The Manchester Procedure: Anatomical, subjective and sexual outcomes

Sissel H. Oversand, MD[1,2]; Anne C. Staff, MD PhD[1,2]; Ellen Borstad, MD[1];

Rune Svenningsen, MD PhD[1]

[1]Department of Gynaecology, Oslo University Hospital, Oslo, Norway

[2]Faculty of Medicine, University of Oslo, Oslo, Norway

Corresponding author: Sissel Hegdahl Oversand, Department of Gynaecology,

Oslo University Hospital, Ulleval, Pb 4956 Nydalen , 0424 Oslo, Norway

E-mail: sisseloversand@gmail.com/sisove@ous-hf.no

Telephone, business: +47 22119800 private: +47 90851474 fax+47 22119775

Financial disclaimer/ conflict of interest: None

SH Oversand: None

AC Staff: None

E Borstad: Speaker fees from Astellas

R Svenningsen: Nordic advisory board for Astellas, Speaker fees from Astellas

Funded by the institution

Author`s contribution to the manuscript:

SH Oversand: Project development, Data collection and analysis, Manuscript writing

AC Staff: Project development, Data analysis, Manuscript writing

E Borstad: Project development, Manuscript writing

R Svenningsen: Project development, Data collection and analysis, Manuscript writing, Study supervision

A limited abstract including some of the data was presented at the Annual Meeting of the Norwegian Association of Gynecology (NGF) in Stavanger, in October 2017

Word count abstract: 250

Word count manuscript: 3235

ABSTRACT

Introduction and Hypothesis: Classical native-tissue techniques for Pelvic Organ Prolapse (POP) repairs, such as the Manchester Procedure (MP), have been revitalized due to vaginal mesh complications. However, there are conflicting opinions regarding sufficient apical (mid-compartment) support by the MP, and concerns about the risk of dyspareunia. The aims of this study were therefore to investigate anatomical and patient-reported outcomes 1 year after MP.

Methods: Prospective cohort study of 153 women undergoing a MP for anterior compartment POP between October 2014 and June 2016. Pre- and 1 year postoperative evaluations included POP-Q measurements and the questionnaires Pelvic Floor Distress Inventory Short Form 20 (PFDI-20) and POP/Urinary Incontinence Sexual Questionnaire (PISQ-12).

Results: At 1 year, 97 % (148/153) attended the follow-up. Significant anatomical improvements ($p<0.01$) were obtained in all compartments. Mean Ba was -1.1(±1.4), mean C -5.9 (±1.7) and mean D -7.0 (±1.2) at follow-up. Point C ≤ -5 was present in 81.1 %. POP-Q stage 0-1 was obtained in 99.3 % in mid-compartment (C < -1), but only in 48.6 % in anterior compartment (Ba < -1). Significant reduction in symptom scores was obtained for PFDI-20 ($p<0.01$) and PISQ-12 ($p=0.01$). No significant changes were seen in dyspareunia rates (q.5, PISQ-12), but 5.6 % reported de novo dyspareunia. Concerning POP symptoms, 96.0 % stated to be cured or significantly improved.

Conclusions: The Manchester Procedure provides adequate apical support. Albeit inferior anatomical anterior compartment results, 96.0% reported being subjectively cured or substantially better at 1 year follow-up, with no significant change in dyspareunia.

KEYWORDS

Dyspareunia

Gynecologic Surgical Procedures

Pelvic organ prolapse

Recurrence

BRIEF SUMMARY

The Manchester Procedure provides adequate apical support. Albeit inferior results in the anterior compartment, 96.0 % considered themselves cured or significantly better of their prolapse symptoms.

INTRODUCTION

Symptomatic pelvic organ prolapse (POP) affects a large proportion of the female population, with anterior compartment prolapse representing the most common form [1]. The incidence of POP surgery ranges from 1.5 to 1.8 per 1000 women years, peaking at the age of 60-69 [2]. High recurrence rates, particularly in the anterior compartment, have been a major dilemma in POP surgery for over a century [3]. There is to date no consensus on which surgical techniques to use for which indications [4]. Concomitant apical repair has been shown to improve outcomes after anterior repairs [5], but there are widely differing views among vaginal surgeons on how to successfully elevate and secure the vaginal apex and whether or not a hysterectomy should be performed [4].

In recent years, several authors have refuted the previously alleged poor outcomes after uterus-sparing native tissue POP repairs [6], and native-tissue procedures such as the Manchester Procedure (MP) are again gaining popularity particularly due to the steady increase in reported complications after vaginal mesh surgeries [7]. There are, however, concerns that a MP might not give adequate elevation of the mid-compartment [8], and some claim it is primarily useful for correcting cervical elongation [9]. Since the procedure was modified shortly after its inception to incorporate a restoration of the perineal body (to act as support for the anterior repair), it has been associated with a risk of dyspareunia, especially when levator ani muscle plication is used [10].

In our Department, the MP has been the surgical technique of choice for anterior compartment POP for decades. Our tertiary center performs about 150 Manchester Procedures yearly. In sexually active women, our Department recommends reconstruction of the perineal body without involving the levator ani muscles [11], in order to reduce the dyspareunia risk. The Department has run an internal quality registry for POP surgery since 2002, and we have previously reported our results from this registry on women having undergone native tissue repairs [11]. Our published registry data revealed significantly better outcomes in women with POP operated with the MP

compared to isolated repairs in the anterior compartment, especially in terms of a low rate of symptomatic recurrences in need of re-operation [11]. However, like other recent publications reporting favorable outcomes after the MP, the study was mainly retrospective in design [11,12].

Our aim was therefore to evaluate anatomical as well as subjective POP-related and sexual outcomes 1 year after the Manchester Procedure in a prospective observational study, with adequate sample size. We also wanted to assess whether postoperative anatomical success was correlated with subjective outcomes.

MATERIAL AND METHODS

The present study was a prospective cohort study of women operated with the Manchester Procedure (MP) at the Department of Gynaecology at Oslo University Hospital (OUS). Inclusion was carried out between October 2014 and January 2016, and surgeries were performed between October 2014 and June 2016. Patients referred for a preoperative evaluation of POP received postal study information previous to their appointment at the outpatient clinic. Women with symptomatic prolapses that included the anterior compartment and no previous prolapse surgery were considered eligible for the study. Patients were excluded if they had previously undergone a hysterectomy (total or subtotal) or if the preoperative evaluation (including transvaginal ultrasound and, on indication, endometrial biopsy) revealed coexisting indications for hysterectomy, such as endometrial pathology. In case of adnexal pathology, evaluation and treatment for this condition had to be concluded before POP surgery.

As the standard treatment for anterior compartment prolapse with a concomitant mid-compartment prolapse up to stage 3 due to cervical elongation at our Department is the MP, study participation had no impact on the choice of surgical method for these patients. Although MP may be performed in larger uterine prolapses, the routine procedure at the Department for the few POP patients evaluated for surgery (less than

10% [11]) with a true uterine prolapse (≥ Stage 2) and not only cervical elongation, is a hysterectomy in combination with either sacrospinous fixation or sacrocolpopexy. These women were excluded from study participation. The position of the uterine corpus was evaluated on palpation (during patient Valsalva or by cervical traction) by identifying the cervico-uterine junction as well as the position of the posterior fornix. The study participants had to be fluent in one of the Scandinavian languages or English to be included. The present study was approved by the Norwegian Regional Ethics Committee (2013/2093) and Oslo University Hospital (OUS) personal data officer. It was registered at ClinicalTrials.gov with registry number NCT02246387. Informed, written consent was obtained from all participants.

The Manchester Procedure was developed in the late 19th century as a uterus-sparing surgical option for POP. It includes an anterior colporrhaphy followed by a uterosacral/cardinal ligament plication in which the ligaments are shortened and repositioned on the proximal anterior aspect of the cervix allowing it to be drawn upwards, inwards and backwards in the female pelvis, see Figure I. This shortening and repositioning of ligaments provide the elevation of the mid-compartment. The extent of cervical amputation depends on the degree of cervical hypertrophy and is not essential for surgical success when the cervix is of normal length. Following cervical amputation, a Hegar dilatator in the cervical canal prevents accidental closure while reconstructing the portio with modified Sturmdorf sutures. In recent publications, the term Manchester Procedure is often used without including a reconstruction of the perineal body [12], possibly omitted due to fear of dyspareunia. In our Department (and in this study) we reconstruct the perineal body if it is reduced in height and thickness, even in the absence of a posterior wall prolapse, as described in the original papers on the procedure [13] The rationale for this is that such anatomical changes will result in a change of vaginal axis and a subsequent loss of support for the anterior compartment[14] . The few

patients with anterior or mid- compartment POP and a completely intact perineal body were not included in this study.

Before surgery, and at the 1 year follow-up, a standardized interview and a clinical examination that included POP-Q measurements [15] was performed. In addition, all patients filled out the study questionnaire on POP-related symptoms (PFDI-20) [16], and those who were sexually active in terms of vaginal intercourse also filled out a questionnaire on sexual dysfunction (PISQ-12) [17]. The Norwegian validated version of PFDI-20 [18] had not been published at the initiation of this study, and PISQ-12 is still not validated to Norwegian. Due to this, translations of the validated Swedish (closely related to Norwegian linguistically and culturally) versions were used [19]. The original English versions were offered to patients not fluent in one of the Scandinavian languages, but who were eloquent in English. Per- and postoperative complications were registered at the 1-year follow-up. To reduce the risk of bias, the 1-year postoperative assessments were not performed by the surgeon, but by another clinician at the Department.

Our primary outcomes at the 1-year follow-up were the percentage of patients with POP-Q stage 0-1 in mid- and anterior compartment, as well as the percentage of women with point C ≤ -5 (eqivalent to stage 0). Secondary outcomes were mean changes in POP-Q point C (cervix), point D (posterior fornix), point Ba (maximum descent of anterior compartment) and Tvl (total vaginal length) as well as mean changes in patient-reported POP-related symptoms and sexual distress. POP-related symptoms were evaluated in several ways. The women were asked at the time of follow-up to self evaluate their results using a question on subjective cure for POP, scaled from 1 (= worse) to 4 (= completely cured). Furthermore, we used the changes in total PFDI-20 score, domain scores of POP Distress (POPDI-6) and Urinary Distress (UDI-6), and the single question: “Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?” (Question 3, POPDI-6). Changes in sexual distress were

evaluated by mean change in PISQ-12 scores, as well as the single question; "Do you feel pain during sexual intercourse?" (Question 5, PISQ-12). In order to evaluate the incidence of de novo dyspareunia, a score of the latter of 3 (usually) or 4 (always) was considered as dyspareunia. Missing were handled according to the original descriptions of the questionnaires [16,17].

Statistical analysis was performed using SPSS version 24. Paired samples t-test was used to compare means and Pearson´s correlation used to analyze bivariate correlations between anatomic changes in anterior compartment (Ba) and Mid-compartment (C) with the above POP-related and sexual symptom scores.

Sample size was estimated for paired data and based on expected proportions. We assumed that 85% of the patients would achieve a POP-Q point C ≤ -5, based on unpublished data from our internal quality registry where 85% of the women operated for POP between 2002-2005 were registered at one year follow-up with Stage 0 in mid-compartment (equivalent to point C ≤ -5). With a power of 80 % and a significance level of 0.05, from statistical table for paired data the estimated number of patients needed was 138 [20]. As we expected some postponed/cancelled surgeries, lost to follow-up etc., our inclusion aim was 160 women.

RESULTS

Originally, 160 women scheduled for MP were included, of whom 7 ended up not being operated with MP for various reasons. Thus, the final dataset consisted of 153 women. There were 5 lost to 1-year follow-up, thus the final analyzes are performed on 148 women (Fig II). Mean age at time of surgery was 61.6 years (Standard Deviation (SD) ± 11.4), mean BMI was 24.8 (SD ±3.6), 8 patients (5.4 %) had chronic diseases affecting bladder, bowel or lung (potentially causing increased intra-abdominal pressure), 14.9% had previously had a laparoscopy, 19.6 % had previously had a laparotomy and 4.7 %

had undergone both procedures. . At time of inclusion, 86.0 % were postmenopausal, of which 9.5 % used systemic Hormonal Treatment, whereas 53.2 % used vaginal estrogens only. Median parity was 2 (range 0-7). Three patients were nulliparous and the remaining women (98.0 %) had given birth vaginally at least once, 5.5% of which had also undergone a cesarean section. Eligible women not included (n=22; of which 7 denied inclusion, see Figure II) and women not included due to insufficient fluency in Scandinavian/English (n=10) (Figure II) were similar to study participants by means of age and POP stage, but had significantly higher BMI (p= 0.02).

Ninety-seven percent attended the 1-year follow-up (148/153). Median time to follow-up was 12 months (range 8-16). POP-Q points (Ba, Bp, C, D, gh, pb and tvl) were near-normally distributed. Pre and postoperative POPQ points and stages are presented in Table I. At the 1-year follow-up, POP-Q stage 0-1 was present in 99.3 % (n=147) in the mid-compartment, but only in 48.6 % (n=72) in the anterior compartment. Of the 47.3 % (n=70) who had Stage 2 in the anterior compartment, 81.4 % (57/70) had point Ba at or above the hymenal plane. Point C ≤ -5 (equivalent to stage 0) was present in 81.1% (120/148). Since our sample size estimation was based on an expected proportion of 85% with C ≤-5, a post hoc study power calculation was performed by means of paired t-test for changes in C, which confirmed adequate sample size (n=101 for effect size 0.81 and SD of change 2.9).

Patient-reported outcomes are presented in Table II. Ninety-six percent reported to be cured or improved from their POP symptoms. Significant symptom reduction was reported in all POP-related and sexual symptom scores ($p < 0.05$), except for dyspareunia ($p = 0.70$). Pre-and postoperative dyspareunia is described in Figure III. De novo dyspareunia was reported in 4/72 women (5.6 %). In addition, 1 of the women who had been sexually inactive prior to operation (and thus no information existed on preoperative dyspareunia) reported dyspareunia postoperatively.

Only 1 of the 148 women underwent repeat POP surgery due to recurrence within the first year of follow-up (0.7 %; 1/148).

By dichotomizing women with postoperative anterior compartment POP stage 2 into Ba above/below the hymenal plane, we found a trend towards increased postoperative symptoms of bulging in the latter group ($p = 0.08$). Not surprisingly, anatomical changes in the anterior compartment (Ba) correlated significantly with changes in C and D ($p = 0.01$). Furthermore, anatomical changes in the anterior compartment were significantly correlated with POP specific symptoms (POPDI-6, $p = 0.01$), Urinary distress symptoms (UDI-6, $p < 0.01$) and with the symptom of bulging (q.3, POPDI-6, $p < 0.01$). In other words, women with the best anatomical reduction of the anterior wall descent seemed to have less POP-related distress symptoms one year after surgery. No significant correlations were demonstrated between changes in mid-compartment (C) and changes in PFDI-20 scores (total or subdomains) except for the single symptom of bulging (q.3, POPDI-6, $p = 0.04$). The changes in the anterior or mid-compartment measurements did not correlate significantly with changes in sexual distress (PISQ 12) or dyspareunia (q.5, PISQ-12).

Postoperative complications are presented in Table III. The overall complication rate was 11.8 % (n = 18), with hematomas and prolonged postoperative pain as main problems. Surgical re-interventions due to complications were performed in 6 patients (3.9 %).

DISCUSSION

This study is to our knowledge one of very few prospective studies evaluating the Manchester Procedure. We were able to demonstrate that the procedure gives adequate apical elevation, in accordance with recent publications comparing MP with vaginal hysterectomy [21,22]. Ideally, point C and D becomes equal after MP. The anatomical improvement in the mid- compartment cannot be explained solely by the cervical

amputation, since a significant elevation was also achieved in point D (posterior fornix). We believe the main cause of the apical point (D) elevation is the shortening and repositioning of the uterosacral and cardinal ligaments (US/CL), as these ligaments are known to contain both elastin and smooth muscle fibers [23]. Although this step is crucial in the original description of the MP [14], we suspect that it is often neglected during surgery. Even though the few early studies evaluating the procedure demonstrated good outcomes [24], the procedure was abandoned in many urogynecological units for reasons unknown, and for the last decade replaced with transvaginal mesh procedures.

POP symptoms are often described to correlate poorly with anatomy [22]. However, in the present study, we found a trend towards decreased symptom scores of bulging in women with postoperative Stage 2, where Ba was at or above the hymenal level (81% of women with stage 2) compared to those with Ba below the hymenal plane ($p=0.08$). This may support the hymenal level as a natural threshold for symptomatic anterior compartment prolapse, as previously proposed by others [25].

In our study, changes in Ba correlated with both reduction in prolapse symptoms and urinary distress, but more surprisingly changes in C also correlated significantly with a reduction of the symptom of bulging. This again adds to the importance of mid-compartment elevation in women with a predominant anterior compartment prolapse. As demonstrated by others, we found that the MP does not fully restore the anterior compartment. However, reducing the anterior prolapse proximal to the level of the hymen has been shown also by others to significantly lower POP symptoms and having a clear correlation to patient satisfaction [25].

The overall complication rate in our study cohort was 11.8 %. This is within expected rates for the MP [12], and other mid-compartment procedures [26]. It is also far lower than what has been reported for anterior compartment surgery using synthetic mesh [27]. Even though cervical stenosis has been reported in the literature as a main

risk after a MP, especially in postmenopausal women [28], we only identified this in one woman in our patient cohort.

In recent publications, the term Manchester Procedure is often used without including a reconstruction of the perineal body [12], possibly omitted due to the fear of causing dyspareunia. Although still controversial, in our opinion, when a MP is performed for anterior compartment repair, a reconstruction of the perineal body will prevent symptomatic recurrence, as this perineal body repair procedure restores the floor on which the anterior wall rests during strain. The effect of the MP on dyspareunia is hard to evaluate. Analyzing the question in the PISQ-12 questionnaire specifically targeting dyspareunia, no significant change was found one year after MP ($p = 0.70$, Table II). De novo dyspareunia was found in 5.6 % of the sexually active women whereas 1 woman, who became sexually active after surgery, also reported dyspareunia. However, 4 women in the cohort reported preexisting dyspareunia, from which half of them improved. All of the above implies that this is a population (mainly postmenopausal) in which the individual impact of surgery is hard to predict. However, overall sexual function as stated by the PISQ-12 scores demonstrated an overall improvement after the MP ($p = 0.01$). We still believe it is important when performing surgery in the posterior compartment that care is taken to avoid including deeper muscular layers (m. levator ani) in sexually active women.

The strength of the present study is the large sample size and the prospective design. To our knowledge, there is to date only published two relatively recent studies on MP with a prospective design [21,22]. Both of these studies compared the MP with vaginal hysterectomy (VH).

As this is a single-center study, the surgeries were attempted performed in a similar manner regardless of different surgeons. Furthermore, residents were always assisted by experienced urogynecologists when performing these MP surgeries. However, there are some weaknesses in the study design, one being the short follow-up

time (only 1 year). We are, however, planning a 5-year follow-up of the cohort. It might also be considered a weakness that the length of the amputated cervix was not measured before surgery so that the degree of apical change solely attributed to US/CL suspension could have been evaluated. The surgeons were not allowed to assess their own patients at the 1-year follow-up, and the doctor evaluating the women was blinded to most of the preoperative study information (such as exact preoperative POP-Q measurements and answers to PISQ-12/PFDI-20). However, the postoperative evaluators had access to information in the medical charts (such as preoperative prolapse staging). Even though this theoretically could introduce bias when evaluating the results, we believe the risk of a significant impact on the results is negligible. Some might claim that our results from uterus-sparing surgery are not necessarily applicable to other populations where hysterectomy rates for benign indications are substantially higher. However, in recent years, hysterectomy rates for benign causes have decreased worldwide, including in the US [29]. We believe uterus-sparing POP surgery will retain its place also in future POP surgery, especially since the risk of vault prolapse is known to be substantially higher after uterus removal [30].

In conclusion, this study shows that the MP provides adequate mid-compartment support and excellent subjective outcomes at 1 year follow-up, whereas the less optimal anatomical outcomes in the anterior compartment may be still considered a challenge. The obtained anatomical changes in mid-compartment correlated well with the changes in the sole symptom of bulging, whereas the anatomical changes in the anterior compartment also correlated with the overall changes in POP symptoms and urinary distress. The inferior anatomical outcome in the anterior compartment did not seem to affect subjective satisfaction, implying that the aim of surgery in the anterior compartment should be to reduce the prolapse to above the level of the hymen, and not necessarily aiming for stage 0-1. In addition, the perineal body restoration might have reduced the potential negative subjective effects of a less optimal anatomical anterior

wall repair.

Acknowledgements

The authors would like to thank Associate Professor Jon Michael Gran, Biostatistician at OUS and UiO for support on statistical analyses.

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520 **Figure Legends**

521 Figure I: Manchester procedure; a. Clamping and dissection of cardinal and uterosacral
522 (C/US) ligament complex; b. C/US ligaments shortened and attached at anterior aspect of
523 the isthmic part of the uterus; c. Supportive effect of uterus sparing surgery and
524 reconstruction of perineal body. SP= Symphysis pubis; B= Bladder; U= Uterus; V=Vagina;
525 C/US ligaments= Cardinal /Uterosacral ligaments.

526 Figure II: Inclusion and follow-up, women operated by Manchester procedure

527 Figure III: Pre- and postoperative dyspareunia, women operated with MP (n=148)

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547 **Tables**
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Table I: Anatomical outcomes before and 1 year after the Manchester Procedure (n=148)[1]				
POP-Q measurements	**Preoperative**	**Postoperative**	**Paired Differences (mean (SD[2]) cm)**	**p**
Anterior compartment				
- Point Ba[3] (mean (SD) cm)	+1.8 (±1.7)	- 1.1 (±1.4)	- 2.9 (±1.8)	< 0.01
- Stage 0-I (% (n))	2.0 (n=3)	48.6 (n=72)		
- Stage II (% (n))	41.9 (n=62)	47.3 (n=70)		
- Stage III (% (n))	56.1 (n=83)	4.1 (n= 6)		
Posterior compartment				
- Point Bp[4] (mean (SD) cm)	-1.1 (±1.4)	-2.8 (±0.6)	-1.7 (±1.4)	< 0.01
- Stage 0-I (% (n))	52.0 (n=77)	98.0 (n=145)		
- Stage II (% (n))	41.2 (n=61)	2.0 (n=3)		
- Stage III (% (n))	6.8 (n=10)	0.0 (n=0)		
Mid- compartment				
- Point C[5] (mean (SD) cm)	-1.2 (±2.8)	- 5.9 (±1.7)	- 4.8 (±2.9)	< 0.01
- Mean point D[6] (cm)	-6.4 (±1.5)	-7.0 (±1.2)	- 0.7 (±2.0)	< 0.01
- Stage 0-I (% (n))	50.0 (n=74)	99.3 (n=147)		
- Stage II (% (n))	31.8 (n=47)	0.0 (n=0)		
- Stage III (% (n))	17.6 (n=26)	0.7 (n=1)		
Other POPQ measurements				
- Tvl[7] (mean (SD) cm)	8.2 (±1.2)	7.9 (±1.1)	- 0.3 (±2.2)	0.03
- Gh[8] (mean (SD) cm)	4.6 (±1.1)	3.4 (±0.8)	-1.2 (±1.1)	< 0.01
- Pb[9] (mean (SD) cm)	2.5 (±1.2)	3.6 (±1.0)	1.1 (±1.5)	< 0.01

549 [1]No women had pre-or postoperative Stage IV in any compartment [2]Standard Deviation [3]Max.
550 desc. ant.comp [4]Max. desc. post. comp [5] Max desc. cervix [6]Max desc. post fornix [7]Total vaginal
551 length [8]Genital hiatus [9]Perineal body

Table II: Patient-reported outcomes 1 year after Manchester Procedures (n = 148)								
			Cured/ Improved		Unchanged		Worsened	
			n/N[a]	%	n/N[a]	%	n/N[a]	%
Subjective results (scaled 0-4):			142/148	96.0[b]	5/148	3.4	1/148	0.7
Changes in symptom scores:	**Mean paired differences (SD)**	**P**						
Pelvic floor distress (PFDI-20)	-54.12 (47.00)	< 0.01	132/147	89.8	0/145	0.0	15/147	10.2
POP symptoms (POPDI-6)	-33.3 (24.21)	< 0.01	134/147	91.2	4/147	2.7	9/147	6.1
"Bulging"(q.3, PFDI-20)	-2.45 (1.64)	<0.01	117/144	81.3	23/144	16.0	4/144	2.8
Urinary Distress (UDI-6)	-15.52 (23.04)	< 0.01	105/147	71.4	13/147	8.8	29/147	19.7
Stress Urinary Incontinence (q.17, PFDI-20)	-0.35 (1.31)	<0.01	35/144	24.3	94/144	65.3	15/144	10.4
Urgency Urinary Incontinence (q.16, PFDI-20)	-0.38 (1.6)	<0.01	47/145	32.4	74/145	51.0	24/145	16.6
Incomplete Bladder emptying (q.19, PFDI-20)	-1.08 (1.58)	<0.01	71/145	49.0	64/145	44.1	10/145	6.9
Sexual Dysfunction (PISQ-12)	-1.60 (5.00)	0.01	33/64	51.6	8/64	12.5	23/64	35.9
Dyspareunia (q.5, PISQ-12)	0.05 (1.12)	0.70	16/65	24.6	32/65	49.2	17/65	26.2

[a]N differs due to missing/incomplete answers

[b] Cured: 70.3% (n=104); Improved: 25,7% (n=38)

Table III: Postoperative complications, Manchester Procedures (n=153)

	n	Percent
Ureteric kink/injury	1	0.7
Minor bleeding/hematoma	5	3.3
Profuse bleeding[b]	2	1.3
Prolonged postoperative pain[c]	6	3.9
Minor infection	3	2.0
Cervical stenosis	1	0.7
Total complications	**18**	**11.8[a]**

[a]Percentages do not add due to rounded values [b]In need of transfusion
[c]More than four weeks duration