

Quality of life and pelvic organ prolapse-related symptoms after pelvic floor reconstruction with a titanized polypropylene mesh for cystocele: long-term results in a 36 month follow-up

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Abstract: Pelvic organ prolapse (POP) significantly impairs the function of bladder, bowel and sexuality and reduces quality of life (QoL). The aim of POP surgery is the reconstruction of the pelvic organ anatomy and improvement of QoL. Conventional native tissue repair has a higher recurrence rate compared to the implantation of an alloplastic mesh. An increased risk of adverse events with first generation-meshes and no significant improvement of QoL is still a matter of debate. The purpose of this study was to investigate anatomical stability, complications, improvement of QoL, and the influence on POP-related symptoms after 36 months. 289 women with a symptomatic cystocele > grade I were treated with a titanium coated polypropylene mesh (TiLOOP® Total 6, pfm medical ag). POP-related QoL and symptoms were evaluated pre- and postoperatively. Mean age of patients was 67 ± 8 years. Preoperative POP-Q grades were diagnosed as following: 47.1% with grade II; 49.8% with grade III, and 3.1% with grade IV. Postoperatively, 21.8% of patients were cured (grade 0), 62.7% were diagnosed with grade I, 15.1% with grade II, and 0.4% with grade IV. The recurrence rate in the treated anterior compartment was very low (2.4% after twelve and 1.9% after 36 months, respectively). Concerning POP-related symptoms patients' condition improved. Furthermore, QoL improved significantly in all nine investigated domains ($p < 0.001$, Wilcoxon test). Therefore, implantation of a second generation-mesh can be offered to patients with a recurrent or a high-grade prolapse after extensive patient information on the risks and benefits of mesh-supported POP repair.

Keywords: Pelvic organ prolapse; Quality of life; Surgical mesh.

INTRODUCTION

Pelvic organ prolapse (POP) is a common disease prevalent in 50% of parous women and can significantly reduce patients' quality of life (QoL)¹. Pelvic organs, such as the uterus, bladder and/or bowel can descend because of failing of the pelvic soft tissue support (ligaments, connective tissue, etc.) and weakness of the vaginal wall. Affected women show various urinary, bowel and sexual symptoms resulting in a profoundly impaired QoL¹⁻⁴. Treatment alternatives range from non-surgical therapies, which are mainly focused on minimization of risk factors, to a great variety of surgical options including abdominal (open or laparoscopic) and minimal-invasive transvaginal techniques with or without the use of surgical meshes¹. Nowadays, native tissue repair with sacrospinial (*Amreich-Richter*) or uterosacral ligament fixation is the preferred surgical method for the treatment of a cystocele and apical prolapse via the transvaginal approach.

The reconstruction of the anatomical location of organs of the true pelvis is the aim of every surgical intervention. However, the functional result is more important for affected patients than anatomically correct reconstruction. QoL is highly dependent on the function of the bladder and bowel, sexuality and pelvic pain. Furthermore, long term stability is of great interest. Due to the high rate of recurrent POP with conservative native tissue treatment options^{1,5} alloplastic meshes were established. Current literature indicates a lower recurrence rate after POP reconstruction with surgical meshes^{1,5,6}. Nevertheless, the high rate of mesh-associated adverse events of first generation meshes discredited these materials and therefore, discussions are still controversial⁶⁻⁹. The aim of this observational study was to investigate the expected anatomic stability and furthermore, the number of adverse events, the effect on QoL and POP-related symptoms after cystocele correction with a modern type 1a polypropylene mesh with titanium containing coating in a long term follow up.

METHODS

Patient and study design

This prospective observational study was carried out at nine German hospitals (clinicaltrials.gov, NCT01084889). Two hundred ninety-two patients with cystocele or POP ≥ grade II (International Continence Society [ICS] classification using the Pelvic Organ Prolapse Quantification [POP-Q] system¹⁰) or patients with grade I prolapse with symptoms requiring surgical intervention were included in the study. Primary procedures as well as surgery for recurrence were permitted. Exclusion criteria were defined as status post mesh implantation in the anterior compartment, status post pelvic radiation, and previous systemic steroid therapy. All patients were able to understand the nature, goals, benefits, results and risks of the study and were briefed in detail about the study. The participants had the right to revoke their consent at any time. Primary endpoints were defined as the erosion rate during the first twelve months of observation and patients' QoL six months postoperatively^{11,12}. Secondary endpoints included documentation of all adverse events during the study course, and feasibility of mesh implantation. Additionally, QoL after twelve and 36 months was assessed¹³. The data were anonymized in accordance with the German Data Protection Act, making it impossible for third persons to identify patients. The protocol of the clinical trial was assessed positively by ethic committees as required by the professional code. The study was supervised through external auditing and 100% monitoring. Patients were examined at six, twelve and 36 months postoperatively. Patients' QoL was recorded using the German version of the validated Prolapse Quality-of-Life (P-QoL) questionnaire^{14,15}. The anatomical results were assessed using the POP-Q system.

Surgical method and mesh implant

A titanized polypropylene mesh (TiLOOP® Total 6, pfm medical ag) with a pore size of > 1mm was implanted via the transvaginal route for cystocele correction. Subsequent to a longitudinal full thickness incision of the anterior vaginal wall the cystocele was dissected. Implantation of the alloplastic mesh was achieved using a tunneler for transobturator and ischiorectal placement. The mesh was then fixed distally, laterally and apically with the apical fixation at the sacrospinal ligament (Figure 1). Additional surgical procedures such as reconstruction of the posterior compartment, hysterectomy or placement of a suburethral sling were allowed. Complete information on the surgical procedure(s) was documented. Patients received vaginal estrogen and a single-dose antibiotic agent.

Anatomical outcome

Anatomical results were determined using the validated standard international classification for prolapse surgery published by the ICS in 1996: the POP-Q system¹⁰. The location of the defective structures is assessed and the severity of the prolapse is measured. All defined points in the three compartments of the pelvic floor (anterior: Aa, Ba; apical: C, D - cervix or vaginal apex; posterior: Ap, Bp) are quantified regarding their distance to the hymenal ring. Thus, the classification of the degree of the prolapse is standardized, quantifiable and reproducible. POP-Q measures were assessed preoperatively and six, twelve and 36 months after the implantation of the surgical mesh.

Prolapse-related quality of life

Impairment of patients' QoL caused by prolapse induced symptoms and particularly bladder or bowel dysfunctions are of superficial interest. However, prolapse sensation, dyspareunia and pelvic pain reduce QoL, too. During this clinical investigation patients' QoL was assessed using the validated German version of the P-QoL questionnaire¹⁴. Data was collected prior to implantation and six, twelve and 36 months postoperatively. The P-QoL questionnaire consists of 40 questions considering patients' perception of their general state of health, the impact of the prolapse, role limitations and physical limitations, questions about patients' personal relationships including sexuality, emotions, sleep and other personal limitations. The higher the score the higher the impairment of QoL (0 = no limitations, 100 = lowest QoL). Patients were free not to answer individual or all questions on their QoL.

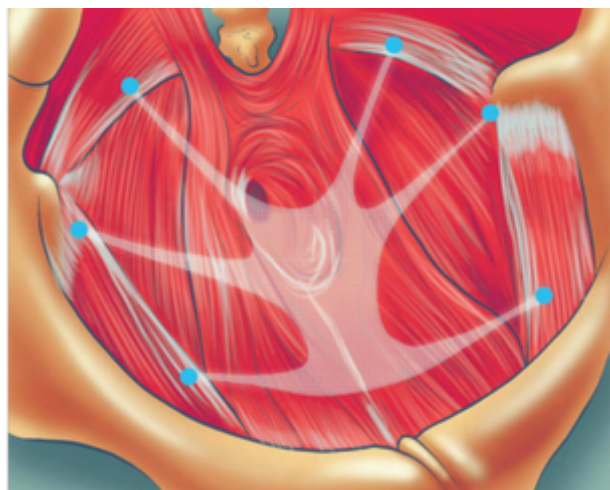


Figure 1. – Distal, lateral and apical fixation of the 6-arm surgical mesh TiLOOP® Total 6 (pfm medical ag).

Statistical analysis

Statistical analysis was done using IBM SPSS, version 22. Wilcoxon test was used for the statistical analysis of patients' pre- and postoperative QoL. For subgroup analysis concerning recurrence Chi-squared test was used. Concerning analyses on erosions, POP-Q and QoL Mann-Whitney U-test was used.

Clinical Event Committee

All adverse events reported during the study course were evaluated by an independent committee of experts (Clinical Event Committee, CEC) using the Common Terminology Criteria for Adverse Events (CTCAE, version 4.0)¹⁶. The experts were selected based on their clinical and scientific experience. To confirm their independence all members disclosed their (financial) interests.

RESULTS

Demography

During the recruitment phase 292 patients were included whereby 289 were treated with the medical device under investigation. Two patients withdrew their consent and for one patient mesh implantation appeared not to be suitable intraoperatively. Six months after implantation 280 patients were available for follow up, at twelve months data on 286 patients were collected and after 36 months 269 patients were followed up. During the study course two patients died for reasons irrespective of the study treatment.

On average patients were aged 67 ± 8 years (43-87 years) and BMI amounted to 27 ± 4 kg/m² (17-37 kg/m²). Birth rate accounted for 2.3 ± 1.2 children. Concerning patients' history of gynecological treatments 31.8% (92/289) of patients had a hysterectomy and 14.9% (43/289) were previously operated on for prolapse. 34.9% (101/289) of patients underwent a conventional posterior colporrhaphy for rectocele repair in addition to the study treatment (mesh implantation in the anterior compartment). Simultaneous implantation of a posterior surgical mesh was conducted in 25.6% (74/289) of patients and in 36.3% (105/289) of cases the uterus was removed.

Anatomical results

The validated international POP-Q system was used to determine the severity of prolapse prior implantation and at every follow up during the clinical study¹⁰. Preoperative grade II prolapse was reported for 47.1% (136/289) of patients; 49.8% (144/289) were diagnosed with grade III, and 3.1% (9/289) of patients had a grade IV prolapse according to the ICS definition.

Concerning the anterior compartment 2.4% (7/286) of patients presented with a recurrence twelve months postoperatively and a further 1.9% (5/269) after 36 months. However, in addition to the anterior recurrent descensus 1.0% (3/286) was as well diagnosed with a concomitant apical/posterior descensus twelve months postoperatively and another 1.5% (4/269) after 36 months, respectively.

Regarding anatomical stability in general 14.0% (40/286) were diagnosed with a recurrent descensus during the first twelve months of observation and a further 5.2% (14/269) showed up with recurrent prolapse after 36 months. Out of the patients suffering from recurrent descensus only 22.2% (12/54) showed recurrent descensus in the anterior compartment either solely or in addition to recurrent descensus in the apical/posterior compartment. Thus, the majority of patients presented with de novo or recurrent descensus in the counter compartment during the observation period of

36 months (42 of 54 patients). However, in the late follow up after 36 months 21.8% (55/252) were cured with no prolapse (grade 0); for 62.7% (158/252) of patients a grade I prolapse was reported; 15.1% (38/252) had a grade II prolapse, and 0.4% (1/252) were diagnosed with a grade IV prolapse.

Prolapse-related quality of life

Data on patients' QoL was collected by the P-QoL questionnaire considering nine different domains including personal relationships¹⁴. During the course of the study a continuously significant improvement of QoL was reported ($p < 0.001$, Wilcoxon test, Table 1 and Figure 2). As early as six months after implantation of the surgical mesh patients' QoL was improved even for the domain "personal relationships" ($p < 0.001$, Wilcoxon test). During the twelve and 36 months follow up further improvement of QoL was stated by the patients. However, improvement of QoL between the twelve and 36 months follow up was stagnating but still significantly improved compared to the preoperative conditions ($p < 0.001$, Wilcoxon test).

Prolapse-related symptoms

Prior to implantation, the major factors impairing patients' QoL were prolapse sensation, pulling pain in the womb area, urinary disorders (voiding dysfunction, stress urinary incontinence (SUI), urge urinary incontinence (UII)), dyspareunia, and anorectal disorders (Table 2).

Concerning the prolapse symptoms described preoperatively the following results were obtained in the postoperative observation period (see also Table 3 and Figure 3):

Foreign-body sensation was reduced from 77.9% (225/289) before implantation to 3.7% (10/269) after 36 months. Pulling pain in the womb area was described by 48.4% (140/289) of patients prior to implantation of the surgical mesh compared to 2.6% (7/269) 36 months postoperatively. Differences concerning SUI were inferior (39.8% (115/289) preoperatively vs. 33.8% (91/269) 36 months postoperatively). The amount of patients suffering from UII was reduced from 36% (104/289) preoperatively to 8.9% (24/269) after 36 months; concerning rectal incontinence 4.8 % (14/289) of patients were affected prior to implantation of TiLOOP® Total 6 and 1.9% (5/269) after 36 months. Dyspareunia was reduced from 15.6% (45/289) to 6.3% (17/269). Defecation disorder differed only slightly

TABLE 1. Quality of life prior and after implantation of TiLOOP® Total 6 (P-QoL questionnaire) - The higher the score, the lower the quality of life. Mean values and standard deviation (SD) were calculated for the anamnestic data, and after 6, 12 and 36 months.

	pre-OP		6-M-FU		12-M-FU		36-M-FU	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
General state of health	39.3	21.0	27.2	17.0	25.5	16.3	26.5	18.2
Negative impact of prolapse	73.5	26.7	19.4	27.6	16.2	24.8	14.7	25.1
Role limitations	58.5	29.2	15.8	24.9	11.3	20.1	11.6	21.4
Physical limitations	55.0	30.2	16.6	26.0	10.9	19.9	11.1	21.0
Social limitations	20.6	26.5	6.0	16.7	3.9	12.8	4.2	12.7
Personal relationships	43.8	37.5	16.5	26.8	11.0	22.2	10.4	19.5
Emotions	29.6	27.7	9.3	18.6	6.5	15.9	5.4	13.7
Sleep/Energy	32.4	22.4	18.5	18.5	16.7	16.3	17.7	17.9
Severity of symptoms	40.8	19.8	17.1	16.4	14.4	16.0	13.5	15.5
p-value	na		< 0.001		< 0.001		< 0.001	

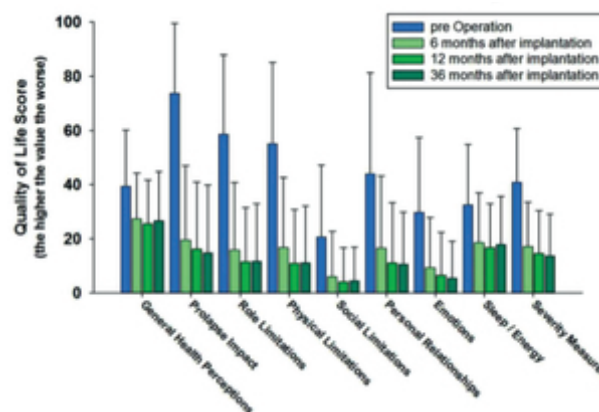


Figure 2. – Development of patients' QoL during the observation period of 36 months: Significant improvement six, twelve and 36 months postoperatively in all investigated domains (general health perceptions, prolapse impact, role, physical and social limitations, personal relationships, emotions, sleep/energy and severity measures).

(12.1% (35/289) preoperatively vs. 10.4% (28/269) 36 months postoperatively).

Adverse events

Adverse events were documented during the course of the study. An independent CEC assessed all events using the CTCAE code. After discounting erroneous or duplicate reports 176 adverse events were evaluable. Out of these 109 were classified as serious and 67 as non-serious adverse events. No adverse event was reported to be probably or definitely related to the study device. The majority of adverse events were classified as "renal and urinary disorders" or "reproductive system and breast disorders" according to the CTCAE code. "Urinary incontinence" was most common accounting for about one fourth of all adverse events.

As described previously, intra- and perioperative complications were rare^{11,12}. Bladder lesions were diagnosed in 1.7% (5/289) of patients; ureteral injury, bleeding requiring blood transfusion, urinary tract infection or infected hematoma just after discharge from hospital was reported for 0.3% (1/289) in each case. Both infections were treated conservatively. Positional pain was described by 0.3% (1/289) of treated patients.

Furthermore, concerning the first primary endpoint previously published data reported on the amount of erosions occurring during the first twelve months of the study^{11,13}.

TABLE 2. History of symptoms (prior to implantation)

	N	%
Foreign-body sensation	225	77.9
Pulling pain in womb area	140	48.4
Prolapse sensation	233	80.6
At least one of the aforementioned symptoms	278	96.2
Dyspareunia	45	15.6
Micturition problems	136	47.1
Urge urinary incontinence (UII)	104	36.0
Stress urinary incontinence (SUI)	115	39.8
Grade I	91	31.5
Grade II	24	8.3
Mixed urinary incontinence	61	21.1
Defecation disorder	35	12.1
Rectal incontinence	14	4.8

TABLE 3. Development of symptoms during observation period of 36 months.

	Baseline		6-M-FU		12-M-FU		36-M-FU	
	N	% of 289	N	% of 280	N	% of 286	N	% of 269
Foreign-body sensation	225	77.9	10	3.6	17	5.9	10	3.7
Pulling pain in womb area	140	48.4	25	8.9	17	5.9	7	2.6
SUI	115	39.8	105	37.5	94	32.9	91	33.8
UUI	104	36.0	31	11.1	29	10.1	24	8.9
Rectal incontinence	14	4.8	5	1.8	9	3.1	5	1.9
Dyspareunia*	45	15.6	17	6.1	19	6.6	17	6.3
Defecation disorder	35	12.1	19	6.8	28	9.8	28	10.4

* At anamnesis the question was binary and had to be answered by "yes" or "no". At later visits, an additional answer option "not assessable" was provided.

Briefly, 10.5% (30/286) of patients were diagnosed with erosion during the first twelve months. Out of these, 56.7% (17/30) were either conservatively treated or an outpatient procedure under local anesthesia was sufficient. Surgical intervention under general anesthesia was necessary in 43.3% (13/30) of the cases. However, no mesh explantation was required. Altogether, patients described no symptoms in 46.7% (14/30) of the reported erosions.

No unknown or unexpected events occurred and none of the reported events was probably or definitely related to the product under investigation.

DISCUSSION

Recurrence of prolapse is one of the major topics of many clinical studies concerning mesh-assisted prolapse repair. Current literature indicates that the rate of recurrences can be significantly reduced using alloplastic meshes compared to native tissue repair^{1,6,17}. The results of the present study with 289 patients are in line with this revealing a low recurrence rate in the anterior compartment 36 months postoperatively. Furthermore, the risk for recurrent descensus in the posterior compartment is reduced to one third by uterus preservation (21.3% vs. 7.6%). To the best of our knowledge, this has not been described in the scientific literature so far.

QoL can be improved independent of the procedure for prolapse correction^{6,8,18}. Differences between native tissue repair and mesh-assisted surgery with respect to the improvement of QoL are minor and significance levels differ depending on the clinical study^{8,18}. The results of the present study show a statistically significant improvement of patients' QoL after implantation when compared to QoL prior implantation in all investigated domains ($p < 0.001$). Furthermore, a gradual improvement of patients' QoL from six to 36 months occurred. Analyses of changing or improving main prolapse symptoms are merely addressed in most studies. However, the Integral Theory by Peter Petros elucidates the relation of prolapse symptoms, functionality of the pelvic floor and anatomical defects¹⁹. Therefore, the development of prolapse symptoms starting from preoperative conditions over an observation period of 36 months postoperatively was investigated during this clinical study. The main focus was on prolapse sensation, micturition disorders, SUI, UUI, fecal incontinence, defecation disorders, pain in the womb area, and impairment of sexuality. As expected, almost all patients reported on an improved prolapse sensation after anatomical reconstruction and simultaneously a low rate of recurrences was described. Concerning UUI symptoms 84.8% of patients with preoperative symptoms were free of symptoms at the 36 months

follow up. De novo UUI was described merely for 5.75% which is in line with current literature reporting on a reduction of urge symptoms by apical fixation²⁰. Concerning SUI the results are different. In some cases SUI continues after implantation of an alloplastic mesh, partially patients are cured completely or patients develop a de novo SUI as observed in 20.3% (58/286) of patients after six months in the present study. This corresponds to current data describing a higher rate of de novo SUI after mesh-assisted cystocele correction compared to conventional colporrhaphy¹. Data on pelvic pain is rare as this symptom is usually not taken into account in clinical studies on POP repair. Here, we considered pelvic pain explicitly. The results show that the amount of patients affected by pelvic pain was significantly reduced from 48.4% prior implantation to 2.6% after 36 months. This supports the hypothesis by Petros that pelvic pain can be caused by POP^{19,21}.

Implantation of surgical meshes is not recommended in sexually active women, since an increased risk of dyspareunia after implantation of alloplastic meshes has been described in the scientific literature²². However, the rate of dyspareunia was reduced from up to 24%²² to as low as 3%¹. The rate of de novo dyspareunia was very low. One should bear in mind that a large percentage of affected patients is not sexually active due to comorbidities, no or impotent partner or no interest.

60.2% of the cystocele correction was accompanied by a reconstruction of the posterior compartment. In 34.9% of cases native tissue repair was conducted while a posterior mesh was implanted in 25.3% of posterior surgeries. Due to this additional treatment, no assessment of the reduction of fecal incontinence (4.8% preoperatively vs. 1.9% postoperatively) and defecation disorders (12.1% preoperatively vs. 10.4% postoperatively) is possible. Thus, it is not possible to evaluate if the anterior or posterior reconstruction surgery causes the improvement of anorectal function.

The aforementioned results of this prospective multicenter study are an important contribution to the still ongoing discussion of alloplastic meshes in POP repair. However, the rate of erosions is still a matter of controversial debate and should be addressed in future studies, too. The sponsor of this current clinical study finished another observational study on a polypropylene mesh with titanium containing coating with an extended pore size of 3 mm and reduced weight (TiLOOP® PRO A, pfm medical ag; NCT02690220). Results of this trial with 52 patients are promising and will be published soon.

There are some limitations of this clinical study which should be taken into account. First of all, there was no control group and thus, it is not assessable if the improvement of patients' QoL after the implantation of a surgical mesh is superior compared to native tissue repair. Furthermore, concomitant or later surgeries in the pelvic area were performed and thus, it is not possible to evaluate if the anterior or posterior reconstruction surgeries cause the significant improvement of patients' symptoms and QoL. Additionally, the study was sponsored by pfm medical ag. However, study data was monitored objectively and supervised by an independent clinical event committee which ensured the objectivity of the presented data.

CONCLUSION

This prospective multicenter clinical trial to investigate the long-term effects of the use of titanized meshes with a distal, lateral and apical fixation revealed anatomical stability. Concerning the anterior compartment recurrence rate was low and far lower than reported for native tissue repair.

Improvement of QoL was highly significant in all considered areas. Typical symptoms of POP such as prolapse sensation, micturition problems, UUI, pelvic pain and sexual disorder were significantly reduced. Mesh-assisted POP reconstruction has its specific risks as every surgical procedure^{1,6,9}. However, the results of this study demonstrate these risks to be acceptable since patients benefit from a significant improvement of QoL. Therefore, the reconstruction of POP using alloplastic meshes can be offered to patients after a thorough patient information and discussion of all risks, benefits and alternative treatment options. Patients with recurrent POP or a higher grade prolapse in a primary setting may benefit from the good results on long-term stability to avoid reoperation for recurrences.

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CLINICAL TRIALS REGISTER AND FUNDING

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DISCLOSURES

The authors state that they have no conflicts of interest beyond the activities listed below. The activities listed here had and have no effect on the results of the study or the study's publication. Christian Fünfgeld: speaker's fees from pfm medical, Serag Wiessner, BARD, AMS, AMI, Astellas, Recordati, Promedon; Mathias Mengel: speaker's fees from pfm medical, AMI; Markus Grebe: speaker's fees from pfm medical; Dirk Watermann: speaker's fees for research from Serag Wiessner, fees from AMS and Johnson & Johnson; Margit Stehle, Brigit Henne, Jan Kaufhold: none.

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