

## EXPERIMENTAL MRI-CONTRAST IMAGING OF SUTURE AND MESH MATERIALS WITH FE<sub>3</sub>O<sub>4</sub> -CONTAINING POLIVINYLDENEFLUORIDE POLYMERS DESIGNED FOR PELVIC FLOOR SURGERY

### Hypothesis / aims of study:

Polypropylene sling procedures have become the standard of care for urinary stress incontinence, and there is early evidence that mesh augmented prolapse repair improve anatomical outcomes. This may be at the expense of a number of graft related complications (GRC), of which shrinkage, dyspareunia and pain are the most frequent ones. Also several of these procedures require the use of trocars and/or anchoring systems, and their use may result in other procedure specific complications. Both knowledge about the in vivo behavior of materials as well as the actual anatomical insertion site may help us understand and manage these complications. Further, in vivo imaging of mesh augmented repairs may be helpful in understanding and managing recurrence as well as yield insights into pathophysiologic mechanisms of prolapse and incontinence. At present, ultrasound is a clinically available imaging modality, though depth and tissue contrast resolution are limiting factors. Currently used implants are neither contrasting (sufficiently) on magnetic resonance imaging (MRI) or Computer Analyzed Tomography (CAT). Recently helical CAT scanning using 1 mm slice thickness with three dimensional reconstruction of barium-impregnated meshes four weeks postoperative was described, though it still requires the use of radiation<sup>1</sup>. We embarked on a in vitro study to test the feasibility and optimal setting for accurate ex-vivo MRI of synthetic suture and mesh materials modified such that they can be imaged with this modality.

### Study design, materials and methods:

Paramagnetic Fe<sub>3</sub>O<sub>4</sub> microparticles were integrated into the polymer material at the stage of production. Fe<sub>3</sub>O<sub>4</sub> exhibit signal voids on T2 sequences and generate susceptibility effects on other sequences. The basic technology was earlier developed in an interdisciplinary research project among the RWTH Aachen University Hospital, (Department of Surgery and Department of Diagnostic Radiology, Aachen, Germany) and Forschungs und Entwicklungs Gesellschaft- Textiltechnik mbH ( Aachen, Germany)<sup>2</sup>. To contrast the Fe<sub>3</sub>O<sub>4</sub> containing material against for instance signal void intestinal air, positive contrast imaging is also required. The manufacturer provided us with both an experimental suture and mesh. The latter is a modification of the commercially available polivinyldene fluoride (PVDF) mesh marketed for cystocele repair (Dyna-mesh-PR4soft, FEG, Aachen, Germany). PVDF is a polymer that is already used clinically in meshes for hernia repair. It may induce a different host reaction as it has a lower immunogenicity<sup>3</sup>. Filament diameter of the DynaMesh-PR4 soft mesh is 85 µm and effective porosity of the mesh is 61 %. For this experiment selected fibers knitted through the mesh contained Fe<sub>3</sub>O<sub>4</sub> at a concentration of 1 mg/g. Also Fe<sub>3</sub>O<sub>4</sub> -containing PVDF sutures were made in the same concentration and a diameter of 230 µm (USP 3-0). Meshes were scanned either alone or embedded in a pumpkin or chicken legs, within a water tank. MR imaging was performed on a 3 Tesla scanner (Siemens, Erlangen, Germany) using a knee coil. T2-weighted imaging was performed with the following parameters: resolution TE (echo time), 132ms; TR (repetition time), 1000 ms; slice thickness, 1 mm; field of view, 200 mm; bandwidth, 289 Hz/pixel. MR scanning parameters of T1-weighted images were: TE, 7.35 ms; TR, 18 ms; slice thickness, 0.5 mm; field of view, 150 mm; bandwidth, 130 Hz/pixel). Parameters for TRUE-FISP imaging were: TE, 1.77 ms; TR 4.1 ms, slice thickness, 2.0 mm; field of view, 263 mm; bandwidth, 977 Hz/pixel).

### Results:

The experimental suture and the fibers containing Fe<sub>3</sub>O<sub>4</sub> microparticles within the mesh material could easily be outlined on all T1 and T2 sequences, whereas the suture control material was not directly visible.

The left two rows of the figure show on the macroscopic aspect of the mesh (M) and sutures in a pumpkin in open (top) and closed (bottom) state. The experimental suture is annotated S(e) and the control suture S(c).

On the MR images (column 2) of the pumpkin in a closed state in a water tank, the experimental material is clearly visible (T2 sequence on top, T1 bottom). Columns 3-5 shows the setup of the chicken leg phantom with experimental suture (S(e)) and control suture material (S(c)) in a water tank. Again only the experimental suture is clearly visible on the TRUE-FISP (column 4) and T1 (column 5) MR images.



Interpretation of results:

The incorporation of Fe<sub>3</sub>O<sub>4</sub>microparticles in a number of PVDF-filaments makes it possible to visualize on MRI images either sutures or implant materials. With the current concentrations and the size of the microparticles containing fibers, as well as adapted MRI sequences a relatively high resolution image could be obtained, which should allow three dimensional reconstruction of the mesh or suture location in vivo.

Concluding message:

Adding Fe<sub>3</sub>O<sub>4</sub>-micro particles allows MR contrast imaging of PVDF filaments, either as a suture or within implant materials. These experiments justify further in vivo evaluation for optimal definitions of MR imaging sequences as well as studies into potential modifications of the host response. When used clinically, MRI imaging of meshes may help in the understanding of the host response, the action mechanism, but potentially also the occurrence of recurrence and GRC.

References

1. Palma P, Riccetto C, Fraga R, Miyaoka R, Prando A. Dynamic Evaluation of Pelvic Floor Reconstructive Surgery Using Radiopadue Meshes and Three-dimensional Helical CT. International Braz J Urol, 2010; 36: 209-217.
2. Krämer N, Donker H, Otto J, Hodenius M, Sénégas J, Slabu I, Klinge U, Baumann M, Müllen A, Obolenski B, Günther R, Krombach G. A concept for Magnetic Resonance Visualization of Surgical Textile Implants. Investigative Radiology, 2010; 45: 477-483.
3. Klinge U, Klosterhalfen B, Birkenhauer V, et al. Impact of polymer pore size on the interface scar formation in a rat model. J Surg Res 2002; 103:208-214.

<b><i>Specify source of funding or grant</i></b>	<b>Unconditional grant of FEG Textiltechnik will support in vivo research as a result of this experiment.</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>NONE</b>