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ORIGINAL ARTICLE

Comparison of dynamic MRI vaginal anatomical changes after vaginal mesh surgery and laparoscopic sacropexy

Hiromi Kashihara · Virginie Emmanuelli · Edouard Poncelet · Chrystèle Rubod · Jean-Philippe Lucot · Bram Pouseele · Michel Cosson

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Abstract The aim of this study is to evaluate anatomical differences in vaginal length and axis between transvaginal mesh surgery (TVM) and laparoscopic sacropexy (LSC) by pelvic magnetic resonance imaging (MRI). Twenty-seven women with stage II or more symptomatic pelvic organ prolapse were involved in this study. Thirteen patients had undergone TVM, and fourteen had LSC. Preoperative and at 1 year postoperative clinical examination and dynamic MRI were performed. The angle between the vaginal axis and horizontal line or pubococcygeal line and the position of the Douglas pouch were evaluated on MRI. In clinical examination, all compartments (Aa, Ba, C, Ap, Bp, D) were significantly improved after both surgeries. Point C and D tended to be higher after LSC than TVM. In MRI assessment, the position of the Douglas was positioned significantly higher after LSC than TVM. There was no difference in postoperative vaginal axis at rest between the two surgical techniques, but the vaginal axis with maximal strain after TVM was more horizontal than LSC (LSC 143.7±6.3° vs. TVM 155.1±12.3°, p=0.003). As a result, the change of vaginal axis from at rest to maximal strain was also apparently greater after TVM. (LSC 10.3±9.1° vs. TVM 20.7±11.3°, p=0.014). Both TVM and LSC significantly improved pelvic organ descent evaluated by clinical examination and MRI. LSC suspends the uterus, and Douglas pouch was significantly higher than TVM. The vaginal axis at rest leans horizontally after both surgeries, but the change of vaginal axis from at rest to maximal strain was significantly higher after TVM.

Keywords Pelvic organ prolapse · Vaginal mesh surgery · Laparoscopic sacropexy · MRI · Vaginal axis

Abbreviations

TVM	Transvaginal mesh
LSC	Laparoscopic sacropexy
MRI	Magnetic resonance imaging
POP	Pelvic organ prolapse
SUI	Stress urinary incontinence
POP-Q	Pelvic organ prolapse quantification
PCL	Pubococcygeal line
HL	Horizontal line
QOL	Quality of life

Brief summary Length and axis of the vagina at rest are comparable 1 year after TVM or LSC surgery for prolapse.

H. Kashihara · V. Emmanuelli · E. Poncelet · C. Rubod · J.-P. Lucot · B. Pouseele · M. Cosson
Department of Gynecologic Surgery, Hopital Jeanne de Flandre, Centre Hospitalier Regional Universitaire de Lille, Lille Cedex, France

H. Kashihara (✉)
Department of Obstetrics and Gynecology, Osaka Police Hospital, 10-31 Kitayama-cho Tennouji-ku Osaka, Osaka 543-0035, Japan
e-mail: hkathy_sky@yahoo.co.jp

B. Pouseele
Department of Obstetrics and Gynecology, OLV van Lourdes Hospital, Waregem, Belgium

Introduction

Pelvic organ prolapse (POP) is one of the most common problems that can compromise women's quality of life. Women have a risk of 11% of undergoing surgery for pelvic organ prolapse or urinary incontinence [1]. There are two surgical routes for the treatment of POP: abdominal and vaginal. Traditional vaginal procedures using weak native tissue were reported to have a high recurrence rate and the reintervention rate is often up to 30% [1].

The transvaginal mesh (TVM) kit has been developed for the treatment of POP to overcome the high failure rate of traditional repair. This minimally invasive method consists of the fixation of a transvaginally introduced tension-free polypropylene mesh for the anterior and posterior compartment. The French Transvaginal Mesh group has established this standardized procedure. They reported a low operative morbidity and a high anatomical success rate [2]. Some randomized controlled trials that compare TVM with traditional vaginal repair suggest a better anatomical success rate, especially for anterior repair [3, 4]. However, there are some possible complications with TVM like mesh exposition and dyspareunia, which consequently lead to a high reoperation rate [4, 5]. In July 2011, the US Food and Drug Administration (FDA) declared the placement of surgical mesh for transvaginal repair for POP as an area of continuing serious concern because of its serious complications.

The abdominal sacrocolpopexy has been regarded as the gold standard procedure for treatment of vaginal vault prolapse [5, 6]. Nowadays, laparoscopic approach is introduced for this procedure with potential advantages in terms of reduced morbidity, shorter hospital stay, and faster recovery. According to some reports, laparoscopic sacrocolpopexy and sacropexy with conservation of the uterus seem to be safe and effective, with low recurrence and morbidity rates (comparable to laparotomy) [7–9]. There are discussions between laparoscopic and vaginal surgeons about the differences of vaginal length and axis after prolapse repair between these two surgical techniques, using different ligaments for the apex suspension (prevertebral ligament for sacropexy and sacrospinous ligament for TVM).

Magnetic resonance imaging (MRI) was introduced to facilitate the diagnosis of pelvic floor disorders because of its excellent soft tissue resolution. Dynamic MRI can detect pelvic organ prolapse with rapid scanning of the pelvis even with multiple compartments involved [10–12]. Several studies have already been conducted to evaluate pelvic reconstructive surgery. Some of them compare the anatomical results of different surgical procedures [13–21], but there is no study analyzing postoperative anatomical differences between transvaginal mesh repair and laparoscopic sacropexy (LSC) by using dynamic MRI.

The aim of this study was to compare anatomical results after two surgical methods, TVM and LSC, with MRI before and 1 year after operation.

Materials and methods

This is a prospective study comparing the anatomical results between TVM surgery and LSC by MRI before and after operation. After the institutional review board approval, patients with symptomatic POP who were introduced to our institution to undergo surgical intervention were recruited in the study. Inclusion criteria were stage 2 or more pelvic organ prolapse in the pelvic organ prolapse quantification (POP-Q) system, subjective symptoms of POP, an age between 40 and 70 years, and the patients' agreement to participate in the study. Exclusion criteria were previous surgery for pelvic organ prolapse or previous hysterectomy for reasons of potential difficulties to assess the vaginal axis in such cases. Twenty-seven patients were involved in this study. Thirteen patients had undergone transvaginal mesh repair (TVM group) and 14 had undergone laparoscopic sacropexy (LSC group) between January and October 2010 in our university hospital. The choice of method of surgery depended on the surgeon's decision. In a first hand, prolapse surgery by laparoscopic sacropexy is used in our institution for younger patients under the age of 60 years and the vaginal approach for patients over 60 years old. All patients had a clinical interview, gynecological examination using the POP-Q system, and a MRI preoperatively and postoperatively. Postoperative assessment was scheduled at 1 year after operation. The surgical technique of TVM was the standardized transvaginal mesh procedure, which was previously described by the French TVM group [2, 22]. All mesh procedures involved use of the Prolift+M™ Total (Prolift Pelvic Floor Repair System; Ethicon Women's Health and Urology, Somerville, NJ), and the mesh was inserted in both anterior and posterior compartments without hysterectomy for all cases. In the LSC group, concomitant subtotal hysterectomy was performed initially and the same partially absorbable monofilament mesh (Ultrapro®, Ethicon Women's Health and Urology, Somerville, NJ) was adopted. Anterior dissection was performed up to the level of the bladder neck, and the mesh was fixed on the anterior vaginal wall using sutures. At the posterior side, dissection was performed bilaterally as for the levator ani muscles and the mesh was secured to the posterior vaginal wall or levator ani muscles using sutures. Both the anterior and posterior meshes were fixed to the uterine cervix with titanium helical fasteners. After dissection of the presacral space, anterior and posterior meshes were sutured to the presacral ligament at the level of promontory with a nonabsorbable suture. All operations were performed by two senior surgeons or under their supervision.

Nine patients (two of TVM and seven of LSC) who suffered from symptomatic stress urinary incontinence (SUI) preoperatively, underwent concomitant placement of a tension-free vaginal tape-obturator sling (TVT-O, Ethicon Women's Health and Urology, Somerville, NJ). In the LSC group, there was one patient who underwent both a rectopexy and culdoplasty at the same time, one patient had a rectopexy, one a culdoplasty, and one a myorraphy of the levator ani muscles concurrently.

MRI was performed with 1.5 T (GE Healthcare; Milwaukee, USA), with the patients lying in the supine position with their legs slightly flexed. Sonographic transmission gel was injected in the vagina and rectum, 50 and 250 mL, respectively. Images were obtained in sagittal, axial, and coronal orientation using body coil at rest, squeeze, and push with maximal strain [Fig. 1]. At first, imaging high resolution T2-weighted turbo spin-echo (TSE) sequences or 3 dimensional T2 was obtained to estimate pelvic anatomical structures. Then, the dynamic series of images were obtained in the midsagittal plane with very fast imaging (one image per second) in echo gradient (EG) T2. Last, three planes (sagittal, axial, and coronal) were performed in EG T2 with maximal strain. The evacuation and post-evacuation sequences with maximal strain were utilized for evaluation of the pelvic organ prolapse and the condition of the anal canal.

A preoperative and postoperative (1 year after surgery) clinical examination and MRI was executed in all patients. All MRI images were analyzed by one experienced radiologist, and measurements were done in a midsagittal plane. The vaginal axis was determined as the line connecting the posterior fornix and the vaginal introitus, and the distance between these two anatomical points at rest was measured as the position of the Douglas pouch on MRI. The position of the Douglas pouch was determined perpendicular to the vaginal axis at the highest part of the posterior fornix or at the level of a enterocele in case of a low enterocele. Both horizontal line (HL) and pubococcygeal line (PCL) were utilized as reference lines because it is still controversial which reference line is the most suitable to estimate pelvic floor disorders. PCL is defined as the line from the inferior part of the symphysis pubis to the last coccygeal joint. The HL is drawn between the inferior border of the symphysis pubis and the convex posterior margin of the puborectalis sling. The angle between the vaginal axis and the reference line were measured on the mid sagittal T2 image at rest and with maximal strain.

Statistical analysis was performed using the R 2.15.3®software, available freely online. The Mann-Whitney-Wilcoxon Rank sum test was used to analyse POP-Q measurements and *MRI* datas. A p value below 0.05 was considered statistically significant.

Results

The LSC group was significantly younger than the TVM group (61.9±3.3 vs. 49.3±4.2 years, $p<0.05$). Median follow-up period was 47 weeks, and there was no difference between LSC and TVM.

The results of POP-Q examinations are shown in Table 1. Because of the missing data on POP-Q examination, three patients of the TVM group and two patients of the LSC group were excluded for evaluation by POP-Q. In the preoperative clinical examinations, no significant difference was detected between the TVM and LSC group, except for genital hiatus (GH). Postoperatively, point C and D tended to be higher in the LSC group than TVM, but there was no difference in TVL. In comparison of pre- and postoperation situation, all compartments (Aa, Ba, C, Ap, Bp, D) were significantly improved after both surgeries.

The result of the position of Douglas pouch measured by MRI is shown in Table 2. Point D and TVL in POP-Q are also listed to be compared. The position of the Douglas pouch was postoperatively significantly higher in the LSC group than TVM. As mentioned in the result of POP-Q, postoperative point D in the LSC group was also significantly higher compared to TVM. Both POP-Q and MRI observations suggest that LSC suspends the uterus and Douglas pouch higher than TVM, as preoperatively there was no difference between TVM and LSC in POP-Q point D and TVL.

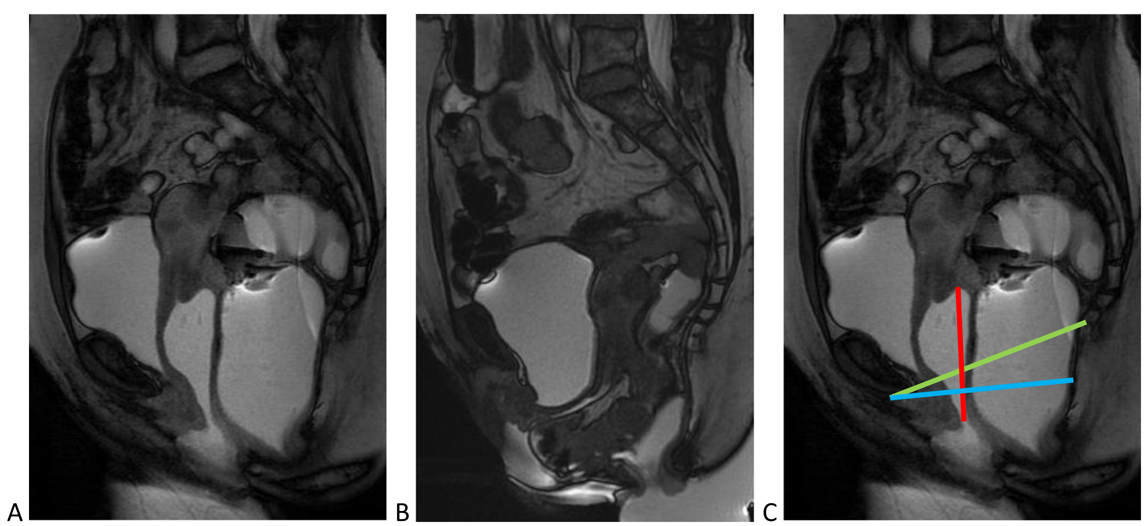

Fig. 1 Dynamic MRI with intravaginal and intrarectal gel. **a** At rest. **b** At maximal pushing. **c** Puboccyeal line (PCL, *green*), horizontal line (HL, *blue*), and vaginal axis (*red*)

Table 1 Comparison of POP-Q clinical measurements before and 1 year after operation for the TVM group and for the LSC group

	Preoperation			Postoperation		
	TVM n=10	LSC n=12	p value	TVM n=10	LSC n=12	p value
Aa	1.2±1.8	1.2±1.2	0.656	−1.2±1.2[a]	−1.8±1.4[a]	0.416
Ba	2.2±1.3	1.8±1.7	0.121	−1.5±1.3[a]	−1.7±1.4[a]	0.797
C	1.9±1.3	2.8±2.4	0.657	−5.0±3.2[a]	−7.6±1.7[a]	0.051
GH	5.2±1.0	4.0±0.6	0.040	4.6±1.3	4.3±1.1	0.443
PB	4.5±0.6	3.7±0.7	0.138	3.5±0.9	3.3±0.6	0.892
TVL	8.2±1.1	8.8±1.9	0.424	9.0±0.9	9.9±1.6	0.165
Ap	0.3±1.4	0.3±1.6	0.947	−2.7±0.9[a]	−2.4±1.0[a]	0.323
Bp	0.4±0.7	0.2±1.9	0.347	−2.2±1.8[a]	−2.3±1.1[a]	0.551
D	−1.0±2.5	−0.3±2.1	0.388	−6.2±2.3[a]	−8.8±1.0[a]	0.003

[a] Statistically significant

The results of MRI analysis are shown in Tables 3 and 4. All MRI images were of good quality, with all points necessary for measurement visible in each MRI analysis. Between TVM and LSC, there was no statistical difference of preoperative vaginal angle at rest and with maximal straining. Compared before and after each operation, the vaginal angle at rest tends to increase postoperatively, and it means that the vaginal axis leans horizontally in supine position after both operations (Table 3). It was statistically significant when PCL was adopted as a reference line (TVM: pre 126.5±9.0° vs. post 134.4±8.4°, p=0.026; LSC: pre 128.4±9.0° vs. post 133.4±5.2°, p=0.036). The vaginal angle with maximal strain significantly changed to horizontal after TVM regardless of reference line (HL: pre 117.5±23.2° vs. post 134.0±16.9°, p=0.048, PCL: pre 136.8±17.3° vs. post 155.1±12.3°, p=0.007). On the other hand, the vaginal angle with maximal strain after LSC did not change from preoperation (HL: pre 124.3±17.2° vs. post 126.3±10.9°, p=0.991; PCL: pre 143.5±14.7° vs. post 143.7±6.3°, p=0.675).

As a result, the change of vaginal axis from at rest to maximal strain became greater after TVM and oppositely, this change became smaller after LSC (Table 4). In comparison of the change of vaginal axis from at rest to maximal strain between the two operations postoperatively, TVM had greater change than LSC. This difference was statistically significant when PCL was used as a reference line (LSC 10.3±9.1° vs. TVM 20.7±11.3°, p=0.011).

Discussion

Our study confirmed a significant improvement of pelvic organ prolapse after TVM and LSC, respectively, and also detected by clinical examination and MRI that the position of the Douglas pouch was held up higher after LSC than TVM. MRI assessment revealed that the vaginal axis at rest leans horizontally after both surgeries, but the change of vaginal axis from at rest to maximal strain was significantly higher after TVM than LSC.

Many publications have described the feasibility of using dynamic MRI for diagnosis of pelvic organ prolapse preoperatively [10–12] and evaluate the effectiveness of surgery and recurrence postoperatively [13–21].

Pelvic organ prolapse usually consists of multiple pelvic compartments, even if patients may present with symptoms that involve only one compartment [10]. All involved compartments should be identified preoperatively or else, misdiagnosis may lead to surgical failure. But it is sometimes difficult to differentiate each compartment by clinical examination, especially for vaginal vault prolapse. Therefore, other

Table 2 Position of the Douglas pouch measured by MRI before and 1 year after operation for the TVM group and for the LSC group

		Preoperation			Postoperation		
		TVM	LSC	p value	TVM	LSC	p value
Position of Douglas	(mm)	70.3±6.9	78.2±6.8	0.014	69.9±10.0	81.0±7.3[a]	0.004
POP-Q D	(cm)	−1.0±2.5	−0.3±2.1	0.388	−6.2±2.3[a]	−8.8±1.0[a]	0.003
TVL	(cm)	8.2±1.1	8.8±1.9	0.424	9.0±0.9	9.9±1.6	0.165

[a] Statistically significant

Table 3 MRI measurement of the vaginal angle at rest and with maximal straining before and 1 year after operation for the TVM group and for the LSC group

		Preoperation	Postoperation	*p* value	Preoperation	Postoperation	*p* value
Vaginal angle (°)	Rest	101.5±9.2	108.4±9.7	0.142	97.1±8.9	105.3±4.7	0.008
HL	Valsalva	117.5±23.2	134.0±16.9	0.048	124.3±17.2	126.3±10.9	0.991
Vaginal angle (°)	Rest	126.5±9.0	134.4±8.4	0.026	128.4±9.0	133.4±5.2	0.036
PCL	Valsalva	136.8±17.3	155.1±12.3	0.007	143.5±14.7	143.7±6.3[a]	0.675

[a] Statistically significant

diagnostic tools such as perineal ultrasonography and dynamic MRI are newly introduced to help clinical examination. Gupta et al. evaluated 30 POP patients and suggested that the diagnosis of enterocele, which may be missed clinically, is efficiently made on dynamic MRI, and it can differentiate enterocele from high rectocele which can further classify the surgery needed [12].

It is still controversial which reference line is suitable to estimate pelvic floor disorders. For grading POP, we usually utilize horizontal line (HL) running the vaginal introitus horizontally. In order to grade pelvic organ prolapse, the distance from HL to the inferior margin of each pelvic organ is measured because we presume that it may correspond with the clinical examination. But seen the fact that this line can be moved with patient's strain, we had to choose another line fixed by bony landmarks seen on MRI to evaluate the vaginal axis. The pubococcygeal line (PCL) was adapted as a reference line for this purpose. In fact, PCL is the most commonly used reference line in the assessment of pelvic organ prolapse [10, 23]. We detected some differences in the results between the two reference lines. Since the HL could move with maximal strain and the change of vaginal axis may be masked, we suppose that the data of PCL are more reliable than those of HL.

There are several MRI studies that assess the effects of TVM and abdominal sacrocolpopexy. They found effectiveness of TVM and abdominal sacrocolpopexy, and positive correlations demonstrated between POP-Q and MRI findings [14–17].

Some MRI studies investigate anatomical changes after abdominal sacrocolpopexy and sacrospinous ligament suspension. Sze et al. [19] compared vaginal configuration on MRI after abdominal sacrocolpopexy and sacrospinous ligament suspension. They demonstrated that abdominal sacrocolpopexy with retropubic colposuspension more closely restored the vagina to its normal configuration, whereas sacrospinous fixation with transvaginal needle suspension creates an abnormal axis. Rane et al. [20] compared the vaginal configuration on MRI and found that significant improvements in the restoration of vaginal configuration were achieved in abdominal sacrocolpopexy, but that transvaginal sacrospinous fixation increases anatomical distortion of the vaginal configuration. Therefore, abdominal sacropexy seems to restore the normal vaginal axis rather than sacrospinous ligament suspension. The distortion of vaginal axis may result in a high recurrence rate after sacrospinous ligament suspension. In our current study, the vaginal axis leans to horizontal after TVM and LSC, but we could not conclude that the vaginal axis after the two operations differs or not from the normal axis, because we have no data compared with normal control.

There is only one report that compares clinical results of LSC and TVM. Maher et al. [24] compared LSC and TVM for vaginal vault prolapse at 2 years after operations. In their study, LSC had a significantly superior performance at POP-Q sites Aa, Ba, C, Ap, and Bp. TVL was unchanged after LSC but significantly shorter after TVM postoperatively. In our study, there was no difference in both anterior (Aa, Ba) and posterior (Ap, Bp) compartment between the two operations, but points C and D were positioned higher in LSC than TVM. TVL did not differ in both groups. Two reasons are considered to explain the different results. One is the presence of the

Table 4 Change of the vaginal axis from at rest to maximal strain, measured by MRI before and 1 year after operation for the TVM group and for the LSC group

		TVM			LSC			Between the two groups
		Preoperation	Postoperation	*p* value	Preoperation	Postoperation	*p* value	postoperation *p* value
Vaginal angle (°) HL	Valsalva-rest	16.1±21.2	25.8±15.5	0.269	27.1±15.2	21.0±10.0	0.048	0.215
Vaginal angle (°) PCL	Valsalva-rest	10.3±19.6	20.7±11.3	0.079	15.1±11.7	10.3±9.1	0.189	0.011

uterus or uterine cervix in our study. Vaginal length after hysterectomy becomes shorter. In addition to that, vaginal scar could cause vaginal shrinkage and lead to a shorter vagina. The other reason may be the shorter follow-up period in our study.

There is one study comparing abdominal sacrocolpopexy and TVM for vaginal vault prolapse by MRI before and after surgery [21]. Sixteen participants (six nulliparous control, five abdominal sacral colpopexy, five vaginal mesh kit repair) were involved in this study. They concluded that there are no differences in anatomical outcomes between abdominal sacrocolpopexy and TVM at 3 months by POP-Q examination and MRI analysis. They also described that the postoperative POP-Q point C and MRI parameters such as the vaginal axis were similar to nulliparous controls. On the other hand, points C and D after LSC were higher than TVM in our study. This different result may be due to the longer follow-up period of our study and the presence of the uterus or cervix. Our median follow-up was 37 weeks after surgery, whereas in the Ginath study, it was only 3 months. We also showed that the vaginal axis with maximal strain became more horizontal only after TVM, but they found no significant difference of the vaginal axis with maximal strain between the two procedures. Some reasons can be considered. They separated the vagina upper and lower part and measured the angle between the lower vagina and the PCL. But the upper part of the vagina has a more horizontal axis than the lower part, and it leans more horizontal by straining [25]. Their measurement of the vaginal axis may not reflect this vaginal axis change by straining. In our study, we measured the angle between the line connecting the vaginal introitus to the posterior fornix and the PCL, so we could reflect the movement of the upper vaginal part. Furthermore, we performed sacrocolpopexy by laparoscopic route but they did by abdominal approach, and paravaginal repair was concomitantly performed in all their cases. We also had four cases with concomitant surgery like rectopexy or culdoplasty in the LSC group, but their data were not far from the average. Those differences of surgical technique might affect the vaginal axis.

Balgobin et al. [26] measured the vaginal axis angle relative to a line between the lowest border of the pubic symphysis and the fourth sacral (S4) foramen at five lumbosacral mesh attachment sites in nine unembalmed cadavers. The mesh fixation point was situated from the lower border of S2 to the lower border of L5. Their result was a 3-fold increase in the vaginal axis angle from S2 to L5. The normal vaginal axis aims toward S3–S4 [25], so they concluded that fixation at the sacral promontory may result in significant anterior deviation of the vaginal axis. However in the living body, there is the abdominal pressure and the bowel compressing the mesh. As surgical technique, it is most important that the mesh should be placed without tension and not to be stretched. We suppose that the mesh after actual operation does not connect the vagina or uterine cervix to fixation point on promontory straightly but tries to hold the pelvic organs at their original position. As a result, the vaginal axis would not deviate excessively.

According to the current study, there was no difference of vaginal axis at rest between TVM and LSC. This may be the proof that both TVM and LSC could hold the vagina at the natural position without tension. The vaginal axis with maximal strain after TVM is more horizontal than LSC. This is because the fixation point of LSC, the sacral promontorium, is higher than that of TVM, the sacrospinous ligament. Though commonly believed that the vaginal axis after LSC becomes vertical, we found that LSC also makes the vagina horizontal at rest in comparison with the preoperative situation. However, it is also impossible to conclude that the vaginal axis after TVM and LSC is more horizontal than that of normal women because of the lack of normal control. At least we can suggest that LSC does not make the vagina deviate too much vertically.

Limitations of our study were the small sample size and the lack of a normal control group. Another weakness of our study is the lack of randomization and the surgical indication depending on surgeon's decision. We prefer the vaginal route in elderly patients and the laparoscopic route in patients younger than 60 years old. It leads to the difference in age between our two groups, and it could affect the anatomical results and the sexual quality of life (QOL). But there was no preoperative difference of POP-Q examination and MRI assessment in the two groups.

Furthermore, the group who underwent LSC is a rather heterogeneous group: 4 of the 14 patients had additional procedures. Procedures like rectopexy could possibly change the position of the Douglas or change the vaginal axis. But as we always implant a posterior mesh in LSC, we do not think that the vaginal axis is modified by an additional rectopexy.

The last limitation of the study is that we always have to keep in mind that any measurements done on dynamic MRI images of valsalva are dependent on the patient's ability to push reproducibly.

The strength of this report is that this is the first study to compare anatomical results of TVM and LSC by MRI measurement including dynamic evaluation. There are no reports about the vaginal configuration after LSC evaluated by MRI. We detected the new findings that the vaginal axis with maximal strain after TVM is more horizontal and that the change of vaginal axis from at rest to maximal strain is significantly greater after TVM than LSC. This anatomical difference might affect the positional relations of pelvic organs, and it can perhaps explain the differences of anatomical success rates or other clinical results such as de novo urinary incontinence or postoperative bowel dysfunctions of these surgical methods.

The necessity of LSC is increasing after the FDA public health notification which highlighted serious complications after transvaginal mesh prolapse surgery [27], but there are still few data about LSC. So, further rigorous evaluation of these procedures is required. There is also a need for standard criteria for estimation of pelvic floor disorders by dynamic MRI to help a correct clinical diagnosis of pelvic organ prolapse.

Conflict of interest M. Cosson is on the speaker's bureau, receives research support, and is a paid consultant for Ethicon Women's Health and Urology. He is a consultant for AMS and performs sponsored educational activities for Ethicon Women's Health and Urology, Olympus and Ipsen. Hiromi Kashihara, Virginie Emmanuelli, Edouard Poncelet, Chrystèle Rubod, Jean-Philippe Lucot, and Bram Pouseele declare that they have no conflict of interest. This study was entirely performed independently of manufacturer.

Informed consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.

Authors contributions H. Kashihara wrote the manuscript and contributed to the data analysis. V. Emmanuell contributed to the project development and data collection. E. Poncelet contributed to the data analysis. C. Rubod contributed to the data collection. J.P. Lucot contributed to the data collection and manuscript editing. B. Pouseele contributed to the manuscript editing and rewriting. M. Cosson contributed to the project development, data collection, and manuscript editing.

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