

Prostheses Used in Laparoscopic Inguinal Hernia Repair: Biocompatibility, Postoperative Complications and Quality of Life – Review of the Literature

Alexandra Florina TRANDAFIR^{a, c, d, *}, Dorin Eugen POPA^{a, c, e}, Danut VASILE^{b, c, d}

^aUniversity of Medicine and Pharmacy „Carol Davila” Bucharest, Romania

^bUniversity Emergency Hospital Bucharest, First Surgery Clinic, Romania

^cGeneral Hospital Värnamo, Sweden

ABSTRACT

Introduction: There is a continuous concern about meshes used in laparoscopic inguinal hernia repair, which mainly relates to their biocompatibility and ability to decrease postoperative complications and recurrence rate; in other words, efforts are made to find the “ideal” prosthesis.

Objectives: To evaluate different prostheses used in laparoscopic inguinal hernia repair in terms of biocompatibility, postoperative complications, recurrence rate and quality of life, so that all the features could lead us to the “ideal” mesh.

Material and method: Randomized controlled trials, reviews, prospective and retrospective studies, retrospective cross-sectional and experimental studies on animals published between 2000 and 2016 were analysed with respect to several features of a mesh: biocompatibility, postoperative complications, recurrence rate and quality of life.

Outcomes: The most common comparison is between heavy-weight and light-weight mesh used in laparoscopic inguinal hernia repair. Experimental studies try to discover the “ideal” prosthesis, which could provide improved biocompatibility, low postoperative complications, decreased recurrence rate and good quality of life. The most commonly used mesh that meets the characteristics of an “ideal” prosthesis is a light-weight monofilament macroporous polypropylene mesh, with a minimum tensile strength $>16 \text{ N/cm}^2$, measuring $10 \times 15 \text{ cm}$.

Conclusions: Published data show that the “ideal” prosthesis used in laparoscopic inguinal hernia repair has not been discovered yet. Regarding heavy- or light-weight meshes, there is no significant effect on recurrence, acute or chronic pain, incidence of seroma or return to daily activity and quality of life (1).

Keywords: prostheses, laparoscopic, inguinal hernia, biocompatibility, recurrence, quality of life

Address for correspondence:

Alexandra Trandafir, MD

Postal address: Mariuca Str, No 12, Bl 115, Sc. 2, Ap. 83, District 4, Bucharest, 042034, Romania

Phone: 0726600947

E-mail: alex_bele@yahoo.com

Article received on the 11th of March 2017 and accepted for publication on the 7th of September 2017.

INTRODUCTION

In the past sixty years, the use of prosthetic materials in inguinal hernia repair demonstrated that it is the only alternative for solving the parietal defects in optimal condition and with maximum efficiency.

There is a continuous concern about the prosthetic materials used in laparoscopic inguinal hernia repair (LIHR), which mainly relates to their biocompatibility, ability to decrease postoperative complications and incidence of recurrence rate, ease of application – in other words, the focus is on the “ideal” mesh.

For a prosthesis to be “ideal”, several features were proposed by Cumberland (2) and Scales (3) between 1952 and 1953, which have been recently reviewed by Hamer–Hodges and Scott (4). These could be resumed as follows: to keep its physical properties in tissue fluid environments, to be chemically inert, not to cause inflammatory reaction or foreign body sensation, to be non-carcinogenic, hypoallergenic, not to cause hypersensitivity, to be resistant to mechanical stress, to have the property of being cut into a desired shape without unravel and to be sterilized. Additional features include the ease of application, pliability and improved biocompatibility.

Our objective was to evaluate different types of prostheses used in LIHR in terms of biocompatibility, postoperative complications, recurrence rate and quality of life (QoL), so that all the features could lead us to the “ideal” prosthesis. □

MATERIAL AND METHOD

Reports of four randomized controlled trials, eight reviews, eight prospective studies, six retrospective studies, one retrospective cross-sectional study and three experimental studies on animals (two on pigs and one on rats), published between 2004 and 2016, were analysed with respect to features of a prosthesis that could lead to improved biocompatibility, lower postoperative complication and recurrence rates, and better QoL. □

OUTCOMES

There are many studies comparing different types of prostheses used in LIHR. The most common comparison is between heavy-weight

and light-weight meshes. There are also experimental studies that are trying to discover the “ideal” mesh in terms of improved biocompatibility, lower postoperative complications, decreased recurrence rate and good postoperative short- and long-term outcome.

Prosthetic materials were initially biological: autologous (external oblique muscle aponeurosis, fascia lata) and heterologous (bovine fascial grafts, bovine pericardium, porcine dermal collagen purified with trypsin). Almost simultaneously with biological prostheses, prostheses with metal thread (silver wire, gold plates, sponge rubber, tantalum, steel) were introduced into practice.

With the development of biochemical and biotechnology industries, polymers appeared to be a modern and accessible option for solving parietal defects, namely nonmetallic synthetic prostheses or high polymer plastics. These prostheses have been classified into three categories: non-absorbable, composites and preformed.

The non-absorbable meshes were divided according to the polymer base in polypropylene (example: Prolene, Vypro, Ultrapro, Ti-Mesh), polyethylene terephthalate (example: terylene or Dacron) and polytetrafluoroethylene (PTFE) (example: GoreTex, Dual Mesh), and in 1977 Amid elaborated a classification into four groups of common used materials according to their porosity (Table 1) (5).

The composite materials resulted from the combination of the polypropylene properties with those of PTFE (example: Parietex, Composix Mesh – Bard).

The preformed prostheses were split in three categories: flat (example: Bard 3D Max, Kugel Hernia Patch), plug and prosthetic system (PHS

Type	Description	Example
Type I	Total macro-porous prostheses with pore size > 75 µ in any of the three dimensions	Prolene, Composix
Type II	Total micro-porous prostheses with pore size < 10 µ in any of the three dimensions	PTFE, GoreTex, Dual Mesh
Type III	Total macro-porous prostheses with micro-porous multi-core components	MycroMesh, Surgipro
Type IV	Biomaterials with submicron pore size; can be used in association with type I and III, like composite materials for intra-peritoneal implantation	Silastic, Cellgrad

TABLE 1. Commonly used materials – Amid classification

– a polypropylene complex prosthetic system consisting of three parts: superior or onlay, inferior or underlay and the element that acts as a plug connector).

Nowadays there is a continuous concern about what type of mesh is the most suitable for use in LIHR, so that it could be considered “ideal”. Many studies comparing different types of meshes used in LIHR focused on biocompatibility, postoperative complications, recurrence rate and QoL. The most common comparison in almost all the studies is between heavy- and light-weight meshes. The International Endohernia Society reported that the classification into heavy- and light-weight meshes does not allow sufficient differentiation (6).

Types of prostheses and their features

I.1. Prolene/Ultrapro – Ethicon

It is a synthetic polypropylene mesh, light-weight, with large pores, containing less prosthetic material and producing less postoperative scarring of the abdominal wall (7).

In an article published in 2015 regarding the gold standard laparoscopic technique for hernias, the authors reported that a high percentage of polypropylene in the mesh was highly irritating and the inflammatory response could affect the visceral contents, causing adhesions (8).

I.2. Ti-Mesh

It is a polypropylene monofilament mesh coated with a thick layer of titanium, an extra-light-weight mesh. It allows for complete reperitonization with less inflammation, less irritation and final parietal rigidity and better safety. It is preferable for intra-peritoneal usage (8).

An experimental study on pigs (six pigs were used and the results were collected after 90 days) comparing the biocompatibility of Ti-Mesh with Dual Mesh concluded that titanium-coated polypropylene mesh was superior to Dual Mesh and suitable for laparoscopic intraperitoneal repair. The authors have also found that a reduction in amount of material and an increase in pore size resulted in better mesh biocompatibility (9).

I.3. PTFE (GoreTex, Dual Mesh)

It is a lightweight, pliable and soft mesh. It is a total microporous prosthesis with pore size smaller than 10 μ . It has good incorporation into

the tissue and general resistance to infection due to the incorporating antibacterial agents (silver and chlorhexidine) in the biomaterial. Given the formation of adhesions with intra-abdominal viscera and the potential erosion into the bowel, it cannot be placed intra-abdominally (10). Dual Mesh is an expanded PTFE (ePTFE) with two layers.

II. Composite mesh (Parietex – Covidien)

It is a polyester, light-weight, macroporous, hydrophilic mesh that promotes tissue ingrowth. It has a limiting prosthetic contraction when compared to a polypropylene mesh (11). The resorbable collagen layer prevents intra-peritoneal adhesions. It is anatomically pre-shaped and measures 10x15 cm. It can be adequately secured around the spermatic cord structures and offers a generous prosthetic overlap laterally to further prevent recurrence.

The authors of an article published in 2004 comparing two composite meshes, in an experimental study on pigs with laparoscopic ventral hernia repair, concluded that a collagen coated polyester mesh induced fewer adhesions than an ePTFE polypropylene composite. In addition, there is no difference in the ingrowth of the two mesh types (12).

The incidence of postoperative adhesions at three weeks, reported by Muller *et al.* in a comparative study, was 20% for Parietex, 50% for ePTFE and 78% for composite mesh (13).

III. Preformed mesh – Bard 3D Max

It is a plane, non-absorbable, large size pore polypropylene mesh, with an anatomical shape, already pre-cut and reinforced on the margins. It has a blue marker for the medial orientation, crest for the axis of inguinal ligament and inferior notch aligns with the external iliac vessels. These features allow an easier application and decrease the recurrence rate (14).

IV. Self-gripping mesh (Progrid)

It is a self-gripping light-weight mesh with large pore sizes (1.1–1.7 mm) composed of monofilament polyester and polylactic acid micro-grips. The immediate adherence to tissue is provided by resorbable micro-grips, and therefore additional fixation is not needed any more. It can be difficult to handle if wrapped too tight due to the micro-grips, because it can adhere to itself.

The initial experience with the Parietex Pro-grip Laparoscopic Mesh used in LIHR (trans-abdominal pre-peritoneal technique – TAPP) by Klobusicky P. and Feyerherd P. showed that the self-gripping mesh proved to be extremely reliable, making the method fast, simple and economical (15).

Complications

The complications after LIHR can be divided into three categories: mesh-related, fixations device-related and recurrence of the hernia.

The mesh-related complications include seroma, mesh migration, bowel obstruction or perforation, hematoma, infection, sensation of foreign body and chronic groin pain. In an article published in 2013, a prospective study on 96 patients treated laparoscopically for inguinal hernia, from which 56 with self-gripping mesh and 40 with prostheses fixed with titanium staple, the authors related that other causes of chronic groin pain were the weight of the material used and the shrinkage of the mesh, more frequent with heavier prostheses (16).

The complications linked to fixation devices include acute and chronic groin pain, sensation of foreign body and recurrence of hernia. The acute and chronic groin pain can be non – neuropathic pain (70%) or neuropathic pain (30%). Non-neuropathic pain can be caused by tissue lesion due to periosteal reaction (after suture or staple into the pubic tubercle), scar-tissue formation or mechanical pressure of rolled-up, folded or wadded mesh. Neuropathic pain can be caused by either intraoperative nerve injuries or nerve compression by perineural fibrosis due to suture materials, staples, tacks and prosthetic materials (17-21).

The aim of a retrospective cross-sectional study that included 151 patients with incarcerated inguinal hernia divided into two groups based on the used technique (mesh repair and tissue repair) was to evaluate the effect of prostheses used on postoperative complications. The conclusion was that a polypropylene mesh could be safely used even for patients undergoing bowel obstruction in emergency inguinal hernia repair (22).

The recurrence rate of inguinal hernia may be affected by surgical factors such as the type of mesh used, mesh location, extent of mesh over-

lap, mesh securement technique and failure to close the fascial defect, as seen in an article published in 2015 (23).

In a double-blind randomized controlled trial that compared the results of using low-cost mesh (synthetic mesh) with commercial mesh (both light-weight), the authors enrolled 302 adult male patients with unilateral reducible inguinal hernias. Their results showed a recurrence rate of 0.7% (one patient) in the low-cost mesh group, and an occurrence of postoperative complications (mesh-related or linked to fixation devices) in 30.8% of cases in the low-cost mesh group and 29.7% in the commercial mesh group. They concluded that the rates of hernia recurrence and postoperative complications did not differ significantly between the two types of prostheses (24).

Another article published in 2015 regarding the first experience with a self-adhesive mesh, concluded that the self-gripping mesh could reduce the incidence of chronic groin pain, without increasing the recurrence rate (15).

Reviews of the literature in using biological prostheses have shown no improvement in hernia recurrence rates or complications compared to the use of synthetic materials (25).

A lower recurrence rate is also influenced by the mesh pore size, because larger pores allow a greater ingrowth, increase the pliability and functionality of the mesh, and provide an inert reduction in amount of polypropylene without decreasing the covered area (26).

According to the consensus recommendations from the International Hernia Society and the European Association for Endoscopic Surgery, adopted in 2012 and updated in 2015, a prosthesis should have the following characteristics: it must be monofilament, with a pore size of at least 1.0-1.5 mm and a minimum tensile strength in all directions $>16 \text{ N/cm}^2$, measuring at least $10 \times 15 \text{ cm}$ and overlapping the inguinal defect with at least 3 cm to prevent recurrence due to dimensions or protrusion (27-29).

Quality of life

The European Registry for Abdominal Wall Hernias (EuraHS) proposed the short, 9-question EuraHS-QoL instrument for the pre- and postoperative assessment done in a prospective multi-center observational study on the QoL. The study

included 101 patients undergoing LIHR with ProGrip self-fixation mesh. The findings showed a significant improvement in QoL at three weeks compared with the preoperative status, a further significant improvement at 12 months and no late complications or recurrence. The conclusion was that using self-fixation mesh for LIHR results in a favorable outcome and significant improvement of QoL compared with the preoperative assessment (30).

Another article published in 2016 about QoL after LIHR also reported that the use of polypropylene, light-weight mesh was associated with early decline but long term improvements in QoL regarding chronic groin pain, sensation of foreign body, movement limitations and physical function. Also, the authors reported that tailoring the mesh to decrease the surface area might improve QoL as long as it did not reduce the coverage provided (26).

The most used prosthesis that is biocompatible, has a low incidence of postoperative complications and recurrence rate, and improves the quality of life is a polypropylene light-weight mesh, monofilament, with large pore size, a minimum tensile strength $> 16 \text{ N/cm}^2$, and minimal dimensions of 10x15 cm. $\square$

DISCUSSIONS

Even though there is a large amount of literature concerning the type of meshes used in

LIHR, it is very heterogeneously distributed and the level of evidence is generally low. Most of the studies are comparative, retrospective, and focus on the incidence of postoperative complications and recurrence rate, QoL in a few studies and biocompatibility in the experimental studies on animals. The results of published randomized controlled trials lack consistency, which suggests that the mesh choice slightly influences the clinical outcome (6).

Thus, we can always start and conduct trials with structured protocols to discover the “ideal” prosthesis. $\square$

CONCLUSIONS

Data published during the last ten years have been showing that the “ideal” prosthesis for laparoscopic inguinal hernia repair has not been discovered yet.

The classification of the prostheses used in laparoscopic inguinal hernia repair in heavy- and light-weight does not allow sufficient differentiation (6), so that there is no significant effect on recurrence, acute or chronic pain, incidence of seroma or return to daily activity; also, the short term and long-term outcomes were similar for both types of prosthesis (1). $\square$

Conflicts of interest: none declared.

Financial support: none declared.

REFERENCES

1. Poelman MM, et al. EAES Consensus Development Conference on endoscopic repair of groin hernias. *Surg Endosc* 2013;27:3505-3519.
2. Cumberland HV. A preliminary report on the use of prefabricated nylon weave in the repair of ventral hernia. *Med J Aust* 1952;1:143-146.
3. Scales JT. Discussion on metals and synthetic materials in relation to soft tissues; tissue reaction to synthetic materials. *Proc R Soc Med* 1953;46:647-653.
4. Hamer-Hodges DW, Scott BN. Replacement of an abdominal wall defect using expanded PTFE sheet (Gore-Tex'). *Surg* 1985;30:65-69.
5. Amid KP. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* 1997;1:15-21.
6. Bittner R, et al. Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society). *Surg Endosc* 2015;29:289-321.
7. Burgmans JJP, et al. Three-month results of the effect of Ultrapro or Prolene mesh on post-operative pain and well-being following endoscopic totally extra-peritoneal hernia repair (TULP trial). *Surg endosc* 2015;29:3171-3178.
8. Salomon L, et al. Laparoscopic parastomal hernia repair: No different than a laparoscopic ventral hernia repair? *Surg endosc* 2016;4:1542-1546.
9. Schug-Pass C, et al. A lightweight polypropylene mesh (TiMesh) for laparoscopic intraperitoneal repair of abdominal wall hernias: comparison of biocompatibility with the Dual Mesh in an experimental study using the porcine model. *Surg Endosc* 2006;3:402-409.
10. Kasperk R, Klinge U, Schumpelick V. The repair of large parastomal hernias using a midline approach and a prosthetic mesh in the sublay position. *Am J Surg* 2000;179:186-188.
11. Gonzalez R, et al. Relationship between tissue ingrowth and mesh contraction. *World J Surg* 2005;8:1038-1043.
12. Dufly AJ, et al. Comparison of two composite meshes using two fixation devices in a porcine laparoscopic ventral hernia repair model. *Hernia* 2004;4:358-364.

13. **Mutter D, et al.** The concept of protected mesh to minimize adhesion formation in intraperitoneal abdominal wall reinforcement. Preclinical evaluation of a new composite mesh. *Hernia* 2000;4:3-9.
14. **Belega A, Popa DE, Vasile D.** Laparoscopic approach for inguinal hernia emergencies. *Proceedings of The Romanian Academy – series B: Chemistry, Life Sciences and Geosciences Suppl.* 2015; 1:7-11.
15. **Klobusicky P, Feyerherd P.** Innovation in Laparoscopic Inguinal Hernia Reparation – Initial Experiences with the Parietex ProGrip Laparoscopic™ - Mesh. *Front Surg* 2015;2:28.
16. **Fumagalli Romario U, et al.** Self-gripping mesh versus staple fixation in laparoscopic inguinal hernia repair: a prospective comparison. *Surg Endosc* 2013;27:1798-1802.
17. **Franneby U, et al.** Risk factors for long term pain after hernia surgery. *Ann Surg* 2006;2:212-219.
18. **Kehlet H, et al.** Persistent postsurgical pain: risk factors and prevention. *Lancet* 2006; 367:1618-1625.
19. **Aasvang EK, et al.** Neurophysiological characterization of postherniotomy pain. *Pain* 2007;1:173-181.
20. **Poobalan AS, et al.** A review of chronic pain after inguinal herniorrhaphy. *Clin J Pain* 2003;1:48-54.
21. **Amid KP.** Causes, prevention and surgical of postherniorrhaphy neuropathic inguinodynia: Triple neurectomy with proximal end implantation. *Hernia* 2004;4:343-349.
22. **Tatar C, et al.** Prosthetic Mesh Repair for Incarcerated Inguinal Hernia. *Balkan Med J* 2016;4: 434-440.
23. **Arita AN, et al.** Laparoscopic repair reduces incidence of surgical site infection for all ventral hernias. *Surg Endosc* 2015;7:1769-1780.
24. **Löfgren J, et al.** A Randomized Trial of Low-Cost Mesh in Groin Hernia Repair. *N Engl J Med* 2016;374:146-153.
25. **Slater JN, et al.** Repair of parastomal hernias with biological grafts: a systematic review. *J Gastrointest Surg* 2011;15:1252-1258.
26. **Arnab Majumder, et al.** Cell-coating affects tissue integration of synthetic and biologic meshes: comparative analysis of the onlay and underlay mesh positioning in rats. *Surg Endosc* 2016;30:4445-4453.
27. **Bittner R, et al.** Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society). *Official Journal of the Society of American Gastrointestinal and Endoscopic Surgeons* 2015:289-321.
28. **Bittner R, et al.** Lightweight mesh and noninvasive fixation: an effective concept for prevention of chronic pain with laparoscopic hernia repair (TAPP). *Surg Endosc* 2010;24:2958-2964.
29. **Brown CN, Finch JG.** Which mesh for hernia repair? *Ann R Coll Surg Engl* 2010;92:272-278.
30. **Muysoms EF, et al.** A prospective, multicenter, observational study on quality of life after laparoscopic inguinal hernia repair with ProGrip laparoscopic, self-fixation mesh according to the European Registry for abdominal wall hernias quality of life Instrument. *Surgery* 2016;5:1344-1357.