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BIOCOMPATIBILITY OF ALLOPLASTIC MATERIALS IN THE SURGERY FOR CONTINENCE AND HERNIA REPAIR

Biocompatibility of alloplastic materials in the surgery for continence and hernia repair

Hypothesis/Aim of study:
The use of alloplastic materials in hernia surgery, continence and prolapse surgery is common. GCP- conform studies are not requested by law and therefore missing. More than 1000 unexpected and severe adverse events (AE´s) have been reported by the American Food and Drug Administration FDA [1] and the Deutsche Ärtzeblatt [2]. Aim of study was the verification of the histological impact of alloplastic materials on surrounding tissue in patients with associated symptoms.

Material and Methods:
In order to answer the question whether alloplastic materials cause foreign body reactions after implantation we explanted different mesh types from patients suffering from clinically relevant symptoms associated with the meshs. Histopathological/immunohistochemical examination of the explanted alloplastic meshs was performed. The results were compared to a cloth showing a classical foreign body reaction after 19 years of deposition in the pelvis of a patient. The cellular reactions in the foreign tissue were determined by the use of antibodies against CD68 (detection of histiocytes and foreign-body giant cells), against vimentin (detection of fibroblasts), against CD34 (identification of vascular endothelial cells) and against smooth muscle actin (marking of vascular wall).

Results:
The resection of the alloplastic material was due to futile pelvic lymphadenectomy after previous surgery for inguinal hernia in 2 cases, treatment refractory pain following the implantation of an inguinal mesh in 1 case. In 7 cases mesh material was partially explanted because of therapy-refractory pain caused by the mesh after implantation for continence and prolapse surgery. The measured changes are independent from the type of mesh being used. Immunohistochemically, the presence of foreign-body giant cells and histiocytes demonstrated distinctive foreign-body reactions. The samples are characterised by considerable vimentin- positive reactions and surrounding connective tissue poor of vital cells. Sporadic endothelial cells can be observed. In contrast to a corpus alienum, the leucocytary infiltration associated with the alloplastic materials is less intense or totally missing. Immunhistochemically, the fibrotic reaction instead is comparable between both types of foreign-body reaction.

Interpretation of results:

Alloplastic materials are responsible for distinctive development of surrounding foreign- body reaction.

Concluding message:
The biocompatibility is poor independent from the explanted mesh type. Despite unfavourable patient selection with mesh-associated adverse events grade IV GCP- conform proceeding regarding the handling of alloplastic materials for the surgery for hernia, incontinence and prolapse seems mandatory.

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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