

RESULTS COMPARISON OF PROLENE MESH AND SACROSPINOUS FIXATION FOR PELVIC ORGANS PROLAPSE; LONG TERM FOLLOW UP OF RANDOMIZED MULTICENTRIC PROSPECTIVE STUDY

Hypothesis / aims of study

Success rate of both methods of vaginal POP surgery is being discussed since 2004 when the first commercial kit was approved for introduction into pelvic spaces.

In 2007 started a multicenter prospective randomized comparative study in five Czech urogynecological tertiary centers with the aim to estimate statistically significant results of POP surgery. The objectives of our study were the success and complication rate comparison of randomized subgroups as well as operation time, blood loss and quality of life and its changes after the operations. Finalizing, we were able to conclude (1):

- the prolapse recurrence rate was at 12 months higher in SSF than in mesh group ($p=0.003$)
- the operation time was longer in the mesh group than in the SSF group ($p=0.001$)
- no statistical difference concerning blood loss between the groups
- the vaginal mesh exposure after one year in the mesh group was 20,8 %, of which 62.5 % required surgical solution
- we found a high incidence of de novo SUI after 1 year in both groups
- no statistical difference in the QOL questionnaires (UIQ, CRAIQ and POPIQ)

Study design, materials and methods

Planned final control of our patients from multicentric randomized prospective study after more than 100 months after the operation was realized. We invited the patients of three of five original centres. Attendance was 49 % (some of the original cohort were lost for follow-up, some were unable to come- health problems, disability, 5 pts died) and examination set up was as follows: Clinical examination including POP-Q, QoL questionnaires (PFDI-20, PISQ-12, UIQ, CRAIQ, POPIQ and ICIQ), VAS (subjective measure of satisfaction with the operation) and complains of patient concerning POP and LUT symptoms. The data were evaluated statistically by Fisher Exact test.

Results

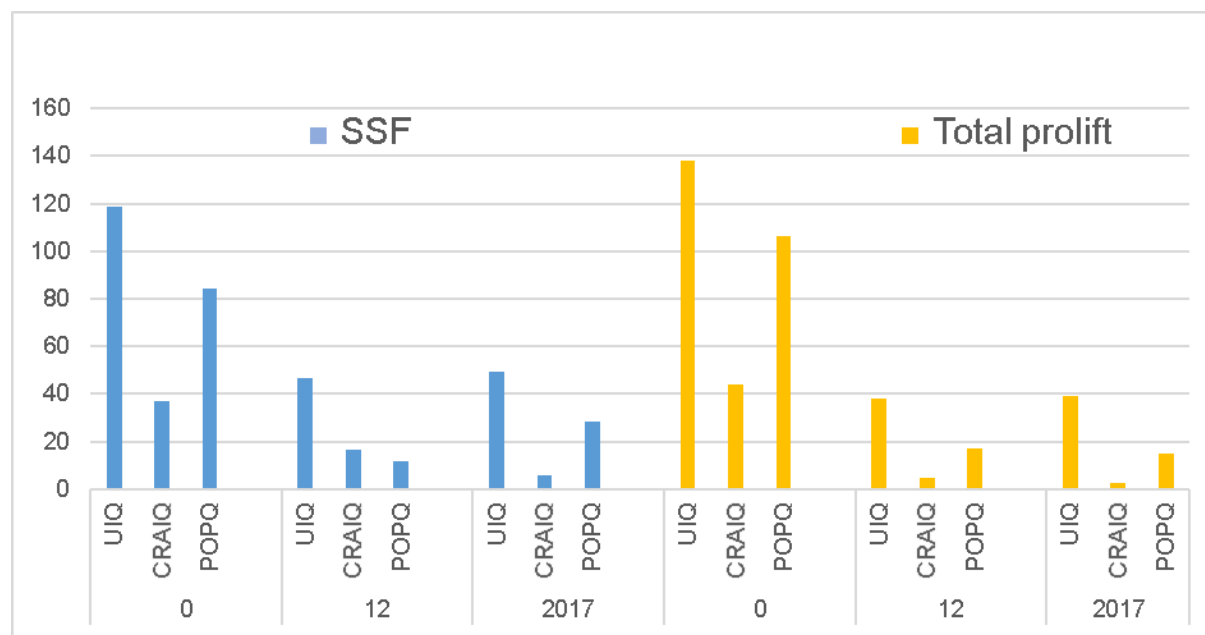
Table 1: Distribution and demography of controlled patients

	Number of patients	Age (years)	Parity	BMI	Follow up (months)
Sacrospinous fixation	16	72.5	2.53	27.14	106.8
Total prolift	23	70.67	2.23	26.82	103.48

Table 2: Complication rates in groups

Complications	Sacrospinous fixation (16)	Total prolift (23)	P
Recurrent prolapse	9	7	0.19
SUI de novo	4	7	1
OAB de novo	5	6	0.73
Erosion asymptomatic	N/A	4	-
Erosion operation	N/A	7	-

Graph 1.



Interpretation of results

Table 1: Demographic data in all the groups are comparable.

Table 2: Complications- prolapse recurrence rate is higher in SSF group (P 0.013) but specific mesh complication- erosion incidence (47,8%) out of which 7 (63,6%) required an operation

Graph 1: We found no difference between the groups in the quality of life

Concluding message

Long time follow-up comparison of vaginal vault prolapse surgery techniques revealed Prolift anatomical superiority. But procedure specific complications (erosion) rate was increasing in the time after the operation (47,8 %).

Comparable outcomes of QOL questionnaires support the use of both techniques in the future

The FDA warnings, started in 2008, concerning specific complications of meshes triggered a move away from the use of foreign materials transvaginally and therefore abdominal and laparoscopic methods of prolapse surgery gains the increasing attention.

References

1. Halaska, M., et al.: A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse

Disclosures

Funding: none **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethical Committee of Charles University **Helsinki:** Yes **Informed Consent:** Yes