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THE USE OF THREE TYPES OF SYNTEHTIC MESH MATERIALS IN THE SURGERY FOR STRESS INCONTINENCE: THE CLINICAL RESULTS

Hypothesis / aims of stud : In the treatment of stress incontinence, as well as the surgical technique, the characteristics of mesh materials used, shape, and their application in the urethra affect the success of surgery. This randomized prospective study aimed to evaluate the clinical results of use of semiabsorbable multifilament Vypro mesh, semiabsorbable monofilament Ultrapromesh and prolene light mesh in a 2 year period in broad based double-forced sling operations.

Study design, materials and methods: Eighty-seven patients were performed broad base double forced sling operation by using 3 different types of mesh materials between June 2004 and January 2007. The patients were randomly allocated into 3 different groups according to the mesh materials used. Group I consisted of 30 patients in whom Vypro mesh semiabsorbable multifilament (non-absorbable polypropylene + absorbable polyglactin) was used; Group II consisted of 30 patients in whom Ultrapromesh semiabsorbable monofilament (non-absorbable polypropylene + absorbable polyglecaprone), and Group III consisted of 27 patients in whom Prolen light mesh (cpp – Condensed monofilament non absorbable polypropylene) was used. Detailed history, systemic and the results of pelvic examination, urine culture, Q-tip and Boney test, supine stress test, and urination diary, 24-hour pad test, cystoscopy and urodymanics measurements (cystometry and Valsalva leak point pressure were recorded for each patient. The patients filled out QoL and Korman questionnaires for urinary incontinence. The data on the patients and the success of the operation were evaluated based on pad test, quality of life scoring, and Korman questionnaire analysis.

Results: The mean age of the patients was 49.7 ± 8.7 years (range: 31-75 years). None of the patients suffered intra operational complications. In all the groups, QoL scores were significantly lower in the 6^{th},12^{th}, and 24^{th} months ($p<0.05$). Similarly, the pad scores of all the groups were significantly lower in the postoperative 6^{th}, 12^{th}, and 24^{th} months ($p<0.05$). According to the results of 24-hour pad test, the postoperative results of pad test were statistically significantly lower than the preoperative results ($p<0.05$). Postoperatively, in the 24^{th} month, 28 patients (93.3%) in Group I, 28 patients (93.3%) in Group II, and 26 patients (96.2%) in Group III were able to control their urine. Three patients (10%) in Group I, 1 patient (3.3%) in Group II, and 2 patients (7.4%) in Group III had vaginal erosion, and 1 patient (3.3%) in Group I had urethral erosion. Two patients in Group I, 2 patients in Group II and 1 patient in Group III had suture granuloma.

Interpretation of results: Our results suggest that the macroporus and monoflaman properities of mixed ultrapro mesh resemble those of type1 macropore monofilament polypropylene mesh. Macropore monofilament meshes are known to be the best among synthetic polypropylene meshes. The only difference is the absorbability of monofilament poliglecaprone in the ultrapro mesh. Poliglecaprone accomplishes the optimal tissue integration and reaction. In our study, the lower rate of complications in the ultrapro group was possibly due to the absorbability of poliglecaprone since it fixes the mesh to the tissue and impedes the mesh movement and friction that results in less erosion and lower complication rates. We suggest that the higher success rate (93,3-96,6%) and less total erosion complications in all groups are due to broad based double forced sling technique together with the properties of the mesh materials. We also suggest that less erosive complications may due to less compression, erosion and enfection by vaginal tissue between synthetic sling mesh and urethra which is under the vaginal wall blockage.

Concluding message: Broad base double-forced sling surgery is successful technique for treatment of stress incontinence. The mesh materials used are just as important as the surgical technique. To determine the ideal mesh material, further clinical and experimental studies are needed.

Table 1. Preoperative and postoperative I- QoL scores

		Preop	Postop 6 month	Postop 12 month	Postop 24 month	P Value**
GROUP 1	Mild QoL score* (n) Moderate QoL score* Severe QoL score (n) Mean total QoL score (± SD)	4 (13.3) 14 (46.6) 12 (40) 22.3 ±3.1	25 (83.3) 4 (13.3) 1 (3.3) 3.8 ± 1.7	27 (90) 2 (6.6) 1 (3.3) 1.8 ± 1.1	27 (90) 2 (6.6) 1 (3.3) 1.4 ± 0.9	**< 0.05**
GROUP 2	Mild QoL score* (n) Moderate QoL score* Severe QoL score (n) Mean total QoL score (± SD)	5 (16.6) 10 (33.3) 15 (50) 22.1 ±3.2	25 (83.3) 3 (10) 2 (6.6) 3.1 ± 1.8	28 (93.3) 2 (6.6) - 1.2 ± 1.3	28 (93.3) 2 (6.6) - 1.09 ± 0.9	**< 0.05**
GROUP 3	Mild QoL score* (n) Moderate QoL score* Severe QoL score (n) Mean total QoL score (± SD)	2 (7.4) 13 (48.1) 12 (44.4) 26.8 ±6.4	23 (76.6) 3 (11.1) 1 (3.7) 2.7 ± 5.8	24 (88.9) 3 (11.1) - 1.7 ± 4.4	25 (92.5) 2 (7.4) - 1.5 ± 4.2	**< 0.05**

** Wilcoxon's nonparametric test

Table 2. Preoperative and postoperative 24 hours pad test results

	Preop	Postop 6 month	Postop 12 month	Postop 24 month	P Value*
Group 1 Mean 24 hours pad test (gr± SD)	27.2 ± 9.1	4.2 ± 6.4	2.3 ± 4.4	1.9 ± 2.1	0.016
Group 2 Mean 24 hours pad test (gr± SD)	28.7 ± 9.3	2.7 ± 6.2	2 ± 4.1	1.6 ± 2.3	0.012
Group 3 Mean 24 hours pad test (gr± SD)	32.4 ± 10.2	3.03 ± 5.8	2.4 ± 3.8	1.9 ± 3.1	0.0076

***** Wilcoxon's nonparametric test

Table 3. Postoperative complications

	Group 1	Group 2	Group3
Vajinal Erosion	3 (%10)	1 (%3.3)	2 (%7.4)
Urethral Erosion	1 (%3.3)	-	-
Sutur Granuloma	2 (%6.6)	2 (%6.6)	1 (%3.7)
Urinary Retantion	3 (%10)	2 (%6.6)	2 (%7.4)
İncontinence	2 (%6.6)	2 (%6.6)	2 (%7.4)

Figure 1. A type incision performed at anterior vaginal wall. The above of the A was used for vaginal sling by minimal dissection.

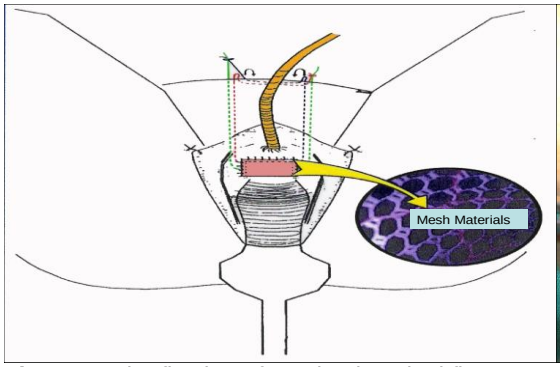


Figure 2. The division of vaginal structure, fixation of mesh on vaginal tissue and the vaginal flep below

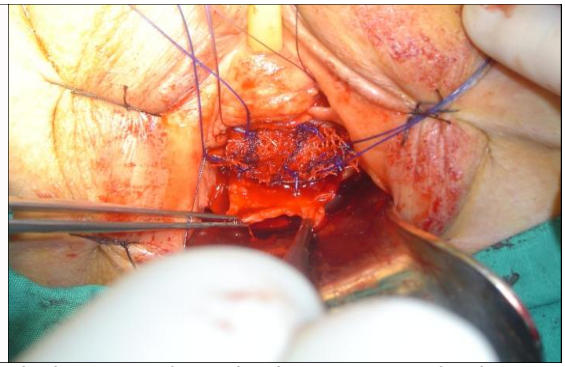
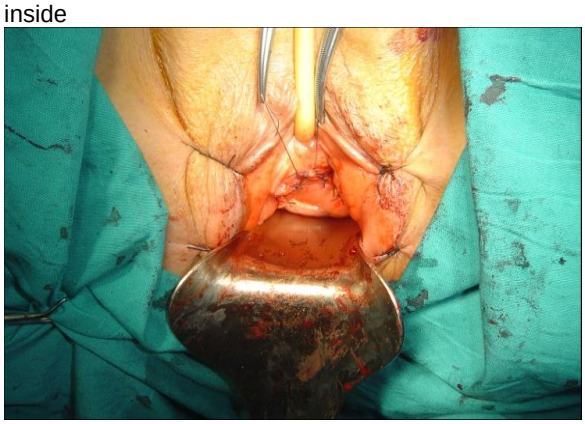


Figure 3. The fixation of proximal vaginal flep on vaginal mucosa above the tissue to cover the tissue patch that keep the mesh inside



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Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Republic of Turkey Ministry of Health Ankara Ataturk Traning and Research Hospital Registration number: 2009/01/02**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Republic of Turkey Ministry of Health Ankara Ataturk Traning and Research Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**