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Repair of pelvic organ prolapse with trocar-less versus trocar systems: Retrospective comparative study

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ABSTRACT

Objectives: The advantages of trocar-less over trocar systems for pelvic organ prolapse (POP) repair with vaginal mesh are gained mainly by bypassing the need of blind trocar insertion, thus potentially reducing complications. The aims of the study were to evaluate the safety and efficacy of trocar-less system designed for POP repair.

Materials and Methods: This is a retrospective, comparative study. One hundred-seven women were operated using the EndoFast Reliant™, trocar-less system (study group), and 123 women underwent surgical POP repair with the IVS TUNNELLER™ (tyco healthcare) trocar system (control group). The patients were evaluated pre- and post-operatively including intra and post-operative complications, anatomical results using the POP quantification and questionnaires on functional symptoms.

Results: Anatomical results were similar in both groups and there was significant improvement in all functional symptoms. There were significantly fewer complications in the study group, mainly intra-operative and immediate post-operative including: Significant bleeding (0.0% vs. 2.4%, p=0.1), bladder injury (0.0% vs. 2.4%, p=0.1), UTI and fever (2.8% vs 17.9%, p<0.001), hematomas (0.9% vs. 3.3%, p=0.23) and post-op voiding dysfunction and catheterization for more than 24 hours (0.9% vs. 13.8%, p<0.001). The surgical technique (Trocar-Less vs. Trocar System) was found as the only variable statistically significant with the correlation to early complications.

Conclusion: The EndoFast Reliant™ system is a trocar-less system for treating POP. The operation has the potential for reducing intra- and post-operative complications, with very satisfactory functional and anatomical results. It was proven safer in this study as compared to trocar system.

Keywords: Pelvic organ prolapse; vaginal mesh; trocar-system; trocarless-system; mesh related complications

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INTRODUCTION

In pelvic reconstructive surgery, recurrence of pelvic organ prolapse (POP), especially of cystocele is one of the main concerns and can reach up to 58%.[1] The Cochrane review, based on new randomized controlled trials, shows that the use of mesh at the time of anterior vaginal wall repair reduced the risk of recurrent anterior vaginal wall prolapse by up to 1.5 times.[2] However, there are some main concerns regarding complications while using vaginal mesh and the Food and Drug Administration (FDA) in July 2011 has published a safety notification regarding POP repair with mesh.[3]

Until 2008, most of the transvaginal mesh kits available to treat stress urinary incontinence (SUI) and POP required trocars to introduce the mesh. The trocars which pass blindly through the pelvic walls can cause intra and post-operative complications including: Hematomas, infections, injury to the surrounding organs like bladder, urethra or rectum and pain in case of nerve capture or injury.[4-8] When using trocar-less systems, the procedure is performed trans-vaginally without any need of per-cutaneous incisions or blind trocar passages, thus, trocar-less mesh kits may be a safer solution for inserting the mesh, if they can be proved as equally effective. Results of POP repair with one of the trocar-less kits, the Elevate™ (AMS, USA) system have been satisfactory, with similar anatomical results compared to trocar systems, but with less intra- and immediate post-operative complications.[9,10]

The EndoFast Reliant™ system is a minimally invasive system for the treatment of POP using a single-incision, trocar-less technique.[11] The system consists of a light polypropylene monofilament mesh (<40 g/m^2), fixation devices that include soft tissue fasteners and a retrieval device. The fasteners are deployed through small incision in the skin into soft tissue, with a shallow tissue penetration (2 mm). The shallow penetration reduces the possibility for visceral damage, muscle hematomas, nerve injury and post-operative pain. Each fastener can support an initial average weight of 1.0 kg, far more than required in a typical POP repair procedure.[12]

The aims of the study were to evaluate the safety and efficacy of a trocar-less system (EndoFast Reliant™) designed for POP repair by comparing the anatomical and functional results as well as complications between trocar and trocar-less systems.

MATERIALS AND METHODS

Study Design and Subjects

This is a retrospective, comparative study of 2 cohorts of patients. A Local Ethical Committee approval was obtained for the study in both Ziv Hospital, Israel and CHU Hospital Caen, France.

The main outcomes were pre- and post-operative POP-Q (ICS POP quantification and staging system[13], functional results, intra-operative complications, immediate and long-term complications.

The study includes in total 230 patients in 2 groups. The study group includes all patients (107) operated for the treatment of POP with the EndoFast Reliant™ system between December 2010 and January 2013 in the gynecology department at Ziv Medical Center, Israel. All patients were operated by one surgeon (NMB) after training with trocar and trocar-less kits designed for POP repair. Data for the study was collected from the patient's files.

The control group includes all patients (123) that were operated with the IVS TUNNELLER™ (Tyco Healthcare) trocar system by one surgeon (PvT) at the gynecology department of the CHU of Caen, France. Data was collected retrospectively between the years 2008-2010.

Data collection included demographic features, pre and post-operative examination and symptoms. Intra and post-operative complications. Patients were seen at 6 weeks, 6 and 12 months post-operatively and annually since. Pre-operative evaluation included a physical examination and review. Prolapse stage was determined by using the POP-Q and cough stress test for SUI (obvious or occult). In addition, all patients were asked systematically pre- and post-operatively about pain, dyspareunia, urinary, and defecation symptoms. Questions included: Urge symptoms, urge incontinence, nocturia, SUI, constipation and dyschezia. Success was defined as no bulge symptoms and prolapse less or equal to stage 2.

Each woman in the study and control group underwent an anterior and/or posterior repair. Apical repair was always carried out by the posterior kit in both groups either with or without rectocele prolapse correction. In both groups, the uterus was usually preserved and a mid-urethral sling procedure was performed on any woman with SUI (obvious or occult), in addition to the anterior/posterior repair.

Surgical Technique

Trocar-less system, study group

The EndoFast Reliant™ system is a minimally invasive system for the treatment of POP using a single-incision, trocar-less technique.[11] The system consists of a light polypropylene monofilament mesh (<40 g/m^2), fixation devices that include soft tissue fasteners- the Spider fasteners and a retrieval device. The fasteners are deployed through small incision in the skin into soft tissue, with a shallow tissue penetration (2 mm) Spider. The anterior mesh is designed for the treatment of cystocele and

has 4 arms. The posterior mesh is designed for the treatment of apical defect either with or without accompanied rectocele or for the treatment of isolated rectocele, and has 4 arms. The Spider fastener attaches the mesh to the soft tissue guided by direct view and/or palpation. In addition, the system includes a retrieval device, which allows intra-operative reversibility of fixation without causing damage to the tissue or the mesh.

Anterior Repair (Anterior Kit)

Dissection: A midline full thickness incision is performed on the anterior vagina extending up to 3 centimeters from the urethral meatus. The bladder is dissected away from the vaginal wall, leaving the Halban's fascia on the epithelium. The para vesical fossas are opened until the ischial spine and the arcus tendineous of the levator ani are reached posteriorly and the ischiopubic rami anteriorly.

Mesh insertion: The posterior part of the mesh is sutured to the uterine cervix or to the vaginal vault with one or two sutures. Using the Spider fasteners, the posterior arms are fixed through the same incision to the soft tissue which covers the ischial spine, 1 cm laterally on both sides. The anterior arms are fixed through the same incision to the fascia of the internal obturator muscle utilizing the fasteners. An additional one or two sutures under the bladder neck can be added in order to prevent mesh slipping. The attachment of the 4 arms in these anatomical landmarks creates a tension-free, sub-vesical hammock to treat the cystocele.

Apical and Posterior Repair (Posterior Kit)

Dissection: A midline full thickness incision is performed on the posterior vagina extending up to 1 cm from the uterus cervix or vaginal vault. The para rectal fossas are opened until the ischial spine and the sacrospinous ligaments are reached.

Mesh insertion: The posterior part of the mesh is sutured to the uterine cervix or the utero-sacral ligaments or to the vaginal vault with one or two sutures. The posterior arms of the mesh are fixed to the sacrospinous ligaments, 2 cm medial from the ischial spine by using the Spider fasteners which are inserted through the same incision. In case of rectocele, the anterior arms are fixed to the pubo rectalis muscle on both sides after dissection of the rectum.

Trocar System, Control Group

Patients were operated with the IVS TUNNELLER™ (Tyco Healthcare) trocar system. The surgical technique was described in full by Eboue et al.[7]

Statistical Analysis

In order to compare the change in variables pre- and post-operative, the paired t-test was applied for the quantitative variables of the POP-Q score, and the McNemar test was used for the categorical variables of the POP functional symptoms. The association between categorical variables and the group they belong to (study group vs. control group) was assessed using the χ^2 test of independence, or the Fisher's Exact test. The variables which were found to be significantly associated with the dependent variable (intra and immediate post-operative complications) in the univariate analyses were entered into a multivariate logistic regression model to test the effect of surgical technique correcting for confounders. All statistical tests applied were 2-tailed and a *p*-value of 5% or less, was considered statistically significant.

RESULTS

Data was collected from patient's files and included 107 patients in the study group and 123 patients in the control group. One patient in the study group and 3 in the control group were lost for follow-up. Demographic features of both groups are summarized in Table 1. Differences between the groups were noted for parity (Israeli versus French populations) and longer average follow-up for the control group. Twenty three percent had previous hysterectomy in the study group versus 15% in the control group. Overall, 12% in the study group and 18% in the control group had previous native tissue prolapse repair.

The occurrence of complications intra- and post-operative is summarized in Table 2. The total early complications (intra and immediate post-operation), included bladder injury, hematomas, fever, post-operative voiding dysfunction and catheterization more than first 24 hours were significantly higher in the control (trocar) group [39/123 (31.7%) versus 4/107 (3.7%) in the trocar-less group, ($p<0.001$)]. Mesh erosion rate was also higher in the control group. These results explain the higher re-operation rate in the control group. Statistical analysis was preformed

Table 1. Demographics of the trocar-less and trocar groups

Trocar-less group	Age	60.7±8.8 (43-82)*
	Parity	4.4±2.5 (1-13)*
	BMI	27.6±4.2 (19.1-37.8)*
	Follow-up (months)	13.6±8.9 (1-36)*
Trocar group	Age	62.3±11.4 (35-81)*
	Parity	2.6±1.4 (0-7)*
	BMI	25.0±3.5 (16.0-35.2)*
	Follow-up (months)	34 (1.5-52)*

*average, standard deviation and range; BMI: body mass index

Table 2. Surgical complications for both groups				
		Trocar-less (n, %)	**Trocar (n, %)**	**p**
Intra-operative complications	Significant bleeding	0/107 (0.0%)	3/123 (2.4%)	0.1*
	Bladder injury	0/107 (0.0%)	3/123 (2.4%)	0.1*
Immediate post-operative complications	UTI/fever	3/107 (2.8%)	22/123 (17.9%)	<0.001*
	Urinary retention and need for short period[#] catheterization	1/107 (0.9%)	17/123 (13.8%)	<0.001*
	Hematoma	1/107 (0.9%)	4/123 (3.3%)	0.23*
Long term post-operative complications	Mesh erosion	2/107 (1.9%)	10/123 (8.1%)	0.03*
	de novo SUI	3/50*** (6.0%)	9/65*** (13.8%)	0.29*
	de novo urgency	8/51**** (15.7%)	12/83**** (14.5%)	0.85*
	Recurrent prolapse-non-mesh repaired site	6/107 (5.6%)	1/123 (0.8%)	0.05**
	Recurrent prolapse-procedure failure	5/107 (4.7%)	7/123 (5.7%)	0.73*
	Recurrent prolapse-due to elongation of cervix	1/107 (0.9%)	1/123 (0.8%)	1**
	Recurrent operation due to complications or *de novo* SUI	5/107 (4.7%)	19/123 (15.4%)	0.01*

*calculated by pearson's χ^2 test; **calculated by fisher's exact test; *** the denominator represents women without SUI post-operatively; **** the denominator represents women without urgency post-operatively; [#] short perid-until 4 weeks; SUI: stress urinary incontinence

to detect potential confounders which might be associated with the early complications. Variables of demographics, prior gynecological operations, type of surgical repair performed (anteior/posterior) and pre-operative symptoms were evaluated as potential confounder variables. Parity, anterior repair, as well as pre-operative voiding difficulty were found to be significantly associated with early complications. In order to test the significance of the surgical technique (trocar-less vs. trocar systems) controlling for the above confounders, a multivariate logistic regression model was applied. In this model, only the surgical technique (trocar versus trovcar-less) remained statistically significant (p=0.001), odds ratio=13.9, as seen in Table 3.

Anatomical results for the study group are presented in Table 4. The anatomical results at last visit were very good with almost 94% success rate. Six patients (5.6%) were considered as failure, all were in the apical compartment, but only four (3.7%) were symptomatic. Data regarding the POP-Q examination of the control group was available only for 6 months post-operatively. The anatomical results were compared between the 2 groups. There were no differences between the groups at 6 months, as

Table 3. Potential confounders which might be associated with the early complications, logistic regression				
	p*	**Adjusted OR**	**95% CI for OR**	
			Lower	**Upper**
Procedure method	**0.001**	13.986	2.979	65.668
Parity	0.990	0.998	0.791	1.261
Voiding difficulty	0.502	1.302	0.603	2.814
Anterior repair	0.478	0.482	0.064	3.613
Constant	0.001	0.058		

*calculated by the wald test; CI: confidence interval; OR: odds ratio

Table 4. POP-Q pre- and post-operation, study group			
	Pre-operation [average ± SD, (range)]	**Post-operation [average ± SD, (range)]**	***p***
Ba	0.5±2.3 [(-3)-6]	-2.3±1.1 [(-3)-2]	<0.001
Bp	-1.2±2.0 [(-3)-7]	-2.8±0.5 [(-3)-(-1)]	<0.001
C	-1.3±4.2 [(-8)-7]	-6.9±2.9 [(-9)-5]	<0.001
D	-2.1±3.8 [(-9)-6]	-8.0±2.5 [(-10)-5]	<0.001

POP-Q: pelvic organ prolapse-quantification; SD: standard deviation

Table 5. Six months post-operatively anatomical results in both groups		
	Trocar-less group (n, %)	**Trocar group (n, %)**
Stage 0-1	103/106 (97.2%)	119/120 (99.2%)
Stage 2	3/106 (2.8%)	1/120 (0.8%)

shown in Table 5. In both groups, anatomical success was 97 and 99 percent.

Functional symptoms of the study group were analyzed before and after surgical intervention and are shown in Table 6. There was improvement in all categories. *De novo* dyspareunia was found only in 2 patients (1.9%), one because of tension on one of the arms and the second due to traction at one of the fixation points. Both had re-operation to release the arm and improved.

DISCUSSION

Vaginal wall reinforcement surgeries with transvaginal mesh for the treatment of POP are well established in the literature with large series and randomized trials proving safety, high cure rates and patient's satisfaction.[2,4,8,14-17] Since the FDA warning in 2011,[3] there is a big debate regarding the use of vaginal meshes and guidelines have been published in order to limit the mesh-related complications rate, mainly advising to limit the use for patients with high risk for recurrence, to have a good inform consent and that the surgeon has an adequate training in the field and keeps high volume practicing.

Many of the commercial kits used for POP repair were trocar-guided for the insertion of the mesh into the pelvic floor. Insertion of the mesh with trocars can cause intra and immediate post-operative complications including: Hematomas, infections, injury to the surrounding organs like bladder, urethra or rectum and pain.[4-8] The use of those kits, can explain many of the mesh-procedure related complication rate and not necessarily the mesh itself. The advantages of the trocar-less systems are gained mainly by bypassing the need of blind trocar insertion. While reducing the probability for complications, the trocar-less system also provides a quicker and less invasive operation with reduced morbidity.

Results of the Elevate™ System (AMS USA), a trocar-less system, have been satisfactory, with long term evaluation with similar anatomical results compared to trocar systems, but with less mesh erosion and extrusion incidence, and with less bladder and urinary injuries.[9,10] First results with the EndoFast Reliant™ system were recently published.[11] The EndoFast Reliant™ system can be easily and directly deployed trans-vaginally in narrow spaces through the soft tissue via a single vaginal incision and support substantially more weight than other available trocar-guided techniques.[12] The fasteners' penetration into the tissue is very superficial (2 mm), thus can reduce the possibility for visceral damage, muscle hematomas, nerve injury and post-operative pain.

When testing a new technique like the trocar-less way for introducing the mesh, few aspects should be considered: Efficacy and safety. Efficacy means that the anatomical and functional results are as good as for the trocar kits. Safety can be compared by the rate of complications.

In this study, actually, the trocar versus trocar-less passage was compared. Both groups were operated in the same way, as the surgeon of the trocar-less group has trained for two years with the surgeon of the trocar group. The operation technique was identical with only the different method for the insertion of the mesh; with or without trocar.

Regarding efficacy, the anatomical results with the EndoFast Reliant™ system were very satisfactory. The pre- and post-operative difference in the POP-Q score is statistically significant, $p<0.001$ in all categories of the POP-Q (Ba, Bp, C, D) (Table 4), and long-term results are promising. When comparing the anatomical results to the control group, it is similar in both groups with the same rate of failure at the long term.

As for safety, comparing surgical complications between the two groups in this study (Table 2), there were significantly fewer complications in the less group. The trocar group complications mainly include intra-operative and immediate post-operative complications such as UTI, bladder injury, fever, hematoma and voiding dysfunction (which resulted in catheterization for more than 24 hours). Those complications can be associated with

Table 6. Functional symptoms pre and post-operation			
	Pre-operation (n %)	**Post-operation (n, %)**	***p****
Dyspareunia	13/48** (27.1%)	7/48** (14.6%)	0.07
SUI	57/107 (53.3%)	8/107 (7.5%)	<0.001
Urgency	56/107 (52.3%)	25/107 (23.4%)	<0.001
Voiding difficulty	63/107 (58.9%)	0/107 (0.0%)	<0.001
Constipation	30/107 (28.0%)	26/107 (24.3%)	0.54
*calculated by mcnemar's test; ** 48 women were sexually active; SUI: stress urinary incontinence			

the use of the trocars which can cause more hematomas and bladder injury. The trocar system can also cause some pressure on the bladder neck due to tension and as a result, cause voiding dysfunction and catheterization.

In regards to the number of patients in each group that suffered early complications (intra and immediate post-operative), there were 4 (3.7%) and 39 (31.7%) in the trocar-less and trocar groups, respectively. This difference in the early complication rate between the groups is statistically significant with $p<0.001$. In a multivariate logistic regression, only the surgical technique remained statistically significant as a cause for the different between the groups ($p=0.001$), odds ratio=13.9 (Table 4).

Regarding the long-term complications, the erosion rate was higher in the trocar group (8.1% in the trocar group vs. 1.9% in the trocar-less group). This finding can be explained by the type of mesh that was used in the IVS system and not necessarily due to the use of the trocars. Ultimately, the overall complication rate and re-operation was higher in the trocar group.

Functional symptoms in the study group were improved as can be seen in Table 6. The difference and improvement pre- and post-operatively in 3 of the symptom variables, SUI, urgency and voiding difficulty was statistically significant.

SUI (obvious or occult) was diagnosed in 57 patients in the trocar-less group and they all had an additional mid-urethral sling inserted during the prolapse repair. Only 3/50 patients (6%) suffered from *de novo* SUI after the surgical procedure. A recent systemic review has shown that combination surgery of prolapse repair and prophylactic SUI intervention reduces the risk of SUI *de novo*.[18] In this cohort of women, only symptomatic or occult SUI patients were treated with mid-urethral sling. Still, the rate of *de novo* SUI was low.

Out of 56 patients that had urgency symptoms pre-operatively in the study group, 39 (69.6%) were cured by the repair of the prolapse and 8 patients developed *de novo* urgency.

All of the patients (100%) in the trocar-less group who suffered from incomplete voiding pre-operatively were cured by the repair of the prolapse and there were no *de novo* cases. In comparison, in the trocar group, 17 patients (13.8%) suffered from *de novo* urinary retention, and out of these patients, 4 needed a surgical intervention to release the tension of the mesh to solve the problem. The insertion of the mesh with trocars can cause excessive tension on the bladder neck and therefore voiding difficulties, although normally transient. The trocar-less system may permit a better adjustment of the tension, thus less post-operative voiding difficulties are likely to occur.

In the study group, pre-operative dyspareunia due to the prolapse disappeared for 7 patients. *De novo* pain and dyspareunia was found in 2 patients (2/107, 1.9%), one due to tension on one of the arms and the second due to traction at one of the fixation points. Both had re-operation for releasing the arm and improved. No case of lasting pain was described. Dyspareunia and perineal pain are major complications after mesh operations with great influence on women's quality of life. The dyspareunia rates are varying and in certain series reach 16.7%.[19-22] Dyspareunia post transvaginal mesh surgery is mainly related to over tension or mesh shrinkage; both are responsible for deformation of the vagina and thereby causing dyspareunia. The use of two separated incisions with two separated meshes when repairing anterior and posterior defects can be the reason for better vaginal results without any deformation and therefore no signs of dyspareunia. Perineal pain which is a rare complication,[4-6] can be caused by post-operative hematoma, nerve captured or nerve injury. The trocar-less systems can decrease the rate of the muscles hematomas and therefore decreased this kind of post-operative pain. The spider fasteners hold the mesh while capturing the fascia very superficially, thus reducing the risk of nerve capture or injury.

Complications related to the adjuvant materials and risk factors are well described in the literature[5,23,24] and infections have nearly disappeared since the generalized use of knitted polypropylene monofilaments implants.[6,25,26] The EndoFast Reliant™ system consists of a monofilament polypropylene mesh of <40 g/m^2. There were two cases of small erosions (1.9%), which improved under estrogen therapy and there was no need for surgical intervention. There were no cases of mesh infections in the trocar-less group.

This study, aimed to prove that mesh-related complications can be reduced, and it is pity that many surgeons abandon the vaginal mesh completely.[27]

Study Limitations

This study has a few limitations due to its retrospective and comparative nature and is therefore susceptible to recall and interpretation biases: Firstly, comparing different groups from two separate countries can be problematic and not all data was available for all patients. In addition, each group was operated in a different hospital with a different surgeon. However, the surgeon operating in Ziv did her training in Caen, France so the surgical methods and techniques were the same. It should also be mentioned that both kits are no more in the market now days. There are strengths to the study: All data was collected by an independent student (as part of his MD thesis) which reduces the chance for bias. In addition, both groups were operated in the same way and surgical technique which truly permit the comparison between the ways of inserting the mesh, with or

without trocars. Finally, up to date, there have been very few publications on the EndoFast Reliant™ system, with small groups and short follow-up, hence the importance of this study.

CONCLUSION

EndoFast Reliant™ is a minimally invasive system for treating POP using a single vaginal incision, trocar-Less technique. The operation has the potential for reducing intra- and post-operative complications, with very satisfactory functional and anatomical results. The surgical technique (trocar-less system vs. trocar system) was found as the only variable statistically significant with the colorations to early complications. It was proven safer in this study as compared to trocar system. Further, larger comparative studies and long-term results are required.

ETHICS

Ethics Committee Approval: A Local Ethical Committee approval was obtained for the study in both Ziv Hospital, Israel and CHU Hospital Caen, France (number: 0076/13, 2013).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Contributions

Surgical and Medical Practices: N.M., P.V.T.; Design: N.M., P.V.T.; Data Collection or Processing: Y.A., C.E.; Analysis or Interpretation: N.M., Y.A.; Writing: N.M., Y.A., C.E., P.V.T.

DISCLOSURES

Conflict of Interest: Prof. Peter von Theobald was consultant for Tyco Healthcare between the years 2004-2010. Dr. Naama Marcus is was consultant for IBI medical 2012-2018.

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