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Stress adapted embroidered meshes with a graded pattern design for abdominal wall hernia repair

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Stress adapted embroidered meshes with a graded pattern design for abdominal wall hernia repair

J Hahn, L Bittrich, A Breier, and A Spickenheuer

Leibniz-Institut für Polymerforschung Dresden e. V., Institute of Polymer Materials,
Department of Composite Materials, Hohe Str. 6, 01069 Dresden, Germany

Email: hahn-judith@ipfdd.de

Abstract. Abdominal wall hernias are one of the most relevant injuries of the digestive system with 25 million patients in 2013. Surgery is recommended primarily using allogenic non-absorbable wrap-knitted meshes. These meshes have in common that their stress-strain behaviour is not adapted to the anisotropic behaviour of native abdominal wall tissue. The ideal mesh should possess an adequate mechanical behaviour and a suitable porosity at the same time. An alternative fabrication method to wrap-knitting is the embroidery technology with a high flexibility in pattern design and adaption of mechanical properties. In this study, a pattern generator was created for pattern designs consisting of a base and a reinforcement pattern. The embroidered mesh structures demonstrated different structural and mechanical characteristics. Additionally, the investigation of the mechanical properties exhibited an anisotropic mechanical behaviour for the embroidered meshes. As a result, the investigated pattern generator and the embroidery technology allow the production of stress adapted mesh structures that are a promising approach for hernia reconstruction.

1. Introduction

A hernia of the abdominal wall is a protrusion of the intestine through a defect or an area of weakness of the wall. The reason for hernia appearance mainly is due to a connective tissue weakness. Because of acute complications like bowel obstructions, an immediate surgery is required. The worldwide incidence of abdominal hernias is estimated to about 25 million per year. A common method for hernia repair is the implantation of synthetic non-absorbable meshes to support the natural tissue. About one million meshes are implanted every year worldwide [1]. An ideal mesh should provide an adequate porosity for tissue integration, a mechanical behaviour comparable to that of the healthy abdominal wall, and the ability to absorb physiological loads [2-4].

The majority of the used meshes are fabricated by wrap-knitting and exhibit significant higher ultimate load values and no adaption to the anisotropic mechanical behaviour of native healthy abdominal wall tissue [5, 6]. Pott et al. (2012) investigated the mechanical properties of six different knitted hernia meshes in longitudinal and transversal direction. They measured significant differences for ultimate tensile load ((11.1 ± 6.4 to 100.9 ± 9.4) N/cm), stiffness ((0.3 ± 0.1 to 4.6 ± 0.5) N/mm) and break elongation ((150 ± 6 to 340 ± 20) %) values considering the loading direction [7]. The force values for all tested meshes were significantly different in longitudinal and transversal direction, respectively. Furthermore, this anisotropic mechanical behaviour is not visible on most of the hernia meshes resulting in a wrong positioning during surgery and an increasing recurrence rate for the patients [8, 9]. Therefore, the anisotropic mechanical behaviour of warp-knitted meshes is demonstrated by these results confirming the paramountcy of the orientation as well as the necessity to transfer this information from the manufacturers to the surgeons.

An alternative fabrication method could be the embroidery technology. This technology allows the production of structures in nearly all dimensions with high design variability associated with minor effort in pattern creation and machine adjustments compared to warp-knitted fabrics. Embroidered structures are already used for tissue engineering approaches like bone scaffolds [10-12] or for the reconstruction of the anterior cruciate ligament [13, 14].

2. Materials and methods

2.1. Pattern design

Stitch patterns are generated by scripted algorithms based on input design parameters. Stitch positions and the stitch thread path strongly influence the elastic properties of the final structure. The successive stitch position data then is transformed by CAM-software like EDOpath to a machine readable CNC data format. Composition and design parameters of a pattern are presented in Figure 1.

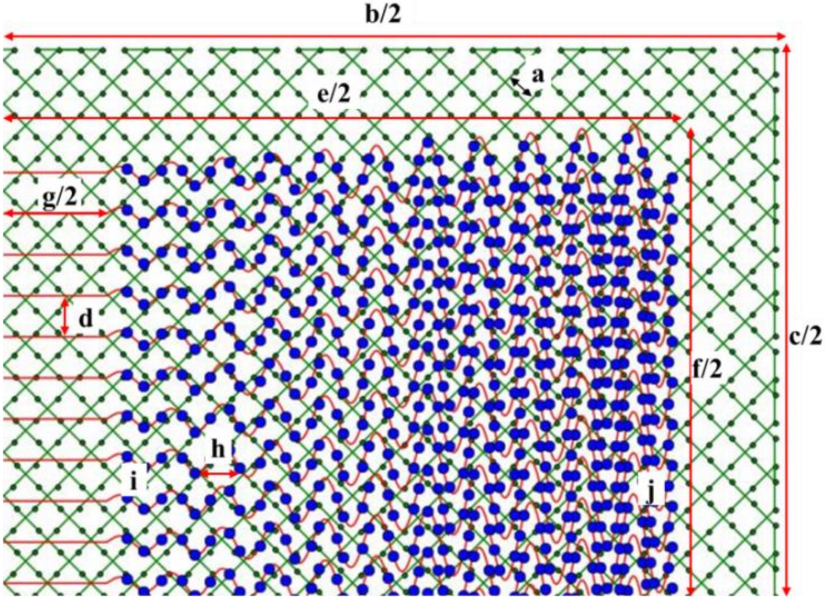

Figure 1. Pattern design for mesh structures composed of base (green) and reinforcement (red with blue dots) pattern

The objective of this pattern design is a tailored stress-strain behaviour showing a high strength at the location of damaged abdominal wall tissue and a soft transition region to healthy tissue to avoid recrudescence due to stress peaks at the mesh boundary. The base pattern (Fig. 1 green) serves as ground fabric for the reinforcement pattern and should ensure appropriate porosity and elasticity. It enables the variation of four parameters, stitch length (distance between two green dots), stitching shift (distance between two green lines (Fig. 1a)) as well as length (Fig. 1b) and width (Fig. 1c) of the complete base pattern. In contrast, the reinforcement pattern (Fig. 1 red with blue dots) allows the precise adaption of the mechanical behaviour for the whole mesh structure due to eight different design parameters. Four parameters are analogous to those of the base pattern, stitch length (distance between two blue dots), stitching shift (distance between two red lines (Fig. 1d)) as well as length (Fig. 1e) and width (Fig. 1f) of the reinforcement pattern. The stretched thread length (Fig. 1g) in the middle of the pattern, the wavelength (Fig. 1h) and the minor/major amplitude (Fig. 1i/j) can be varied to design a graded transition with regions of high stiffness and strength in the range of the hernia opening and regions of high elasticity for the transition to the base pattern.

2.2. Embroidery technology

The meshes were fabricated using an embroidery machine (ZSK JCZ 0209-550, ZSK Stickmaschinen GmbH, Krefeld / Germany) with a multi-needle header on a water soluble polyvinylalcohol (PVA, Freudenberg, Weinheim/Germany) nonwoven. This base material was washed out after the embroidery process in warm water for 90 minutes remaining a porous mesh structure [16, 19].

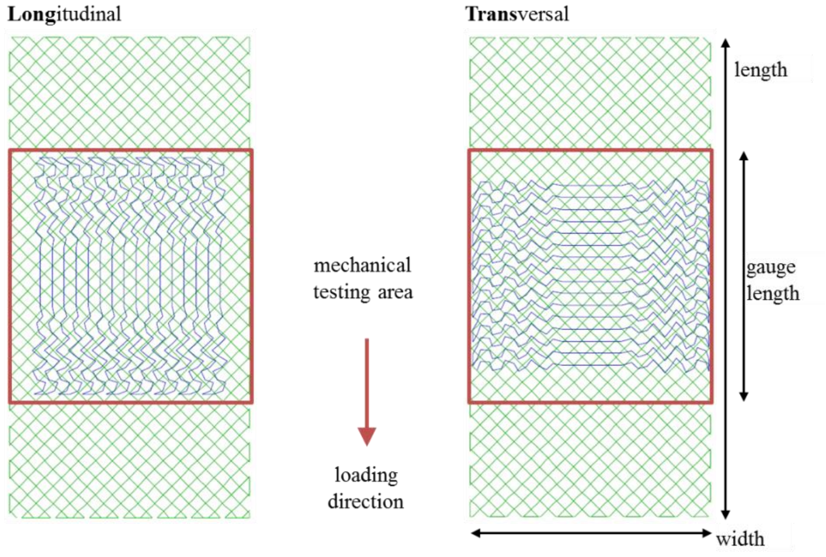

Figure 2. *Specimen 1* for tensile testing (testing area red framed) with a mesh structure consisting of a base (green) and a reinforcement (blue) pattern design arranged in longitudinal or transversal direction

A commercial monofilament based on polypropylene (PP, Dr. Karl Wetekam & Co. KG, Melsungen / Germany) with a yarn count of Tt = 6.4 tex was used as thread material. The embroidered meshes were composed of the base pattern (Fig. 2 green) and the reinforcement pattern (Fig. 2, blue). The base pattern (*specimen 1*: 2.0 mm stitch length, 1.5 mm stitching shift) was embroidered on the PVA in the first fabrication process. After that, the reinforcement pattern (*specimen 1*: 2.0 mm stitch length, 1.5 mm stitching shift, 20 mm length of stretched thread, 2.0 mm wavelength, 0.5 mm / 5.0 mm minor / major amplitudes) was positioned directly over the base pattern in longitudinal (Long) or transversal (Trans) orientation. The orientation of the graded reinforcement pattern was investigated for *specimen 1* in respect to its influence on the load-elongation behaviour and mechanical properties.

2.3. Mechanical testing

The mechanical properties were investigated using a uniaxial tensile testing machine (Zwick / Roell Z2.5, Ulm / Germany) controlled with TestXpert software. A 1000 N load sensor and pneumatic metal clamps were used. The specimens were prepared with a length of 100 mm and a width of 40 mm. The gauge length was set at 50 mm (Fig. 2, red frame). The test speed was 100 mm/min. Ten specimens for each reinforcement pattern orientation were tested. Three mechanical values were determined from the load-displacement curves as described before [13]. The maximum load value defines the ultimate tensile load F_{max} (in N). The associated displacement l_{max} at F_{max} specifies the ultimate tensile elongation ε_{max} (in %) with $\varepsilon_{max} = (l_{max}/l_{gauge}) \cdot 100$. The stiffness S (in N/mm) is defined as ratio of the applied load ΔF to displacement Δl in the linear slope of the load-displacement curve. In addition, the elongation $\varepsilon_{F=5N}$ (in %) at a load of 5 N was evaluated to define and compare the structural deformation of the embroidered specimen. Results for mechanical properties were represented as boxplot with the first (bottom band) and third (top band) quartiles as well as the median (inside band). Mean values (dots) and standard deviations (positive and negative whiskers) were additionally specified. The significance level was set at 5 % ($p < 0.05$).

3. Results

Diverse patterns for embroidered mesh structures with high design variability were realized in this study. Different textile parameters were varied and resulted in mesh structures with adjustable structural characteristics (Fig. 3). For example, porosity and pore sizes could be influenced by varying stitch length and density of the base pattern (Fig. 3 A, B) or minor and major amplitude of the reinforcement pattern (Fig. 3 C, D).

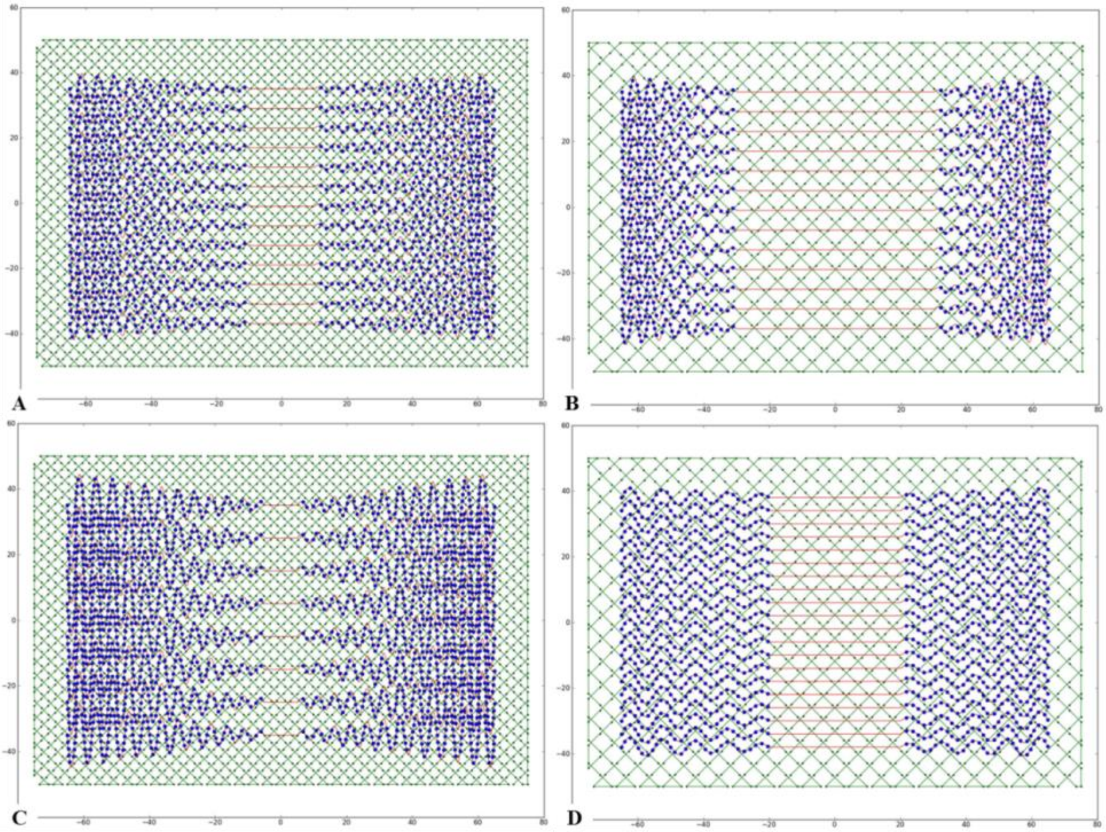

Figure 3. Examples for different pattern designs for embroidered mesh structures (base pattern: length 150 mm, width 100 mm; reinforcement pattern: length 130 mm, width 80 mm)

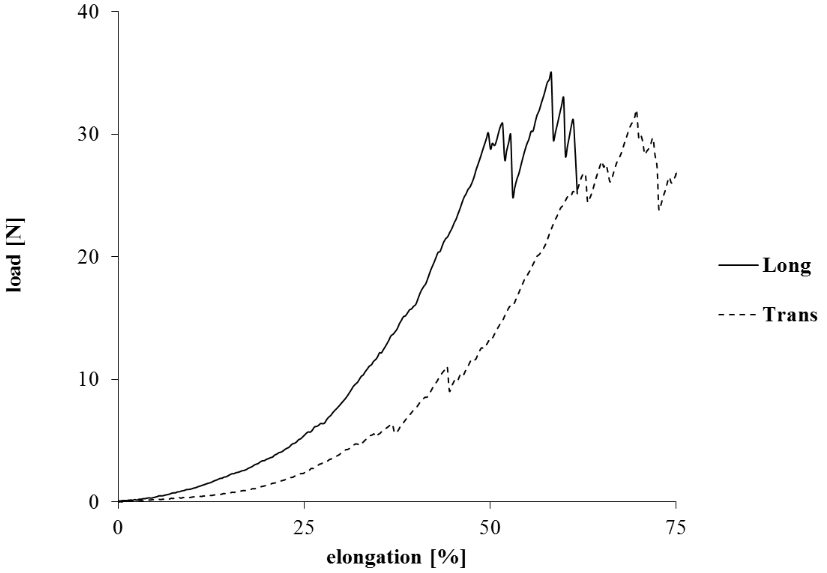

Figure 4. Exemplary load-elongation curves of embroidered mesh structures for *specimen 1* with the reinforcement pattern oriented longitudinal (Long) and transversal (Trans) to the tension direction

Anisotropic material properties were demonstrated by orienting the reinforcement pattern longitudinally and transversally to the direction of tension for mechanical testing (Fig. 4). The pattern oriented in longitudinal direction exhibited a significantly higher ultimate tensile load (34 N ± 3 N vs. 31 N ± 3 N) compared to the transversally arranged pattern (Fig. 5 A). In contrast, the ultimate tensile elongation (55 % ± 5 % vs. 71 % ± 6 %) and the elongation at 5 N (19 % ± 2.5 % vs. 33 % ± 3.2 %) values were significantly lower in the longitudinal compared to the transversal direction (Fig. 5 B, C). Only the stiffness values for both mesh types were in the same range and showed high mean variations (2.2 N/mm ± 0.5 N/mm vs. 2.4 N/mm ± 0.7 N/mm) (Fig. 5 D).

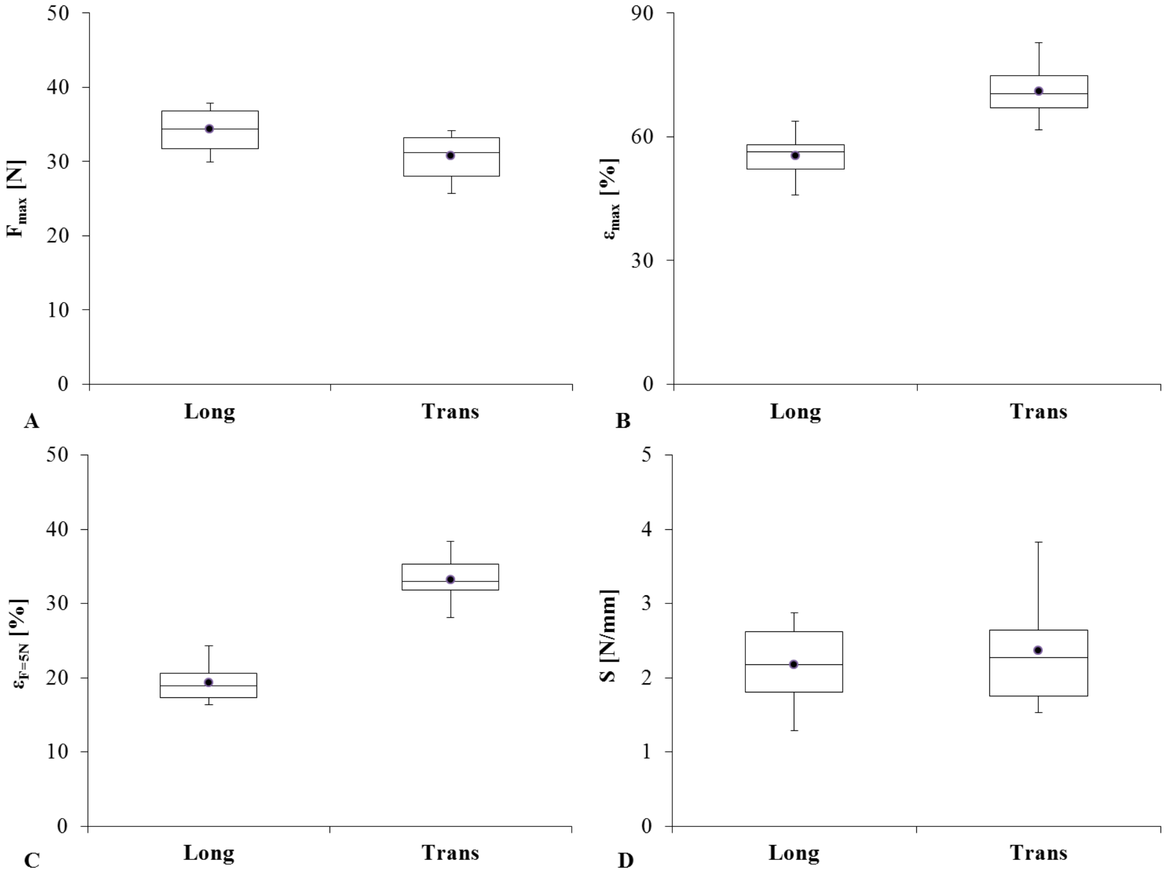

Figure 5. Mechanical properties of the embroidered mesh structures for *specimen 1* tested in longitudinal (Long) and transversal (Trans) direction, A – ultimate tensile load (F_{max} in N), B – ultimate tensile elongation (ε_{max} in %), C – elongation at load F = 5 N ($\varepsilon_{F=5N}$ in %) and D – stiffness (S in N/mm)

4. Discussion

For an optimal reconstruction of abdominal wall hernias, it is essential to use a mesh with adapted stress-strain behaviour and adequate mechanical properties comparable to those of healthy tissue [1]. Challenging in this field is the insufficient data situation regarding *in vivo* information about the mechanical properties of abdominal wall tissue. Therefore, a fabrication method for hernia meshes has to be chosen that offers the possibility to adapt the mechanical and structural properties individually.

This work presents the first demonstration of the feasibility of embroidery technology for producing hernia mesh structures with a specific adaption of the pattern design (Fig. 3) and thus of mechanically adapted structures (Fig. 4). This adaptability was also demonstrated in studies regarding a mechanically adjusted scaffold design for the reconstruction of the anterior cruciate ligament [13]. Stress-strain behaviour and mechanical properties were affected by different pattern design parameters or material selection. The pattern design influences the stress-strain behaviour of the structural deformation of the textile mesh while the material deformation is diversified by the selected thread material. Force values for the embroidered meshes were lower compared to commercial hernia meshes but by varying thread material or size the mechanical properties could be improved. The used thread material (polypropylene (PP)) has an ultimate load F_{max} of 2.8 N. Established thread materials for hernia meshes like medical grade PP or polyvinylidene difluoride (PVDF) were investigated and exhibited F_{max} between 2.3 N – 8.3 N and 3.4 N – 10.8 N depending on their yarn count. This wide range in the thread material characteristics is useful to adjust the ultimate tensile properties of the embroidered meshes. Nevertheless, the vital non-linear behaviour in the elasticity could be demonstrated.

The embroidered meshes were composed of two different design structures, an almost isotropic support structure and a directional reinforcement structure. This twofold design enabled clearly different elastic properties for transversal and longitudinal loads applicable for mimicking the behaviour of natural tissue. Especially the strain behaviour showed the strongest directional dependence. The maximum load also exhibited a directional effect. However, clamping of the specimens was not applied at the reinforcement structure but extended to the environing transition patterns modifying the effect to lower values. Future works will focus on the targeted tailoring of this anisotropic behaviour to the behaviour of human tissue and thus improve medical applicability.

5. Conclusion

In this study different pattern designs were created by various parameters composing a mesh structure with a base and a reinforcement pattern. Based on these designs, mesh structures were fabricated using embroidery technology. An adjustable anisotropic mechanical behaviour was presented for these embroidered meshes. Ongoing experiments consider the adjustments of the ultimate tensile properties, the determination and their influence on the mechanical behaviour of various numbers of design parameters, especially for the reinforcement pattern, as well as the use of these data for numerical simulation of the stress-strain behaviour.

6. References

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