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MRI visible Fe₃O₄-polypropylene mesh: 3D reconstruction of spatial relation to bony pelvis and neuro-vascular structures

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Abstract

Introduction and hypothesis—To demonstrate mesh magnetic resonance (MR) visibility in living women, the feasibility of reconstructing the full mesh course in 3D and document its spatial relationship to pelvic anatomical structures.

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L Chen: reconstruction method development, data evaluation, manuscript writing

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Methods—This is a proof of concept study of three patients from a prospective multi-center trial evaluating women with anterior vaginal mesh repair using a MR-visible Fe₃O₄-polypropylene implant for pelvic floor reconstruction. High resolution sagittal T2-weighted sequences, transverse T1-weighted (T1w) FLASH 2D and transverse T1w FLASH 3D sequences were performed to evaluate Fe₃O₄-polypropylene mesh MR-visibility and overall postsurgical pelvic anatomy three months after reconstructive surgery. Full mesh course as well as important pelvic structures were reconstructed using the 3D Slicer® software program based on T1 and T2 MR-images.

Results—Three women with POP-Q grade III cystoceles were successfully treated with a partially absorbable MR-visible anterior vaginal mesh with 6 fixation arms showing no recurrent cystocele in the 3 months follow-up examination. The course of mesh in the pelvis was visible on MR-images in all three women. The mesh body and arms could be reconstructed allowing visualization of the full course of the mesh in relationship to important pelvic structures such as the obturator or pudendal vessel-nerve bundles in 3D.

Conclusions—The use of MR-visible Fe₃O₄-polypropylene meshes in combination with post-surgical 3D reconstruction of the mesh and adjacent structures is feasible suggesting it might be a useful tool to more precisely evaluate mesh complications and might be a valuable interactive feedback tool for surgeons and mesh design engineers.

Keywords

3D mesh reconstruction; Fe₃O₄; MR-visible anterior mesh; pelvic floor mesh surgery; pelvic organ prolapse

Introduction

Pelvic organ prolapse is a distressing condition that requires surgery in over 200,000 women each year in the United States; a number that is expected to substantially increase in the coming decades [1–3]. Besides the performance of classic urogynecological surgery techniques, the use of synthetic material for pelvic organ prolapse (POP) repair has been established in the past decades. Synthetic transvaginal mesh was permanently implanted to reinforce the weakened vaginal wall for POP repair usually with arms anchored in structures near the pelvic side wall. However, surgery outcome results have shown heterogeneous data in terms of mesh erosions, post-surgical pain and dyspareunia or recurrent prolapse [4, 5].

Visualizing the mesh can be helpful in evaluating patients with mesh complications. 2D, 3D/4D Ultrasound (US) has proven to be useful to visualize mesh adjacent to the vagina, demonstrate folding or inappropriate positioning of the implant and assess vaginal mobility in relationship to the mesh location [6–8]. It is difficult, however, to visualize the entire mesh including the course of the arms through deep body structures such as the obturator neurovascular bundle or the sacrospinous ligament and the pudendal neurovascular structures. In order to achieve full mesh visualization in the female pelvis a MR-visible mesh was developed applying an iron compound onto the mesh material, for iron has previously shown to be visible with some MR-imaging sequences [9–11]. The newly developed MR-visible Fe₃O₄-polypropylene-mesh has demonstrated MR-visibility in a cadaver study [9]. Whether or not the fine mesh structure could be seen in living women

where tissue movement from vascular pulsation and breathing and muscle activity might reduce visibility is not known.

As a proof of concept study, the goal is to 1) describe the technique, 2) assess the mesh MR-visibility in living women, 3) demonstrate the feasibility to reconstruct the full course of the mesh and 4) visualize the mesh's spatial relationship to important pelvic floor anatomical structures for example if the mesh is invading any surrounding organ or whether it is close to blood vessels or nerve bundles. This valuable information could potentially aid the clinical diagnosis and revision surgery planning.

Material and Methods

Study design

This is a proof of concept study of three patients from an ongoing prospective multi-center clinical trial (ethical board reference number: S-473/2007, amendment July 9th, 2015) to observe and evaluate women with anterior vaginal mesh repair using a magnetic resonance (MR) visible Fe₃O₄-polypropylene implant. All women participating in this examination matched the inclusion criteria (symptomatic grade 2 cystocele with apical prolapse scheduled for anterior mesh surgery with apical fixation through the sacrospinous ligaments, no contraindication for surgery or MRI, age ≥ 18 years) and gave their written informed consent. Exclusion criteria were vaginal reconstructive surgery without anterior mesh, general contraindications for surgery or MRI, age < 18 years).

Mesh information and implantation

Partially absorbable (PA) anterior vaginal meshes (Seratom® E PA MR or Seratom® P PA MR by Serag Wiessner GmbH & Co. KG, Naila, Germany) were implanted. These meshes have six fixational arms of which the posterior arms are fixed in the sacrospinous ligaments while the middle and anterior arms are placed via the obturator muscle-membrane-complex [12]. The non-absorbable material is MR-visible, as described in our previous study [9]. The two meshes (Seratom® E PA MR being 6×10cm and the Seratom® P PA MR 4×9cm) differ only in size/shape. The MR-visibility of this alloplastic material is created with a defined concentration of (0.2 weight-%) Fe₃O₄ added to the polypropylene - unlike other MR-visible meshes on the market that integrate paramagnetic Fe₃O₄ microparticles into polyvinylidene fluoride (PVDF) polymer filaments [9, 13]. The MR-visible meshes produced by Serag Wiessner GmbH & Co. KG have been on the clinical market with CE certification since 2013. The implantation of the mesh was performed according to the company recommendations with help of the mesh implantation tools (multi-incision trocar-guided technique with reusable introducers/needles) [12]. The anterior and middle arms were placed through the obturator foramen, and the posterior arms penetrated the sacrospinous ligament on both sides and passed outwards through the ischioanal fossa [12].

Magnetic Resonance Imaging

All patients underwent a pre- and postsurgical (10–12 weeks after surgery) MRI with moderately filled bladder in a 1.5 Tesla scanner (Siemens Symphony, Siemens Medical Solutions, Erlangen, Germany). Sterile gel (Endosgel®) was inserted into the vagina to

ensure better visualization of the vaginal walls [14]. All images were obtained in the supine position. The examination protocol included high resolution sagittal T2-weighted (T2w) turbo-spin-echo (tse) sequence for morphological visualization of the pelvic tissues and organs (TR 3460–4219ms, TE 77–85ms, slice thickness 5mm, matrix 512×282) and transverse T2w tse sequence (TR 3460ms, TE 88ms, slice thickness 6mm, matrix 512×282). To delineate the mesh structures a transverse T1-weighted (T1w) FLASH 2D (fl2D) sequence (TR 128–132ms, TE 4.7ms, slice thickness 6mm, matrix 256×154) and a transverse T1w FLASH 3D (fl3D) sequence (TR 15.0ms, TE 6.0ms, slice thickness 1mm, matrix 512×384) was performed. In this scan the threads of the mesh containing Fe₃O₄ particles demonstrate hypointense signal due to circumscribed susceptibility artifacts. The field of view (FOV) of the sequences covered the entire pelvis including the promontory and the pelvic floor. Only post-surgical MR-images were analyzed in this study.

Mesh and pelvic structure 3D-reconstruction

The three dimensional (3D) reconstruction of the mesh implant and the neighboring anatomical structures was performed using the 3D Slicer® software program (version 4.3.1-2) and the original Digital Imaging and Communications in Medicine (DICOM) static MR-images of the above mentioned sequences [15]. First, bony landmarks such as most inferior pubic symphysis, ischial spines and sacrococcygeal junction (SCJ) were identified on T1w and T2w images [16]. These landmarks were used to align different MR image sequences in the same 3D space. The pelvic bone, as well as organs and ligaments were manually traced from T2w images in all slices in which they could be identified and then three-dimensional volume rendering models were reconstructed.

The mesh was identified on T1w fl2D and fl3D images as small hypointense, "dark", spots compared to surrounding tissues on T1w images. Fiducials, single point identifiers, were placed on these locations to produce a "cloud" of visible points and confirmed in all three projection views (transverse, coronal and sagittal) as well as in 3D space (Figure 1). This "point cloud" technique [17] was applied rather than the 3D volume-rendered models to avoid the lofting and smoothing errors introduced by computer algorithms used for model reconstruction and because point placement was more precise than the line drawing needed for model construction. Using the same technique, important anatomical structures such as obturator vessels and pudendal neuro-vascular-bundles were reconstructed based on T1w and T2w images to demonstrate their relationship with implanted mesh.

Results

Patients

Three postmenopausal patients with a cystocele (paravaginal defect, which was clinically diagnosed as the descent of the lateral vaginal sulcus) and POP-Q state III° were treated with an anterior mesh-repair and an additional POP-Q stage I–II° rectocele with a posterior colporrhaphy. The complete surgical procedures were performed by two expert urogynecological surgeons (surgical experience > 10 years) according to the company recommendations for mesh implantation. Patient A (67 years old) and patient C (74 years old) both received a Seratom E PA MR implant and patient B (66 years old) a Seratom P PA

MR implant. Hysterectomy was not carried out in any of the three cases. All operations were performed without complications. The patients were discharged approximately 48 hours after surgery. The 12 week postsurgical gynecological assessment showed a good local healing process with no mesh erosion, dyspareunia or POP-recurrence in any treated compartment. POP-grading under Valsalva maneuver was determined as grade 0–I° in all patients.

Mesh visualization in MR images

The MR-visible mesh including all six arms could be identified in all three patients' postsurgical T1w MR images. Example images of three axial MR sequences at the level of the arcuate pubic ligament and ischial spine level of one patient are shown in Figure 2. The mesh is best seen on T1w images while traditional T2w images were best for identifying anatomical structures (Figure 2). T1w f13D sequences provide superior contrast and details for mesh visualization than T1w f12D images due to the thin slice thickness that had less spatial averaging effect (Figure 2). No postoperative complications like free fluid, seroma or hematoma were present on MRI and the pelvic organs showed morphologically without pathological findings.

Mesh 3D-reconstruction and its relationship to important anatomical structures

A reconstruction of each implanted mesh was feasible using the 3D-Slicer® in all 3 subjects including both the main body of the mesh and each arm (Figure 3). In addition, adjacent structures such as the sacrospinous ligament as well as the pudendal and obturator nerve could be identified and displayed. The location of the main body of the anterior mesh is seen between the bladder/bladder neck and the anterior vaginal wall (Figure 2 and supplement video). All six arms could be reconstructed in full course from the main body to and through the pelvic sidewalls, sacrospinous ligament area and ischiorectal fossa demonstrating their course via either the obturator foramen (anterior and middle arms) or the sacrospinous ligament (posterior arms) (Figure 3 and supplement video). The 3D spatial relationship between mesh and important anatomical structure such as obturator vessel and pudendal nerve-vessel-bundles can be appreciated in detail (Figure 4).

Discussion

The results of this study demonstrate the feasibility of complete 3D mesh reconstructions after anterior vaginal mesh-repair in living women using a MR-visible polypropylene mesh. The implanted Fe₃O₄-polypropylene mesh is visible in sufficient detail in all three cases so that the contour and mesh location could be identified and reconstructed. We used a point-cloud based technique instead of traditional 3D volume rendering technique to reconstruct the mesh [13], allowing for precise location identification of all visible parts of the mesh and avoiding lofting artifacts that can occur in volume (solid) model creation. This display enabled the following important relationships to be studied: (1) the anterior and middle arms through the obturator foramen with its relationship to obturator vessel/nerve bundle; (2) the posterior arms passing through the sacrospinous ligament in relationship to the pudendal vessel/nerve bundle; (3) the mesh body location relative to vaginal wall and bladder/bladder neck.

To date, studies published have shown MR-visibility of mesh material experimentally, in a cadaver [9], rat models [11] and abdominal hernia reconstruction using polyvinylidene fluoride (PVDF) as matrix [10, 18–20], and only one study group using a MR-visible PVDF-mesh for pelvic floor reconstruction [13]. This report extends what has previously been reported in literature by demonstrating the feasibility of using Fe_3O_4 -polypropylene mesh in living women and reconstructing the 3D course of its body and arms in relationship to important anatomical landmarks. This is an extension of the cadaver work [9] to show that healing process, and the movements of the organs during breathing and pulsatile movement of blood vessels in living women do not prevent visualization of the fine mesh filaments.

Ultrasound has been widely used in clinic and demonstrated its capability to detect implanted meshes and help with the diagnosis of mesh complication. It demonstrates excellent visibility of segments of the mesh between the vagina and bladder [6]. It has proven to be especially useful in diagnosing mesh folding or dislodgement [6] or in evaluating recurrent cystoceles after anterior colporrhaphy using alloplastic material [21, 22]. Because of its favorable cost/benefit ratio and the ability to do real-time viewing, we believe ultrasound will remain the main-stay for most clinical situations. However, ultrasound technique has its limitations in evaluating the course of the mesh arms laterally in the pelvis and their relationship to adjacent structures near pelvic sidewalls due to its limited scope of the ultrasound volume. The combination of MRI-visible mesh and MRI can provide additional information in some circumstances that justifies its higher cost. For example perineal pain that might be from mesh irritation of the pudendal nerve, leg pain possibly from obturator irritation. In these circumstances, the MRI-visible mesh and MRI can provide additional information by capturing the entire pelvic region including bony pelvis, soft tissue structure and implanted mesh simultaneously. Being able to follow the course of the mesh arms through deep pelvic structures, which cannot be reached by ultrasound, and demonstrate 3D relationship between implanted mesh and important anatomical structures (e.g. pudendal nerve, obturator foramen), can help detect and evaluate mesh-related complications (such as post-surgical pain, dyspareunia). MRI cannot replace clinical examination for the detection of the origin of neuropathic pain; however, MRI is able to depict anatomical changes close to the course of a specific nerve. Furthermore, if the mesh is located close to neurovascular structures, knowing where the vessels and the mesh are in 3D space can help the surgeon to stay out of danger zone in the revision surgery. In addition, unlike ultrasound, MRI is performed following a predefined protocol, is user independent, allowing a reliable pre- and post-surgical comparison and long term follow-up examinations with inter-subject comparison without depending on ultrasound operators' skill and experience.

The interactive nature of 3D reconstructed models, with the free open source 3D Slicer® software or other model building programs, allows the physician to add or subtract anatomical structures or rotate the constructed 3D model according to user-defined importance for better visualization of certain pelvic areas and could be used to measure distances between the mesh and anatomical landmarks. This could be a useful feedback tool in an educational and clinical setting allowing surgeons to visualize the complete mesh with MRI and re-evaluate the personal implantation technique. For example, on figure 1 and 2, the distal portion of the mesh can be found beneath the proximal part of the urethra on MR-

images three month post-surgery, while the intended most inferior location of mesh is at the bladder neck level by mesh designer and surgeon [23]. The evaluation of post-surgical mesh positioning might also help surgeons and mesh designers optimize mesh dimensions and its fixation strategies to provide sufficient support with least possible side effects. This use of 3D visualization has been used by Larson et al. who compared manufacturer-specified placement of non-MR-visible anterior wall mesh kits to 3D vaginal models in women with normal support [23]. Enhancing this information, the MR-visible Fe₃O₄-polypropylene-mesh and its 3D-reconstruction in post-surgery MRI can provide a wider range of information to study the mesh and its fixation behavior in living women than solely evaluating clinical exam and ultrasound results. This could potentially lead to improved design or innovation to help decrease future mesh complications.

Several factors should be kept in mind in interpreting the results of this study. We recognize the small number of women examined limiting a widespread data evaluation and subsequent research will be needed to determine how consistently the mesh can be seen. Despite the fact, that we are of the opinion of this technique being very valuable for clinical life and urogynecological research forthcoming, we are aware of the time consuming and expensive nature of MR-imaging and 3D-reconstruction in a normal clinical setting limiting its use for more complicated cases instead of an extensive use.

The MR-visible mesh allows the visualization of the mesh body, as well as the course of mesh arms. This technique allows the relationship between the mesh and adjacent muscular, bony and neurovascular structures to be displayed and evaluated. Although we focused on the pelvic bones, sacrospinous ligament and pudendal and obturator neurovascular bundles, the full complement of anatomical structures in and around the pelvis that can be seen in MR-imaging could be modeled and examined in relationship to the mesh.

Conclusions

MRI of the MR-visible mesh and its 3D-reconstruction technique allows us to visualize the full course of the mesh including both mesh body and mesh arms in relationship to important pelvic floor structures. It has promised to be a useful tool to assist in evaluating possible mesh complications such as suspected neurovascular injury. It could also be a valuable interactive biofeedback tool for the surgeon. Furthermore, the technique allows the biomedical engineers to exam the mesh structure mechanics in living women providing insights to optimize the future mesh design.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Brief summary

3D reconstruction of MR-visible Fe₃O₄-polypropylene meshes for anterior vaginal compartment repair is feasible.

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Figure 1.

Creation of 3D Slicer model from the transverse planes T1w f13D sequence showing images a, c and e at level of mid urethra (U) and images b, d and f at level of bladder (B) in patient 1 after anterior compartment repair using a six arm Fe₃O₄-polypropylene mesh. Panel a & b are unlabeled original MR images. The visible mesh is marked with yellow dots in the two-dimensional view (Panels c & d). Images e and f show the tilted 3D model of the pelvis and the location of the implanted mesh with the MR images of panel a and b for better spatial evaluation and understanding. In panel a and c the distal part of the mesh body can be seen beneath the urethra, as well as the left anterior and middle arm (arrowheads in panel c) that

can be traced through the left obturator foramen. The posterior arms are seen passing through the pararectal tissue (arrows in panel c). Panel d: The ischial spine (IS) is marked and the mesh can be followed as it comes around the rectum (R) heading to the sacrospinous ligament. 3D reconstruction of the pubic bone (Panel e & f) was based on the blue tracing on images c and d.

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Figure 2.

Comparison of three MR sequences at two levels (left, urethra; right bladder). Panels a & b: T2-weighted turbo spin echo sequence with 5 mm slice thickness. Panels c & d: T1-weighted flash 2D sequence with 6 mm slice thickness. Panels e & f: T1-weighted flash 3D sequence with 1 mm slice thickness. Note the T2-weighted images visualize best the soft tissue contrast for morphological information, however, the mesh is best seen on T1-weighted images due to the artifacts of the iron components (arrows). Using thin sliced T1w FLASH 3D the thin mesh structure can be seen best. fl2D: FLASH 2D; fl3D: FLASH 3D;

tra: transverse; U: urethra; V: vagina; PS: pubic symphysis; B: bladder; R: rectum; asterisk: sacrouterine ligament; star: ischial spine; x: obturator foramen

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Figure 3.

3D models created from postsurgical MR-images of all three patients. In the left column the reconstructed pelvic bones including the sacrum are demonstrated as well as vagina/uterus (brown), sacrospinous ligament (blue) and the MR-visible mesh (yellow dots). The reconstruction software allows structures to be turned on or off as needed for evaluation. In the middle column, the vagina/uterus and sacrum (but not coccyx) are hidden for better illustration of the mesh placement in the pelvis. In the right column the models are rotated to a three-quarter view revealing a different impression on how the left anterior and middle mesh arms are positioned in the obturator foramen or where the posterior arms pass through the sacrospinous ligament.

Figure 4.

MR visible mesh visualization and 3D reconstruction, demonstrating mesh placement in the pelvis and its spatial relationship with important anatomical structures in patient 1. Panels a, c and e: axial MR-images (T1w f13D sequence), mesh marked with yellow asterisk. Panel b: In-to-out view of same patient's reconstructed 3D model of the pelvis and mesh. The anterior and middle mesh arms pass outwards through the obturator foramen in safe distance away from the obturator vessels (orange dots). Panels c & d: 3D reconstruction shows the pudendal nerve-vessel-bundle (red arrows (c) or dots (d)) in adequate distance from the mesh and its arms. Panels e & f: Penetration of the sacrospinous ligament (blue arrows (e)

and three-dimensionally reconstructed blue (f)) by the posterior mesh arms in safe distance from the pudendal nerve-vessel-bundle and ischial spine (IS). B: bladder. R: rectum. S: symphysis.

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