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Research Article

Retrospective Study of 710 Patients Treated with 4DDome[®] Mesh: A New Chance for Open Inguinal Hernia Repair

Abstract

Introduction: Although mesh techniques are used with increasing frequency, they are correlated to major long-term complications such as chronic inguinal pain (8.6%) and recurrence (1.6-8.6%). It is due to a non-development of an ideal mesh, which simultaneously ensures inguinal wall strength and a lower inflammatory foreign body reaction, which also seems to be correlated to the use of a non-absorbable mesh.

Materials and methods: They were retrospectively analyzed from January 2007 to June 2014, 710 patients (103 women with mean age of 62, (14.54%) and 607 men with mean age of 51.8, (85.45%) underwent a surgical groin hernia repair. In 96 patients (13.66%), we used the dome only and in 614 patients (86.36%), both the dome and the onlay mesh were used for inguinal hernia repair. In all cases, we used a 4DDome[®] mesh (dome, lay patch) for reconstruction. This prosthesis is made of 10% light polypropylene and 90% absorbable poly-L-Lactic Acid (PLLA).

Results: Mean operative time was 45 minutes (range: 20-70 minutes). There were no intraoperative complications. The majority of patients were discharged after a mean time of 12 hours (range: 12-72 hours). In 12 (1.81%) cases, there were a subcutaneous hematoma and a seroma in one case.

Fifty (7.2%) patients presented with incisional scar swelling. There were no wound infections. These minor complications resolved within 1 month.

Three (0.42%) patients had chronic inguinal pain (>3 months). Five (0.70%) recurrent hernias were observed.

Conclusion: In our study, we observed an adequate mesh tolerance: the majority of patients did not present chronic pain at 1 year, except in 0.42% of cases, with a low rate or recurrence of only 0.70%. Postoperative stay was reduced with an immediate return to physical activities. Consequently, according to our initial experience, absorbable meshes for inguinal hernia repair seem stand.

Introduction

One of the first description of inguinal hernia was in an ancient egyptian medical text, the "Ebers Papyrus" dating to 1550 BC [1,2]. Since, the evolution of this disease has been chaotic until modern era.

It is interesting to note that for a common disease [2], a lot of different techniques have been proposed (open and laparoscopic approaches) using several devices (absorbable and non-absorbable) and different fixation procedures (stitches, fibrin glue, etc.) [3-5].

Although the use of mesh procedures is widespread all over the world, they are correlated with major long-term complications such as chronic inguinal pain (8.6-38.3%) [3,6,7] and recurrence (1.6-8.6%) [6]. While recurrence could be prevented since it is most specifically due to technical mistakes (mesh dimension and position), chronic pain, save from nerves injury, is caused by a reaction to mesh implantation.

An ideal mesh should simultaneously ensure inguinal wall strength as well as a lower inflammatory body reaction.

The heavyweight polypropylene (PP) mesh is strong and is able to compensate for intra-abdominal pressure. However, it stimulates inflammatory reaction responsible for mesh shrinkage when scar tissue evolves [5,8].

This cell-mediated reaction due to a foreign body (i.e., mesh), which could persist for a long period, involves all inguinal groin structures (vessels, nerves, deferent duct). This leads to a lot of complications such as chronic pain, neuritis, paresthesia, testicular atrophy, infertility (these last two complications occur in animal models) [3,5].

Consequently, the reduction of non-absorbable materials should decrease the inflammatory response but it cannot, due to parietal strength, which is essential for hernia recurrence prevention.

Additionally, shrinkage seems to be correlated to the amount of non-absorbable materials.

In our non-randomized study, we proposed to use a partially absorbable mesh, namely the 4DDome[®] mesh (Cousin Biotech) for

inguinal hernia repair as it seems to offer the two characteristics of an ideal mesh (less foreign body with a lower inflammatory response).

Materials and Methods

They were retrospectively analyzed from January 2007 to June 2014, 710 patients (103 women with mean age of 62, 14.54%; 607 men with mean age of 51.8, 85.45%) underwent a surgical groin hernia repair in our surgical department.

It was explained to all patients the type of intervention and the material used with authorization to perform the procedure.

All operations were carried out by the same surgical team with experienced surgeons. Almost all total hernias were primary ones, except for 22 (3.098%) cases, which were recurrences, 10 cases after laparoscopic repair, and 12 cases after open techniques. All cases were operated on under spinal anaesthesia, and only unilateral hernias were treated.

Femoral hernias and emergency operations were excluded.

In 81 patients (11.55%), we used only the 4DDome[®] mesh for inguinal hernia repair and in 15 (2.11%) only the plug. In the other 614 patients (86.36%), onlay mesh and plug were used.

The 4DDome[®]. It is a prosthesis which consists of a cap, with a structure in the shape of dome made in the same way and the mesh material. They provide a patch onlay reinforcement, composed of 10% light polypropylene and 90% Poly-L-lactic acid (PLLA). PLLA is an absorbable synthetic polymer of amino acid lactate, immunologically inert.

All patients were submitted to antibiotic therapy post-operating with cephalosporin (cefotaxime).

After the operation, all patients were controlled with a clinical examination at discharge, 10 days, 1 month, and at 1 year.

The surgical technique consists in an arcuate skin incision on the inguinal site with successive dissection of subcutaneous tissues and fascia. We usually open the external oblique muscle fascia in order to dissect the spermatic cord and the cremaster muscle, and to identify the deferent duct. After identifying them, the hernia sac is dissected and repositioned into the abdominal cavity (through the inguinal ring if it is an indirect hernia). Sometimes, when the sac is too big, it is closed with a stitch at the base. Maintaining the sac deeply, the 4DDome[®] mesh is placed to close the defect and it is fixed by means of 3 or 4 absorbable sutures, which are stitched to the edge of the inguinal ring or to the wall of the defect if there is a direct hernia. Finally, the mesh is placed around the spermatic cord on the transversalis fascia and it is fixed by means of one absorbable suture stitched to the pubic tubercle.

The external oblique muscle fascia, the subcutaneous layer, and the skin are re-approximated using an absorbable running suture.

Results

The mean operative time was 45 minutes (range: 20-70 minutes).

The majority of patients were discharged after a mean time of 12 hours (range: 12-72 hours).

In 12 cases (1.81%), there was a subcutaneous hematoma, which was treated conservatively in 8 cases. In 4 cases, it was necessary to perform surgery using site drainage and lavage. In one case, it was necessary to perform a laparotomy for a retroperitoneal bleeding due to an injury to left epigastric vessels. It was a nephropathic and cardiovascular patient presenting with cardiac transplantation and coagulation deficiency. In only one case (0.90%), a major persistent seroma was found in a patient who was surgically treated for prostate cancer. In 50 cases (7.2%), an incisional scar swelling was found with no wound infections.

In 27 cases (3,8%) of transitory hypoesthesia solved in 30 days.

In 5 cases (0.70%) persistent hypoesthesia and other 5 (0.70%) hyperaesthesia after three months and there is only one case (0.14%) of keloid skin.

These minor complications resolved spontaneously within one month. No problems were found at 1 year.

In 497 patients (70%), postoperative pain was present but disappeared after 10 days. Only in 25 cases (3.63%), postoperative pain disappeared within 3 months.

Three patients (0.42%) had chronic inguinal pain (> 3 months) with no functional limitation.

Only 5 (0.70%) recurrent hernias were observed. No infection was reported (Table 1).

Discussion

The use of the mesh has become common for the majority of surgeons, and thanks to the development of new materials, fewer recurrences occur but there is no ideal outcome in all patients managed. In several studies, the incidence of chronic inguinal pain reaches 30% with 15% of recurrence [3,6].

Recently, the Food and Drug Administration published major complications following hernia repair. According to this review, which included 252 events, the polypropylene mesh had more mechanical failures (80 vs. 14%; $p < 0.05$), the biomaterial mesh had more reactions (57 vs. 7%; $p < 0.05$), the PTFE/PP mesh had more infections (75 vs. 41%; $p = 0.07$). As a result, specific mesh materials are related to specific complications [9].

Table 1: Shows the percentage of complications in our study of 710 patients treated.

Complications	Patient N°	%
<i>Subcutaneous hematoma</i>	12	1,81
<i>Seroma</i>	1	0,90
<i>Incisional scar Swelling</i>	50	7,2
<i>Transitory Hypoaesthesia</i>	27	3,8
<i>Persistent Hypoaesthesia</i>	5	0,70
<i>Persistent Hyperaesthesia</i>	5	0,70
<i>Keloid skin</i>	1	0,14
<i>Relapse</i>	5	0,70
<i>Pain after 3 months</i>	3	0,42

In the recent past, the polypropylene (Prolene®) mesh was regarded as a “gold standard” in groin hernia repair [10]. Now, it is a subject of controversy because of fears concerning the long-term effects of their implantation.

As a matter of fact, in contrast to the strength of the inguinal wall, the mesh is responsible for a major foreign body inflammatory response. It appears with macrophage infiltration and proliferation, foreign body giant cell reaction, transient edema, angiogenesis conducive to mesh adherence to surrounding spermatic cord structures (vessels and nerves). This reaction could well persist for a long time. It is responsible for nerve injury and infertility in an experimental animal study [11-14].

In addition, inflammatory reaction is accountable for the well-known PP shrinkage when scar tissue evolves. The latter acts as 20% of the original mesh size [15]. Shrinkage is one of the causes of recurrence since mesh surface decreases and does not cover the defect.

Technical mistakes with inadequate mesh dimension and position represent other causes of recurrence.

On the other hand, it is not possible to prevent or reduce the amount of PP because of an increased risk of recurrence due to a significant loss in tensile strength as shown by Klosterhalfen.

Additionally, it is difficult to place a light mesh in situ.

Hence, it is very difficult to find the adequate balance between inguinal wall strength and a lower inflammatory body reaction.

The importance of material selection was demonstrated in the study by Weyhe where the surgical approach to hernia results in an independent prognostic factor for clinical outcome. In addition, mesh construction and composition (pore size and filament structure) appeared to be more important determinants of foreign body reaction than absolute material reduction of 1 gram or more per implant [14,15].

In their study, Champault et al., have demonstrated that chronic pain is not correlated to the surgical techniques. In fact, its incidence is the same in laparoscopic approaches and in Liechtenstein procedures (17.9% vs. 20.7%) while the comparison between Beta-D glucan-coated mesh and PP shows a lower incidence of chronic pain in the first (4.8%) vs. PP mesh (26.5%) [11,16].

To improve biocompatibility and safety, a large variety of newly developed meshes have been introduced on the marketplace. Nowadays, a lot of composite meshes are available. They combine absorbable components (polyglactin, poliglecaprone 25, PLLA) with standard PP. They present different scaffolds.

The aim of our study is to prevent two major complications, which have been described previously, using a new composite 4DDome® mesh (Cousin Biotech). We infer that these devices offer the best mesh quality: good tolerance thanks to absorbable PPLA (less inflammatory response) and a good inguinal wall strength.

The 4DDome® mesh is a prosthesis which consists of a plug, with a dome-shaped structure made in the same manner and material

as the mesh. They provide a reinforcement onlay patch, composed of 10% light polypropylene and 90% Poly-L-Lactic Acid (PLLA) [17-19]. PLLA is an absorbable synthetic polymer of amino acid lactate, immunologically inert (Figure 1). It is used in several medical products such as stitches and screws. It is also used to repair broken bones. It increases dermal thickness by causing a local reaction, leading to an increase in collagen deposits. It is eventually degraded and undergoes resorption.

The dome and mesh are pre-shaped, and it is available in three diameters, i.e., 24, 30, and 38mm; as a result, it should adapt to different hernia defects. In addition, they are designed to be implanted extra peritoneally.

The dimensional stability of the dome shape combined with the physiological absorption of PLLA first ensures that the hernia sac is well kept in place, and secondly that the transversalis fascia is strengthened thanks to the PLLA generating cellular fibrosis.

The property of PLLA has been analyzed and compared with PP in experimental animal studies [16,17].

They showed a lower inflammatory response in PLLA samples with less macrophage infiltration without angiogenesis and edema, weak activation of cell-mediated immunity, and consequently there is a better mesh tolerance. In fact, it does not present shrinkage as the mesh is significantly larger when retrieved at 8 weeks as opposed to the other one. A fibrotic reaction can be observed as it is due to a slow PLLA absorption.

In addition to this improved tolerance, the mesh only requires 1 month before it adheres to anatomical structures as compared to PP, which helps to prevent persistent pain.

In addition, the particular shape of the dome allows for a great support to the hernia defect. In fact, it presents a geodesic structure (struts arranged in a circle lying on the surface of a sphere), which creates local triangular rigidity and distributes tension; as a result, it is possible to reduce the PP amount of mesh onlay.

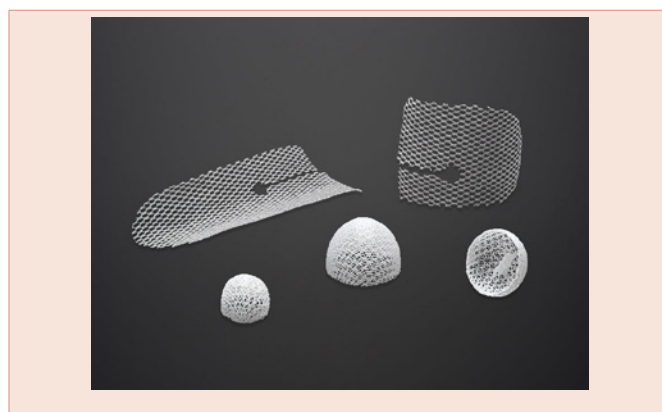


Figure 1: shows the 4DDome®. it is a prosthesis which consists of a cap, with a structure in the shape of dome made in the same way and the mesh material. They provide a patch onlay reinforcement, composed of 10% light polypropylene and 90% Poly-L-lactic acid (PLLA). PLLA is an absorbable synthetic polymer of amino acid lactate, immunologically inert.



Our study is supported only by clinical observations along with feelings and discomforts reported by our patients.

All patients underwent spinal anesthesia as it simultaneously ensures a better compliance of the patient (no intraoperative pain) and an appropriate approach to anatomical structures (no tissue dissociation edema due to anaesthetic infiltration).

Furthermore, the same surgical techniques were performed in all patients.

In indirect hernia, the sac is dissected until the inguinal ring. The 4DDome[®] mesh is placed in the defect, maintaining the sac deeply. We prefer to fix it using four non-absorbable 3/0 stitches to the resistant edge of the internal ring. The key is to position the slipped onlay mesh around the spermatic cord and ensure its fixation with non-absorbable sutures.

While in 15 (2.11%) direct hernia patients, we preferred to use the dome only in the same way as the sac is dissected up to the transversalis fascia. Thanks to its shape and its different sizes, the dome alone is able to cover the posterior defect. It is then fixed in the same way as described previously.

To easily ensure plug and mesh position, we perform a cylindrical dissection of cremasteric fibers.

Patients were controlled with a clinical examination at discharge, at 10 days, at 1 month, at 1 year. All patients were asked to stand up to 12 hours postoperatively and to live a life without any efforts during the first 10 days and to resume heavy activities no earlier than after one month.

It is interesting to note that all patients have a good mesh tolerance. The majority of them did not present chronic pain at 1 year, except in only 3 (3.63%) cases. Although initial postoperative pain was present in the majority of patients (70%), it was controlled with simple anti-inflammatory therapy (1 gram of Paracetamol x 3 p.o.), and pain disappeared within 10 days. Only in 25 (3.63%) cases, inguinal pain disappeared within 3 months using an anti-inflammatory therapy performed in alternating cycles with ketoprofen (200mg for 7 days x os), nimesulide (100mg x 2 for 10 days) or paracetamol (1 gram x 3 for 7 days x os) and rest. In such cases, we could anticipate an abnormal inflammatory response with compression of nerve structures if there were no objective signs of wound inflammation.

We did not have any explanation for 3 cases (0.42%) of chronic pain. These cases were without functional impairment and were treated with analgesic drugs as required. None were treated surgically.

In addition, biomaterial compliance is substantiated by the low presence of wound complications. Twelve subcutaneous hematomas (1.69%) developed in patients with anti-platelet and anti-coagulation therapy. They were treated conservatively in 8 cases. In 4 cases, it was necessary to perform a surgical procedure using site drainage and lavage in 3 cases, while in 1 case it was necessary to perform a laparotomy for a retroperitoneal bleeding due to an injury to left epigastric vessels. It was a nephropathic and cardiovascular patient with cardiac transplantation and coagulation deficiency. In only one case (0.90%), we had a major persisting seroma in a patient surgically

treated for prostate cancer. In 50 cases (7.2%), we found an incisional scar swelling with no wound infections. These minor complications resolved spontaneously within a month. No problems were found at 1 year.

While 50 cases (7.2%) only showed incisional scar swelling without inflammatory signs, it was potentially and merely due to a mesh reaction because all complications disappeared within one month spontaneously. No problems were found at 1 year. They did not require surgical treatment but only clinical control.

We have only 5 (0.70%) recurrent hernias controlled at one year after the operation, and all of these were treated by means of a laparoscopic trans abdominal preperitoneal approach (TAPP), which led to a complete resolution. No postoperative infection was observed.

Conclusion

This retrospective study has shown that the 4DDOME[®] is associated with a reduction in complications compared to those reported in the literature.

The results described have low incidence rates in the two main complications of inguinal hernia repair, which are chronic pain and recurrence (0.42 and 0.70%, respectively).

The combination of the domed shape and the bicomponent mesh including a part absorbable meet the opposing requirements of initial resistance with a low long-term weight material to minimize shrinkage and fibrosis.

However, we believe that our encouraging results (low recurrence rate, less chronic pain groin) requires further investigation.

This project represents a potential advance anterior tension-free hernia repair with mesh.

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