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# MODIFICATION OF MESH MATERIALS FOR PROLAPSE AND URINARY INCONTINENCE REPAIR BY AUTOLOGOUS PLASMA COATING: A FEASIBILITY TRIAL

Hypothesis / aims of study

Optimized biocompatibility is a major requirement for alloplastic materials currently applied in surgical approaches for incontinence (SUI) and prolapse (POP) conditions. In our preliminary studies the mesh modification by autologous plasma coating resulted in the increased adherence score in vitro and improved biocompatibility in an animal model (1,2). A consecutive second step (development and exploration) of *IDEAL*-criteria of surgical innovations with the first use of plasma coated meshes in human is presented.

Study design, materials and methods

Before the implantation the modified meshes are incubated with autologous plasma, which is obtained from the respective patient by vein puncture before the induction of anesthesia. The surgical technique is not altered by the application of our technology and the operation time is not significantly increased. Between 04/2013 and 01/2014 16 patients (13 women and 3 men) with the indication for SUI and/or POP repair were selected for different procedures (TVT, TOT male, anterior colporrhaphy, sacrocolopopexy) in a single institution. The applied meshes (TVT®, Ultrapro®, Seratom®, Vitamesh®, Dynamesh®) were modified by autologous plasma coating prior to implantation. Peri- and early postoperative complications were assessed retrospectively following ICS-IUGA classification of complications (Tab. 1). Functional outcome and QoL were evaluated pre- and postoperatively. The mean follow-up was 3 mos (1-7).

Results

The functional outcome and QoL improved in all groups (except for TOT male). Two reoperations with the endoscopic loosening of the TVT-mesh due to the prolonged obstruction were needed. No other severe complications were registered.

**Tab. 1 Perioperative data and complications**

| **Procedure** | **TVT** | **TOT** | **Ant. Vag. mesh** | **Sacrocolpopexy** | **Total** | **IUGA/ICS-class.** |
|---|---|---|---|---|---|---|
| Number of patients (gender) | 6 (female) | 3 (male) | 1 (female) | 6 (female) | 16 | |
| Age, mean (yr) | 67 (57-85) | 71 (70-72) | 58 | 67 (57-75) | 62 (57-85) | |
| Operation time, mean (min) | 36 (31-49) | 46 (42-55) | 51 | 57 (43-71) | | |
| Follow up, median (mos) | 2 (1-3) | 4 (2-7) | 3 | 2 (1-4) | 3 (1-7) | |
| Concomittant procedures | 1xSSF | no | SSF | 6x Burch | | |
| **Complications,** number (%) | | | | | | |
| Prolonged pain/neurological | | 1 (33%) | | 1 (17%) | 2 (12.5%) | 6Be/S4 |
| Hematoma | 1 (17%) | 1 (33%) | | | 2 (12.5%) | 7A/S3/S4 |
| Urge de Novo | 3 (50%) | | | | 3 (19%) | 4B/site? |
| Obstruction (prolonged cath.) | | | 1 (100%) | | 1 (6%) | 4B/site? |
| Obstruction (**reoperation**) | 2 (33%) | | | | 2 (12.5%) | 4B/S1 |
| UTI | 2 (33%) | | | 2 (33%) | 4 (25%) | 4B/site? |
| Bladder/bowel injury | | | | | 0 | 4A/S3, 5A/B/S5 |
| Fistula | | | | | | 4/5B/S1 or S2 |
| Mesh exposure | | | | | 0 | 2B or 3B/S1 or S2 |
| **QoL improved** | 5 (80%) | 1 (33%) | 1 (100%) | 5 (80%) | 12 (75%) | |

SSF, sacrospinous fixation; Burch, abdom. colposuspension.

Interpretation of results

The perioperative and early postoperative results after the use of modified mesh for POP and/or SUI showed mostly good functional results with no increase of perioperative complications in our patient collective. The reoperations were due to the operation technique and our management strategies. Other complications were corresponding with the current literature (3).

Concluding message

For the first time we applied the mesh modification by autologous plasma in a human setting as a consecutive step of the *IDEAL*-procedure based on the positive preliminary experimental results. A prospective randomized trial proving a positive effect of plasma coating on the biocompatibility and morbidity outcome is planned.

References


1. 1. Gerullis H, Georgas E, Eimer C et al.: Evaluation of Biocompatibility of Alloplastic Materials: Development of a Tissue Culture In Vitro Test System. Surg Technol Int. XXI: 21-27, 2011.
2. 2. Gerullis H, Klosterhalfen B, Borós M et al.: IDEAL in meshes for prolapse, urinary incontinence, and hernia repair. Surg Innov. 20: 502-8, 2013.
3. 3. Novara G, Artibani W, Barber MD, et al.: Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010 Aug;58(2):218-38.


Disclosures


**Funding:** This work was partly supported by the DAAD/DFG (German Research Foundation) ID50753662. **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** retrospective trial permission of local government for the application of the new method **Helsinki:** Yes **Informed Consent:** Yes