TEXTILE COMPOSITE MATERIALS FOR SMALL INTESTINE REPLACEMENT

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Abstract:

Down to the present day there are no sufficient techniques for a small intestine replacement, mostly because of the high standards for such implants. An indication for the need of novel operation techniques is the small patient survival rate of just 80 % for isolated small intestine transplantation and 62 % for combined liver-small intestine transplantation. The five year survival rates of the patients are merely 42 %. In order to overcome these limitations the authors are developing a partly resorbable textile-foam-composite for small intestine replacement
The novel implant consists of a non resorbable textile PVDF mesh which is foamed with a micro porous, resorbable, and drug loaded polymer. The resorbable polymer serves on the one hand as initial sealing, therefore no intestine substance and bacteria can leak out into surrounding tissue, on the other hand it needs to be micro porous in order to ensure cell ingrowth. For the macro porous textile mesh warp knitting technology is used. The warp knitted tubular structure remains inside the body as a long term implant and provides mechanical support to ingrowing cells. In order to evaluate biomechanical properties of the warp knitted tubular PVDF meshes to compare them to the mechanical characteristics of small intestine tissue, tensile tests were conducted. Results of tensile tests on warp knitted structures with three different loop densities of 8, 12, and 16 loops per cm were compared to tensile tests on native small intestine tissue probes.
The recorded curves of small intestine and warp knitted structures showed similar characteristics. The two characteristic Young Modules as well as the curve progression of the warp knitted structure with 12 loops per cm showed good accordance to the values of the native small intestine. Morphological analysis of the textile structures by digital image processing showed adequate pore size and porosity of the textile mesh.

Key words:

Small intestine, implant, composite, warp knitting

Introduction

Transplantation of organs is nowadays a standard therapy in many fields of medicine for replacement of inoperable organs such as kidney, liver, heart or lung. An essential part for establishment of organ transplantation as routine procedure besides novel surgical techniques is the development of a sufficient immunsuppressive therapy. Whereas the one year survival rate after organ transplantation is in the range of 80 % to 90 % by now, it must be stated that despite modern immunsuppressive therapy most organs suffer a slow immunological caused loss of function over time. Furthermore foreign body reactions after transplantation of foreign organs cause severe problems [1].

Thus presently a main focus of research is the development of biocompatible organs resp. components. New developed artificial organs are implanted for temporary help until regeneration of the natural organ or as permanent substitutes of defect organs. Huge difficulties still exist in the substitution of the small intestine. The small intestine is a tubular structure which connects the stomach and the large intestine. It completes the digestion which is induced in the stomach and resorbs chemical components and nutrients out of the food and passes it to the blood circuit. An operational ablation of segments of the small intestine is necessary as life saving procedure in some cases. The complete or partially loss of the small intestine which is called short bowel syndrome is caused mainly by cancer, intestinal loops or thrombosis of arteries subserving the small intestine [2]. The short bowel syndrome is characterized by the disability to abide protein-, energy-, and fluid balance

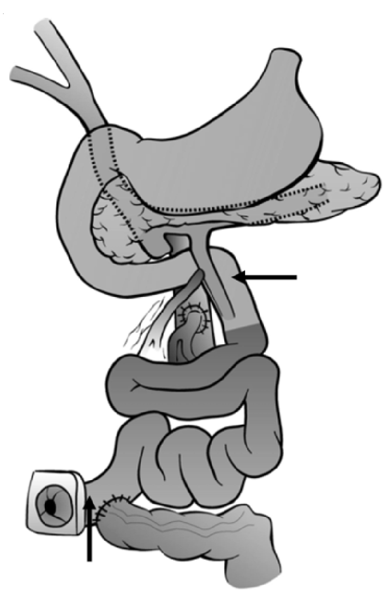

Figure 1. Schematic drawing of small intestine transplant [2].

State of the art

The first successful small intestine transplantation was accomplished by Deltz [3] in the year 1987 followed by combined liver-small intestine transplantations by Grant [4,5]. During the last five years, clinical small intestine transplantation has significantly improved. Since 2001, more than 150 small intestine transplantations per year are performed worldwide. Anyway up to date there are no sufficient techniques for a small intestine replacement. One main issue are rejection reactions after transplantation of foreign organs. An indication for the need of novel operation techniques are the small patient survival rates of 70% - 80% for isolated small intestine transplantation and 62 % for combined liver-small intestine transplantation. The five years survival rates of the patients are merely 42 % [6].

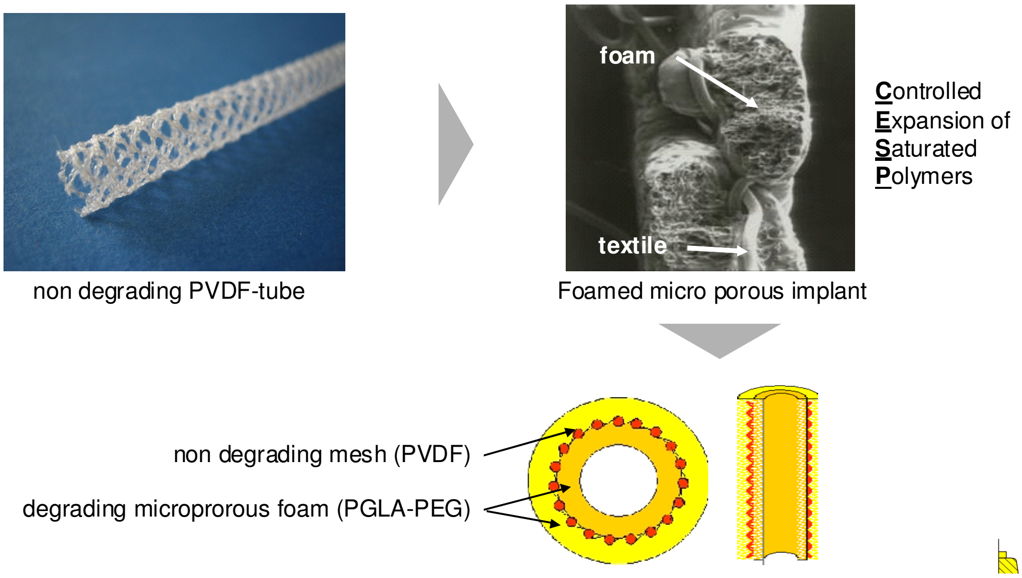

Figure 2. Concept of textile-foam-composite for small intestine replacement.

Furthermore there are no existing approaches for an artificial replacement of the small intestine due to the high complexity of such an implant.

The use of textile materials as base for an artificial small intestine replacement could be a promising approach. Textiles for soft tissue replacement are becoming more important nowadays. Examples for established textile implants for soft tissue replacement or soft tissue assistance are synthetic vascular grafts, hernia meshes or synthetic ligaments as well as resorbable or non resorbable suture material.

Concept

An artificial small intestine replacement needs to fulfill several demands. One main requirement to the implant is the ability to colonize biofunctional small intestine specific mucosa cells in order to preserve the physiological resorption function. Therefore microporosity of the implant which allows ingrowth of mucosa cells is essential. Furthermore the implant needs to be fatigue endurable against peristaltic movement, and initial impermeable in order to avoid leakage of intestine substance into the surrounding tissue.

In order to fulfil these requirements the Institut für Textiltechnik, RWTH Aachen University, is developing in close collaboration with the Institute of Plastics Processing and the University Hospital Aachen a partly resorbable textile-foam-composite for small intestine replacement.

The novel implant consists of a non resorbable textile PVDF (Polyvinylidenfluoride) mesh which is foamed with a micro porous, resorbable, and drug loaded polymer as illustrated in Fig. 2. The resorbable polymer serves on the one hand as initial sealing, so no intestine substance and bacteria can leak out into surrounding tissue, on the other hand it is micro porous in order to ensure cell ingrowth. The macro porous textile mesh remains inside the body as a long term implant. On the one hand mechanical parameters such as Young Modulus and elasticity of the textile mesh need to be adapted to the target tissue, furthermore the textile mesh needs to resist the mechanical forces caused by the peristaltic movement of the small intestine enduringly. As well it is known that inflammatory and fibrotic intensity of a foreign body reaction largely depends on the porosity of the implanted material. The size of the pores and its geometry define the capability to allow tissue ingrowth. Based on experiences in textile structures for hernia repair and investigations on formation of scar tissue around synthetic fibres it is known that formation of a scar plate, takes place for textile constructions with a pore diameter below 1 mm [7]. Hence morphological mesh parameters such as porosity and pore structure of the textile mesh need to be adapted to the application of small intestine replacement as well.

Textile Materials and Methods

Medical Grade Polyvinylidenfluoride (PVDF Solef 1008, Solvay Solexis S.A.) was used for fibre production. PVDF is frequently used in textile implants such as hernia meshes and suture materials. PVDF is a non resorbable very bioinert material with a high amount of fluorine. The polymer was melt spun into multi filament fibres with 10 filaments and a fibre titre of 180 dtex.

In order to produce a highly porous textile structure a custom-designed double raschel warp knitting machine, DR 16 EEC/EAC, Karl Mayer Textilmaschinenfabrik GmbH, Germany was used (Fig. 3). This production machine has 16 guide bars and enables the production of textiles with different yarn materials and counts. Two-dimensional textiles as well as three-dimensional textile structures, such as spacer-fabrics, tubes, and dendritic tubular structures can be produced. The machine is equipped with two different gauges, E18 and E30. Due to the modular machine design parameters such as size, shape, Young Modulus, and porosity of the textile structure can be adjusted. For fabrication of a macroprorous structure with adequate mechanical properties a warp knitted tulle-filet structure was chosen. Fabrics with different loop densities were produced and compared regarding their biomechanical compatibility to native small intestine of a pig. The manufacturing settings of the macroporous PVDF mesh are listed below:

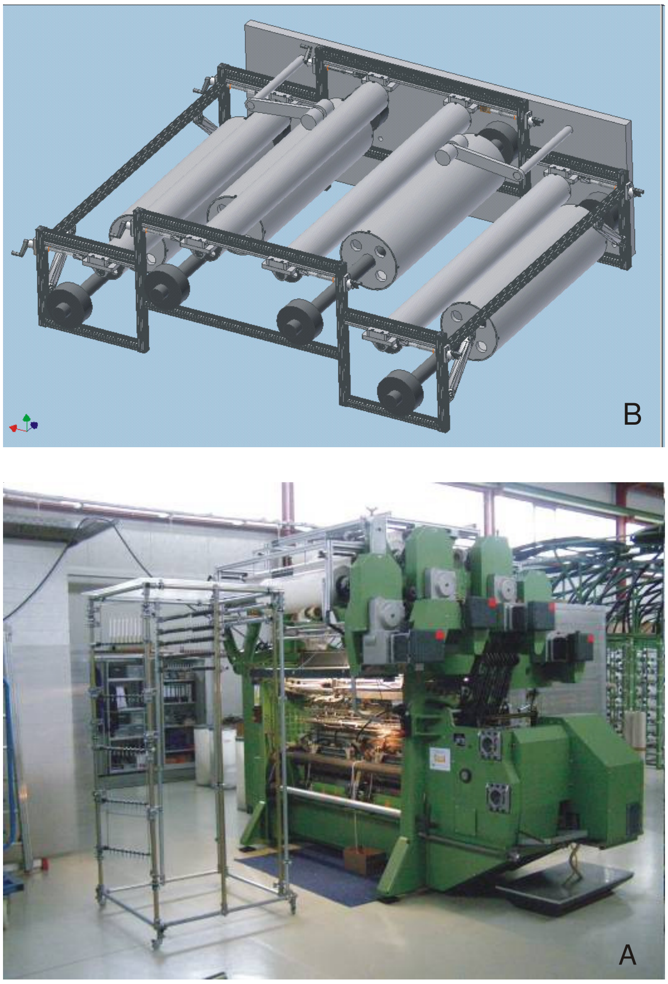

Figure 3. Double-needlebar raschel machine (A); developed yarn supplying system (B).

- Pattern: tulle filet,
- Design: tube, o 25 mm,
- Needle gauge: E18,
- Loop density: 8 loops/cm, 12 loops/cm, 16 loops/cm.

Evaluation of the morphological characteristics of the processed structures was accomplished by two dimensional projection of the textiles by optical microscopy. Subsequently the images were analysed by digital image processing using the software Image Pro Plus, Company MediaCybernetics Inc., USA. In a pore size histogram 2D porosity as well as pore size was illustrated In order to evaluate the mechanical properties of the different warp knitted PVDF meshes and compare them to the mechanical characteristics of small intestine tissue, tensile tests were conducted in radial and axial direction. Results of tensile tests on structures with three different loop densities of 8, 12, and 16 loops per cm were compared to tensile tests on native small intestine tissue probes.

Results and Discussion

Subsequent morphological analysis by digital image processing showed two peaks in pore diameter as can be seen in Figure 5.
One peak could be detected at an averaged pore size of 0,45 mm and a second peak at an averaged pore size of 2,9 mm. The 2D porosity resulted in 66 %. Out of these results it can be assumed that formation of a scar plate is unlikely due to the big pore sizes.

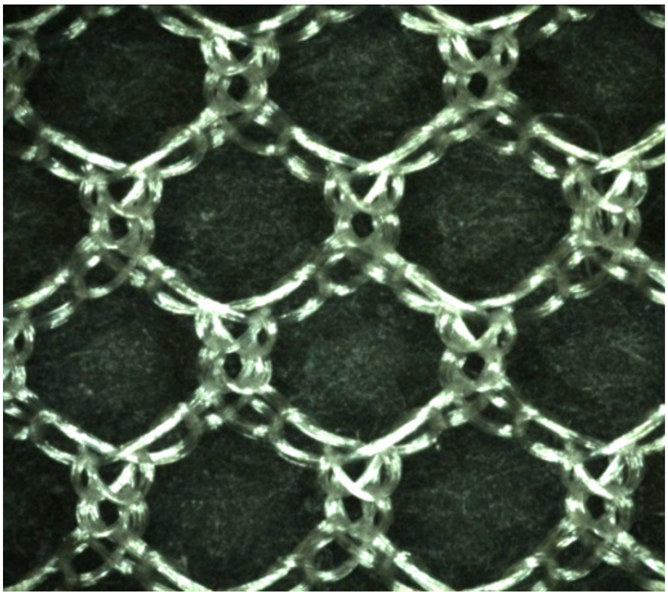

Figure 4. Microscopic picture.

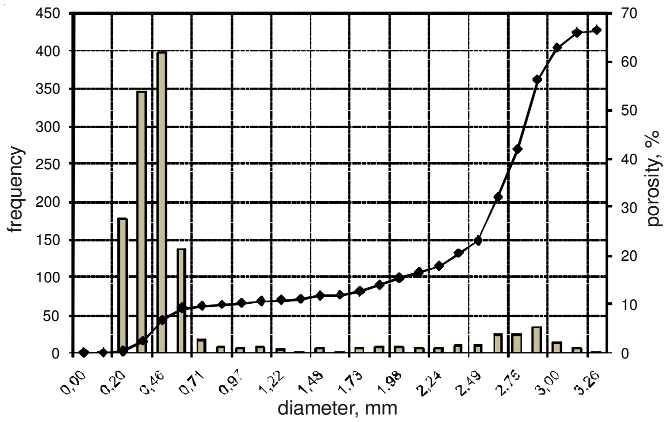

Figure 5. Pore size histogram.

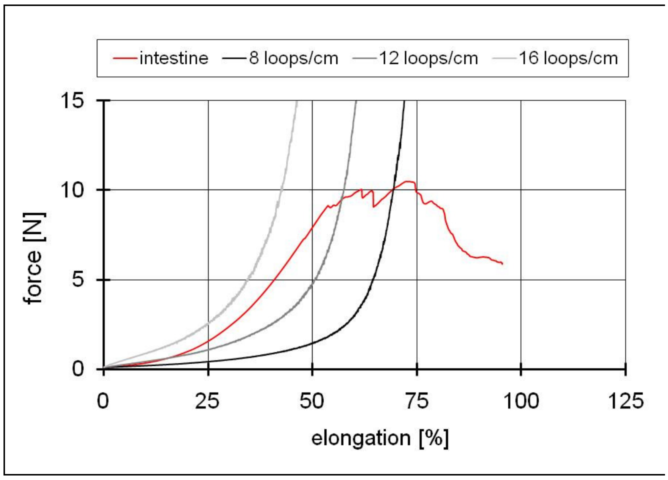

Figure 6. Stress-strain curves of small intestine and textiles in radial direction.

Stress strain measurements of native small intestine and warp knitted structures were conducted in axial and radial direction. As illustrated in Figure 6 the tensile strength of the textile meshes in radial direction is 13 to 26 times higher than the small intestine. Therfore a rupture of the textile structure in vivo can be excluded. Furthermore the recorded stress strain curves of native small intestine and warp knitted structure showed similar characteristics, with an initial small Young Modulus in the beginning structure elastic part of the textiles and a second increased Young Modulus in the material elastic part of the textiles. The two characteristic Young Modules as well as the curve progression of the warp knitted structure with 12 loops per cm showed the best biomechanical accordance to the values of the small intestine. Thus this machine setup was used for production of 3D tubular structures with diameters of 2.5 cm.

Summary

Warp knitted tubular PVDF meshes show promising characteristics for the use as long term implant for small intestine replacement. The mechanical properties as well as morphological properties can be adjusted according to the demands of a small intestine replacement. Ongoing studies evaluate the foaming behaviour of the processed textiles into micro porous foams. Furthermore in vitro and in vivo tests are planned to demonstrate the feasibility of the textile-foam-composite for small intestine replacement.

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Acknowledgements

We gratefully acknowledge the “Arbeitsgemeinschaft Industrieller Forschungsvereinigungen Otto von Guericke e.V.” for the financial support of the research project “Development of a partly resorbable drug loaded textile-foam composite structure for small intestine replacement”.

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