Int Urogynecol J (2010) 21:1455–1462
DOI 10.1007/s00192-010-1223-0

ORIGINAL ARTICLE

Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study

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Received: 25 October 2009 / Accepted: 4 July 2010 / Published online: 4 August 2010

Abstract
Introduction and hypothesis To evaluate clinical outcomes at 3 years following total transvaginal mesh (TVM) technique to treat vaginal prolapse.
Methods Prospective, observational study in patients with prolapse ≥stage II. Success was defined as POP-Q-stage 0-I and absence of surgical re-intervention for prolapse. Secondary outcome measures were: quality of life (QOL), prolapse-specific inventory (PSI), impact on sexual activity and complications.
Results Ninety women underwent TVM repair, 72 a hysterectomy. Anatomical failure rate was 20.0% at 3 years. Three patients required re-intervention for prolapse. Improvements in QOL- and PSI-scores were observed at 1 and 3 years. Vaginal mesh extrusion occurred in 14.4% patients. After 3 years, 4.7% asymptomatic extrusions remained present. Of 61 sexually active women at baseline, a significant number of patients (41%) ceased sexual activity by 3 years; de novo dyspareunia was reported by 8.8%. One vesico-vaginal fistula resolved after surgery.
Conclusion Medium-term results demonstrate that the TVM technique provides a durable prolapse repair.

Keywords Pelvic organ prolapse · Polypropylene mesh · Prolift · Transvaginal mesh · Vaginal surgery

Abbreviations

BMI	Body mass index
ICS	International Continence Society

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LOCF	Last observation carried forward
POP	Pelvic organ prolapse
POP-Q	Pelvic organ prolapse quantification
PSI	Prolapse-specific inventory
QOL	Quality of life
SD	Standard deviation
TVM	Trans vaginal mesh

Introduction

Pelvic organ prolapse (POP) is a major health-care problem. No less than 50% of women above the age of 50 years are affected, with a lifetime prevalence between 30% to 50% [1]. Collagen and smooth muscle content are found to be altered in women with POP [2–4]. These progressively weakened pelvic floor structures, often after sustaining obstetric trauma, contribute to the high recurrence rates associated with traditional surgical treatment options to address POP. Re-operation rates in almost 30% of patients are reported [5]. These failures become even more apparent when considering the treatment of anterior vaginal wall prolapse [6]. Analogous to the introduction of mesh prostheses in inguinal hernia surgery, early reports on mesh use in vaginal reconstructive surgery convey a possible advantageous effect [7, 8]. A group of nine French surgeons, under the guidance of the senior author (BJ) of this article, built upon this concept and conceived the idea to establish a standardised delivery tool for the synthetic graft to increase the chance of obtaining consistent results. This had been the case for three devices addressing the problem of urinary stress incontinence [9–11].

The work on this transvaginal mesh (TVM) prototype and the publication of the early follow-up results of the TVM procedure led to the development of a commercial device (Prolift Pelvic Floor Repair System™, Ethicon, Somerville, NJ, USA) [12, 13]. Recent literature on these commercially available devices seem to confirm the results published on the TVM procedure, stating that prosthetic mesh placed in a tension-free, standardised fashion reduces the chance of recurrence [14–17]. As all of these publications relate to short-term follow-up, it is important to report on the medium-term results (3 years) of their prototype, the TVM, as their claim is to deliver a durable support of the pelvic floor.

Materials and methods

The study was conducted at eight French gynaecology centres. The study was approved through the centralised ethics review process by the Lille University Hospital Ethics Committee (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale de Lille). All subjects gave their written informed consent to participate in this study.

The objective of the study was to assess effectiveness, both anatomic and subjective, and complications for the TVM technique for POP repair. It was a prospective single-arm, non-comparative design involving routine, standardised, pre-operative assessment, surgery and follow-up care at 6 weeks, 6 months, 1 and 3 years. Longer-term follow-up is scheduled at 5 years.

To be eligible for the study, patients were to be candidates for anterior and posterior surgical repair with a symptomatic prolapse with the most dependent part of the vaginal wall at least 1 cm beyond the hymenal ring. Patients were to be older than 21 years of age and had to have completed their family. Patients with a uterus were required to undergo concurrent hysterectomy to limit the number of different factors that could influence anatomic success, mesh exposure and pain. Uncontrolled diabetes or coagulation disorders were considered to be exclusion criteria.

The primary effectiveness endpoint was prolapse recurrence, defined as a POP-Q stage II or more (leading edge of the prolapse ≥ -1 cm) or surgical intervention to repair recurrence of vaginal prolapse. Prolapse assessment was performed according to the POP-Q scoring system [18]. Pre-operatively, patients' demographic details, medical and surgical history were recorded. Other secondary outcome parameters that were prospectively recorded were the impact of the prolapse on sexual activity, the clinical examination of the vaginal mucosa and any vaginal pain reported by the patient, categorized as unprovoked or provoked through examination or activity. The Prolapse-Specific Inventory and Quality of Life questionnaire (PSI-QOL) was used [19]. Questions 1 to 11 relate to symptoms associated with prolapse, while questions 12 to 15 describe the impact of these symptoms on daily activities of living.

Intra and post-operative complications and adverse events were collected throughout the study. The TVM technique comprised placement of the polypropylene mesh (Gynecare Gynemesh* PS, Ethicon Inc, Somerville, NJ, USA) of a specific size and shape (Fig. 1). The anterior component was inserted between the bladder and the vagina and secured bilaterally by two arms through each obturator foramen, using an Emmet-like needle. The posterior component was placed between the rectum and the vagina, and secured by one arm passing through each ischiorectal fossa and sacrospinous ligament. The intermediate section corresponding to the vaginal apex separated the anterior and posterior parts.

A hysterectomy was systematically performed if the patient had an intact uterus. The treatment of pre-existing or

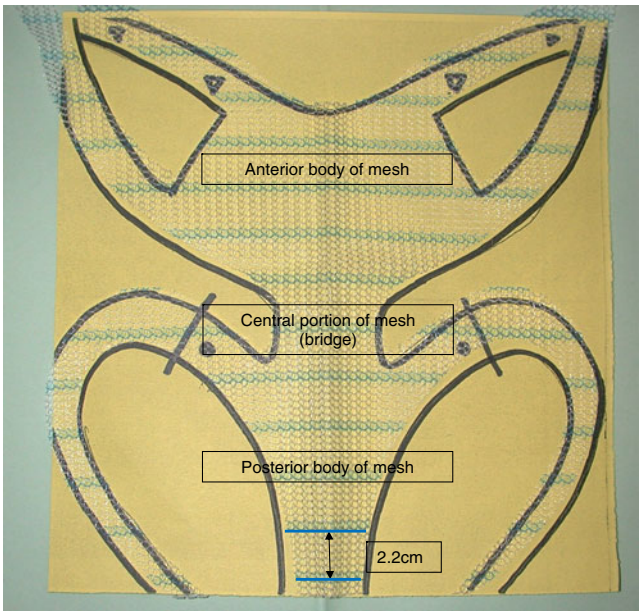

Fig. 1 Template for mesh shape

occult urinary incontinence was left to the discretion of the surgeon. Packing of the vagina, using gauze for up to 2 days following the procedure, was also optional. A urinary Foley catheter was left in situ until removal of the packing.

The study is still ongoing and all patients are currently being reviewed at 5 years post-surgery.

All data were analysed using SAS® (Version 9.1.3 Cary, NC, USA).

As this study was designed as a prospective cohort study and not a comparative study, only two-sided 90% confidence intervals (CI) were estimated. A sample size of 90 subjects to obtain at least 82 evaluable was selected as this would provide 80% power to detect if the proportion of treatment failures was less than 20%. The protocol defined success if the upper 90% two-tailed CI did not exceed 20% indicating we could be at least 95% certain the true failure rate was below 20%.

Results

Between January and December 2004, 90 women were enrolled into the study. Eighty-five patients were available for 3 years follow-up. Two patients withdrew consent from the study on day 46 and 361 after the study procedure. One patient, aged 85, died prior to the 3-year visit due to unrelated causes. A further two patients did not attend their 3-year follow-up visit.

Demographic data are summarised in Table 1. A total mesh repair was performed in 89 patients; one woman had an anterior mesh repair only as insertion of a posterior mesh

Table 1 Baseline demographics

Baseline characteristics	*N*=90
Mean age in years (SD)	65.2 (10.4)
Mean BMI kg/m^2 (SD)	25.3 (3.5)
Previous prolapse repair	4 (4.4%)
Previous surgery for incontinence	5 (5.6%)
Prior hysterectomy	18 (20.0%)
Concomitant hysterectomy	72 (80.0%)
Postmenopausal patients	78 (88.6%)
Hormonal treatment (post-menopausal)	21 (23.3%)

Data are expressed as *n* (%) except where otherwise indicated

SD standard deviation, *BMI* body mass index

was deemed unsafe by the surgeon after an inadvertent rectal injury had occurred during dissection. The mean operating time was 95.1 min (±37.7) and the mean number of nights spent in the hospital post-operatively was 4.6 nights (±1.5).

Fifty-six (62.2%) patients required no urinary incontinence treatment, three (3.3%) had a tension-free vaginal tape placed and 31 (34.4%) had a transobturator tape placed.

There were five (5.6%) patients with intra-operative adverse events: one patient had a rectal perforation during the dissection, in two patients a significant peri-operative haemorrhage was encountered; both could be managed by applying haemostatic clips and manual compression. In one patient, urinary retention occurred; this required release of the mesh 1 month after surgery. In one patient, the needle trajectory caused a vaginal laceration which was managed by suturing.

Early post-operative complications included a vesico-vaginal fistula which was probably related to an undiag-

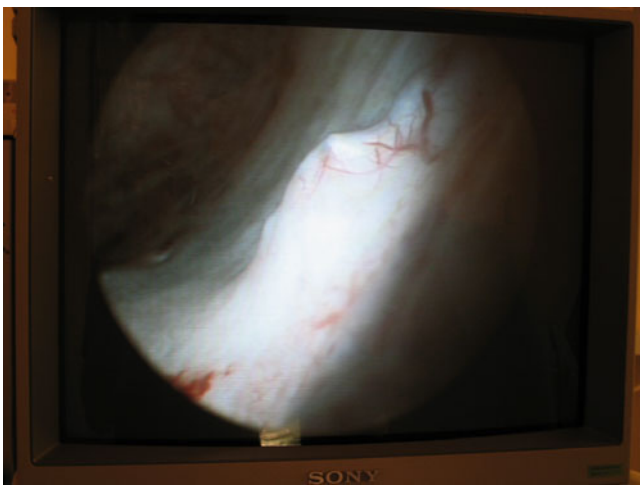

Fig. 2 Cystoscopic view of a protrusion at the level of the bladder base secondary to excessive mesh contraction

Table 2 ICS POP-Q stages

	Baseline (N=86[a])	6 months (N=86)	1 year (N=86)	3 years (N=85)
Stage 0	–	41 (47.7%)	38 (44.2%)	37 (43.5%)
Stage I	–	35 (40.7%)	33 (38.4%)	31 (36.5%)
Stage II	14 (16.3%)	8 (9.3%)	13 (15.1%)	14 (16.5%)
Stage III	49 (57.0%)	2 (2.3%)	1 (1.2%)	–
Stage IV	23 (26.7%)	–	–	–
Re-intervention			1 (1.2%)	3 (3.5%)

[a] For four patients, actual baseline stage was unknown but at least Stage II or greater. Data are expressed as *n* (%)

nosed peri-operative bladder perforation. There were four (4.5%) haematomas: one infected and drained spontaneously, one required surgical evacuation, one resolved spontaneously and one led to extrusion of the mesh which required resection. Urinary infections were reported in 15 (16.9%) of patients at the 6 weeks follow-up visit. One abscess was recorded and this drained spontaneously.

The patient who encountered the rectal injury and who only had the anterior mesh placed in combination with a transobturator tape, continued to complain of dysuria, urinary tract infection, and hematuria at 3 months post-operative. Cystoscopy revealed an inflammatory reaction around the mesh which had shrunk significantly and protruded at the level of the trigonum (Fig. 2). A total resection of the mesh needed to be performed via the vaginal route, 17 months after the initial procedure. This patient remains symptom free.

Anatomical failure rates evolved from 11.6% after 6 months to 17.4% (90% CI 11.1 to 25.6; n=86) after 1 year, and remained at 20.0% (90% CI 13.2 to 28.5; n=85) after 3 years, implying that the primary endpoint (upper confidence interval <20%) was not met.

These rates were reported based on the patients returning for each visit, which makes the assumption that data were missing at random. However, alternative failure rates were calculated based on different approaches to handling missing data; these rates and the POP-Q stages over time are presented in Tables 2 and 3, while Table 4 summarises the median POP-Q scores.

Table 3 Failure rates

Rate of anatomic failure (90% CI), assuming	1 year	3 years
Patients returning for POP-Q examinations	15/86	17/85
	17.4% (11.1–25.6)	20.0% (13.2–28.5)
Missing data as failures	19/90	22/90
	21.1% (14.3–29.4)	24.4% (17.2–33.0)
LOCF for missing data	16/89	18/89
	18.0% (11.6–26.0)	20.2% (13.5–28.5)

LOCF last observation carried forward

Of the 14 failures (stage ≥II), ten were stage II with the leading edge above the hymen, and none of them had required further intervention by the 3-year follow-up visit. Three patients (3.5%) had undergone re-intervention for recurrent prolapse within the 3 years of follow-up. Seven months post-operatively, one patient underwent a laparoscopic sacrocolpopexy for a recurrent anterior wall prolapse after the total vaginal mesh procedure. The second patient who required a re-intervention presented with recurrent apical and posterior vaginal wall prolapse 14 months after the primary surgery. She underwent an enterocele repair and a right sided sacrospinous ligament fixation with two vaginal flaps for posterior and apical defects. This patient continues to have a stage III posterior defect. Lastly, a re-intervention was carried out after 15 months, in a patient in whom a large mesh exposure was excised. The subsequent recurrent anterior wall defect warranted surgical treatment. Of the two patients who withdrew from the study prior to 1-year follow-up, one did not have any post-operative anatomical assessment, and the other was a failure at the 6-month visit.

The mean PSI score reduction from 13.9 (standard deviation (SD) 5.7) to 1.9 at 1 year, (SD, 2.5) was statistically significant (P<0.001, signed-rank test), indicating a reduction of symptoms caused by the prolapse. The positive effect on the PSI score of mesh surgery was maintained over time, with a mean score after 3 years of 2.1 (SD, 3.6). Similarly the impact of symptom improvement on daily living activities were sustained over time; the mean QOL score decreased from 3.4 (SD, 3.1) pre-operatively, to 0.4 (SD, 1.0) and 0.1 (SD, 0.4) after 1 and 3 years, respectively (P<0.001, signed-rank test).

Overall, there were 5 ongoing cases of mesh exposure at the 3-year follow-up time point. Details of mesh exposure and pelvic pain are summarised in Tables 5 and 6.

Moderate or severe vaginal stiffness (loss of elasticity) could be detected by digital examination in 11 (12.6%) patients after 1 year. No new cases were reported at the 3-year follow-up examination.

Figure 3 summarises the sexual disposition of patients at the time of entry into the study and 3 years after the procedure. Of the 61 patients who were sexually active at baseline, only 36 (59%) remained so at 3 years. Three

Table 4 Comparison of median pre-operative and post-operative POP-Q scores

	Baseline	Median POP-Q values in cm (range)		
		6 Months	1 Year	3 Years
Ba	3 (−2, 14)	−3 (−3, 3)**	−3 (−3, 0)**	−3 (−3, 3) **
C	2 (−5, 14)	−7 (−12, −2)**	−7 (−13, −2)**	−7 (−11, −2)**
Bp	1 (−3, 14)	−3 (−3, 5)**	−3 (−3, 5)**	−3.0 (−3, 3)**
TVL	8 (4, 15)	8 (4, 15)*	8 (4, 15)*	8 (4, 15)**
GH	5 (2, 10)	4 (2, 9)**	4 (2, 9)**	4 (2, 9)**
PB	3 (1, 8)	3 (1, 7)	3 (1, 7)	3 (2, 6) *

SD standard deviation

*$p<0.05$; **$p<0.001$, statistically significant changes from baseline

patients, who had not been sexually active at baseline resumed activity as opposed to 23 patients who ceased sexual activity; this is a statistically significant difference (McNemar's test $P<0.001$). The reasons stated for ceasing sexual activity were not related to dyspareunia nor were prolapse symptoms, further details were not collected. There were five out of 57 patients who reported de novo dyspareunia (8.8%). Of patients who were sexually active at baseline reporting dyspareunia symptoms, two reported resolution of these symptoms, one remained unresolved and one did not resume sexual activity for other reasons. Therefore, of the total number of sexually active patients at 3 years, 6/39 (15.4%) reported dyspareunia.

Discussion

The primary effectiveness endpoint was prolapse recurrence, defined as a POP-Q Stage II or more (leading edge of the prolapse ≥−1 cm) or surgical intervention for recurrence of prolapse. After 3 years an anatomical success rate of 81.2% was recorded. The fact that this does not differ from the success rate after 1 year (81.6%) is a key finding of this 3-year follow-up study. This finding may indicate that the use of graft material will lead to a more durable anatomical correction of the pelvic floor, as opposed to traditional repairs relying on endogeneous tissues. The initial high failure rate of 11.6% after 6 months may be perceived by some as high; however, these are caused by asymptomatic "theoretical" failures based on the POP-Q scoring system. It should be mentioned that one of the shortcomings of the POP-Q scoring system that this investigator group identified was that the POP-Q scoring system does not have the ability to describe mid vagina support in the presence of compromised distal vaginal support. Many asymptomatic anatomical failures refer to "point A failures". The term, "point A failure", warrants an explanation. The anterior component of the total vaginal mesh does not address a urethro- or trigonocele when present. They may also be caused by a distal retraction of the mesh. In these patients point Aa is the most dependent part of the vaginal wall and will therefore determine the value of point Ba. Similarly, points B are co-linear with points A in situations often seen after apical prolapse repair when a distal repair such as perineorrhaphy or urethropexy is not indicated. These situations will all lead to anatomical failures (POP-Q stage >I) despite the fact that these vaginas may demonstrate perfect midvaginal and apical support. A final observation regarding the primary endpoint is that only three patients (3.3%) had undergone re-intervention for recurrent prolapse, and thereby reflecting a much lower rate of re-operation compared with other published studies using traditional vaginal approaches [6, 20–22]. The total re-intervention rate of 12/90 (13.3%) is thus made up by three operations for recurrence of prolapse, eight interventions for mesh exposure and one procedure to treat the vesico-vaginal fistula. A meta-analysis by Diwadkar et al. calculated a lower re-operation rate for prolapse (1.3%), but a higher total re-operation rate (8.5%) after mesh kits [23]. This can possibly be attributed to a shorter follow-up time

Table 5 Mesh exposure

Incidence of mesh exposure	Incidence (%)	Cured (%)	Ongoing (%)
Overall	13/90 (14.4)	9/13 (69.2)	4/85 (4.7)
Requiring surgery	8/13 (61.5)	8/8 (100)	–
Requiring medical treatment	1/13 (7.7)	1/1 (100)	–
Asymptomatic requiring no treatment	4/13 (30.8)	–	4/85 (4.7)

Table 6 Incidence of pelvic pain

Type of pelvic pain	Baseline	6 months	1 Year	3 Years
Unprovoked	3 (3.3%)	2 (2.3%)	1 (1.1%)	1 (1.2%)
On exam	6 (6.7%)	11 (12.6%)	7 (8.0%)	3 (3.5%)
Cystalgia	5 (5.6%)	1 (1.1%)	1 (1.1%)	–
On defecation	5 (5.6%)	–	2 (2.3%)	–
During other activity	5 (5.6%)	3 (3.4%)	3 (3.4%)	2 (2.4%)

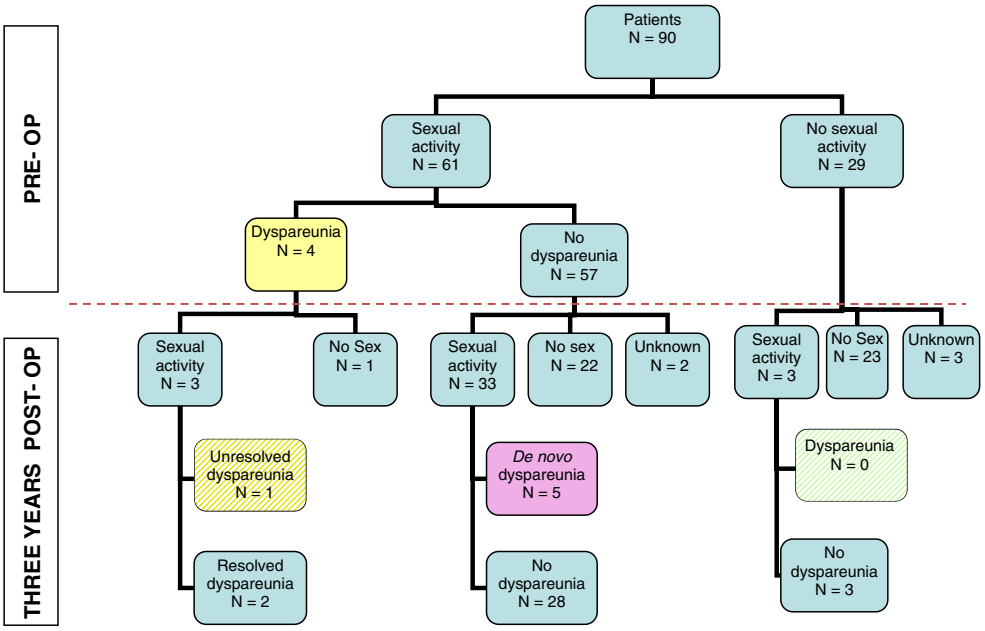

Fig. 3 Sexual disposition of patients

(26 months) and the fact that Diwadkar's study reflects outcomes after fully standardised mesh kits. These series will be less impacted by learning curves reflected in this series and the fact that the addendum of cannula's may affect the erosion rates as we discuss later.

For the secondary outcome measure, the improvements in subjective outcome following the TVM procedure were also significant and appear to remain stable over the studied time period. These improvements were observed, even when the procedure was not considered to be an anatomical success. This finding can probably be explained by the fact that of the 16 failures detected after 3 years, 13 were POP-Q stage II, with the leading edge remaining at, or above the level of the hymen. It is well documented that prolapse only tends to become symptomatic once it protrudes beyond the level of the hymen [24, 25] This too, in our opinion, points at an aspect of the POP-Q scoring system, that remains open for debate; namely the fact that a prolapse at 1 cm above the hymen (−1 cm), which is often asymptomatic, is staged equivalently to a prolapse 1 cm beyond the hymen (+1 cm). To us this partially explains why it has been reported in the past that the correlation between measured prolapse anatomy and patient-reported symptoms is not strong [26]. Anatomical and subjective measures weighted equally as outcome measures should be considered for future clinical studies in POP. Barber et al. recently proposed a composite outcome defined by anatomic recurrence, recurrence of bothersome vaginal prolapse symptoms and/or retreatment assessed 2 years after the index surgery [27]. According to this new outcome measure, and counting loss to follow-up as a failure, our study would have reached a 91.1% success rate after 3 years.

Thirteen patients (14.4%) experienced mesh exposure during the 3 year follow-up. Of these, nine had undergone a concurrent hysterectomy. Collinet et al. reported an increased relative risk of 5.17 compared with the situation when the uterus was preserved or when the patient had had a hysterectomy in the past [28]. The numbers in our study are too small to confirm this observation. The implications of mesh exposure continue to be studied, but these results are suggestive that in many cases mesh exposure can be managed by partial excision and/or oestrogen application. Asymptomatic cases may not even require treatment. Cannulas have subsequently been introduced in the Prolift™ device to reduce the amount of tissue disruption and concomitant bleeding. This can be expected to lead to a reduced erosion rate as hematomas and inadequate spreading out of the mesh may be a risk factor for the development of mesh exposure. It must also be noted that the mesh was self-cut and that different kinds of needles were used throughout the study. Therefore, the TVM procedure reported upon does not truly represent a "standardised" procedure.

Also related to the foreign body reaction was the 12.6% rate of observed increased vaginal wall stiffness. This observation was not necessarily associated with any shortening of the vagina but was always associated with mesh contraction. We deemed the increased fibrosis responsible for the loss of elasticity of the vaginal walls. Important is that this rate does not appear to increase over time.

In one patient, only an anterior mesh was placed, following rectal injury due to the dissection. Subsequently the anterior mesh needed to be removed due to persistent symptoms of dysuria, recurrent urinary tract infections and hematuria. Based upon this single case we now recommend

that in the event of a rectal perforation, mesh placement, even in the anterior compartment alone, should be abandoned or postponed to a later stage. We hypothesise that peroperative mesh contamination may have led to a more pronounced inflammatory response and subsequent mesh contraction. One case of a vesico-vaginal fistula, which resolved with surgery, was reported. The case illustrates, however, that performing a cystoscopy, or checking for bladder patency with a dye test after placement of the trocars or mesh, may prevent this kind of severe complications, as it was probably caused by a peroperative intravesical needle placement.

The strength of this study is that it represents 3 years follow-up on a mesh needle suspension technique using standardised, validated outcome measures. There are, however, certain weaknesses to the study. First of all, the lack of a comparative study population does not allow us to draw conclusions with regards to the possible superiority of a total vaginal mesh repair as a treatment option compared with traditional vaginal techniques. Another shortcoming of the study is that no attempt was made at blinding of the follow-up assessments, as it was not common study design yet at the time when this study was initiated. As all authors have declared different degrees of conflicting interests, this may have led to a positive reporting bias. Also, at the time the study was initiated, the experience of some surgeons with the POP-Q scoring system was limited. Inclusion criteria required the patient to present with a stage III prolapse; 14 patients, however, with the leading edge at +1 cm were included, as the surgeons had erroneously classified them as a stage III. A final weakness of our study is the outcome measures used. We have already pointed at the shortcomings of the POP-Q score and the fact that symptom scores and quality of life do not correlate to anatomical success. As we recognise that implantation of a foreign body has introduced new kinds of morbidity (e.g. mesh contraction and erosion), we feel that a time has come to further investigate the possibility of a compound measure of success, as recently discussed by Barber et al. [27] and Diwadkar et al. [23]. This compound measure, in our opinion, should take into account the anatomical success rate, the impact on quality of life (including sexuality in sexually active patients), the re-operation rate for prolapse, an adverse event score and finally a health economic assessment. Finally, we have assessed the sexual disposition of the patients, and noted that there is a de novo dyspareunia rate of approximately 8.2% after 3 years in the patients remaining sexually active, but the study lacks the use of validated sexual questionnaires. Moreover, it does not account for the high reduced sexual activity rate post-operatively; a study has demonstrated that this is not infrequently due to partner related issues [29, 30]. The significant decrease in sexual activity may be partially related to the very high rate of sexual activity (67.8%, 61/90) at the onset of the study for this kind of population when compared with similar studies by Lowman and Altman with pre-operative sexual activity rates of 36.4% and 40%, respectively [29, 30]. The post-operative sexual activity rate of 45.9% (39/85) certainly isn't lower than those reported by Lowman and Altman: 44.1% and 36.2%, respectively [29, 30]. However, it remains a concerning finding that no less than 41% of patients ceased sexual activity after this procedure which may be related to mesh placement or the method of mesh insertion. This finding warrants future studies specifically addressing the impact of vaginal mesh repairs on sexual function.

In conclusion we would like to state that the early positive anatomical findings and positive impact on patients' quality of life scores are sustained after 3 years. The TVM procedure is associated with a high total re-intervention rate (13.3%) but the low re-intervention rate for prolapse (3.3%) suggests that a total vaginal mesh seems to lead to a stable repair of the pelvic floor.

Conflicts of interest Bernard Jacquetin holds the patent for Prolift®, for which he receives royalties from Ethicon. B.Jacquetin, B. Fatton, C. Rosenthal, H. Clavé, P. Debodinance, O. Garbin, J. Berrocal, R. Villet, D. Salet Lizée and M. Cosson all have had consultancy positions for Ethicon. P. Hinoul and J. Gauld are employed by Ethicon.

Source of financial support ETHICON Women's Health & Urology.

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