Original article

From polymer to optimal textile implants - A challenge for the engineer

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Abstract: In some respects implants are like any other engineered device: they have to be designed carefully and must fulfill specific requirements according to their application. What makes the development of implants special is the necessity for close interdisciplinary cooperation. Good communication between physicians and engineers is essential. The physician should provide the engineer with the requirements; while the engineer has to translate those requirements into specific values and find the best compromise possible between conflicting requirements. This paper explains this concept by the means of two examples and gives an overview of the main questions which have to be considered when designing a new implant.

Key words: Polymer; Textile implants; Materials; Engineer.

I. INTRODUCTION

Engineering a new implant is not a trivial task. There is definitely not the one mesh of choice for every application. Different anatomic structures call for distinct textile structures (Figure 1).

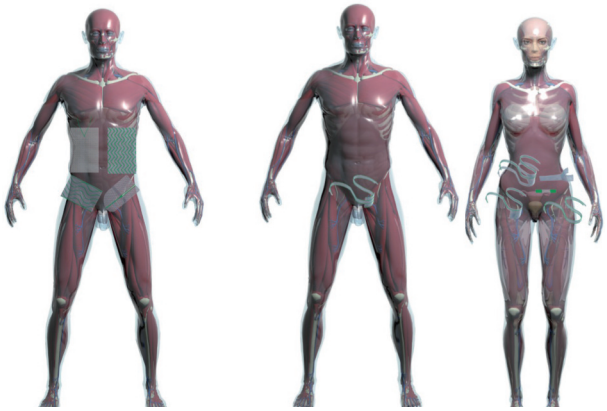

Figure 1. – Different mesh structures used for hernia repair (left) and m/f pelvic floor repair (right).

Therefore it is very important to define specific requirements for specific applications. An engineer calls this "compiling a requirement profile". It is a huge challenge to comply with every requirement as there are many potential conflicts between them (e.g. sufficient stability vs. high effective porosity). An optimal implant always represents the best compromise possible. To determine necessary and desirable properties a close interdisciplinary cooperation is essential. Physicians provide engineers with either precisely worded requirements, specific values or autopsy specimens for testing. On the other hand engineers translate their requirements into specific values. To explain this concept we will exemplary have a look at meshes used for hernia repair or more precisely on three important requirements: stability, elasticity and porosity.

II A. EXAMPLE OF A REQUIREMENT PROFILE FOR AN INCISIONAL HERNIA MESH

To determine the tensile strength of the human abdominal wall, engineers used a simple analogous model for the human torso: a cylinder. The required stability can be calculated using the law of Laplace (Figure 2). With a maximum inner pressure of 20 kPa and a circumference of the abdomen of 100 cm the tensile force is 32 N/cm in transversal direction and 16 N/cm in longitudinal direction. [1]

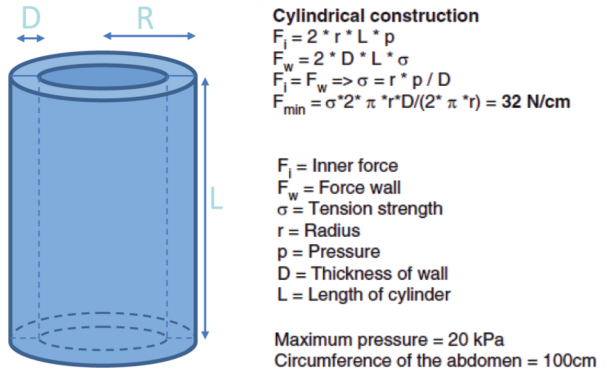

Figure 2. – Cylindrical construction for the human torso 1.

To determine the elasticity of the human abdominal wall, autopsy specimens were used. Figure 3 shows the experimental set-up. The results likewise showed a clear anisotropic behaviour of the human abdominal wall and a big difference between longitudinal and transversal direction (38 % to 20 % at max. tensile force)[1].

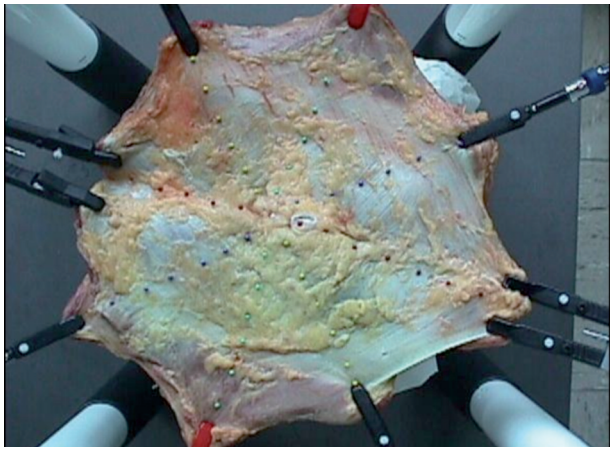

Figure 3. – Experimental set-up to measure the elasticity of explanted abdominal walls 1.

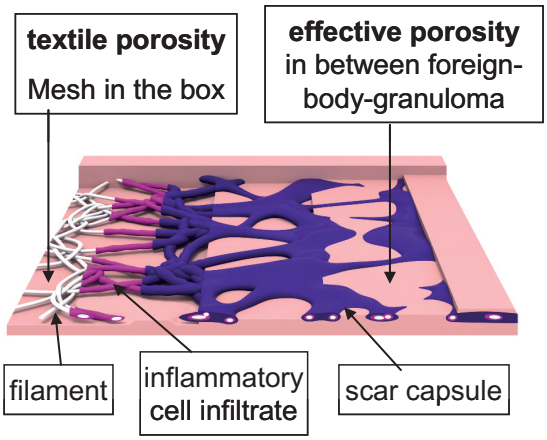

Figure 4. – Textile vs. effective porosity.

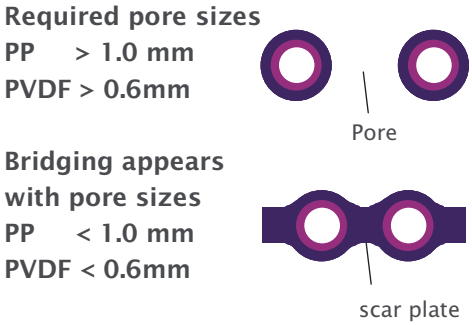

Figure 5. – Bridging limits for PP and PVDF.

Finally, the analysis of about 1,000 explanted meshes showed that a high porosity is essential for optimal incorporation. To avoid the bridging-effect (side by side granuloma leading to a continuous scar plate formation), the pore size must be bigger than 1 mm for PP and bigger than 0.6 mm for polyvinylidenfluoride in every direction (Figure 5)[2]. There is a major difference between "textile porosity" and "effective porosity". Textile porosity is the percentage of the mesh surface that is not covered by filaments including all sizes of pores; whereas effective porosity describes only the resulting pores which are available for tissue ingrowth after scar tissue formation (Figure 4).

A new objective system to measure the effective porosity was developed at FH Aachen University (Figure 6). A high resolution digital image is evaluated with graphical data procession. Only the pores with dimension over 1 mm in every direction (0.6 mm for PVDF) are taken into consideration[3].

Figure 7 shows the difference between textile and effective porosity through the example of three different mesh structures (class Ia and II according to Klinge et al)[4].

In summary: the close interdisciplinary cooperation between physicians and engineers led to a profound understanding of needed values regarding "stability", "elasticity" and "effective porosity" and a better understanding of hernia meshes and implants. The final requirement profiles are shown in figure 8.

This knowledge enables the textile engineer to construct an "optimal" hernia mesh for the repair of incisional hernias.

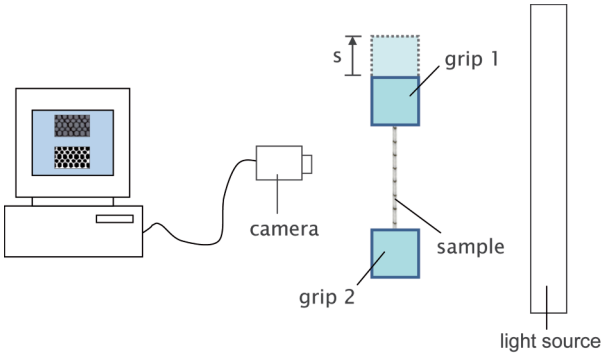

Figure 6. – Set-up for porosity measurement.

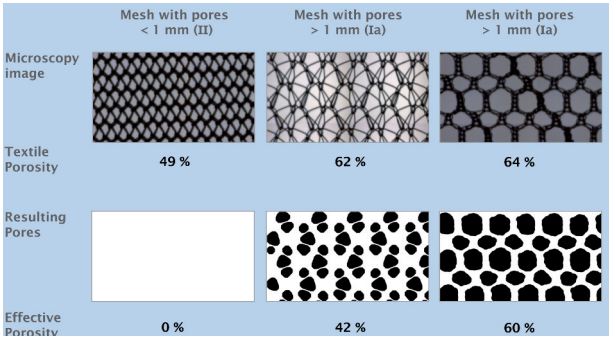

Figure 7. – Textile and effective porosity of different mesh structures.

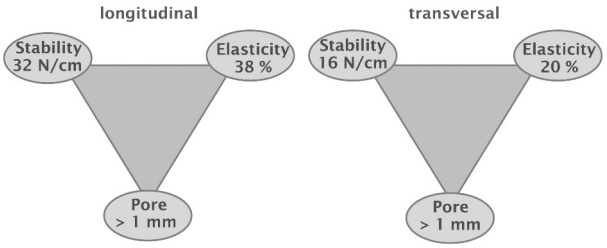

Figure 8. – Requirements for incisional hernia meshes in longitudinal and transversal direction.

II B. EXAMPLE OF A REQUIREMENT PROFILE FOR AN INCONTINENCE SLING

Compared to the anisotropic hernia mesh, slings for pelvic floor repair are clearly under uniaxial condition.[5] Almost tension-free when implanted, there is a certain force applied in longitudinal direction during implantation. This force is the minimal value required for structure stability. So far it has not been quantified. Measuring the tensile strength of explanted ligaments seems to be one option to determine a rough reference point for required stability.

A value of 2 N/cm with an elasticity of less than 10% has been suggested as rough estimates.[5] This estimate however is only sufficient for the implanted device. The pull-through force requires a greater stability during implantation (see figure 16). As foreign body reaction and scar tissue formation should always follow the same principles, the pore sizes indicated for hernia meshes can be used analogously (Figure 9)[5].

III. ENGINEERING A NEW IMPLANT (EXAMPLE INCONTINENCE SLING)

When starting to engineer a new implant, there are at least 3 main questions to consider:

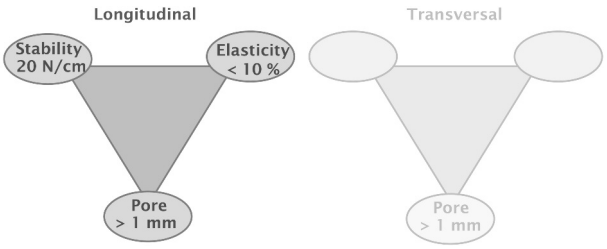

Figure 9. – Requirements for slings.

Which polymer should be used?
Which kind of threads should be used?
Which structure should be used?

1) Which polymer should be used?

The polymer choice depends on a variety of factors. Important properties for the use as implants are high biocompatibility, low evocation of foreign body reaction, high resistance to bacterial adherence, as well as stability under hydrolytic conditions.

Concerning biocompatibility it is also preferable if fewer additives are used. Table 1 shows a comparison between polypropylene (PP) and polyvinylidenfluoride (PVDF) with regard to main requirements. PP is the most commonly used material for pelvic floor surgery. PVDF has been the favoured material for cardio-vascular implants for decades and has also successfully been used in hernia surgery for the past ten years.

TABLE 1. – Comparison of PVDF and PP.

	PVDF	PP
Low foreign body reaction	++	-
Biocompatibility	++	+
Resistence to bacterial adherence	++	-
Stability	++	+
Long term stability	++	-
No necessity for additives	++	- -
Price	-	++

In several studies it was shown that PVDF induces much less foreign body reaction than PP[6,1]. An analysis of 100 explants showed that PP is not inert[7]. The inflammatory infiltrate as well as the foreign body granuloma are significantly reduced (Figure 10)[8].

Tests with different bacterial strains also showed that the bacterial adherence to PVDF fibres is smaller than to PP fibres or a combination of PP fibres and absorbable fibres (Figure 11). Consequently the risk of infection is reduced with PVDF[9].

The Young's modulus is a material parameter that describes the resistance of the material towards its deformation - the higher the Young's modulus the higher the resistance. It can be measured by the slope of the tangent of the initial, linear portion of the curve in a stress-strain diagram. The Young's modulus of PP varies between 1300 and 1800 N/mm², whereas the Young's modulus of PVDF varies between 2100 and 2900 N/mm². Hence PVDF opposes more resistance towards deformation than PP, which results in more stable fibres.

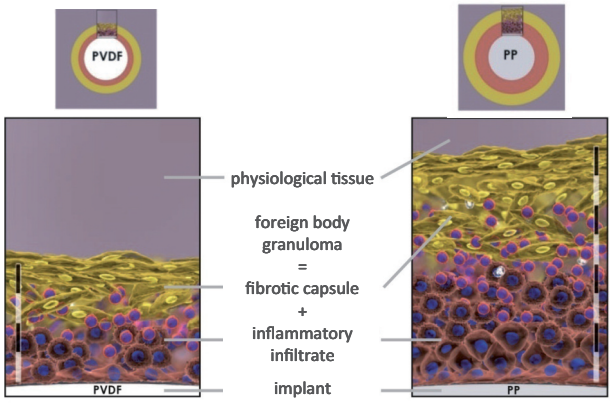

Figure 10. – Foreign body reaction of PVDF and PP[8].

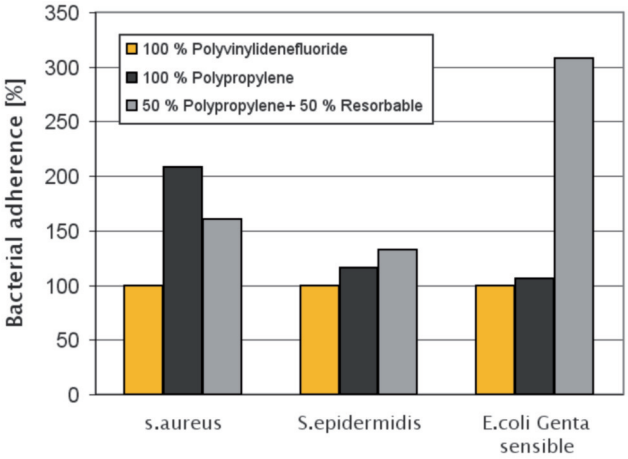

Figure 11. – Bacterial adherence on PVDF, PP and composite fibres.

A higher initial stability of PVDF coincides with a higher long-term stability[10]. Laroche et al. demonstrated during an in-vitro study over a period of 7 years that under hydrolytic conditions PP lost 46.6 % of its original tensile strength while PVDF only lost 7.5 % during the same period (Figure 12)[10]. In vivo studies confirmed the results[10]. Figure 13 shows SEM images of explanted PVDF and PP filaments. Only the PP samples show signs of surface cracking.

Another important advantage of PVDF over PP is that there is no need for operational additives such as diluents, stabilizers or antioxidants.

Like Polypropylene, PVDF can be coloured, but has furthermore the technological advantage of modifications regarding visibility in MRI[11,12] or bioactive coatings (Table 2) [13,14].

TABLE 2. – Additives used for PVDF and PP..

	PVDF	PP
Operational Additives	None	Diluents (softeners)
		Stabilizers
		Antioxidants
Optional Additives	Colorants for orientation	Colorants for orientation
	Particles for visible meshes	
	Bioactive coating	

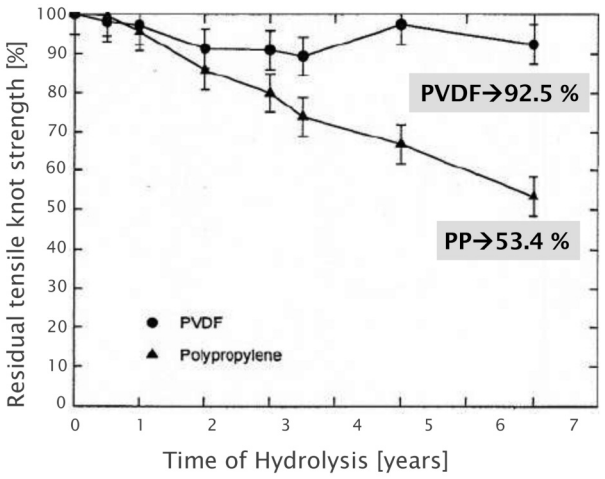

Figure 12. – Residual tensile strength of PVDF and PP sutures during exposure to hydrolytic conditions 10.

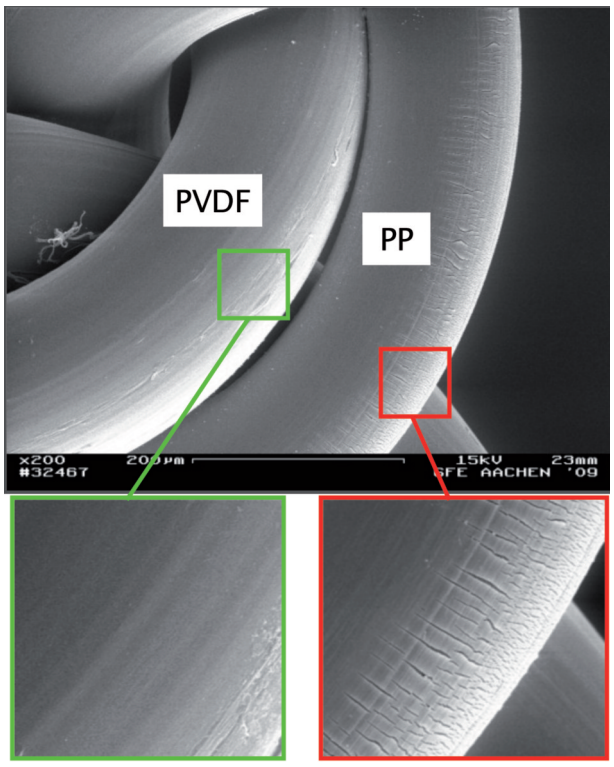

Figure 13. – Explanted PVDF and PP filaments, PP shows signs of surface cracking.

However, despite the superior properties of PVDF, it is still not the standard for pelvic floor implants. The reason for this is simple: higher costs and the fact that most manufacturers are unable to process this high-tech polymer. It is not processable on conventional spinning units for it contains fluorine which behaves aggressively during the process. Nevertheless the fluorine is advantageous in the final product for it provides long-term stability and elasticity even in fibres with a small diameter.

2) Which kind of threads should be used?

Figure 14 shows a schematic diagram of the melt spinning process. The properties of the filaments can be varied within wide limits but it is also a challenge to find parameters which ensure sufficient process stability and reproducibility.For most applications a multifilament – a thread composed of many small fibres – is advantageous as it offers a greater stability than a monofilament – a thread made from one single fibre. In a multifilament thread the different filaments buttress each other and inhomogenities can be balanced out. However, for the use in the human body a monofilament is preferable for it offers much less surface for bacterial adherence and foreign body reaction (Figure

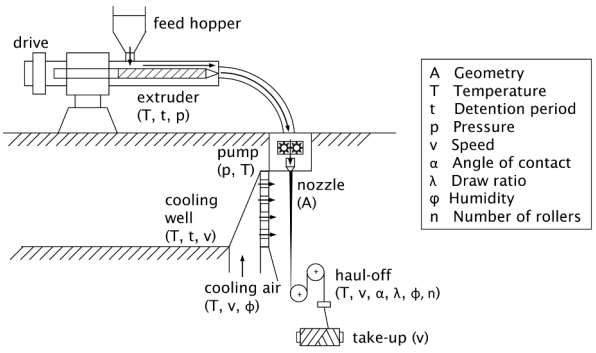

Figure 14. – Melt spinning machine.

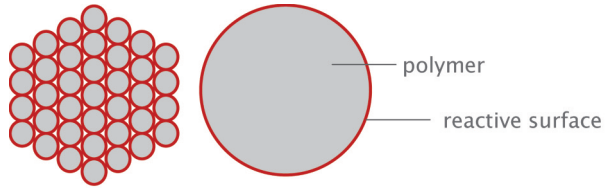

Figure 15. – Comparison of the reactive surface of multi- and monofilaments.

15). This coincides with the suspicion of many surgeons that multifilaments lead to increased infection rates.

3) Which structure should be used?

The structure of implants must be open-porous and soft but nevertheless stable. The edges should also be soft without sharp filaments sticking out ("saw-chain edge") to avoid tissue traumatization.

The structural stability for pelvic floor implants is especially important during implantation. An implant with insufficient stability can be deformed plastically which means the deformation remains even after the load has vanished. The plastic deformation is usually accompanied by a reduction of the effective porosity – the pores are elongated while their width is narrowed significantly ("collapse of pores"). This can turn a large pore class I structure into a small pore class II structure with an accumulation of foreign body material and an increased foreign body reaction and scar tissue formation. Insufficient stability can also lead to rolling-in which has the same negative effects as a material accumulation but can also lead to erosions when only the edges instead of a flat surface are in contact with sensitive structures like the urethra.

There are two technical options to prevent plastic deformation and the reduction of effective porosity during implantation. The first is a plastic sleeve around the implant which absorbs the tensile force and is removed after implantation. One disadvantage of this solution is the difficult handling during implantation. Subsequent repositioning after the sleeve has been removed is also impossible. Additionally the question of what happens after implantation remains. The second technical option is a stable structure. A well-engineered structure can absorb the tensile force without unacceptable deformation (Figure 16).

There are also two ways to avoid tissue traumatization with sharp edges during implantation. The first option is used most commonly because most of the implants are cut to fit and therefore have traumatic edges: a plastic sleeve around the implant which is removed after implantation.

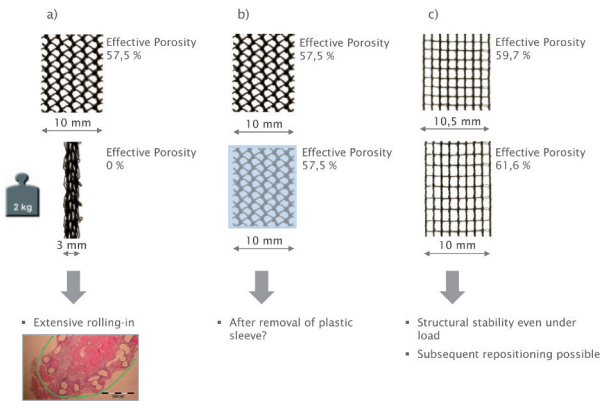

Figure 16. – a) unstable structure, b) unstable structure with plastic sleeve, c) stable structure.

But even though the extensive traumatization during pull-through is avoided, the filaments sticking out can still potentially harm surrounding tissue afterwards and lead to erosions.

The second option which avoids the complicated handling with plastic sleeves is a structure with soft, knitted edges (Figure 17).

IV. POST-MARKET SURVEILLANCE

To improve the knowledge of implants in the human body there is a need for intensified post-market surveillance with comprehensive registries as a basis. The benefits of registries over clinical studies are numerous. For one they provide a much greater data pool. They have a significantly longer follow-up time than studies and therefore can cover even delayed complications. Considering that usually only experts participate in studies, registries also represent the clinical reality much better. An accumulation of complications becomes apparent much quicker with registries so that potentially harmful devices can be identified and taken of the market earlier. However, so far the problem of data privacy remains. The solution is a fail-safe system for effective patient anonymization. In the long run, with registries providing more reliable data, patient safety and comfort will be ensured and improved which should convince even the sceptics.

Additionally a great option to support follow-up after implantation are MRI visible meshes[12]. They provide confirmation of the accurate implant position which gives optimal control of the healing process. This way, exposure to radiation (contrary to conventional x-rays) and unnecessary secondary interventions can be avoided. Figure 18 shows various visible meshes in MRI, figure 19 shows a 3D reconstruction of a visible mesh.

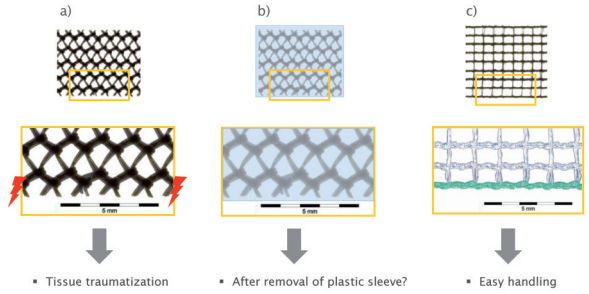

Figure 17. – a) “saw-chain” edge, b) “saw-chain” edge with plastic sleeve, c) soft, knitted edge.

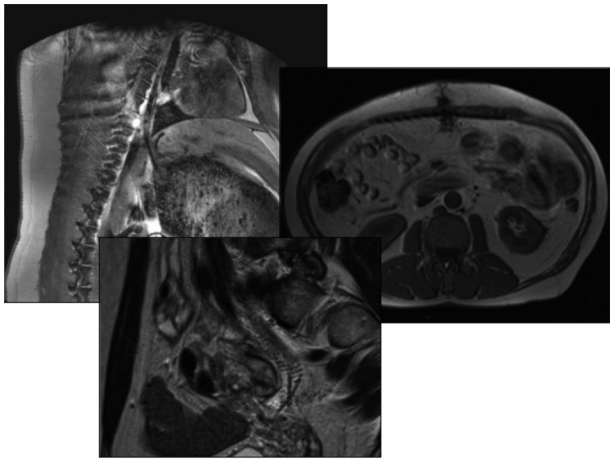

Figure 18. – Different visible mesh structures in MRI.

Figure 19. – 3D reconstruction of a hernia mesh.

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