Three-dimensional analysis of implanted magnetic-resonance-visible meshes

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Abstract
Objective Our primary objective was to develop relevant algorithms for quantification of mesh position and 3D shape in magnetic resonance (MR) images.

Methods In this proof-of-principle study, one patient with severe anterior vaginal wall prolapse was implanted with an MR-visible mesh. High-resolution MR images of the pelvis were acquired 6 weeks and 8 months postsurgery. 3D models were created using semiautomatic segmentation techniques. Conformational changes were recorded quantitatively using part-comparison analysis. An ellipticity measure is proposed to record longitudinal conformational changes in the mesh arms. The surface that is the effective reinforcement provided by the mesh is calculated using a novel methodology. The area of this surface is the effective support area (ESA).

Results MR-visible mesh was clearly outlined in the images, which allowed us to longitudinally quantify mesh configuration between 6 weeks and 8 months after implantation. No significant changes were found in mesh position, effective support area, conformation of the mesh’s main body, and arm length during the period of observation. Ellipticity profiles show longitudinal conformational changes in posterior arms.

Conclusions This paper proposes novel methodologies for a systematic 3D assessment of the position and morphology of MR-visible meshes. A novel semiautomatic tool was developed to calculate the effective area of support provided by the mesh, a potentially clinically important parameter.

Keywords Magnetic Resonance · Mesh · Prolapse · Semiautomatic analysis · Graft-related complication · Contraction · Conformational measurements

Introduction

The lifetime risk for surgery because of pelvic organ prolapse (POP) is estimated to be around 19 % [1]. Similar to abdominal hernia repair, surgical implants have been suggested to replace or support the damaged pelvic floor tissues for instantaneous and long-term relief. Synthetic meshes have shown to provide better anatomical results compared with native-tissue repairs, though without clear benefit on subjective outcomes [2, 3]. However, around 10 % of patients experience graft-related complications (GRC), i.e., mesh exposure, wound-healing problems, contraction, and pain, and some may require reintervention [4]. The nature of the mesh, surgical
technique, level of surgeon experience, and patient characteristics such as smoking, age, hormonal status, and body mass index (BMI) are risk factors for GRCs. The most common complications are mesh exposure, contraction, and pain [5, 6], which may be due to inappropriate biomechanical properties of the mesh [7]. Contraction, for instance, is usually explained by contraction of collagen fibers within the scar. Chronic pain may be due to excessive inflammation irritating nerve structures around the mesh [8]. Pain can also be caused by fixation to or passage of mesh arms through anatomical structures by direct injury [9, 10].

In vivo visualization of the mesh may reveal useful information, e.g., shape and position over time. Ultrasound (US) has been used to demonstrate folding or inappropriate positioning of the implant, but penetration depth and tissue contrast offer limited visualization potential [11]. Implants used at this time are not (sufficiently) contrasted on magnetic resonance imaging (MRI) or computed tomography (CT). To enhance contrast on CT, barium impregnation has been used. High-quality images and reconstructions of sling repairs have been obtained by helical CT scanning using 1-mm slice thickness [12]. Though current dynamic CT equipment allows for shorter scanning times with lower radiation exposure, it still requires radiation. It also has limitations in terms of the exact orientation in the patient’s body [13].

Integration of paramagnetic iron oxide (Fe₃O₄) microparticles into the mesh filaments allows visualization of the entire implant on MRI, as has been experimentally demonstrated [14, 15]. At the time of production, paramagnetic Fe₃O₄ microparticles (0.2 μm) at a concentration of 10 mg/g are integrated into polyvinylidene fluoride (PVDF)-polymer filaments used for knitting meshes. PVDF has a better biocompatibility than polypropylene, with moderate inflammatory response and higher elasticity and tensile strength, thus achieving appropriate textile properties with thinner fibers and less material [16]. Fe₃O₄ particles in the polymer generate susceptibility-induced hypointensity against surrounding hyperintense tissue, causing obvious signal voids on most MRI sequences and allowing easy visualization and segmentation.

Thus, MR-contrasting implants can be used for non-invasive monitoring of the mesh’s configuration over time. These MR-visible implants are marketed in Europe for hernia and vaginal reconstructive surgery. The primary goal of this study was to develop robust semiautomatic workflows to quantitatively characterize the position and shape of such MR-visible meshes. Development of such algorithms and eventually automated workflow will allow for a wider standardized clinical use of MR for the surveillance of meshes in vivo.

### Methods

#### Mesh implantation

MR-visible polyvinylidene fluoride (PVDF) PR4 1B soft meshes (DynaMesh Visible™, FEG Textiltechnik, Aachen, Germany) was used for mesh-augmented cystocele repair. This is a four-arm construct made of knitted monofilament PVDF fibers containing paramagnetic Fe₃O₄ microparticles, with a pore size of 1.3 × 2.3 mm and an effective porosity of 61.1%. This construct has a pyramidal central part and an additional posterior segment for fixation onto the cervix (Fig. 1). This mesh is on the clinical market with CE certification in Europe and widely used in Germany. PVDF meshes (with or without Fe₃O₄ particles) have been studied extensively for their biocompatibility both in animal models and clinical trials [17–19].

The mesh was implanted using a single-incision trocar-guided technique with reusable needles (IVT01 and IST02, FEG), bringing the arms through the obturator membrane. The patient’s postoperative course was unremarkable, with spontaneous voiding immediately after catheter removal and discharge at postoperative day 2 (Table 1). Clinical assessment at 6 weeks and 8 months postoperatively showed good anatomical and functional outcome, without GRC (Table 1).

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Fig. 1 PR4 1B mesh
Imaging methodology

The patient underwent an MR examination of the pelvic floor at 6 weeks and 8 months postoperatively on a 3-T MR scanner (Ingenia, Philips, The Netherlands) in the supine position. Routine clinical T2-weighted turbo spin-echo (TSE) sequences, complemented with axial, sagittal, and coronal true fast imaging with steady-state precession (TrueFISP), and a high-resolution non-contrast-enhanced 3D fast-field echo (FFE) sequence (voxel resolution 0.65×0.65×1 mm) was used to facilitate mesh detection and visualization (Fig. 2). The total scan duration was <15 min. As a control, MR images were taken of the same type of mesh embedded in a water-based modelling compound (Play Doh, Hasbro Inc, US). The use of MR for longitudinal follow-up studies in patients undergoing prolapse repairs has been approved by the Ethics Committee of the University Hospitals Leuven.

3D reconstruction

The Fe₃O₄ particles in the mesh cause a susceptibility-induced decrease in signal intensity in its surroundings [20]. The signal voids appear as dark regions on MRI, cumulatively composing a volume that we reconstruct as a 3D object. Given that the particles are within the mesh fibers, this 3D object represents the space wherein the mesh lies. For clarity, we note that this 3D object is not representative of the ingrown tissue. A 2×2 median filter was applied on all axial image slices to remove noisy pixels. Dynamic region growing, a semiautomatic segmentation technique, is used to separate the paramagnetic signal. The resulting “mask” was corrected manually wherever needed and triangulated to obtain a 3D stereolithography (STL) model. The 3D model was smoothed and wrapped to remove image artefacts. The models were verified by clinicians by overlaying the contours of the 3D object onto MR images (GC, IU). The central part and arms of the mesh were separated using 3D curves drawn manually under supervision of a clinician (GC, IU). Two 3D objects were created from images at 6 weeks and 8 months. All image processing, 3D generation, and separation of different mesh parts was done in Mimics Innovation Suite v16.0 (Materialise NV, Leuven, Belgium) by a single operator (NS).

Temporal changes in mesh geometry

To observe changes in mesh geometry over time, a partcomparison analysis was done using 3-Matic (Materialise). Both 3D models generated from the 6-week and 8-month postoperative MR images were first overlaid onto each other using global registration to negate differences due to different patient positioning. The analysis calculates the local differences between two 3D models, which may be representative of global changes in mesh configuration, transient movement of the mesh, and contraction between the two postoperative time points.

Fig. 2 Midsagittal (a) and axial (b) magnetic resonance (MR) image of the pelvic floor. Contrasting mesh is annotated with white arrows and its supporting arms encircled in white. B, urinary bladder; R, rectum; S, sigmoid colon; U, uterus; V, vagina.
Measurements on mesh arms

The length of the arms was defined as the length of their center-lines. A center-line is a 3D curve created by interpolating a second order spline through the centers of the circular cross sections of a tubular object, i.e., the mesh arms. These center lines were generated with an automated procedure in Mimics Innovation Suite using their respective 3D models, verified, and manually corrected wherever necessary.

Reslicing the MR images along the center-line curves gives a set of cross-sectional images at regular intervals along the length of the arms. Thus, the hypointense signal from the arms can be examined along its geometrical cross-section (Fig. 3a). In resliced images, the shape of the arms ranges from elliptical (Fig. 3b) to circular (Fig. 3c). In comparison, in resliced MR images from the control experiment, arms appear largely elliptical (Fig. 3d). The appearance of the arm in these resliced images indicates that arms change from a flat to a tubular configuration after implantation.

To study this morphological change, the ellipticity of the arm is measured along its length. Ellipticity is defined as 

$$e = \sqrt{\frac{a^2 - b^2}{a^2}},$$

where $a$ and $b$ are the major and minor axis lengths of the best-fit ellipse, respectively. The ellipticity is calculated by an automatic measurement method in Mimics Innovation Suite, and all further analysis is done in Matlab (Mathworks Inc.). The ellipticity profiles of each arm at 6 weeks and 8 months were compared using a paired $t$ test.

Effective support area

We interpret the middle of the 3D object created by the signal voids as being the mesh surface. The middle of the 3D object is a thin, sheet-like structure. Since the area effectively supported by the mesh is very likely an important surgical outcome measure, we propose a method for its quantification. A custom tool developed in Matlab (v2012b, Mathworks Inc.) is used to semi-automatically measure the area of mesh support, which we refer to as the effective support area (ESA). Briefly, the tool takes the 3D object and a wall-thickness analysis file created in 3-Matic as input and creates a continuous, differentiable nonuniform rational B-spline (NURBS) surface. Area and edge-length measurements of the effective support surface were also made here. Complete details of the algorithm used can be found in the “Appendix”. It is important to note that this surface area is different from the surface area of the 3D model we created earlier: the ESA measurement does not contain contributions from folds or any other local topologies that may be present in the 3D model. The method was tested for reproducibility and robustness. Interoperator repeatability of the ESA measurement was confirmed, since the difference between measurements made by three independent operators (IU, GC, AF) was <2 % (data not shown).

Fig. 4 3D models of mesh created from magnetic resonance (MR) images at 6 weeks (left) and 8 months (right). Center lines (red) and their corresponding lengths are shown, along with the percentage increase or decrease in length compared with the 6-weeks scan.

Fig. 5 Results from the part-comparison analysis. Left color map showing how the mesh 3D object at time point 1 differs from at time point 2. Right histogram showing the absolute differences in millimeters in accordance with the color map. Differences are insignificant, indicating the mesh does not deform in shape during the observation period.
Results

Anatomical position of the mesh

Analysis of MR images taken 6 weeks postoperatively showed the mesh was situated between the bladder and the anterior vaginal wall and there was no obvious prolapse. The arms were not symmetrical in location: The anterior arms on both sides passed through the obturator foramen to end in the obturator externus muscle. Posteriorly, the left arm followed a similar trajectory through the obturator foramen and ended in the external obturator muscle. On the right side, the posterior arm ended in the internal obturator muscle, very close to the anterior left arm.

3D model comparison

The part-comparison analysis of the two 3D models (at 6 weeks and 8 months postimplantation) shows a mean difference of 0.83±0.70 mm (Fig. 5). The minor differences illustrate that the position of the mesh between 6 weeks and 8 months postoperatively is relatively unchanged. The difference in the length of the arms was 2.69±1.76 mm. Exact values with percentage changes are shown in Figs. 4 and 5.

Ellipticity of the arms

The average ellipticity of each arm at 6 weeks and 8 months is shown in Fig. 6. Using a paired analysis, the ellipticity profile of anterior right (AR) and anterior left (AL) arms does not change significantly over time (p=0.4 and p=0.119, respectively). However, profiles of posterior left (PL) and posterior right (PR) arms were significantly different (p=0.009 and p=0.023, respectively) between 6 weeks and 8 months postimplantation.

Effective support area of the central part

The ESA calculated from MR images at 6 weeks was 1,030.2 mm² and that at 8 months was 1,050.7 mm². Thus, the ESA varies very little between the two time points. The average change in surface edge lengths was 1.43±1.48 mm, which is also negligible. The effective support surfaces are shown in Fig. 7.

Discussion

MR-visible PR4 1B mesh was clearly outlined in MR images, which allowed us to longitudinally quantify the mesh configuration between 6 weeks and 8 months after implantation in a patient with a good anatomical and functional short-term outcome. We performed an anatomical assessment of mesh position and also created a methodology for full 3D reconstruction of the mesh. Using these 3D models, it was possible to develop a framework by which to quantitatively measure deformations of both the mesh arms and the central body.

PR4 1B mesh was visible at both time points with equal contrast, allowing us to create the 3D object, which has a
larger thickness than the mesh ex vivo. It is also thicker than the 3D object reconstructed from the control experiment. The thicker appearance of the paramagnetic signal may be caused by the different surroundings of Fe₃O₄ particles, i.e., biological tissues and control. There is a body of research investigating differences in susceptibility-induced signal voids due to the surrounding tissues and to the direction of magnetic-field gradient relative to the Fe₃O₄-loaded mesh fibers [21–23]. Therefore the thickness is, at least in part, an artefact. Ignoring the actual thickness may, however, be a limitation should it have clinical relevance. For instance, it might be representative of microfolding [11]. In that case, however, this would show up in a concomitant reduction in ESA.

The part-comparison analysis showed negligible changes in mesh morphology between 6 weeks and 8 months after implantation. In general, during 3D model generation, minor differences may arise due to different patient positions, limited MRI resolution, or errors during segmentation. However, using semiautomatic segmentation and global registration, such errors are minimized. The analysis clearly indicates that the mesh as a whole moved very little during the observation period in this patient.

For analysis of mesh arms using center lines, the user must first manually separate the arms from the main mesh body. To minimize any user-dependent variability, this step should be performed by an experienced user under supervision of a clinician. There is also negligible difference in the length of different arms, as shown by the centerline measurements. The ellipticity profiles of the arms at 6 weeks and 8 months are very similar for the anterior arms. However, we observed a statistically significant increase in ellipticity for the posterior arms. These changes indicate that the morphology of the arms may change longitudinally. Further studies are necessary to ascertain the effect of such changes.

We proposed a novel semiautomatic way of measuring the effective support surface provided by the implant. The ESA could be used as an objective measure to directly assess the support provided by the mesh, and as such, correlate it to surgical outcome. Over the study period, we observed no measurable change in the support area provided by the mesh.

This case study does not address the issue of immediate dimensional/morphologic changes in the ESA. The preimplantation surface area of the mesh is more than double compared with the ESA measured after 6 weeks. This change may occur due to wrinkling, folding, or as a response to the geometrical and biomechanical environment, which could add to later progressive contraction and/or fibrosis [11, 24]. To study these phenomena, higher-resolution, microscale images must be acquired immediately postoperatively, which seems feasible in animal models only. Nonetheless, we propose to use the methods presented here in future preclinical and clinical studies.

Conclusion

This paper proposes novel methodologies for a systematic 3D assessment of the position and morphology of MR-visible meshes. A novel methodology was developed to calculate the ESA provided by the mesh, a potentially clinically important parameter. Such semiautomated measurements would be ideal for longitudinal clinical monitoring of patients undergoing mesh-augmented prolapse repair, irrespective of mesh shape.

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Andrew Feola: project development, methodology development
Frederik De Keyzer: data collection
Filip Claus: data collection, project development
Geertje Callewaert: clinical guidance
Iva Urbanova: clinical guidance
Sebastien Ourselin: project development
Jan D’Hooge: project development
Jan Deprest: project development, clinical guidance

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