A Multicentric Comparison of Transabdominal versus Totally Extraperitoneal Laparoscopic Hernia Repair using PARIETEX® Meshes

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ABSTRACT

The authors report a series of 1972 inguinal hernias treated between 1993 and 1997 by the insertion of a PARIETEX® mesh via either a transabdominal-preperitoneal (TAPP) (1290 procedures) or a totally extraperitoneal TEP approach (682 procedures). Pain scores were equivalent in both groups, while the hospital stay and time to return to normal activity was lower in the TEP group than in the TAPP group ($p<0.001$). In both groups, the average incidence of the total reported events (complications) was around 10% with no statistical difference. This ratio seemed to compare favorably to previously published reports. Chronic pain was extremely rare (0.6% and 0.7% in the TAPP and TEP groups, respectively). Whatever the approach was, sepsis was also very rare (1/1526 laparoscopic procedures). These findings illustrate the local tolerance of the mesh. Recurrence rates were below 1% with no statistical difference between groups. This retrospective study demonstrates the clinically apparent local tolerance of this type of mesh. Prospective and long-term clinical results will be necessary to demonstrate that the optimized short-term tolerance of PARIETEX® mesh will influence the long term functional results.

Key Words: Inguinal hernia, Mesh, Laparoscopy.

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INTRODUCTION

Numerous techniques are, or were, used for inguinal hernia repair. These techniques can be divided into two main categories, depending on whether an abdominal wall augmentation device, usually called mesh, was used.

Herniorrhaphies without mesh, based on different closing techniques of the inguinal space under tension[1] (Bassini's technique, McVay and Shouldice), have often been associated with chronic inguinal pain resulting from tensions created by non-absorbable sutures (up to 15%) and to a relatively high, long-term recurrence rate probably due to the wall relaxation around the suture line. A randomized study[2] comparing the different herniorrhaphy techniques has shown an average recurrence rate of 8% at 8.5 years, the lowest rate of 6.1% being obtained with the Shouldice's technique. Moreover, annual statistics over several years from various countries show that 10 to 15% of inguinal hernia operations are for recurrent hernias.[3] With a constant European population, and considering that techniques using meshes (especially the laparoscopic ones) are still in the minority and/or too recent to provide a significant input, this figure shows that the average recurrence rate, largely induced by all herniorrhaphy techniques taken together, is around 10% to 15%.

In order to avoid such chronic pain and to decrease the overall recurrence rate, several techniques, all using a mesh, have been developed. The main techniques using meshes are the direct hernioplasties through anterior approach associated to a mesh implantation between the edges of the weak area (Lichtenstein's technique also called "Tension-free,"[4] the indirect hernioplasties through posterior approach and implantation of an oversized piece of mesh in the preperitoneal space largely covering the whole crucial area (Stoppa's technique),[5] and the indirect hernioplasties via a laparoscopic approach of the posterior wall reproducing the basic idea introduced by Stoppa but using a minimally invasive technique.[6-10]

Recent publications tended to demonstrate that the expected mid- and long-term results when using meshes through a laparoscopic approach were at least equivalent

and probably superior to the results obtained with previous techniques.[8-11]

Thereafter, modern inguinal hernia repair depends more and more on synthetic materials. However, minor and local complaints such as seromas, discomfort and chronic pains are still observed in a significant number of cases.[8,12-14]

As the structural properties of any material used as an implant are well known in other applications to be the key points in the quality and the stability of the results,[15-18] the influence of the mesh material itself, and not only the surgical technique, on the local tolerance and complications would need further clinical investigation.

Despite the fact that one of the first successful experiences with mesh[19] was dealing with multifilament polyester implants, up to now, polypropylene was the most popular material for such use.[20] However, multifilament polyester offers several theoretical advantages. The multifilament's structure and the modern woven technologies can maximize both micro and macroporosity to any expected level. The high conformability and softness of this material would optimize the local tolerance and prevent edge effects due to a mechanical mismatching with the surrounding tissues. This mechanical mismatching between a rigid mesh (a dense polypropylene one) and the abdominal wall was considered recently as a significant parameter that influences the intensity of scar formation and, subsequently, the local tolerance.[21,22] Finally, polyester is the most hydrophilic non-absorbable polymer used to produce implants, and hydrophilicity is well known to be one of the key properties for biocompatibility and tissue ingrowth.[23]

The purpose of this study was to report the clinical results on a recently introduced polyester-based mesh material (PARIETEX®) and to compare the obtained results to those published in the literature.

MATERIAL AND METHODS

Urban and rural hospitals familiar with the use of PARIETEX® mesh were asked to participate in a retrospective multicentered study. The only criteria used to include a center was its capability to review the patients at least one time after the initial recovery period. The consecutive series of each selected center were then enrolled in the study.

Studied Population

All patients who had undergone surgical repair of an inguinal hernia via a laparoscopic approach with placement of a PARIETEX® implant were eligible for the study. Use of any other mesh material during the hernia repair excluded the patient from the study. All participating surgeons were experienced and free to use their usual totally extraperitoneal (TEP) or transabdominal-preperitoneal (TAPP) approaches, suture techniques and anaesthetic protocols. Mechanical fixation (staples or Tacker, two on the Cooper's ligament and usually two on the medial side of the epigastric vessels) was predominantly used. Concerning pain medication, only a single dose of antalgic (paracetamol) was systematically given a few hours after surgery.

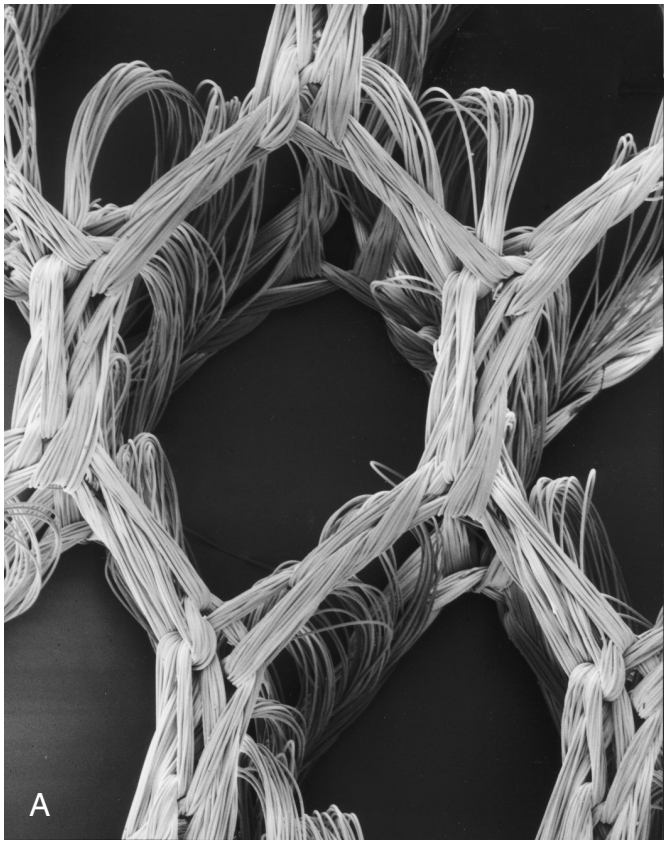
Mesh Material

All patients were treated using PARIETEX® mesh (Sofradim, Villefranche sur Saône, France). The minimum size of the mesh was 14 x 10 cm.

All PARIETEX® implants were made from a multifilament polyester fabric coated with purified type I collagen. This range of products is *CE* marked, which certifies proven safety, tolerance and efficacy of the device and receives the approval of the French Ministry of Health with regard to viral and microbiological safety. This mesh was introduced in the French territory in 1992, and results were reported for the first time in 1995.[23] Compared to conventional polypropylene meshes, PARIETEX® implants provide larger porosities and an increased softness, while the handleability of the products remain compatible with a laparoscopic placement **(Figure 1)**. The polyester-based chemistry and the rapidly absorbed biological coating increased the hydrophilicity of the mesh, resulting in a fast and intimate tissue ingrowth.[24,25]

Data Collection and Follow-Up

Standardized data collection was performed by the surgeon using a form that included the following items: identification of the patient, date of surgery, indications for surgery (unilateral or bilateral inguinal hernias), surgical approach (TEP or TAPP), postoperative pain (evaluated on day 2 using a 10-cm visual-analogue scale: scores ranged from 0 for no pain to 10 for unbearable pain), postoperative hospital stay (number of days in the hospital after the day of surgery), time to return to normal activity (time to return to work for employed



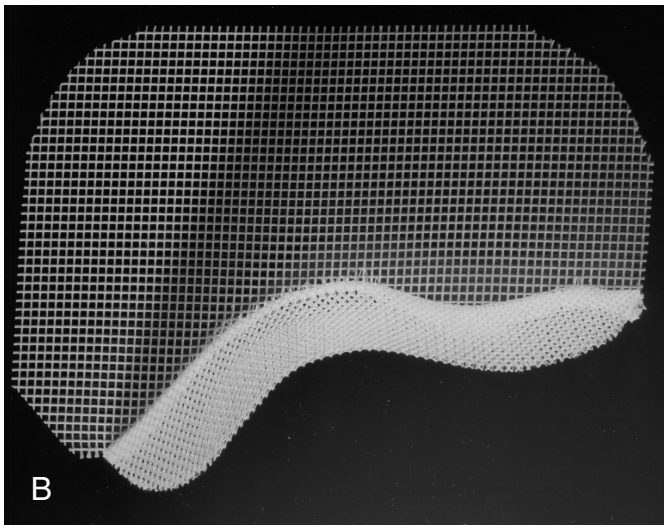


Figure 1. PARIETEX® meshes. A) appearance of one polyester fabric used for PARIETEX® meshes (sealed open-worked hexagonal and three dimensional stitches) noted the large opened porosities and the relative thickness (Scanning Electron Microscopy, x20). B) PARIETEX® anatomical mesh for posterior open or laparoscopic approach (15x10 cm).

patients, time to return to normal activities for unemployed or retired patients), early and late postoperative complications (all potential complications, such as hematoma, seroma, bleeding, chronic pain, testicular syndrome, nerve entrapment, sepsis, recurrence, etc., were assessed), and dates of follow-up.

Statistical Analysis

TEP and TAPP approaches were compared with respect to complication and recurrence rates, postoperative pain scores, length of hospital stay and time for recovery. All data are expressed as means ± stdv (standard deviation). For the analysis of differences between groups, non-parametric tests (Mann & Whitney and eventually Kruskal Wallis tests) were used.

RESULTS

Population Description

One thousand five hundred and twenty-six patients representing 1972 hernias, operated on between April 1993 and June 1997, were included in this study. The overall population description according to the different clinical indications and surgical techniques are presented in **Table 1**. As expected, males were predominant (87%). Eight percent of the patients in the TEP group were operated on for recurrent hernias, as well as 9% in the TAPP group. Follow-up was done on 91.2% of the patients. The average length of follow-up was 53 days after the surgery.

Postoperative Recovery

The visual-analogue pain scores after surgery (day 2), the length of hospital stay and the length of time before returning to normal activity are respectively presented in

Table 1.
Population description.

Indications	TEP	TAPP	Total
Inguinal Hernias			
Unilateral	316	764	1080
Bilateral	183	263	446
Total	499	1027	1526

Table 2.
Pain, hospital stay and return to normal activity.

	TEP	TAPP
Pain - analogue score	1.6 ± 1.1	1.6 ± 1.1
Hospital stay*	3.0 ± 1.5 d	3.8 ± 1.2 d
Return to activity*	13 ± 6 d	17 ± 10 d

*statistically significant p<0.0001 (TEP < TAPP)

Table 3.
Total reported events (%).

	TEP	TAPP	Mean
Inguinal Hernias			
Unilateral	11.3%	10.5%	10.7%
Bilateral	14.4%	9.1%	11.1%
Mean	12.5%	10.1%	10.8%

Table 4.
Type of reported events (%).

	Laparoscopic approach	
	TEP	TAPP
Seroma - hematoma	8%	6.8%
Bleeding	0%	0%
Chronic local pain	0.7%	0.6%
Testicular events	2.9%	1.1%
sepsis (n)	0.2% (n=1)	0%
neuralgia	0%	0.6%
Others	1%	1%
Total	12.5%	10.1%

Table 5.
Recurrences.

	Laparoscopic approach	
	TEP	TAPP
Total number (%)	3 (0.6%)	9 (0.9%)

Table 2. The visual-analogue pain score was identical in both groups. The patients in the TEP group were able to leave the hospital and return to normal activity sooner than the patients in the TAPP group (p<0.0001).

Complications

The total reported events (complications excluding recurrences) and the different types of reported events are presented in **Tables 3 and 4**. In both groups, the average ratio of the total reported events was approximately 10% to 12%, with no statistical difference. Bilateral TEP approaches exhibited the highest ratio (14.4%), while bilateral TAPP exhibited the lowest (9.1%).

When considering the types of reported events, the distribution appeared similar. The relative infrequency of these complications might explain the lack of any statistical difference. However, one may note that testicular events were more frequent in the TEP group, while neuralgia was only observed in the TAPP group. In both groups, seroma and hematoma were the most frequently reported events.

Whatever the approach was, sepsis were very rare (0/1027 in the TAPP group, 1/499 in the TEP group) as well as the chronic local pain (0.7% and 0.6%, respectively).

Recurrences

The early recurrence rates in each group are presented in **Table 5**. Whether the approach was TEP or TAPP, recurrences were very rare (below 1%), with no statistical difference.

DISCUSSION

Postoperative Recovery

The results of this study showed that patients recover more rapidly after TEP repair than after TAPP repair.

This study seems to be in accordance with previous reports.[8,26] An English study published in Lancet,[26] reports that there were 14 rest days before a return to work after a laparoscopic technique (TAPP). Recently, in a study published in the *New England Journal of Medicine*,[7] the authors report also a 14-day period before a return to work.

Considering comparative published data, the hospital stay in the literature appeared shorter and the return to

normal activity quicker after the laparoscopic technique than after the Lichtenstein open technique: 28 days[26] and 21 days,[8] respectively.

In this study, no statistical difference was observed when comparing the visual pain-analogue scores. The visual-analogue scores after two days obtained in this study compared favorably to those already published,[7] which have been shown previously to be significantly lower when using laparoscopic techniques.[7,10,26-28] A randomized study published in Surgery[27] comparing the TEP laparoscopic technique and the tension-free open technique showed that all the pain scores (rest or moving) were statistically lower for the TEP technique and that this tendency lasted one week.

Complications

The published data concerning the complication rates are very inconsistent. These rates clearly depend on the selected definition and the author's experience in the described technique.

A randomized study[2] reported an average complication rate ranging from 7% to 10% according to the herniorrhaphy technique used (Shouldice, Bassini or Mac Vay). In a multicentric study published[12] that compiled 3229 cases of inguinal hernia operated on with the laparoscopic approach, the complication rates were 7%, 10% and 14% for the TAPP, TEP and IPOM (intraperitoneal onlay mesh) techniques, respectively.

The prospectives studies comparing laparoscopy and the open anterior approach (tension-free) for inguinal hernia repair gave the following results with respect to complication rates: 1) according to Goodwin,[13] 23% for the TAPP approach, 12% for the open approach, 2) according to Payne,[14] 12% for the TAPP approach, 18% for the open approach, and 3) according to Liem,[8] 57% for the open approach (20% if chronic pains are included), 9% for the TEP technique (11% if chronic pains are included).

Whatever these published rates were, complications were mainly local complications related to the healing phase in the open approaches (hematoma and chronic pains), complications related to laparoscopy itself and to the dissection involved in the mini-invasive approaches (hematoma, seroma and neuralgia).

In this study, based on the follow-up of more than 1500 inguinal hernia repairs, no statistical difference was found due to the different approach techniques. However, as described previously,[12] the TEP approach seemed to induce a higher ratio of total reported events. The average number of total reported events in this series seemed to compare favorably to the previously published ratios. In particular, chronic pains were extremely rare in this series (0.6% versus 2% in a recent study[8]). This finding illustrated the local tolerance of the mesh, which did not induce any thick, encapsulating membrane.

Moreover, the extremely low level of sepsis (1 out of 1526 laparoscopic procedures) clearly demonstrates that the argument claiming multifilament meshes could promote infection[20] is no longer valid in modern surgery where up-to-date implants are used.

In this study, despite the fact that each type of reported event was too rare to make valid any statistical comparison, the TEP approach seems to increase the risk of testicular events. On the contrary, the TAPP approach was associated to few neuralgia that were not observed in the TEP group.

Recurrence Rate

Although recurrences are a type of complication, they are considered as the predominant factor in the assessment of the groin hernia repair techniques and, thus, require a special assessment.[29,30] Controlled and multicentric prospective studies have shown an average recurrence rate of 8% at eight years for conventional techniques, with 73% of the recurrences occurring within three years.[2] However, the quality of the results published by the specialized centers[1,4] imposed a 2% to 5% rate as being the reference value to which any new technique or material should be compared, at least for its short- and medium-term evaluation period.[30]

Since 1994, the compilation of the randomized studies on laparoscopic versus open surgery showed a global rate of 1% for an average follow-up of about one year.[8,14,26] When using meshes, the authors looking for the causes of these recurrences[12,13] agreed on the fact that most of them were early recurrences due to technical errors.

The main reasons reported are in order of frequency: 1) strengthening material (inferior to 100 cm^2) that is too small since it does not completely cover the weak region, 2) the absence of fixation responsible for early migration of flat standard mesh, and 3) incorrect positioning.

In this study, even if the follow-up period was not long enough to reach a conclusion, the observed recurrence rate was below 1%. These preliminary results confirmed a previous study[31] in which a monocentric prospective series of almost one thousand TEP hernia repairs using the same material had a recurrence rate of 0.2% after more than one year. Longer follow-up and extensive comparisons would be necessary to determine if the mesh design would influence the recurrence rate.

CONCLUSION

In the surgical treatment of abdominal wall defects, the implanted mesh must provide mechanical support to the surgical reconstruction, while causing a minimal adverse effect. With such an objective, the local tolerance and the functionality are optimum when the tissular integration of the implant is fast and intimate. To allow a fast and intimate tissue ingrowth without any peripheral fibrous capsule (which can cause discomfort or chronic pain), the mesh must have porosities that are as large as possible. The size of these porosities must only be limited by the minimal ultimate strength and the handleability of the product in the surgeon's hands. Moreover, to be adapted to its implantation site, the physical properties of the meshes must coincide with the mechanical behavior and with the geometric environment of the abdominal wall. PARIETEX® mesh has been designed to meet these prerequisites. The clinical results presented in this study demonstrate the safety and effectiveness of PARIETEX® mesh in hernia repair and particularly in chronic pain prevention. Long-term clinical results would be necessary to demonstrate that an optimized short-term tolerance would influence the long-term functional results, clinical outcome and recurrent hernia rate.

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