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HOW STABLE IS THE MESH AFTER IMPLANTATION? LONGITUDINAL PROSPECTIVE OBSERVATIONAL STUDY

Hypothesis / aims of study

Recent studies have shown that highly significant postoperative mesh dimensions changes are due to intraoperative folding rather than postoperative mesh retraction. In other retrospective studies assessing late postoperative changes in mesh dimension, there was again no evidence of mesh retraction. But there are still a lot of conflicting results and not enough evidence about the late complications of mesh based on prospective longitudinal follow up.

We already know that apart from the folding effect on meshes, there is a small effect on the sagittal mesh dimensions during the first three months. It might be due the scaring process or/and the further folding. It is still controversial what is happening with the mesh later after implantation.

We analyzed the ultrasound data of patients with Prolift anterior with ultrasound follow-up at 3 months and one year or later after surgery

Study design, materials and methods

In this prospective, longitudinal observational study we analyzed data of all patients operated on between 10/2007 and 10/2011 with anterior mesh (Prolift anterior) using standard technique or with anchoring of upper arm to the sacrospinous ligament. All patients underwent a preoperative clinical and ultrasound examination and ultrasound examination after the surgery, at 3 months and one year or later after surgery. Ultrasound examination was performed with GE Voluson 730 Expert system (GE Medical Systems, Zipf, Austria) equipped with 8–4 MHz curved array volume transducer and 9-5 MHz vaginal volume transducer with acquisition angle 146° x 120°. After introducing the vaginal probe into the vagina, the proximal and distal ends of the mesh were localized in the mid-sagittal plane and at least two 4D volume were measured.(1)All measurements were taken 3 times from saved 4D volumes using the proprietary software GE Kretz 4D View v. 9.1 (GE Medical Systems). We used the mean value of all three measurements for further analysis. We assessed the reliability of the measurements. There were firstly analyzed using the one year data and followed by the analysis of 3 month data. The operator was blinded against the previous measurements. Descriptive analyses are provided, and comparisons between the different time point measurements were performed after normality distribution assessment by dependent two-sample t-test. For correlations we performed Spearman's correlation

Results

In period between 10/2007 – 10/2011 we included 70 patients. The 7 data sets from late ultrasound were not available, therefore there were 63 patients left for complete analysis. The mean age was 60.4 years (min 33; max 81, SD 10.1), mean BMI 27.9 (min 19.9; max 38.6 SD 3.9) and the mean parity 2.1.

The mean time between two ultrasound examinations was 17.9 month (min 8.5, max 38.3, SD 9.2). The analysis comprises 94.0 woman-years.

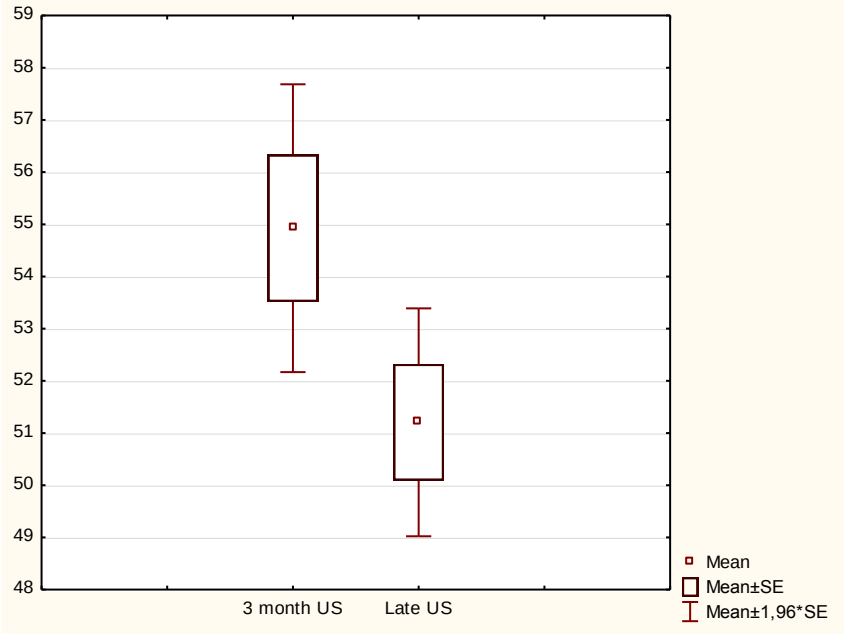
The mean length at 3-month follow up was 54.8 mm (SD 11.2) comparing at late follow up with 51.2 mm (SD 8.8.) t-test: p=0.0002 (Graph 1). The mean length difference was -3.8 mm (max -24mm, min + 14mm).

Because there was variability in length changes and the time frame between two examinations, we provide correlation if the larger change in mesh dimensions is associated with longer follow-up. There was no correlation. The correlation coefficient r=-0.07 and p=0.56. (Graph 2)

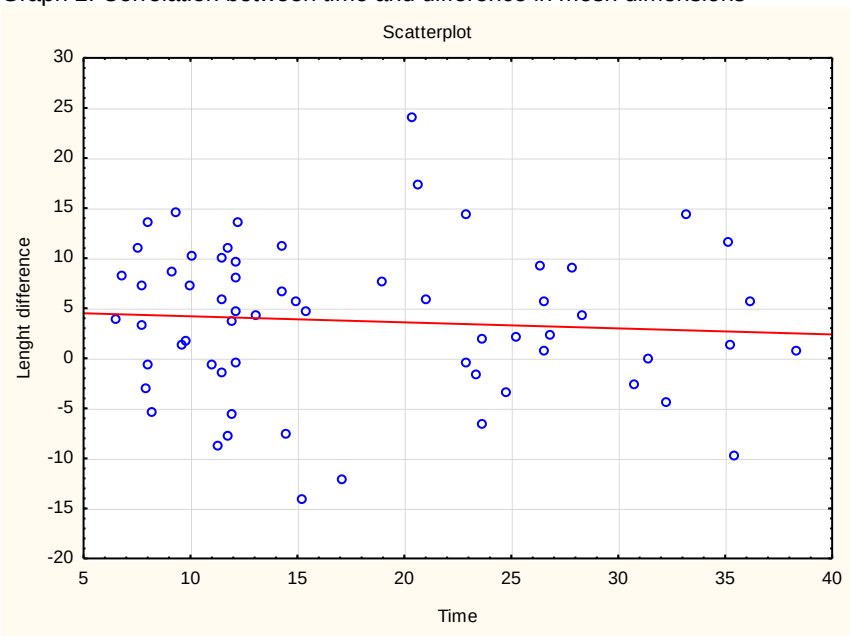
Regarding the measurement accuracy, the mean variability within three measurements was 4.2 mm (SD 3.3)

There were 7 mesh exposures during the 3 month follow up (10%). Five of them were resected during the TVT-o procedure for urinary stress incontinence and 2 remained untreated and were asymptomatic. There were no further de novo mesh exposures at later follow up.

Graph 1: Box plot comparing two time point ultrasound measurements (US)



Graph 2: Correlation between time and difference in mesh dimensions



Interpretation of results

. In our cohort we detected the mesh length difference of 3.3 mm, which was statistically significant, but the change in correlation with the 17 month follow up period is quite small. In light of the measurement accuracy (4.2 mm) of ultrasound and the absence of correlation between the time and mesh length difference, the clinical significance of 3.3 mm length change seems questionable.

Concluding message

This is the second study using the two time point ultrasound measurement for later mesh assessment and first in prospective longitudinal design. The study shows, that the mesh stability after its implantation and after the healing period is high.

Disclosures

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