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DO MESHES REALLY SHRINK OR DO WE FOLD THEM?

Hypothesis / aims of study

Polypropylene meshes are routine in vaginal surgery today. There is general acceptance of mesh-associated complication like protrusion and retraction. These consequences are frequently blamed on unpredictable mesh and tissue integration. The majority of available experimental studies on mesh retraction are performed on an animal abdominal hernia model with precise measurement and stretching of the meshes. The shrinking of the polypropylene macroporous mesh in this animal model is described as around 16% in length, with a 28% reduction of mesh area(1). According to these animal studies, tissue with macroporous polypropylene mesh achieves stability after three months due to the scaring process which takes place. There is no study available to confirm shrinking in humans. There have been a few attempts to describe retraction of the anterior vaginal mesh after implantation with ultrasound, and these record mesh retraction of as much as 60% of its initial length, or an associated degree of retraction with recurrence of prolapse (2,3).

At least two mechanisms cause the shortening of mesh after implantation – shrinking and folding. To distinguish between those two mechanisms we need a minimum of two time points for ultrasound observation. To fulfill the essential criteria for retraction measurement we provide a prospective study with postoperative follow-up, using ultrasound at two time points after Prolift anterior™ implantation, to establish post implantation mesh retraction.

Study design, materials and methods

We included in the analysis patients with symptomatic prolapse of anterior vaginal wall (stage 2 or higher on Pelvic Organ Prolapse Quantification system (POPQ)) who underwent an operation with Prolift anterior
All patients underwent preoperative clinical (POPQ) and 4D vaginal ultrasound examination with GE Voluson 730 Expert system. The Prolift procedure was performed in accordance with the original technique. We defined time points as follows:

Time point 0: during the surgery we measured the actual midline length of the mesh (Initial length).

Time point 1: on the fourth day after the surgery we performed early ultrasound examination and measured the mesh length (Early US length) in mid-sagittal plane.

Time point 2: an ultrasound examination was performed 3 – 5 months after surgery to measure the mesh length. (Late US length).

Measurements were taken 3 times - once at the time of examination and twice from saved 4D volumes analyzed using the proprietary software GE Kretz 4D View v. 7.0. In analysis we compared mean values of the Initial, Early US and Late US length. Reliability series were provided for each value.

Results

We analyzed 36 patients with Prolift anterior , mean age 60.4 years (SD-10.6) , mean height 163.3 cm (SD - 5.9) mean weight 76.2 kg (SD - 11.0) mean body mass index 28.6 (SD - 3.8), parity 2.0 (QR - 1.0). There were 20 patients after hysterectomy and 16 with preserved uterus. 6 patients failed to attend the Early US scan and 2 the Late US scan. The Initial length in the Prolift anterior group was 90 mm in all patients except one.

On comparing the intraoperative mesh length with the ultrasound measurement obtained on the fourth postoperative day, there was a marked reduction in midsagittal mesh length 90.3 (SD 1.8) mm vs. 57.1 (SD 10.0) mm, P< 0.001. When early and late ultrasound measurements were compared (n=30, Time Point 1 and 2), we observed a further reduction of about 15% in midsagittal dimensions [57.1 (SD 10.0) mm vs. 48.3 (SD 10.2) mm, P<0.001] (Table 1) Reliability is indicated in Table 2.

Table 1	Prolift anterior		
	N	mean (SD)	t-test p-value
Time point 0 to Time point 2 [mm]	34	- 42.0 (10.2)	<0.0001
Time point 0 to Time point 1 [mm]- FOLDING	30	- 33.2 (10.0)	<0.0001
Time point 1 to Time point 2 [mm]- SHRINKING	30	- 8.8 (10.5)	<0.0001

Table 2				
Intra-observer	ICC	CI		p-value
Early US length	0.90	0.76	0.95	0.0000
Late US length	0.97	0.94	0.98	0.0000
Inter-observer				
Early US length	0.74	0.51	0.86	0.0000
Late US length	0.82	0.63	0.91	0.0000

Interpretation of results

This is the first clinical ultrasound study applying two essential time points in order to distinguish early and late implanted mesh behavior. The degree of shrinkage corresponds with data from experimental animal studies with similar type of mesh, where shrinkage was between 15% and 28% of the area lost. It seems obvious that insufficient extension of the mesh has a major impact on final mid-sagittal diameter of the Prolift anterior.
We should point out that the surgical impact on final mesh length is markedly greater than the mesh-induced tissue reaction behavior – shrinking.

Concluding message

This statement is of enormous importance, because our data re-focuses attention on improving the size of the meshes and changing the surgical and preparation technique, anchoring points etc., rather than searching for a solution only in terms of developing new meshes. We should be using imaging to monitor and follow up our surgical results as standard.

References

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Is this study registered in a public clinical trials registry?	**No**
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	**Ethics Committee of General University Hospital in Prague IRB 00002705**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**