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# IMPROVEMENT OF THE BIOCOMPATIBILITY OF ALLOPLASTIC MATERIALS FOR SURGERY DUE TO HERNIA, INCONTINENCE AND ORGAN PROLAPSE

**Improvement of the biocompatibility of alloplastic materials for surgery due to hernia, incontinence and organ prolapse**

**Hypothesis/Aim of study:**

The american Food and Drug Administration (FDA) issued a warning concerning the application of alloplastic materials for the surgical treatment of female incontinence and prolapse reporting more than 1000 severe adverse events associated with the used materials.
Special surgical training together with the management of risk and AE´s are recommended [1, 2]. The improvement of the biocompatibility coating foreign materials with e.g. autologous substances seems to be mandatory and was performed in an in-vitro setting using autologous plasma for the coating of meshs.

**Material and Methods:**

In order to answer the question whether coating of alloplastic materials with autologous material can lead to improved biocompatibility, the following study approach was established:
12 patients were included. Written informed consent of each patient was obligatory prior to the start of the procedure. 10ml of blood, plasma and serum of each patient were preserved. Myoblasts, endothelial cells and fibroblasts of each patient were cultivated separately. Cell count and growth are comparable in all approaches within a test duration of 6 weeks.
Immunohistochemical and microscopic evaluation of cell count and adherence is performed considering the chosen coating for the alloplastic material.

**Results:**

The in vitro analyses are independent from gender and individual patient features.
Regarding tissue specifity different cell growth can de defined in favour of fibroblasts:
fibroblasts > myoblasts > endothelial cells. Improved cell adhesion is found on alloplastic meshs covered with autologous plasma compared to non- covered meshs. This finding includes all types of cells being tested. A covering of meshs with serum or collagen seems to be of disadvantage. Looking at the intensity of cell adhesion on the different meshs the following ranking can be disposed:

1. TFT Motifmesh ®, ProxyBiomedical
2. Dynamesh®, FEG Textiltechnik
3. Surgimesh ®, Aspide Medical, Resorba
4. PDS Plate ®, Johnson & Johnson
5. Mersilene Band, Johnson & Johnson
6. Vitamesh ®, ProxyBiomedical
7. Vicryl Band, Johnson & Johnson
8. TiLoop ®, PFM

Cell adhesion on the following alloplastic materials could be verified neither in the uncovered nor in the covered approach:

Ethisorb Patch ®, Ethicon
Proceed surgical mesh ®, Ethicon
Collagenmesh
Resodont mesh ®, Resorba
Parasorb mesh ®, Resorba
Dualmesh®, Fa.Gore
Mycromesh®, Fa.Gore
PCL scaffold
AdVance male sling ®, AMS
Seratim®, Serag-Wiessner

**Interpretation of results:**

Cell adhesion to the tested alloplastic materials regarding cells of the pelvic floor is insufficient. This observation may explain the occurrence of foreign-body reaction and missing integration of alloplastic materials into the pelvic floor.

**Concluding message:**

Coating of meshs with autologous plasma results in an improvement of the biocompatibility of alloplastic materials.

References
1. 1. U.S. Food and Drug Administration (FDA); Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. www.fda.gov/cdrh/safety/102008- surgicalmesh.html; Issued October 20, 2008.
2. 2. Otto T. Warnung vor der Verwendung alloplastischen Materials. Deutsches Ärzteblatt 106(34-35),A1654,2009.

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