondly, each patient requires less anaesthesia time and has a faster post-operative recovery.

In comparison with ONSTEP, the OPEN-TEP technique requires approximately double the duration (32.6±10.5 minutes) a higher rate of complications with about 11.3 % compared to 1 % verified with ONSTEP in study I. The recurrence rate is similar to ONSTEP.

A comparative study between ONSTEP and Lichtenstein was also performed in relation to sexual dysfunction, which made it possible to conclude the superiority of ONSTEP. Pain associated with sexual function was verified in 17 patients with ONSTEP and in 30 with Lichtenstein. While 4 patients treated with Lichtenstein presented pain, which impeded sexual intercourse, this did not occur with any of the patients treated with ONSTEP. It was concluded that the ONSTEP technique allowed improvement of most cases in which pain associated with sexual function already existed before surgery despite having originated some new cases. Reduced sexual dysfunction associated with ONSTEP may be due to the fact that this does not imply sutures and therefore the risk of nerve damage is lower. (15)

One of the scores used to evaluate post-operative pain is CCS (Caroline´s Comfort Scale), which was used in a study of initial evaluation of ONSTEP. The rate of postoperative pain with ONSTEP according to the CCS was 5.2 %. The other techniques presented higher rates, TEP with 5.3 %, TAPP with 9.6 % and modified Lichtenstein with 5.9 %. (11) The rate of patients with complaints in this study is superior to that in study I, which can easily be explained taking into account the limitations of this study, the small sample, the fact that many surgeries were performed with the intention of training and that with the first 80 patients, surgeons were still in their learning curve.

Patient satisfaction is extremely important and the degree of satisfaction with the ONSTEP technique speaks for itself. According to study II, 81.5 % of patients rated satisfaction as excellent and 94.9 % of patients considered it good, very good or excellent. The use of more sophisticated measuring instruments could determine a better degree of satisfaction, but this implied an incompatible workload with the available means.

The ONSTEP technique has been the subject of attention of several authors. It has been mentioned in the HerniaSurge Group (World Guidelines for Hernia Management), where it is

considered a valid solution as the results presented, though scarce, seem to reveal non-inferiority in comparison with other surgical options. However, it is necessary to conduct further studies. (16)

Studies I and II are dependent on the study population, with this being minimised by its magnitude and representativeness of the general public. Another factor is that surgeries were performed by two surgeons, one of them the creator of the technique and the other who collaborated in its development and diffusion. Currently, other multicentre studies are being developed in various Portuguese hospitals in which we do not participate as practitioners.

In terms of the registered patent, it was acquired by CRBard-Davol®. This was incorporated into the new OnFlex®, the company's new commercial product which contests world leadership in this segment.

The programme of diffusion depends on the commercial policy of CRBard-Davol®.

6. Conclusions

The ONSTEP technique is easy to perform. It has a short learning curve, approximately ten cases in contrast to the 50-100 cases referred with the endoscopic technique. (17) (18) Furthermore, it allows good visualisation of anatomical structures. The duration of hospital admission is between 2 and 23 hours and return to normal daily life activities occurs in a short space of time, approximately 6 days.

The ONSTEP technique is accessible to any surgeon and due to the duration of each procedure (17±6 minutes) and the fact that there is no need for special surgical instruments, it is associated with low unit costs. It can be performed with various anaesthetic techniques, from general anaesthesia with laryngeal mask to loco-regional or local anaesthesia with sedation. Also, the opinion of the residents is that it is much easier to learn ONSTEP than Lichtenstein.

I consider it an added value that in all the studies carried out until the moment, no cases of chronic pain were registered.

It is necessary to conduct further studies to confirm and validate this technique for the treatment of inguinal hernia.

7. Future Perspectives

Soon, a comparative study between the technique carried out with Polysoft® mesh and ONFLEX® will be ready for publication.

I continue to closely follow all work related to ONSTEP.

Another study point, to which I believe I will dedicate more time to, is the evolution of the concept of mesh. Despite the expectations placed on biological meshes, these proved to have poor mechanical qualities and are associated to higher costs.

I have some interest in the behaviour of late re-absorption materials, which I await.

I believe that one of the paths will be the creation of hybrid meshes with something that could be called the dematerialisation of the polypropylene mesh.

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Attachments

Attachment I – Consent Form

TERMO DE CONSENTIMENTO INFORMADO

Destina-se a doentes candidatos a tratamento de hérnia inguinal com prótese.

É proposto o tratamento cirúrgico com a técnica ONSTEP que consiste na aplicação de uma prótese, Polysoft (BARD-DAVOL), existente no mercado há vários anos, através de uma via de abordagem anterior, por uma pequena incisão (3-4 cm), com a colocação da prótese no espaço pré-peritoneal, reparando o defeito e os potenciais defeitos da parede abdominal.

Apresenta como vantagens um tempo operatório curto em relação às outras técnicas, um nível de recidiva baixo (igual ou inferior às outras técnicas), baixo nível de dor pós-operatória, e a não existência de casos de dor crónica até ao momento.

Nome .....

Proc. Clínico nº .....

Declaro que fui informado(a) acerca da técnica cirúrgica ONSTEP e que me responderam a todas as perguntas que coloquei, e que aceito de um modo informado ser operado com essa técnica.

Assinatura .....

Data .....

Attachment II – Patent Register

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(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: IMPLANTABLE HERNIA PROSTHESIS WITH AN UNINTERRUPTED RING

(57) Abstract: The implantable hernia prosthesis of the present invention comprises at least one piece of mesh (1) arranged to cover at least a portion of the hernia, at least one support element (2) attached to said piece of mesh (1), said support element (2) comprising at least one resilient, deformable biasing filament, characterized by said support element (2) being an uninterrupted tension providing ring surrounding a portion of said mesh (1) and further comprising an indentation directed towards the center of said ring.

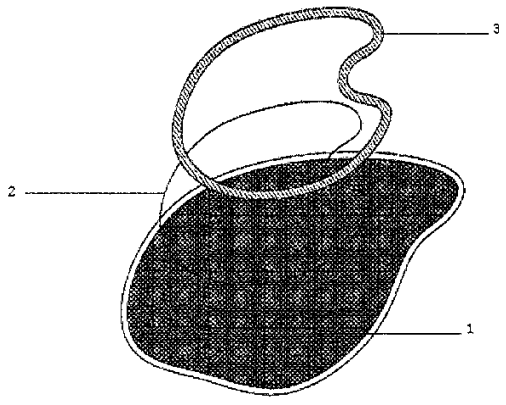

Fig. 7

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— *with international search report (Art. 21(3))*

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DESCRIPTION

IMPLANTABLE HERNIA PROSTHESIS WITH AN UNINTERRUPTED RING

Technical Field

The present invention is related to an implantable prosthesis suitable for use in the correction and repair of hernias (indirect and direct inguinal or femoral hernias) without the need of fixing the prosthesis to any part of the body.

Background Art

For several decades, the preferred method of treating anatomical defects has been through the use of prosthetic materials of varied shapes and features. They are typically put and fixed into place by means of sutures, staples, tackers, biological glues or simply anchored on top of, below or on the defect. Tissue growth through the prosthetic mesh, which results from the body's reaction to a foreign object, then completes the repair.

In the specific case of inguinal hernias, the prosthesis typically consists of a mesh which is woven as a net of a specific fiber. Said prosthesis is put in the location to be treated and may then be cut and/or adjusted if necessary, so that its shape and size are perfectly adapted to the inguinal area where it will be implanted.

In patients of the male sex, so as to accommodate the spermatic cord, it is normally necessary to cut the prosthesis into two separate yet still attached leafs and

then adapt them to the area so as to allow for the passage of said cord and the reinforcement of the internal inguinal ring. There are already today meshes that have these areas pre-cut and others which have the areas to be cut in surgery pre-defined on the prosthesis.

Patent document no. WO2006/034117 describes various embodiments of an implantable prosthesis which are similar to the present invention. The preferred embodiment described in patent document no. WO2006/034117 is a non-absorbable, ellipsoid and symmetric along its longest axis, implantable prosthesis with a non-continuous and non-absorbable ring which substantially follows the external border of the mesh with the exception of an indentation aimed at protecting the femoral vessels, said ring being attached by means of stitching on both sides of the ring all along its length, there being two reinforcements around the edges of the ring where it is discontinued so that these do not protrude out of the channel created by said sewing of the two layers of mesh. The implantable prosthesis described in patent document no. WO2006/034117 seems to have been designed in that way (i.e, having a discontinuous ring) so as to allow for the passage of the spermatic cord through the prosthesis during the treatment of indirect inguinal hernias.

The inventors of the present invention have determined that the surgery techniques for the treatment of inguinal hernias of the prior art are not the most suitable. Indeed, several advantages can be obtained if one opts for a new surgical technique developed by the inventors of the present invention and which consists of making a much higher entry incision, thus allowing for a much better access to the ideal location for placing prostheses of the

abdominal wall and to the structures, as well as enabling an easier dissection of these, a large reduction of the risk of nerve damage, less aggressive impact and a reduction in post-operatory pain, as well as a significant reduction of the time of operation. The technique of this procedure involves a 3-4 cm transversal incision in the skin two fingers above the pubic symphysis, followed by a transversal incision of the external oblique aponeurosis (the only structure that is cut in the procedure) and a broad dissection of the pre-peritoneal area (Retzius space), the isolation of the structures of the spermatic cord, the identification of the Cooper ligament and the disruption of the Fascia Transversalis at that level. After this, one proceeds with the placement of a prosthesis (e.g., a pre-formed mesh with a memory ring) in the various locations of existing or potential defects and, after verifying a correct haemostasis, the surgeon sutures the external oblique aponeurosis and closes up the surgical intervention. As mentioned above, the prostheses currently known and used in the prior art are not suitable, namely because the rings have discontinuations (breaks) in them or it is necessary to make such discontinuations during surgery, particularly when operating on male patients.

A continuous ring increases the memory effect, as well as a more medial placement does not interfere with the subaponeurotic placement of the external part of the prosthesis, which enables a better adjustment to the new surgical technique described above that is used by the inventors, as well as a reduction of some complications resulting from the format of the prosthesis ring shown in document WO2006/034117.

The new surgical technique developed by the inventors, which is not yet part of the state of the art because it has not been publically disclosed, can not only be optimized with the prosthesis of the present invention but also vice-versa.

Disclosure of Invention

The present invention consists of an implantable prosthesis for the repair and prevention of hernias (indirect and direct inguinal or femoral hernias).

Said implantable prosthesis comprises at least one piece of mesh attached to at least one support element which serves to provide said piece of mesh with resilience/memory properties. The resilience/memory (biasing) properties enable the implantable prosthesis to be deformed and then return to its initial shape and thus maintain the piece of mesh connected to the support element stretched.

Said support element may be connected to the piece of mesh by several alternative fixing means, provided that they do not affect the health of the patient or the ability to perform the surgery. The fixing means that are currently considered most suitable include gluing with specific glues, vulcanization, adhesiveness, impregnation or sewing.

The piece of mesh is shaped in the format of a deformed water drop, with one of the extremities being wider then the opposing extremity. The main surface area of the piece of mesh shaped like a deformed water drop borders the wider extremity and is essentially ellipsoid.

The purpose of said main surface area of the piece of mesh shaped like a deformed water drop is to cover at least part of an aperture or defect in the muscle wall (i.e., hernia) of the patient.

The wider extremity of the piece of mesh (1) has an internal angle larger than the external angle of the narrower extremity, and the internal border of the narrower extremity and external border of the wider extremity have different convexities. In other words, the wider extremity is generally obtuse and the narrower extremity is acute.

In a specific embodiment of the invention, it is also foreseen that the piece of mesh also have a cephalic axial extension, which serves to be placed over possible apertures or defects of the muscle wall above the inguinal floor. Aside from this cephalic axial extension, said piece of mesh has another laterocaudal extension, the purpose of which is to be placed over crural hernias and therefore prevent and/or correct them.

In a specific preferred embodiment, the piece of mesh (1) is asymmetric both on its major (x) and minor axis (y), and has two slight indentations, one positioned between the aforementioned cephalic axial and latero-caudal extensions and another medial in relation to the interior angle of the wider extremity.

The shape of the piece of mesh on its more medial side is also designed to prevent potential relapses in the most common location, which is the most inferior and internal and, therefore, in a preferred embodiment of the invention, said piece of mesh extends beyond the support element so that its adjustment to the location to be corrected is even

better. The piece of mesh is flat and can be inverted so that it can be applied both on the right and the left sides of the patient. However, one should note that in other embodiments of the invention, the piece of mesh may adopt other shapes (e.g., concave or convex or other more complex shapes) provided that it enables a perfect adjustment to the location where it will be placed.

The piece of mesh can be made of any absorbable and/or non-absorbable woven net that allows the maintenance of the necessary properties for the correction of the herniary defect and also the maintenance of the malleability characteristics for its comfortable use, both during and after implantation. In a particularly preferred embodiment of the invention, said woven net is made of single filaments of polypropylene. As is known in the prior art, this material, when implanted, promotes rapid tissue growth through its pores and around the net of the mesh. Other materials may be used in the manufacture of the mesh such as BARD MESH® (sold by C.R. Bard, Inc.), SOFT TISSUE PATCH® (micro-porous ePTFE sold by W.L. Gore & Associates, Inc.), SURGIPRO® (sold by US Surgical, Inc.), PROLENE® e MERSILENE® (sold by Ethicon,Inc.).

As will be evident to a skilled person in the art, the size of the piece of mesh may vary and the dimensions of the prosthesis are not a fundamental aspect for the comprehension of the invention. In general, and taking into consideration the average size of the adult body of a human male and female, the size of the piece of mesh should be between 14 to 17 cm along its longest (major) axis and 8 to 10 cm along its shortest (minor) axis. In a particularly preferred embodiment of the invention, the piece of mesh should have a length of approximately 14.7 cm along its

longest (major) axis and approximately 8.8 cm along its shortest (minor) axis. For embodiments of the present invention designed for the female sex or for smaller pelvises, the piece of mesh shall be approximately 16.2 cm along its longest (major) axis and approximately 9.7 cm along its shortest (minor) axis.

The support element is shaped in the form of a continuous (uninterrupted) ring. The purpose of the support element is to maintain the piece of mesh stretched, but also to provide the implantable prosthesis with properties that enable it to be deformed and then return to its initial shape. This characteristic is fundamental for the handling of the prosthesis when it implanted in the location where the hernia is to be repaired. The support element returns to its initial shape either automatically or by applying an external force. This elasticity forces the piece of mesh to remain open after it has been placed in its final destination in the patient's body.

The support element in the shape of a ring does not need to be a perfect (regular) ring. In other embodiments of the invention, the support element may be an ellipsoid ring, an ovoid ring or a geometric angled biasing structure capable of providing tension, such as, for example, a polygon with six or more sides.

The support element substantially surrounds a portion of the main surface of the piece of mesh shaped like a deformed water drop.

The support element shall have an indentation. The purpose of the indentation is to receive the inguinal cord or another structure and, in that way, protect and house that

structure of the patient's body. The indentation also aims to limit an area where, if necessary, an incision can be made on said piece of mesh. Said indentation of the support element should be concave and directed towards the centre of the support element (ring) of the piece of mesh.

In a preferred embodiment of the invention, the support element is fixed to the piece of mesh so that the base of the indentation existing on the support element generally faces the narrower extremity of said piece of mesh.

In a preferred embodiment of the invention, the support element should be a filament (monofilament). It is possible, however, to foresee alternatives with more than one filament. Said support element should be made of either an absorbable or non-absorbable biasing (with memory) material, capable of being deformed and then resuming its previous shape, so as to maintain the piece of mesh stretched. In particularly preferred embodiment of the invention, the support element shall be made of extruded polydioxanone (PDO), polyglatin (e.g., VICRLY® sold by Ethicon, Inc.) or polyglycolic acid (e.g., DEXON® sold by US Surgical, Inc.). This list of materials should be understood as being non-limitative, since other materials (for example materials derived from collagen) may also be used provided they possess the above mentioned characteristics.

The diameter of the support element should be sufficient to ensure that the properties of resilience and elasticity. In a preferred embodiment, the diameter of the support element should up to 2.00 mm and, in an even more preferred embodiment, the diameter of the support element should be 1.20 mm.

In an alternative embodiment of the invention, there is a second piece of mesh. This second piece of mesh may or may not have a shape identical to the piece of mesh described above (hereinafter, the "first piece of mesh").

In a specific preferred embodiment of this alternative embodiment of the invention, said second piece of mesh will have an essentially ovoid shape which, when placed on said first piece of mesh, will be capable of partially accompanying the exterior border of the principal area of said first piece of mesh.

In another specific preferred embodiment, the second piece of mesh has a configuration similar to that of the support element only wider.

As in the case of the first piece of mesh, the second piece of mesh shall consist of a woven net made either of an absorbable or non-absorbable material.

The second piece of mesh is attached to said first piece of mesh, one on top of the other, so that the contours of the second piece of mesh essentially accompany the exterior border of the main surface area of said first piece of mesh shaped like a deformed water drop, thus creating an area of the prosthesis with two layers of mesh.

In this alternative embodiment, the support element is fixed (sandwiched) in between the first and second pieces of mesh. The support element may be fixed in any way that ensures its deformability with memory (elasticity) and does not harm the health of the patient. In a particularly preferred embodiment of the invention, the support element is sewn in between the first and second pieces of mesh

using stitches of either an absorbable and/or non-absorbable monofilament material, such as polypropylene,(PFTE), amongst other materials available in the market.

The stitches are made along the inner and outer borders of all or part of the length of the support element. Preferably, the stitches are made using a specific programmable sewing machine that enables the sewing of the two pieces of mesh with great detail, thus ensuring that the three components (first and second pieces of mesh and the support element) form a unified whole that maintains the deformability with memory properties (i.e., elasticity).

The embodiments of the invention mentioned above are based on the concept of an implantable prosthesis that is essentially flat (plane). However, it is possible to design the prosthesis in different shapes and sizes so as to address more easily the correction of herninary defects, particularly in inguinal hernias. Consequently, the prosthesis of the present invention may be shaped so that it has a concave or convex shape or any other complex shape.

The major advantage of the implantable prosthesis of the present invention is that it does not require any grasping or fixing means to the body structures in the inguinal region. Indeed, in addition to the accommodation of the spermatic cord, which is not retained to or by any structure but is merely adjusted, there is no need for any sutures to maintain the prosthesis in the desired location (i.e. the present invention presents a truly tension-free solution). This does not mean that the surgeon can not employ some sutures with absorbable or non-absorbable threads or other fixing means should he so deem necessary.

The prosthesis of the present invention is the ideal medical device to complement the new surgical technique also invented by the inventors.

An additional advantage of the prosthesis of the present invention is the fact that it does not have a discontinuation (break) in the support element. By not having any discontinuation (break), it is possible to maintain the deformability and elasticity properties, whilst simultaneously avoiding the overlapping or folding of the support element's extremities in the section of the discontinuation (break).

Another advantage of the implantable prosthesis of the present invention is the fact that it does not require any reinforcements in any of its areas or sections, as is the case with many other prostheses of the prior art.

The implantable prosthesis of the present invention is suitable for inguinal hernias that manifest themselves in persons of both sexes, irrespectively of their classification, and is adequate for potential and existing defects in the inguinal floor.

Brief Description of Drawings

The present invention will be described below in more detail, by making reference to a preferred embodiment of the invention as shown in the attached drawings, said preferred embodiment being presented as an example and not to be interpreted as having any limitative effect on the scope of protection. Accordingly:

Figure 1 shows an overall perspective view of an implantable prosthesis with the support element (2) fixed to the first piece of mesh (1);

Figure 2 shows an overall perspective view of the implantable prosthesis with the two pieces of mesh (1 and 3), where it is possible to see the major (x) and minor (y) axis, as well as the area that may be cut(4) when treating inguinal hernias in patients of the male sex;

Figure 3 shows a top view of the first piece of mesh (1);

Figure 4 shows a top view of the second piece of mesh (3);

Figure 5 shows a top view of the support element (2);

Figure 6 shows a section view of area (5) of Figure 2, illustrating the manner in which the second piece of mesh (3) is sewn to the first piece of mesh (1), with two continuous lines of stitching (6), one internal and the other external to the support element (2), so that said support element is free within the tunnel that is formed by the two pieces of mesh;

Figure 7 shows a perspective view of the implantable prosthesis with all the components (1, 2 and 3) spatially separated although placed "in loco" in different planes.

Best Mode for Carrying Out the Invention

By making reference to the drawings, a preferred embodiment of the invention will now be described below.

As illustrated in Figure 1, the implantable prosthesis comprises a first piece of mesh (1) connected to a support element (2) capable of providing properties of resilience/elasticity to said first piece of mesh (1).

The first piece of mesh (1) consists of a woven net made of a non-absorbable material. Said first piece of mesh (1) is shaped like a deformed water drop, asymmetric on its major (horizontal) or minor (vertical) axis, having one wider extremity and another opposite narrower extremity, with the main surface area of the first piece of mesh (1) having an essentially ellipsoid shape.

It is also foreseen that the first piece of mesh (1) have an axial cephalic extension. In addition to this, it is foreseen that first piece of mesh (1) also have another latero caudal extension.

The internal and external borders of said extremities have different convexities.

Making reference to Figure 1, the lower extremity of the first piece of mesh (1) has an internal angle larger than the external angle of the opposite extremity. In other words, the lower (wider) extremity is generally obtuse and the top (narrower) extremity is acute.

The first piece of mesh (1) also has two slight indentations, one between the axial cephalic and latero caudal extensions and another medial in relation to the lower interior angle.

The first piece of mesh (1) is flat and capable of being inverted, so that it can be applied both on the right and left side of the patient.

The first piece of mesh (1) for an adult male shall have a length of 14.7 cm along its major (largest) axis and

approximately 8.8 cm along its minor (shortest) axis. In embodiments for adult females or pelvises of smaller dimensions, the piece of mesh shall be 6.2 cm along its major (longest) axis and 9.7 cm along its minor (shortest) axis.

The support element (2) is shaped as a continuous ellipsoidal ring, with a concave indentation facing towards the centre of the ring.

When said ring is fixed to said first piece of mesh, the base of the indentation faces opposite to the narrower extremity of the first piece of mesh (1).

The support element (2) is preferably made from re-absorbable material (for example a monofilament of extruded polydioxanone), with a diameter of 1.20 mm.

Said indentation of the support element (2) seeks to limit an area (4) where, if necessary, an incision can be made in the first piece of mesh (1). There are no reinforcements of the prosthesis in any of its parts (and none are needed).

The support element (2) is fixed to the first piece of mesh (1) by means of a second piece of mesh (3).

The shape of the second piece of mesh (3) is similar to that of the support element (2) only flat and wider and, when placed over the first piece of mesh (1), follows partially the exterior contour of the first piece of mesh (1).

The second piece of mesh (3) may be made of the same material as the first piece of mesh (1) or of another

absorbable or non absorbable material. The second piece of mesh (3) is sewn to the first piece of mesh (1), one on top of the other, with two continuous lines of stitching (6) in absorbable material, one external and the other internal in relation to the support element (2), thus enabling the support element (2) to remain free within a tunnel that is formed in between the two pieces of mesh (1 and 3).

It should be understood that the above description can incorporate various modifications of the parts that make up the prosthesis of the present invention which are presented merely as examples of possible embodiments and should not be considered as in any way limiting the scope of protection that is sought, the latter being defined solely by the claims of the present patent application.

CLAIMS

1. An implantable prosthesis for the repair of inguinal and femoral hernias, the implantable prosthesis comprising: at least one piece of mesh (1) arranged to cover at least a portion of the hernia, at least one support element (2) attached to said piece of mesh (1), said support element (2) comprising at least one resilient, deformable biasing filament, characterized by said support element (2) being an uninterrupted tension providing ring surrounding a portion of said mesh (1) and further comprising an indentation directed towards the center of said ring.

2. The implantable prosthesis according to claim 1, characterized by the support element (2) being an ellipsoid ring.

3. The implantable prosthesis according to claim 1, characterized by the support element (2) being an ovoid ring.

4. The implantable prosthesis according to claim 1, characterized by the support element (2) being a polygon with a number of sides equal or superior to six.

5. The implantable prosthesis according to claim 1, characterized by the piece of mesh (1) being shaped like a deformed water drop, whereby one of its extremities is wider than the opposing extremity, said piece of mesh (1) shaped like a deformed water drop

having a main surface area that borders the wider extremity and has an essentially ellipsoid shape.

6. The implantable prosthesis according to claim 5, characterized by the wider extremity of the piece of mesh (1) having an internal angle larger than the external angle of the opposing extremity, and the internal border of said opposing extremity and the external border of said wider extremity having different convexities.

7. The implantable prosthesis according to claim 5, characterized by the piece of mesh (1) further including a cephalic axial extension and a latero-caudal extension.

8. The implantable prosthesis according to claim 7, characterized by the piece of mesh (1) being asymmetric both on its major (x) and minor axis (y), and further including two slight indentations, one positioned between the cephalic axial and latero-caudal extensions and another medial in relation to the interior angle of the wider extremity.

9. The implantable prosthesis according to any of the preceding claims, characterized by the indentation of the support element (2) being essentially concave.

10. The implantable prosthesis according to claim 1, characterized by the fact that the support element (2) is attached to the piece of mesh (1) so that the base of the indentation faces the extremity opposite to the wider extremity of said piece of mesh (1).

11. The implantable prosthesis according to any of the preceding claims, characterized by the support element (2) being sandwiched between the piece of mesh (1) and a second piece of mesh (3).

12. The implantable prosthesis according to claim 11, characterized by one of the pieces of mesh being made of an absorbable material and the other of a non-absorbable material.

13. The implantable prosthesis according to claim 11, characterized by the second piece of mesh (3) having a shape similar to that of the support element (2) only wider.

14. The implantable prosthesis according to claim 11, characterized by the piece of mesh (1) being sewn to the second piece of mesh (3) with continuous stitches (6) of absorbable material, one external and the other internal in relation to the support element (2), said support element (2) remaining free within a tunnel formed between the piece of mesh (1) and the second piece of mesh (3).

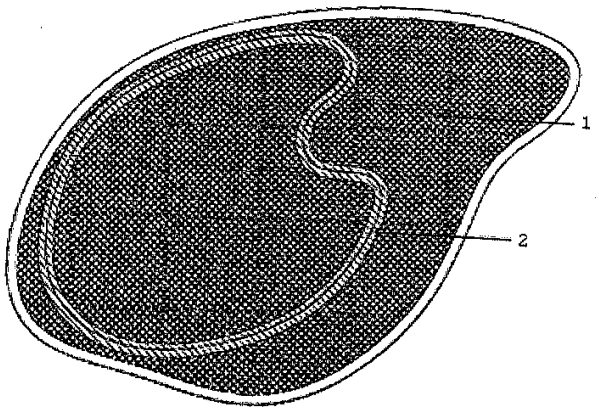


Fig. 1

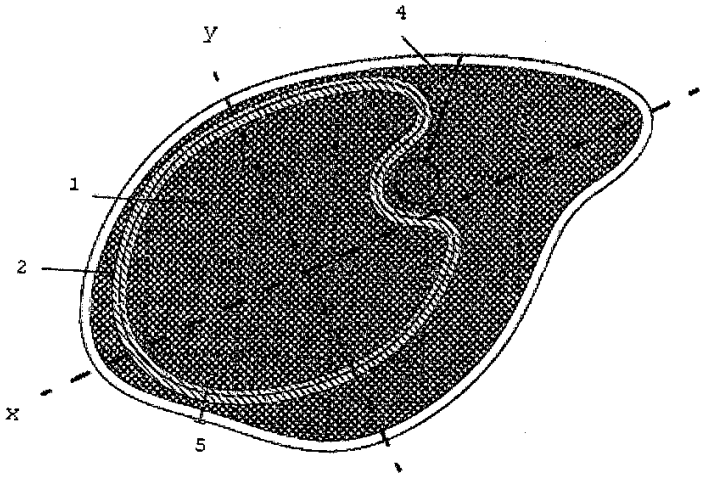


Fig. 2

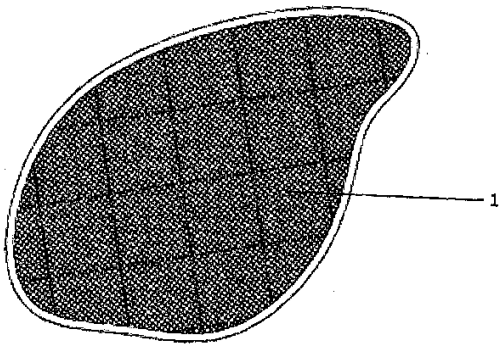
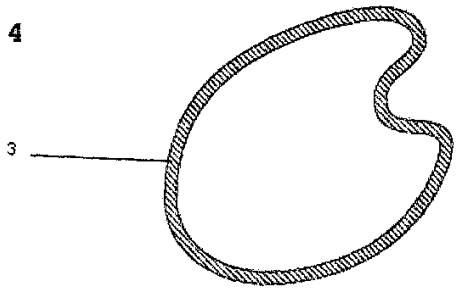


Fig. 3

Fig. 4



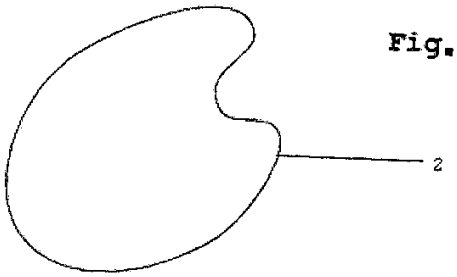


Fig. 5

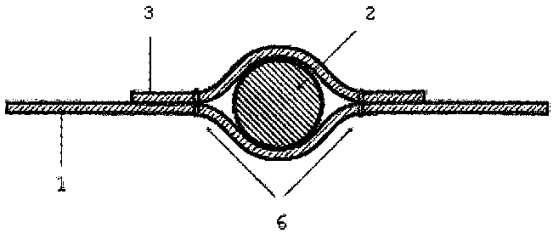


Fig. 6

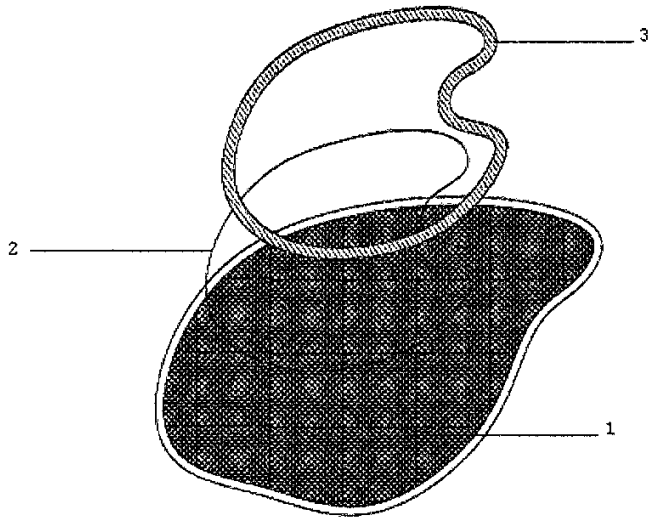


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/PT2012/000038

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 824 082 A (BROWN RODERICK B [US]) 20 October 1998 (1998-10-20) column 2, lines 36-62; figure 1 -----	1-4,9,10 5-8, 11-14
Y	US 2006/064175 A1 (PELISSIER EDOUARD [FR] ET AL) 23 March 2006 (2006-03-23) cited in the application paragraphs [0043], [0047], [0058] - [0060]; figure 1 -----	5-8
Y	WO 2006/053291 A2 (PROXY BIOMEDICAL LTD [IE]; GINGRAS PETER [IE]) 18 May 2006 (2006-05-18) page 16, lines 15-22 page 21, lines 16-20 figure 1h -----	11-14

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 December 2012	02/01/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Espuch, Antonio

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/PT2012/000038

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5824082 A	20-10-1998	DE 19830804 A1	06-05-1999
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		US 2006141012 A1	29-06-2006
		WO 2006053291 A2	18-05-2006

Form PCT/ISA/210 (patent family annex) (April 2005)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

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A61F 2/00 *(2006.01)*

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PCT/PT2012/000038

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WO 2013/048272 (04.04.2013 Gazette 2013/14)

(54) **IMPLANTABLE HERNIA PROSTHESIS WITH AN UNINTERRUPTED RING**

IMPLANTIERBARE LEISTENPROTHESE MIT EINEM UNUNTERBROCHENEN RING

PROTHÈSE HERNIAIRE IMPLANTABLE COMPORTANT UN ANNEAU D'UN SEUL TENANT

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **26.09.2011 PT 10590711**

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06.08.2014 Bulletin 2014/32

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WO-A2-2006/053291
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US-A1- 2006 064 175

Printed by Jouve, 75001 PARIS (FR)

EP 2 760 370 B1

Description

Technical Field

[0001] The present invention is related to an implantable prosthesis suitable for use in the correction and repair of hernias (indirect and direct inguinal or femoral hernias) without the need of fixing the prosthesis to any part of the body.

Background Art

[0002] For several decades, the preferred method of treating anatomical defects has been through the use of prosthetic materials of varied shapes and features. They are typically put and fixed into place by means of sutures, staples, tackers, biological glues or simply anchored on top of, below or on the defect. Tissue growth through the prosthetic mesh, which results from the body's reaction to a foreign object, then completes the repair.

[0003] In the specific case of inguinal hernias, the prosthesis typically consists of a mesh which is woven as a net of a specific fiber. Said prosthesis is put in the location to be treated and may then be cut and/or adjusted if necessary, so that its shape and size are perfectly adapted to the inguinal area where it will be implanted.

[0004] In patients of the male sex, so as to accommodate the spermatic cord, it is normally necessary to cut the prosthesis into two separate yet still attached leafs and then adapt them to the area so as to allow for the passage of said cord and the reinforcement of the internal inguinal ring. There are already today meshes that have these areas pre-cut and others which have the areas to be cut in surgery pre-defined on the prosthesis.

[0005] Document US5824082 describes a prosthesis for use in hernia repair surgery having a preformed prosthetic fabric supported along its periphery by shape memory alloy wire having a transformation temperature corresponding to normal body temperature allowing the prosthesis to be tightly rolled into a cylindrical configuration for delivery through a laparoscopic instrument and which deploys to a predetermined shape as it warms up to body temperature.

[0006] Patent document no. WO2006/034117 describes various embodiments of an implantable prosthesis which are similar to the present invention. The preferred embodiment described in patent document no. WO2006/034117 is a non-absorbable, ellipsoid and symmetric along its longest axis, implantable prosthesis with a non-continuous and non-absorbable ring which substantially follows the external border of the mesh with the exception of an indentation aimed at protecting the femoral vessels, said ring being attached by means of stitching on both sides of the ring all along its length, there being two reinforcements around the edges of the ring where it is discontinued so that these do not protrude out of the channel created by said sewing of the two layers of mesh. The implantable prosthesis described in patent document no. WO2006/034117 seems to have been designed in that way (i.e, having a discontinuous ring) so as to allow for the passage of the spermatic cord through the prosthesis during the treatment of indirect inguinal hernias.

[0007] The inventors of the present invention have determined that the surgery techniques for the treatment of inguinal hernias of the prior art are not the most suitable. Indeed, several advantages can be obtained if one opts for a new surgical technique developed by the inventors of the present invention and which consists of making a much higher entry incision, thus allowing for a much better access to the ideal location for placing prostheses of the abdominal wall and to the structures, as well as enabling an easier dissection of these, a large reduction of the risk of nerve damage, less aggressive impact and a reduction in post-operatory pain, as well as a significant reduction of the time of operation. The technique of this procedure involves a 3-4 cm transversal incision in the skin two fingers above the pubic symphysis, followed by a transversal incision of the external oblique aponeurosis (the only structure that is cut in the procedure) and a broad dissection of the pre-peritoneal area (Retzius space), the isolation of the structures of the spermatic cord, the identification of the Cooper ligament and the disruption of the Fascia Transversalis at that level. After this, one proceeds with the placement of a prosthesis (e.g., a preformed mesh with a memory ring) in the various locations of existing or potential defects and, after verifying a correct haemostasis, the surgeon sutures the external oblique aponeurosis and closes up the surgical intervention. As mentioned above, the prostheses currently known and used in the prior art are not suitable, namely because the rings have discontinuations (breaks) in them or it is necessary to make such discontinuations during surgery, particularly when operating on male patients.

[0008] A continuous ring increases the memory effect, as well as a more medial placement does not interfere with the subaponeurotic placement of the external part of the prosthesis, which enables a better adjustment to the new surgical technique described above that is used by the inventors, as well as a reduction of some complications resulting from the format of the prosthesis ring shown in document WO2006/034117.

[0009] The new surgical technique developed by the inventors, which is not yet part of the state of the art because it has not been publically disclosed, can not only be optimized with the prosthesis of the present invention but also vice-versa.

Disclosure of Invention

[0010] The present invention consists of an implantable prosthesis for the repair and prevention of hernias (indirect and direct inguinal or femoral hernias). The invention relates to a device as described in claim 1. Insofar as the terms "invention" and/or "embodiment" are used

in the following, and/or features are presented as being optional, this should be interpreted in such a way that the only protection sought is that of the invention as claimed.

[0011] Said implantable prosthesis comprises at least one piece of mesh attached to at least one support element which serves to provide said piece of mesh with resilience/memory properties. The resilience/memory (biasing) properties enable the implantable prosthesis to be deformed and then return to its initial shape and thus maintain the piece of mesh connected to the support element stretched.

[0012] Said support element may be connected to the piece of mesh by several alternative fixing means, provided that they do not affect the health of the patient or the ability to perform the surgery. The fixing means that are currently considered most suitable include gluing with specific glues, vulcanization, adhesiveness, impregnation or sewing.

[0013] The piece of mesh is shaped in the format of a deformed water drop, with one of the extremities being wider then the opposing extremity. The main surface area of the piece of mesh shaped like a deformed water drop borders the wider extremity and is essentially ellipsoid.

[0014] The purpose of said main surface area of the piece of mesh shaped like a deformed water drop is to cover at least part of an aperture or defect in the muscle wall (i.e., hernia) of the patient.

[0015] The wider extremity of the piece of mesh (1) has an internal angle larger than the external angle of the narrower extremity, and the internal border of the narrower extremity and external border of the wider extremity have different convexities. In other words, the wider extremity is generally obtuse and the narrower extremity is acute.

[0016] In a specific embodiment of the invention, it is also foreseen that the piece of mesh also have a cephalic axial extension, which serves to be placed over possible apertures or defects of the muscle wall above the inguinal floor. Aside from this cephalic axial extension, said piece of mesh has another laterocaudal extension, the purpose of which is to be placed over crural hernias and therefore prevent and/or correct them.

[0017] In a specific preferred embodiment, the piece of mesh (1) is asymmetric both on its major (x) and minor axis (y), and has two slight indentations, one positioned between the aforementioned cephalic axial and laterocaudal extensions and another medial in relation to the interior angle of the wider extremity.

[0018] The shape of the piece of mesh on its more medial side is also designed to prevent potential relapses in the most common location, which is the most inferior and internal and, therefore, in a preferred embodiment of the invention, said piece of mesh extends beyond the support element so that its adjustment to the location to be corrected is even better. The piece of mesh is flat and can be inverted so that it can be applied both on the right and the left sides of the patient. However, one should note that in other embodiments of the invention, the piece of mesh may adopt other shapes (e.g., concave or convex or other more complex shapes) provided that it enables a perfect adjustment to the location where it will be placed.

[0019] The piece of mesh can be made of any absorbable and/or non-absorbable woven net that allows the maintenance of the necessary properties for the correction of the herniary defect and also the maintenance of the malleability characteristics for its comfortable use, both during and after implantation. In a particularly preferred embodiment of the invention, said woven net is made of single filaments of polypropylene. As is known in the prior art, this material, when implanted, promotes rapid tissue growth through its pores and around the net of the mesh. Other materials may be used in the manufacture of the mesh such as BARD MESH® (sold by C.R. Bard, Inc.), SOFT TISSUE PATCH® (micro-porous ePTFE sold by W.L. Gore & Associates, Inc.), SURGIPRO® (sold by US Surgical, Inc.), PROLENE® e MERSILENE® (sold by Ethicon,Inc.).

[0020] As will be evident to a skilled person in the art, the size of the piece of mesh may vary and the dimensions of the prosthesis are not a fundamental aspect for the comprehension of the invention. In general, and taking into consideration the average size of the adult body of a human male and female, the size of the piece of mesh should be between 14 to 17 cm along its longest (major) axis and 8 to 10 cm along its shortest (minor) axis. In a particularly preferred embodiment of the invention, the piece of mesh should have a length of approximately 14.7 cm along its longest (major) axis and approximately 8.8 cm along its shortest (minor) axis. For embodiments of the present invention designed for the female sex or for smaller pelvises, the piece of mesh shall be approximately 16.2 cm along its longest (major) axis and approximately 9.7 cm along its shortest (minor) axis.

[0021] The support element is shaped in the form of a continuous (uninterrupted) ring. The purpose of the support element is to maintain the piece of mesh stretched, but also to provide the implantable prosthesis with properties that enable it to be deformed and then return to its initial shape. This characteristic is fundamental for the handling of the prosthesis when it implanted in the location where the hernia is to be repaired. The support element returns to its initial shape either automatically or by applying an external force. This elasticity forces the piece of mesh to remain open after it has been placed in its final destination in the patient's body.

[0022] The support element in the shape of a ring does not need to be a perfect (regular) ring. In other embodiments of the invention, the support element may be an ellipsoid ring, an ovoid ring or a geometric angled biasing structure capable of providing tension, such as, for example, a polygon with six or more sides.

[0023] The support element substantially surrounds a portion of the main surface of the piece of mesh shaped like a deformed water drop.

[0024] The support element shall have an indentation. The purpose of the indentation is to receive the inguinal cord or another structure and, in that way, protect and house that structure of the patient's body. The indentation also aims to limit an area where, if necessary, an incision can be made on said piece of mesh. Said indentation of the support element should be concave and directed towards the centre of the support element (ring) of the piece of mesh.

[0025] In a preferred embodiment of the invention, the support element is fixed to the piece of mesh so that the base of the indentation existing on the support element generally faces the narrower extremity of said piece of mesh.

[0026] In a preferred embodiment of the invention, the support element should be a filament (monofilament). It is possible, however, to foresee alternatives with more than one filament. Said support element should be made of either an absorbable or non-absorbable biasing (with memory) material, capable of being deformed and then resuming its previous shape, so as to maintain the piece of mesh stretched. In particularly preferred embodiment of the invention, the support element shall be made of extruded polydioxanone (PDO), polyglatin (e.g., VICRLY® sold by Ethicon, Inc.) or polyglycolic acid (e.g., DEXON® sold by US Surgical, Inc.). This list of materials should be understood as being non-limitative, since other materials (for example materials derived from collagen) may also be used provided they possess the above mentioned characteristics.

[0027] The diameter of the support element should be sufficient to ensure that the properties of resilience and elasticity. In a preferred embodiment, the diameter of the support element should up to 2.00 mm and, in an even more preferred embodiment, the diameter of the support element should be 1.20 mm.

[0028] In an alternative embodiment of the invention, there is a second piece of mesh. This second piece of mesh may or may not have a shape identical to the piece of mesh described above (hereinafter, the "first piece of mesh").

[0029] In a specific preferred embodiment of this alternative embodiment of the invention, said second piece of mesh will have an essentially ovoid shape which, when placed on said first piece of mesh, will be capable of partially accompanying the exterior border of the principal area of said first piece of mesh.

[0030] In another specific preferred embodiment, the second piece of mesh has a configuration similar to that of the support element only wider.

[0031] As in the case of the first piece of mesh, the second piece of mesh shall consist of a woven net made either of an absorbable or non-absorbable material.

[0032] The second piece of mesh is attached to said first piece of mesh, one on top of the other, so that the contours of the second piece of mesh essentially accompany the exterior border of the main surface area of said first piece of mesh shaped like a deformed water drop, thus creating an area of the prosthesis with two layers of mesh.

[0033] In this alternative embodiment, the support element is fixed (sandwiched) in between the first and second pieces of mesh. The support element may be fixed in any way that ensures its deformability with memory (elasticity) and does not harm the health of the patient. In a particularly preferred embodiment of the invention, the support element is sewn in between the first and second pieces of mesh using stitches of either an absorbable and/or non-absorbable monofilament material, such as polypropylene,(PFTE), amongst other materials available in the market.

[0034] The stitches are made along the inner and outer borders of all or part of the length of the support element. Preferably, the stitches are made using a specific programmable sewing machine that enables the sewing of the two pieces of mesh with great detail, thus ensuring that the three components (first and second pieces of mesh and the support element) form a unified whole that maintains the deformability with memory properties (i.e., elasticity).

[0035] The embodiments of the invention mentioned above are based on the concept of an implantable prosthesis that is essentially flat (plane). However, it is possible to design the prosthesis in different shapes and sizes so as to address more easily the correction of herninary defects, particularly in inguinal hernias. Consequently, the prosthesis of the present invention may be shaped so that it has a concave or convex shape or any other complex shape.

[0036] The major advantage of the implantable prosthesis of the present invention is that it does not require any grasping or fixing means to the body structures in the inguinal region. Indeed, in addition to the accommodation of the spermatic cord, which is not retained to or by any structure but is merely adjusted, there is no need for any sutures to maintain the prosthesis in the desired location (i.e. the present invention presents a truly tension-free solution). This does not mean that the surgeon can not employ some sutures with absorbable or non-absorbable threads or other fixing means should he so deem necessary.

[0037] The prosthesis of the present invention is the ideal medical device to complement the new surgical technique also invented by the inventors.

[0038] An additional advantage of the prosthesis of the present invention is the fact that it does not have a discontinuation (break) in the support element. By not having any discontinuation (break), it is possible to maintain the deformability and elasticity properties, whilst simultaneously avoiding the overlapping or folding of the support element's extremities in the section of the discontinuation (break).

[0039] Another advantage of the implantable prosthesis of the present invention is the fact that it does not require any reinforcements in any of its areas or sections, as is the case with many other prostheses of the prior art.

[0040] The implantable prosthesis of the present invention is suitable for inguinal hernias that manifest themselves in persons of both sexes, irrespectively of their classification, and is adequate for potential and existing defects in the inguinal floor.

Brief Description of Drawings

[0041] The present invention will be described below in more detail, by making reference to a preferred embodiment of the invention as shown in the attached drawings, said preferred embodiment being presented as an example and not to be interpreted as having any limitative effect on the scope of protection. Accordingly:

Figure 1 shows an overall perspective view of an implantable prosthesis with the support element (2) fixed to the first piece of mesh (1);
Figure 2 shows an overall perspective view of the implantable prosthesis with the two pieces of mesh (1 and 3), where it is possible to see the major (x) and minor (y) axis, as well as the area that may be cut (4) when treating inguinal hernias in patients of the male sex;
Figure 3 shows a top view of the first piece of mesh (1);
Figure 4 shows a top view of the second piece of mesh (3);
Figure 5 shows a top view of the support element (2);
Figure 6 shows a section view of area (5) of Figure 2, illustrating the manner in which the second piece of mesh (3) is sewn to the first piece of mesh (1), with two continuous lines of stitching (6), one internal and the other external to the support element (2), so that said support element is free within the tunnel that is formed by the two pieces of mesh;
Figure 7 shows a perspective view of the implantable prosthesis with all the components (1, 2 and 3) spatially separated although placed "in loco" in different planes.

Best Mode for Carrying Out the Invention

[0042] By making reference to the drawings, a preferred embodiment of the invention will now be described below.
[0043] As illustrated in Figure 1, the implantable prosthesis comprises a first piece of mesh (1) connected to a support element (2) capable of providing properties of resilience/elasticity to said first piece of mesh (1).
[0044] The first piece of mesh (1) consists of a woven net made of a non-absorbable material. Said first piece of mesh (1) is shaped like a deformed water drop, asymmetric on its major (horizontal) or minor (vertical) axis, having one wider extremity and another opposite narrower extremity, with the main surface area of the first piece of mesh (1) having an essentially ellipsoid shape.
[0045] It is also foreseen that the first piece of mesh (1) have an axial cephalic extension. In addition to this, it is foreseen that first piece of mesh (1) also have another latero caudal extension.
[0046] The internal and external borders of said extremities have different convexities.
[0047] Making reference to Figure 1, the lower extremity of the first piece of mesh (1) has an internal angle larger than the external angle of the opposite extremity. In other words, the lower (wider) extremity is generally obtuse and the top (narrower) extremity is acute.
[0048] The first piece of mesh (1) also has two slight indentations, one between the axial cephalic and latero caudal extensions and another medial in relation to the lower interior angle.
[0049] The first piece of mesh (1) is flat and capable of being inverted, so that it can be applied both on the right and left side of the patient.
[0050] The first piece of mesh (1) for an adult male shall have a length of 14.7 cm along its major (largest) axis and approximately 8.8 cm along its minor (shortest) axis. In embodiments for adult females or pelvises of smaller dimensions, the piece of mesh shall be 6.2 cm along its major (longest) axis and 9.7 cm along its minor (shortest) axis.
[0051] The support element (2) is shaped as a continuous ellipsoidal ring, with a concave indentation facing towards the centre of the ring.
[0052] When said ring is fixed to said first piece of mesh, the base of the indentation faces opposite to the narrower extremity of the first piece of mesh (1).
[0053] The support element (2) is preferably made from re-absorbable material (for example a monofilament of extruded polydioxanone), with a diameter of 1.20 mm.
[0054] Said indentation of the support element (2) seeks to limit an area (4) where, if necessary, an incision can be made in the first piece of mesh (1). There are no reinforcements of the prosthesis in any of its parts (and none are needed).
[0055] The support element (2) is fixed to the first piece of mesh (1) by means of a second piece of mesh (3).
[0056] The shape of the second piece of mesh (3) is similar to that of the support element (2) only flat and wider and, when placed over the first piece of mesh (1), follows partially the exterior contour of the first piece of mesh (1).
[0057] The second piece of mesh (3) may be made of the same material as the first piece of mesh (1) or of another absorbable or non absorbable material. The second piece of mesh (3) is sewn to the first piece of mesh (1), one on top of the other, with two continuous lines of stitching (6) in absorbable material, one external and the other internal in relation to the support element (2), thus enabling the support element (2) to remain free within a tunnel that is formed in between the two pieces of mesh (1 and 3).
[0058] It should be understood that the above description can incorporate various modifications of the parts that make up the prosthesis of the present invention

which are presented merely as examples of possible embodiments and should not be considered as in any way limiting the scope of protection that is sought, the latter being defined solely by the claims of the present patent application.

Claims

1. An implantable prosthesis for the repair of inguinal and femoral hernias, the implantable prosthesis comprising: at least one piece of mesh (1) arranged to cover at least a portion of the hernia, at least one support element (2) attached to said piece of mesh (1), said support element (2) comprising at least one resilient, deformable biasing filament, said support element (2) being an uninterrupted tension providing ring surrounding a portion of said mesh (1) and further comprising an indentation directed towards the center of said ring, **characterised in that** said the at least one piece of mesh (1) is shaped like a deformed water drop, whereby one of its extremities is wider than the opposing extremity, said at least one piece of mesh (1) having a main surface area that borders the wider extremity and having an essentially ellipsoid shape, the support element (2) being attached to the piece of mesh (1) so that the base of the indentation faces the extremity opposite to the wider extremity of said piece of mesh (1).

2. The implantable prosthesis according to claim 1, **characterized by** the support element (2) being an ellipsoid ring.

3. The implantable prosthesis according to claim 1, **characterized by** the support element (2) being an ovoid ring.

4. The implantable prosthesis according to claim 1, **characterized by** the support element (2) being a polygon with a number of sides equal or superior to six.

5. The implantable prosthesis according to any preceding claim, **characterized by** the wider extremity of the piece of mesh (1) having an internal angle larger than the external angle of the opposing extremity, and the internal border of said opposing extremity and the external border of said wider extremity having different convexities.

6. The implantable prosthesis according to any preceding claim, **characterized by** the piece of mesh (1) further including a cephalic axial extension and a latero-caudal extension.

7. The implantable prosthesis according to claim 6, **characterized by** the piece of mesh (1) being asymmetric both on its major (x) and minor axis (y), and further including two slight indentations, one positioned between the cephalic axial and latero-caudal extensions and another medial in relation to the interior angle of the wider extremity.

8. The implantable prosthesis according to any of the preceding claims, **characterized by** the indentation of the support element (2) being essentially concave.

9. The implantable prosthesis according to any of the preceding claims, **characterized by** the support element (2) being sandwiched between the piece of mesh (1) and a second piece of mesh (3).

10. The implantable prosthesis according to claim 9, **characterized by** one of the pieces of mesh being made of an absorbable material and the other of a non- absorbable material.

11. The implantable prosthesis according to claim 9, **characterized by** the second piece of mesh (3) having a shape similar to that of the support element (2) only wider.

12. The implantable prosthesis according to claim 9, **characterized by** the piece of mesh (1) being sewn to the second piece of mesh (3) with continuous stitches (6) of absorbable material, one external and the other internal in relation to the support element (2), said support element (2) remaining free within a tunnel formed between the piece of mesh (1) and the second piece of mesh (3).

Patentansprüche

1. Implantierbare Prothese zum Reparieren von Inguinal- und Femoralhernien, wobei die implantierbare Prothese Folgendes umfasst: mindestens ein Stück Netz (1), das dazu angeordnet ist, mindestens einen Abschnitt der Hernie zu bedecken, mindestens ein Stützelement (2), das an dem Stück Netz (1) angebracht ist, wobei das Stützelement (2) mindestens ein elastisches, verformbares Vorspannfilament umfasst, wobei es sich bei dem Stützelement (2) um einen ununterbrochenen, Spannung bereitstellenden Ring handelt, der einen Abschnitt des Netzes (1) umgibt und weiter eine zur Mitte des Rings gerichtete Einbuchtung umfasst, **dadurch gekennzeichnet, dass** das mindestens eine Stück Netz (1) wie ein verformter Wassertropfen geformt ist, wodurch eines seiner Extremitäten breiter ist als die gegenüberliegende Extremität, wobei das mindestens eine Stück Netz (1) einen Hauptflächenbereich aufweist, der an die breitere Extremität grenzt und eine im Wesentlichen ellipsoide Form aufweist, wobei das Stützelement (2) derart an dem Stütz Netz

(1) angebracht ist, dass die Basis der Einbuchtung der der breiteren Extremität gegenüberliegenden Extremität des Stücks Netz (1) zugewandt ist.

2. Implantierbare Prothese nach Anspruch 1, **dadurch gekennzeichnet, dass** es sich bei dem Stützelement (2) um einen ellipsoiden Ring handelt.

3. Implantierbare Prothese nach Anspruch 1, **dadurch gekennzeichnet, dass** es sich bei dem Stützelement (2) um einen ovoiden Ring handelt.

4. Implantierbare Prothese nach Anspruch 1, **dadurch gekennzeichnet, dass** es sich bei dem Stützelement (2) um ein Vieleck mit einer Anzahl von Seiten handelt, die gleich oder größer als sechs ist.

5. Implantierbare Prothese nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, dass** die breitere Extremität des Stücks Netz (1) einen inneren Winkel aufweist, der größer ist als der äußere Winkel der gegenüberliegenden Extremität, und die innere Grenze der gegenüberliegenden Extremität und die äußere Grenze der breiteren Extremität unterschiedliche Konvexitäten aufweisen.

6. Implantierbare Prothese nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, dass** das Stück Netz (1) weiter eine kephalische axiale Ausdehnung und eine laterocaudale Ausdehnung aufweist.

7. Implantierbare Prothese nach Anspruch 6, **dadurch gekennzeichnet, dass** das Stück Netz (1) sowohl auf seiner Haupt(x)-Achse als auch seiner Neben(y)-Achse asymmetrisch ist, und weiter zwei geringfügige Einbuchtungen aufweist, von denen eine zwischen der kephalischen axialen und der laterocaudalen Ausdehnung und eine andere medial in Bezug auf den inneren Winkel der breiteren Extremität positioniert ist.

8. Implantierbare Prothese nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, dass** die Einbuchtung des Stützelements (2) im Wesentlichen konkav ist.

9. Implantierbare Prothese nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, dass** das Stützelement (2) sandwichartig zwischen dem Stück Netz (1) und einem zweiten Stück Netz (3) angeordnet ist.

10. Implantierbare Prothese nach Anspruch 9, **dadurch gekennzeichnet, dass** eines der Stücke Netz aus einem absorbierbaren Material und das andere aus einem nicht absorbierbaren Material hergestellt ist.

11. Implantierbare Prothese nach Anspruch 9, **dadurch gekennzeichnet, dass** das zweite Stück Netz (3) eine Form aufweist, die der des Stützelements (2) ähnlich, aber breiter ist.

12. Implantierbare Prothese nach Anspruch 9, **dadurch gekennzeichnet, dass** das Stück Netz (1) mit durchgehenden Nähten (6) aus absorbierbarem Material, von denen eine außenliegend und eine innenliegend in Bezug auf das Stützelement (2) ist, an das zweite Stück Netz (3) genäht ist, wobei das Stützelement (2) in einem zwischen dem Stück Netz (1) und dem zweiten Stück Netz (3) gebildeten Tunnel frei bleibt.

Revendications

1. Prothèse implantable pour la réparation d'hernies inguinales et fémorales, la prothèse implantable comprenant : au moins une pièce de filet (1) disposée pour couvrir au moins une partie de la hernie, au moins un élément de support (2) attaché à ladite pièce de filet (1), ledit élément de support (2) comprenant au moins un filament de sollicitation résilient, déformable, ledit élément de support (2) étant un anneau ininterrompu exerçant une tension qui entoure une partie dudit filet (1) et comprenant en outre une indentation dirigée vers le centre dudit anneau, **caractérisée en ce que** ladite au moins une pièce de filet (1) est conformée en goutte d'eau déformée, si bien que l'une de ses extrémités est plus large que l'extrémité opposée, ladite au moins une pièce de filet (1) ayant une superficie principale qui borde l'extrémité plus large et ayant une forme essentiellement ellipsoïde, l'élément de support (2) étant attaché à la pièce de filet (1) de telle sorte que la base de l'indentation soit tournée vers l'extrémité opposée à l'extrémité plus large de ladite pièce de filet (1).

2. Prothèse implantable selon la revendication 1, **caractérisée en ce que** l'élément de support (2) est un anneau ellipsoïde.

3. Prothèse implantable selon la revendication 1, **caractérisée en ce que** l'élément de support (2) est un anneau ovoïde.

4. Prothèse implantable selon la revendication 1, **caractérisée en ce que** l'élément de support (2) est un polygone ayant un nombre de côtés égal ou supérieur à six.

5. Prothèse implantable selon l'une quelconque des revendications précédentes, **caractérisée en ce que** l'extrémité plus large de la pièce de filet (1) à un angle interne supérieur à l'angle externe de l'extrémité opposée, et la bordure interne de ladite extré-

mité opposée et la bordure externe de ladite extrémité plus large ont des convexités différentes.

6. Prothèse implantable selon l'une quelconque des revendications précédentes, **caractérisée en ce que** la pièce de filet (1) comporte en outre une extension axiale céphalique et une extension latéro-caudale.

7. Prothèse implantable selon la revendication 6, **caractérisée en ce que** la pièce de filet (1) est asymétrique à la fois sur son axe majeur (x) et son axe mineur (y), et comportant en outre deux légères indentations, une positionnée entre les extensions axiale céphalique et latéro-caudale et une autre médiale relativement à l'angle intérieur de l'extrémité plus large.

8. Prothèse implantable selon l'une quelconque des revendications précédentes, **caractérisée en ce que** l'indentation de l'élément de support (2) est essentiellement concave.

9. Prothèse implantable selon l'une quelconque des revendications précédentes, **caractérisée en ce que** l'élément de support (2) est pris en sandwich entre la pièce de filet (1) et une seconde pièce de filet (3).

10. Prothèse implantable selon la revendication 9, **caractérisée en ce que** l'une des pièces de filet est réalisée en un matériau absorbable et l'autre en un matériau non absorbable.

11. Prothèse implantable selon la revendication 9, **caractérisée en ce que** la deuxième pièce de filet (3) a une forme semblable à celle de l'élément du support (2) mais simplement plus large.

12. Prothèse implantable selon la revendication 9, **caractérisée en ce que** la pièce de filet (1) est cousue sur la seconde pièce de filet (3) avec des points continus (6) de matériau absorbable, l'une externe et l'autre interne relativement à l'élément de support (2), ledit élément de support (2) restant libre à l'intérieur d'un tunnel formé entre la pièce du filet (1) et la seconde pièce de filet (3).

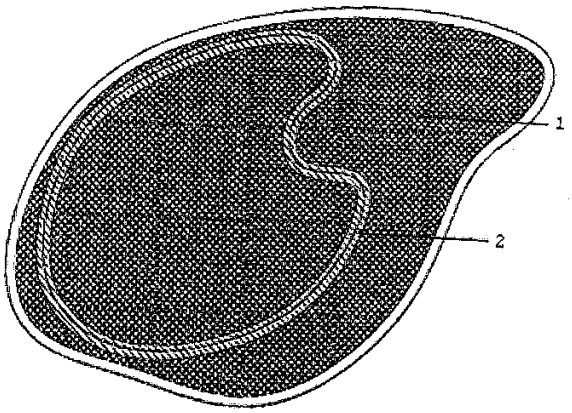


Fig. 1

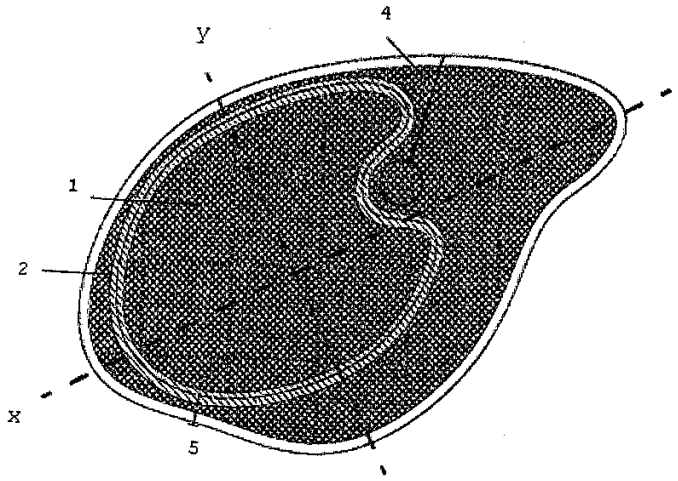


Fig. 2

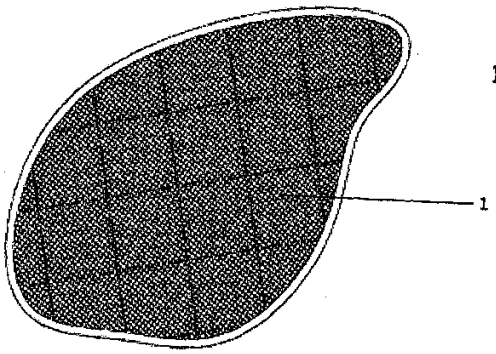
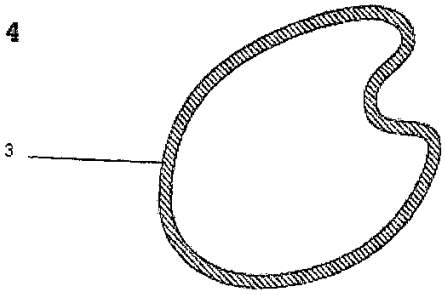


Fig. 3

Fig. 4



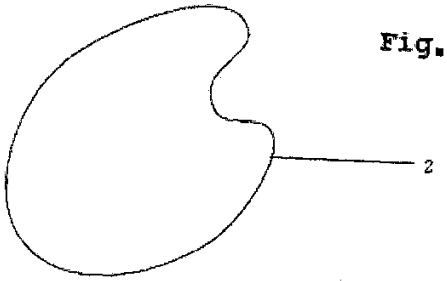


Fig. 5

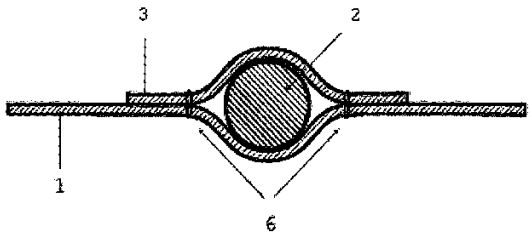


Fig. 6

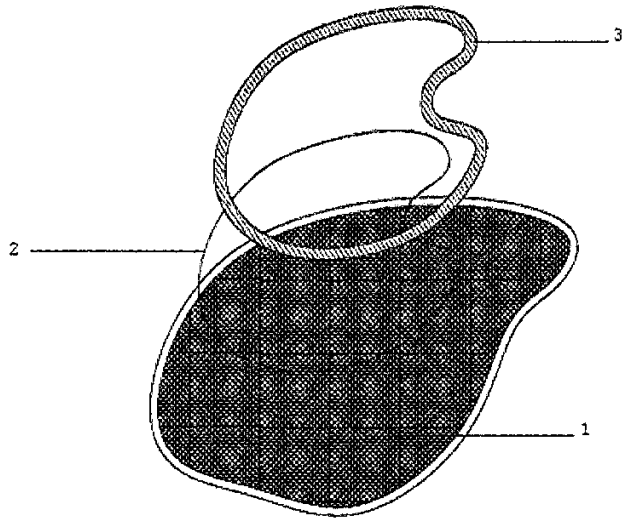


Fig. 7

REFERENCES CITED IN THE DESCRIPTION

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