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3 Year outcome after treatment of uterovaginal prolapse with a 6-point fixation mesh☆

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ABSTRACT

Introduction: The aim of this study was to describe the intermediate outcome of a single-incision 6-point fixation transvaginal mesh for the treatment of primary and recurrent pelvic organ prolapse (POP).
Study design: This was a prospective cohort study including consecutive patients undergoing POP repair with the InGYNious anterior transvaginal mesh. Inclusion criteria were women with symptomatic stage II POP or higher. Exclusion criteria were the unwillingness or inability to give written informed consent, malignant diseases, neuro-muscular disorders, chronic pain syndrome or previous radiation in the pelvis. Every study participant completed a structured questionnaire, a urogynecological examination according to the IUGA-ICS POP-Q staging system and the validated P-QoL questionnaire before the operation and three years postoperatively.
Results: 254 patients were included into the study, 179 were available for the three-year follow-up (70 %). Sixteen patients (8.2 %) had undergone reoperation for recurrent or de novo prolapse (12/16 patients underwent reoperation in the posterior compartment) and were excluded from the objective outcome analysis. In the final study group, all POP-Q measurements, urge urinary incontinence and voiding dysfunction were significantly improved. The de novo SUI rate was 27/ 120 (23 %) in women without reoperation for SUI and/ or POP and without primary SUI. No serious adverse events occurred. Four (1.5 %) patients had mesh exposure at the one-year follow-up and been treated with local oestrogen. At three-year follow-up, no new mesh exposure was seen. De novo dyspareunia rate was low (n = 5 (3 %)).
Conclusions: In this study, the objective outcome three years after anterior POP repair with the InGYNious transvaginal mesh was good. The reoperation rate both for mesh related problems or prolapse were rare.

Introduction

Primary Pelvic organ prolapse (POP) occurs in up to 50 % of women [1]; recurrent POP up to 30 % upon native tissue surgery [2]. The high rates of recurrent POP have led to the implementation of synthetic meshes for primary and secondary vaginal POP repair. Perioperatively, native tissue surgery shows comparable rates of complications to transvaginal mesh () surgery [3]. According to a review from the British Society of Urogynecology, the short-term effectiveness of vaginal mesh POP repair seems to be satisfying, with over 96 % of women showing improvement on the patient global impression of improvement scale at the 12 months follow-up [4]. However, long term objective anatomical outcome seems to be higher after TVM surgery than after native tissue surgery [5]. The FDA has released several warnings concerning transvaginal meshes for POP due to high numbers of side effects, including mesh erosion, contraction and pain [6,7]. These warnings were based on the first generation of vaginal meshes and led to a withdrawal of transvaginal meshes from the American market and resulted in several countries banning vaginal meshes all over the world.

☆ The manufacturer of the mesh kit was a cosponsor of the trial. The company did not provide the products used in the study and was not involved in data collection, analysis or in the decision to submit the results for publication. All authors are consultants for AMI.

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Pain, exposure, extrusion and dyspareunia are common problems after transvaginal placement of meshes [8,9]. Nowadays, it is known that light meshes have more preferable properties with fewer complications compared to heavy meshes [10]. We have already published the one-year follow up of an ultra-lightweight mesh kit that was introduced into POP surgery recently [11]. The aim of this study was to describe both anatomical and subjective outcome of this mesh kit three-years after surgery for anterior compartment POP.

Methods

This study was designed as a prospective observational study at 6 urogynecological centres in Germany. Patients undergoing operation for POP and who received an anterior isoelastic transvaginal mesh (InGYNious ®, A.M.I. Austria) (Fig. 1) were included between November 2014 and June 2016. The InGYNious mesh is made from monofilament polypropylene mesh is ultralightweight (21 g/m^2) and consists of large micropores and macropores (of 100–150 μm and 1.9–2.8 mm, respectively). The local ethics committees granted ethical approval. Inclusion criteria were the same as published in the one-year follow-up. Specifically, patients aged 18–90, with symptomatic stage II prolapse or higher, primary or recurrent POP were included for data analysis. In cases of primary POP, patients were included in the advent of an especially large or lateral defect. Exclusion criteria were neuromuscular disorders, previous radiation in the pelvis, unwillingness to give written informed consent, malignant diseases, or chronic pain syndromes. Both preoperatively and postoperatively, all patients completed a questionnaire and examination according to the IUGA-ICS POP-Q staging system [12]. The surgery was performed by 6 different experienced urogynecological surgeons (AB, AK, CF, AN, LH, MM) as published recently [13]. Shortly, the mesh was placed according to the manufacturer's protocol in the paravesical space using the i-Stitch instrument (A.M.I., Austria). Concomitant hysterectomy was optional depending on the patient's preference or medical indications; further concomitant operations like posterior colporrhaphy or incontinence surgeries were also performed as indicated [14]. The vaginal mucosa was sutured with braided resorbable sutures. The vagina was packed and a catheter was placed for at least 24 h according to the study protocol.

After three years, anatomical (objective) success was defined as POP-Q Ba < -1 and C < -1 [9,15]. Patients were examined by a gynaecologist other than the surgeon. Data analysis was only performed on patients who were available for the follow-up visit. The validated visual analogue scale (VAS) was used for postoperative pain on the day of discharge. Several complications peri- and postoperatively up to the three-year follow-up were recorded in the case report forms (CRFs).

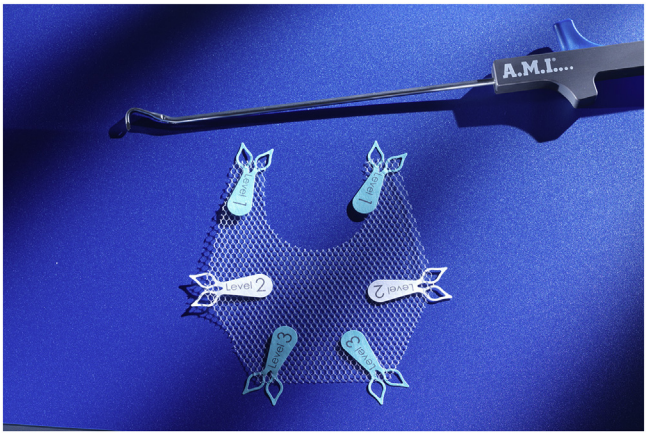

Fig. 1. InGYNious mesh and i-Stitch instrument.

For subjective outcome analysis, the validated P-QoL Questionnaire was used [16]. The questionnaire has 40 items, with lower values indicating better quality of life (QoL). Voiding dysfunction was assessed using two questions out of the questionnaire (Intermittent flow/ straining for emptying the bladder). Similarly, urgency urinary incontinence (UUI) [17] was assessed subjectively from the questionnaire.

The manufacturer of the InGYNious mesh was a cosponsor of the trial but did not provide the mesh kit and was not involved in any clinical or statistical parts of the study. The corresponding author (DU) collated the data, but was not involved in the surgical part of the study.

Statistical analysis

Descriptive statistics are presented as mean and standard deviation for numerical variables and as counts and percentages for categorical variables. Differences between pre-operation and three-year follow-up are analysed by means of the Wilcoxon signed-rank test for matched pairs for numerical variables and the McNemar test for categorical variables. A p-value of 0.05 % was regarded significant.

Ethical approval

The study received approval of all ethics committees; the primary ethics vote was approved from the ethics committee in Offenburg (IRB F- 2013- 102); all women gave written Informed Consent.

Results

278 patients were recruited for the study and underwent POP repair with the InGYNious mesh-kit. At the three-year follow-up, 83 patients were not available for a gynaecological examination, hence 195 (70 %) datasets could be analysed. Reasons for loss of follow-up was death of patients, unwillingness of patients or that contact details had changed. The demographic parameters of patients operated with the InGYNious mesh are presented in Table 1. There was no significant difference for any demographic parameter between women with and without 3 year assessment. Intraoperative complications have already been reported in the one-year follow-up [11].

At the three-year follow-up, patients underwent a standardized interview and an urogynecological examination. At this point in time, 16 patients (8.2 %) had undergone reoperation for recurrent or de novo POP and were hence excluded from the objective outcome analysis. Of these 16 patients, 12 patients (75 %) received a transvaginal mesh for posterior repair and 4 patients were treated with a BSC mesh ® to repair the apical compartment. All 16 patients had satisfactory objective outcome at time of follow-up.

In the remaining study group (n = 179), POP-Q measurements showed significant improvement at three-year follow-up (Table 2). Anatomical (objective) success according to the POP-Q as mentioned abovewas achieved in 77 % of cases in the anterior compartment, in 82 % in the apical compartment and in 72 % in both the anterior and apical compartments. If success had been set to any point < 0 (POPQ), then anatomical success would have been achieved in 91 % for the treated compartments.

Urinary and bowel symptoms are listed in Table 3. 37 % of patients had UUI before POP surgery; this number decreased significantly to 11 % at the three-year follow-up. Similarly, voiding dysfunction decreased significantly from 38 to 3 %. Also obstructed

Table 1
Demographic data of patients at time of InGYNious operation.

	N = 254 (entire study group)	N = 195 (study group with 3a fu)
Age (years)	70.62 ± 9.56	70.50 ± 8.75
BMI (kg/m^2)	26.54 ± 3.98	26.55 ± 4.04
Smoking	10 (3.9 %)	8 (4.1 %)
Parity, median (range)	2 (0–8)	2 (0–8)
Mode of delivery		
Vaginal delivery	2.10 ± 1.24	2.07 ± 1.12
Caesarean section	0.06 ± 0.26	0.05 ± 0.24
vaginal-operative delivery	0.07 ± 0.27	0.09 ± 0.30
Previous surgery		
Hysterectomy	76 (29.9 %)	62 (31.8 %)
POP surgery	44 (17.3 %)	26 (13.3 %)
Anti-incontinence procedures	10 (3.9 %)	7 (3.6 %)
Comorbidities		
Diabetes	13 (5.1 %)	7 (3.6 %)
Lung disease	5 (2.0 %)	4 (2.1 %)
Sexual activity (with or without partner)	180 (71 %)	170 (87 %)
Length of hospital stay (days)	6.04 ± 2.45	6 ± 2

Data are given as mean (± standard deviation) or number (percent). Fu, follow-up.

Table 2
POP-Q measurements preoperatively and at three years follow up excluding patients with reoperation for POP.

Variable	Preop. n = 179	At 3a follow-up	p- value*	Preop. excluded n = 16	3 a excluded	p- value*
Aa	1.11 ± 1.05	−1.99 ± 1.02	<.001	1.31 ± 1.20	−1.88 ± 0.89	<.001
Ba	1.61 ± 1.54	−2.08 ± 0.98	<.001	1.94 ± 1.39	−1.94 ± 0.85	<.001
C	−1.16 ± 3.43	−5.32 ± 2.86	<.001	0.69 ± 3.74	−4.19 ± 3.35	<.001
Ap	−1.49 ± 1.21	−1.70 ± 1.12	.118	−1.13 ± 0.72	−2.13 ± 0.81	.011
Bp	−1.48 ± 1.46	−1.69 ± 1.16	.372	−1.25 ± 0.78	−2.25 ± 0.58	.005
TVL	8.84 ± 1.45	8.82 ± 1.56	.975	8.31 ± 1.85	8.75 ± 0.86	.277
GH	4.66 ± 1.05	4.33 ± 1.06	.001	4.81 ± 1.17	4.88 ± 0.81	.942

Data are shown as mean ± SD, standard deviation. POP-Q measurements as defined by IUGA-ICS prolapse staging.
* Wilcoxon test for matched samples.

Table 3
Urinary and anal incontinence symptoms pre- and postoperatively excluding patients with reoperation for POP.

Variable	Preop.	3 a follow-up	p- value*	Preop. excluded	3a follow-up excluded	p- value*
Bladder symptoms						
SUI	59 (33.0 %)	53 (29.6 %)	.488	5 (31.3 %)	7 (43.8 %)	.727
UUI	67 (37.4 %)	20 (11.2 %)	<.001	2 (12.5 %)	1 (6.3 %)	>.999
Voiding dysfunction	69 (38.5 %)	6 (3.4 %)	<.001	8 (50.0 %)	0 (0.0 %)	.008
RU (M ± SD)	62.4 ± 81.5	27.5 ± 39.3	<.001	62.5 ± 62.9	21.6 ± 17.5	.078
Bowel symptoms						
Obstructed defecation	17 (9.5 %)	5 (2.8 %)	.004	0 (0.0 %)	2 (12.5 %)	.500
Fecal Incontinence	2 (1.1 %)	5 (2.8 %)	.453	0 (0.0 %)	0 (0.0 %)	n.a.

Data are shown as n (%) except for residual urine. SUI, stress urinary incontinence. UUI, urgency urinary incontinence. UI, urinary incontinence. RU, residual urine. Na, not applicable.
* McNemar-test, except for residual urine for which the Wilcoxon test for matched samples was used.

defecation showed a significant improvement, decreasing from 9 to 3 %.

In regards to stress urinary incontinence (SUI), 59 (33 %) patients had pre-existing SUI. 8 received a concomitant suburethral tape; 31 received a suburethral tape within three years after the InGYNious mesh was placed. At the three-year follow-up, 53 (30 %) had SUI. 59 women had pre-existing SUI with 31 (53 %) of them having persistent SUI. The de novo SUI rate was 27/ 120 (23 %) in women without reoperation for SUI and/ or POP and without primary SUI.

No serious adverse events were reported within 36 months after the mesh augmented anterior repair using the InGYNious mesh. Complications were rare, with 10 patients suffering from recurrent urinary tract infections (UTIs) (6 %); 6 had subjective voiding dysfunction. At three-year follow-up, no new mesh exposure was seen. Four patients had been treated with local oestrogen at the one-year follow-up and the mesh exposure resolved. Pelvic pain was also rare; only 24 patients (13 %) described pain, with 14 patients rating it only with VAS 1. Hence the median pain score of VAS was 1. Similarly, the de novo dyspareunia rate was also low with 5 patients (3 %) at the three-year follow-up out of 170 women having sexual activity with or without a partner. Other mesh related complications like infection, abscess formation or mesh contraction did not occur.

For subjective outcome analysis, data of the P-QoL questionnaire were used. Study participants showed significant improvement in all QoL, POP and bladder symptoms (Table 4). These data are in line with the reported objective outcome.

Table 4
Results of the P-QoL- Questionnaire at 3 years follow-up excluding patients with reoperation for POP.

	Preoperatively	At three years follow up	p- Value*
General Health Perception	47.77 ± 22.53	27.23 ± 18.11	<.001
Prolapse Impact	85.86 ± 22.44	16.57 ± 26.45	<.001
Role Limitations	62.98 ± 32.38	8.33 ± 17.43	<.001
Physical Limitations	63.55 ± 33.04	8.67 ± 19.16	<.001
Social Limitations	41.00 ± 34.20	3.90 ± 10.26	<.001
Personal Relationships	40.49 ± 33.38	5.42 ± 15.48	<.001
Emotions	37.04 ± 32.96	4.68 ± 11.67	<.001
Sleep Energy	38.33 ± 28.08	13.53 ± 17.76	<.001
Symptoms			
Frequency	66.67 ± 34.88	26.81 ± 32.18	<.001
Urgency	62.11 ± 37.47	23.50 ± 29.34	<.001
Urge incontinence	44.36 ± 39.72	19.30 ± 27.59	<.001
Stress urinary incontinence	36.09 ± 36.25	23.56 ± 28.36	.001
Feeling a bulge/ lump from or in the vagina	83.71 ± 28.31	8.77 ± 20.47	<.001
Heaviness or dragging feeling as the day goes on	72.09 ± 33.54	10.34 ± 21.97	<.001
Vaginal bulge interfering with you emptying the bowels	30.58 ± 37.91	9.09 ± 19.72	<.001
Discomfort in the vagina, which is worse when standing and relieved by lying down	65.05 ± 36.28	8.06 ± 18.71	<.001
Intermittent flow	43.73 ± 35.52	15.73 ± 24.16	<.001
Dribble	29.57 ± 35.62	10.48 ± 20.10	<.001
Straining	39.06 ± 35.27	15.10 ± 23.98	<.001
Incomplete bowel emptying	32.24 ± 36.09	14.48 ± 24.61	<.001
Constipation	33.06 ± 38.77	21.67 ± 27.21	.001
Strain to empty the bowels	28.29 ± 36.21	14.57 ± 25.54	<.001
Vaginal bulge which gets in the way of sex	37.29 ± 42.07	4.24 ± 16.62	<.001
Lower backache worsens with vaginal discomfort	29.31 ± 36.02	5.17 ± 17.36	<.001
Use of fingers to help emptying the bowels	21.39 ± 33.97	7.50 ± 19.06	<.001
How often does bowel open	31.36 ± 26.45	32.84 ± 25.90	.389
Use tampons/ pads / firm knickers to help	52.55 ± 43.93	40.78 ± 41.62	.004
Push up the POP	38.43 ± 31.61	3.14 ± 10.41	<.001

Data are expressed as mean ± standard deviation except for the p-values.
* Wilcoxon test for matched samples.

Discussion

In this study, we analysed the objective anatomical outcome after insertion of the InGYNious mesh for anterior POP repair at the three-year follow-up. Anatomical success was high and complication rate was low, similar to other recently published papers on different vaginal meshes [18,19]. The reoperation rates both for mesh specific problems and recurrent POP were also rare in contrast to previous results [5].

Previously, success rates of 75–88% in TVM studies have been reported, which are similar to our results [20]. Apical support seems to be critical in POP repair. Our results show that the 6-point mesh fixation provides a long-lasting anatomical success, with low reoperation rates. In our cohort, women were mostly re-operated for posterior compartment prolapse which is probably related to the fixation of the mesh in the anterior and apical compartment. It is well known that de novo POP in the untreated compartment can be as high as 47 % [21], however, this number was much lower in our cohort study.

According to the study of Borstad et al. one third of women with SUI get cured after POP surgery. Since reoperation for incontinence is easily accessible in Germany, only 14 % of women received a concomitant sling. 47 % of women with pre-existing SUI had cure of SUI at time of follow-up which is even higher than previously reported. De novo SUI is also a commonly reported side effect of TVM surgery [18,22]. In our study, less than a quarter of the patients had de novo SUI without secondary treatment. 16 % had undergone reoperation for de novo SUI. All other aspects of lower urinary tract measures had improved significantly three years postoperatively; especially voiding dysfunction and overactive bladder (OAB).

In line with previously reported results, no additional serious complications occurred since the one-year follow-up [23]. After conservative treatment of mesh exposure that had been present at the one-year follow-up, all exposures had resolved. One possible explanation might be that the new meshes fold less in vivo compared to first generation meshes leading to lower incidences of mesh exposure.

The complication rate was low and is comparable to previous reports from first generation vaginal meshes [24] and native tissue surgery [25]. Common problems after TVM are pain and dyspareunia; these problems were seldom and lower than previously reported [5,26]. In this study, only experienced surgeons operated in high volume centres from Germany. Also, the InGYNious mesh is isoelastic and the sutures of the mesh are fixed without any anchors. As with any operation, there are mesh specific risks that need to be discussed with the patient before the operation.

QoL increased significantly in all subdomains of the P-Qol questionnaire except for defecation. In accordance to the anatomical results patients seem to be satisfied with all urogynecological domains after the operation. Similar to previously reported results patient satisfaction seems to be even better than objective success [27], since an increase in all domains occurred, also in patients with a recurrent stage II prolapse.

Uterine preservation does not necessarily improve objective success after POP surgery [28]. In our cohort only 4 % had concomitant hysterectomy with good anatomical cure rates. Subgroup analysis between women with or without hysterectomy was not possible in our study due to the high number of uterine preservation.

Vaginal mesh surgery is of course under heated debate and needs to be considered carefully and discussed with the patients. European guidelines suggest using mesh only in complex cases with recurrent POP in the same compartment by specialized gynaecologist [29]. In our study, mesh was also used in the primary setting, however, all surgeons have had at least 200 mesh

operations before the start of the study probably explaining the low complication rates. Alternative treatment options like laparoscopic mesh sacropexy should be offered to patients in centres with good laparoscopic skills [30].

The mean hospital stay seems to be quite long in this study. It has to be noted that the day of admission before surgery was included. Furthermore, in contrast to many other countries; reimbursement is dependent on the length of hospital stay leading to slightly longer stays in this study.

Vaginal packing and placement of a bladder catheterization has not been associated with any benefits in regard to POP recurrence or vaginal bleeding [31], however, this is still current practice in our centres and did not seem to positively or negatively affect the patients.

Strengths of the study are the prospective study protocol, additional subjective outcome data and the standardized method of mesh insertion. Surgical success is often used for POP studies, however patient reported outcome data are necessary to analyse how satisfied patients really are. A limitation of the study is the single-arm design; however, a large patient group would have been necessary in a randomized setting. Second, the high rate of follow-up rate might lead to bias in the results. Either women who are very satisfied do not want to show up for routine check-up or women with problems have changed to another hospital. Hence, interpretation of our data needs to be performed with caution. In conclusion, the anatomical outcome after InGYNious mesh insertion for anterior POP repair seems to be a good option with low complication rates.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ejogrb.2020.10.030.

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