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PAIN SYMPTOMS RELATED TO VAGINAL PROLAPSE CAN BE CURED BY PELVIC FLOOR RECONSTRUCTION WITH ELEVATE ANTERIOR/APICAL OR ELEVATE POSTERIOR/APICAL

Hypothesis / aims of study
1996 Petros postulated that severe pelvic pain can be caused by apical vaginal descent, which could be cured by pelvic floor surgery. With the Propel-study the longterm effects of pelvic floor reconstructions with Elevate anterior/apical and Elevate posterior/apical have been studied. Based on the answered questions of the PFDI (Pelvic Floor Disorder Inventory) at baseline, 6, 12 and 24 months after surgery we pursued the question whether and to which severity pain symptoms occur in patients with vaginal prolapse and how they have been improved or cured after surgery in the longterm.

Study design, materials and methods
With the prospective multicentre (10 US & 6 EU) Propel-study *(IRB/EC approved protocol and ICF)* time and efficacy effects of surgical pelvic floor reconstruction with Elevate anterior/apical or posterior/apical were investigated in female patients with cystoceles stage II-IV (N = 142) or rectoceles stage II-IV (N = 135) with or without apical prolapse. The preoperative apical prolapse stage was measured to 0 (N = 24), 1 (N =104) and 2-4 (N=124). The patients were observed and interrogated preoperatively (baseline) and 6, 12 and 24 months after surgery using POP-Q-measurements and the PFDI questionnaire. For the present essay we focused our interest on the PFDI questions 1 (pressure in the lower abdomen), 2 (pain in the lower abdomen or genital area), 3 (heaviness or dullness in the pelvic area), 6 (pelvic discomfort when standing or physically exerting), 7 (pain in lower back on most days) and 46 (abdominal or lower back pain when straining for any reason) and considered for each of these symptoms only three categories “no symptoms or not at all”, “somewhat or moderately” and “quite a bit”. Based on the prevalence rates (relative frequencies) of the single symptom categories in the four time phases we evaluated statistically the interesting effects by applying on them the nonparametric Cochran Q-tests for the global effects and McNemar tests for the simple effects. As nominal level of significance (type I error) α=0,05 was accepted. To avoid an inflation of the type I error all post-hoc tests for the simple effects were performed at a reduced level of significance (Bonferroni correction).

Results
The prevalence rates of the outcome “no symptom or not at all” in the total population for all investigated symptoms significantly increased during the time from 45,5 % - 60,3 % preoperatively to 75,2 – 92,4 % 24 months after surgery, whereas the prevalence rates of the symptome outcome “quite a bit” was significantly reduced from 9,4 – 22,7 % preoperatively to 1,1 – 4,9 % at the end of the observation period. The improvement effects even appeared 6 months after surgery and lasted to 2 years (see table). Further analysis revealed similar significant time and efficacy effects on all symptom categories when considering the subpopulations defined by the cystocele (N=142) or rectocele (N = 135) repair (data not shown). Moreover, it is to remark, that the same results have also been obtained, when evaluated the intent to treat (ITT) population after replacing missing values according to the LOCF (last observation carried forward) method.

Interpretation of results
Prolapse associated pain symptoms occur in 39,7 – 54,5 % (severe symptoms in 9,4 – 22,7 %) of patients with cystoceles or rectoceles stage II-IV with or without apical prolapse. Pelvic floor reconstruction using the Elevate meshes increases the symptomfree patients in the longterm significantly. The severe symptoms of PFDI 1, 2, 3 and 6 are improved in about 80 – 90 %; improvements also occurred in the severe symptoms of PFDI 7 and 46. Especially the anchor at the sacrospinous ligament as fixation point of the macroporous monofilament meshes is very safe. Presumably this high effective apical reconstruction should be important for curing/improving pain symptoms in the longterm, as the mechanism of pain induction in vaginal prolapse could be distension of the pelvic plexus.

Concluding message
Prolapse related pain symptoms can significantly be cured/improved by pelvic floor surgery.

Pain symptoms related to vaginal prolapse before and after surgery									Cochran's Q-Tests	McNemar Tests
Cystoceles or rectoceles stage 2-4 with or without apical descent (n=277)	Baseline (0)		6 M after OP (1)		12 M after OP (2)		24 M after OP (3)		for testing global effects (p-values)	for localizing simple effects (pairs with significant differences)
	abs. frq.	rel. frq.	abs. frq.	rel. frq.	abs. frq.	rel. frq.	abs. frq.	rel. frq.		
PFDI 1 *(Pressure in the lower abdomen)*										
no or not at all	131	47,30%	213	82,90%	213	85,90%	163	88,10%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	102	36,80%	37	14,40%	27	10,90%	20	10,80%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	44	15,90%	7	2,70%	8	3,20%	2	1,10%	p < 0.00001	0/1, 0/2, 0/3
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 2 *(Pain in the lower abdomen or genital area)*										
no or not at all	167	60,30%	217	84,40%	218	87,90%	171	92,40%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	84	30,30%	33	12,80%	24	9,70%	12	6,50%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	26	9,40%	7	2,70%	6	2,40%	2	1,10%	p < 0.00001	0/1, 0/2, 0/3
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 3 *(Heaviness or dullness in the pelvic area)*										
no or not at all	141	50,90%	226	87,90%	223	89,90%	170	91,90%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	100	36,10%	27	10,50%	19	7,70%	13	7,00%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	36	13,00%	4	1,60%	6	2,40%	2	1,10%	p < 0.00001	0/1, 0/2, 0/3
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 6 *(Pelvic discomfort when standing or pshysically exerting)*										
no or not at all	107	38,60%	218	84,80%	224	90,30%	169	91,40%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	115	41,50%	32	12,50%	21	8,50%	14	7,60%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	55	19,90%	7	2,70%	3	1,20%	2	1,10%	p < 0.00001	0/1, 0/2, 0/3
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 7 *(Pain in lower back most days)*										
no or not at all	126	45,50%	182	70,80%	178	71,80%	139	75,10%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	88	31,80%	50	19,50%	41	16,50%	30	16,20%	p = 0.0077	0/1, 0/2, 0/3
quite a bit	63	22,70%	25	9,70%	29	11,70%	16	8,60%	p < 0.00001	0/1, 0/2, 0/3
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		
PFDI 46 *(Abdominal or lower back pain when straining for any reason)*										
no or not at all	167	60,30%	210	81,70%	205	82,70%	156	84,30%	p < 0.00001	0/1, 0/2, 0/3
somew. or moder.	78	28,20%	31	12,10%	31	12,50%	20	10,80%	p < 0.00001	0/1, 0/2, 0/3
quite a bit	32	11,60%	16	6,20%	12	4,80%	9	4,90%	p = 0.0533	n.s.
observed cases	277	100,00%	257	100,00%	248	100,00%	185	100,00%		

Table: *Absolute und relative frequencies of the three symptom outcomes before (baseline) and 6, 12 and 24 months after surgery for the PFDI symptoms 1, 2, 3, 6, 7 and 46 in the total sample population (n=277). The frequencies at each observation time point (phase) refer to the number of subjects observed at that phase. Global time effects on the prevalence rates of the single outcomes were tested about significance with the Cochran's Q-tests. Whenever a global effect was significant, differences in the prevalence rates between phase pairs were tested about significance with the McNemar tests. Red colored p-values and phase pair numbers indicate statistical significances at a Bonferroni corrected level of significance (say α^*, where $\alpha^* < \alpha = 0.05$).*

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