White Paper

New creative textile construction using innovative braiding technology and materials

DSM and Meister Provide Foundation for Medical Device Design

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Summary

Meister & Cie AG, a trusted manufacturing partner of DSM Biomedical, was seeking an automated continuous process to produce loop-like braided structures using DSM's medical-grade UHMWPE fibers, known as Dyneema Purity® fibers. Pairing a new braiding technology with the unique material properties of Dyneema Purity® fiber led to novel concepts and the international publication of the patent entitled "IMPLANTABLE HOLDING DEVICE" (WO2017/0167). This platform technology creates opportunity in medical device design applications in minimal invasive surgery (MIS) and sports medicine. Several production methods were evaluated and a family of new maypole braiders (with dynamic switches and coupled gears) proved to be the most viable for the automated manufacturing of branched structures in a single-step performing process.

We believe that Dyneema Purity® fibers with their unique material properties, in combination with new automated continuous production methods and Meister's processing expertise, will further expand the presence of textile loops as a key design feature for the next generation of textile implants in many different clinical fields.

Introduction

Currently, minimal invasive surgery is common practice in operating rooms all over the world. MIS approaches are present in a variety of therapeutic areas, from spine surgery and laparoscopic surgery to arthroscopic interventions in sports medicine. One thing that all the different disciplines have in common is the significant improvement of the overall outcomes with less reported post-surgical pain, followed by a faster recovery time and, therefore, an earlier return to normal life. The MIS technique requires not only small instruments, but wherever possible small, flexible and/or foldable - expandable implants. To fulfill all these requirements while providing enough mechanical strength, braided textiles made using DSM's medical-grade UHMWPE Dyneema Purity® fibers are an excellent choice.

There is a general trend towards implants to be made partly or completely of textiles. During the design and development phase of such new implants, it is essential to address the future need of interfacing textile with either hard and soft tissue or an additional metal device component. Today, knotting, splicing or sewing are options often seen as the solution for this interface. However, all three solutions can be manufactured only through manual or semi-manual processes.

Meister & Cie AG, a processor of the medical-grade Dyneema Purity® fibers, was scouting for an automated continuous process to replace the manual process. An automated process has not only the advantage to reduce the production time, but offers higher repeatability and potentially less loss of initial strength, which could be experienced with the current interfacing solutions. The ability to produce with

consistent product quality can most likely lead to better patient outcome and satisfaction. This new braiding technology, for loop-like structures, offers a high potential for the automated manufacturing of a branched structure in a single-step performing process. This branched-like structure resembles an eyelet and is the defining element of this new interface (Figure 1). Pairing the unique material properties of Dyneema Purity® fibers - the market's first medical-grade ultra-high molecular weight polyethylene fiber - with this new braiding technology, led to a series of novel interface devices demonstrating promising mechanical results, even using a Dyneema Purity® fiber as small as 55 dtex.

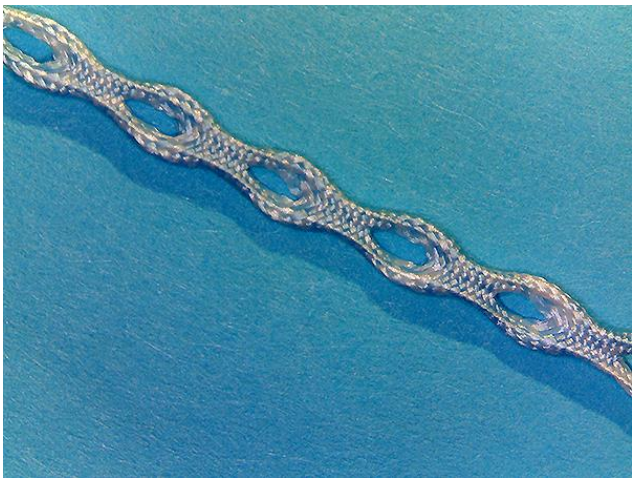

Figure 1: Example of branched textile structure

This work resulted into a platform interface technology called "IMPLANTABLE HOLDING DEVICE", which in combination with DSM's Dyneema Purity® fibers, provides a strong basis to generate innovative products with the aim to solve clinical needs.

Loops as key design feature for the next generation of textile implants

Loops are playing an important role in the world of textile implants today. Fixed or variable loop button devices made from a textile fabric in combination with a titanium button, are a well-known example. They create a sort of suspensory femoral fixation for a torn anterior cruciate ligament (ACL) that is repaired by an auto graft. This category of implants has gained popularity in recent years. The family of Dyneema Purity® fibers with a broad range of grades and colors are ideal to create textiles with the necessary mechanical strength and visualization options needed for applications, like ACL-loops.

Furthermore, it is also anticipated that this new design feature could offer several options for the connections of small instruments with remote guidable tips. For example, two continuous braided loops in the form of sutures, at both ends of tensile load transmitting elements, can be a cost effective and simple solution to manipulate an instrument over a long narrow tube without using complex joints.

Platform Technology Features

This new braiding technology can be distinguished from others as it allows each bobbin carrier to be guided through individual paths, making it possible to achieve a branched like structure resembling an eyelet. Each branch structure itself represents a tubular braid (Figure 1). A controller offers not only control of the individual path, but it allows individual control of the pic counts of the different braided sections.

These features open many new design options for Meister as a medical textile designer and manufacturer. First, we explored this new technology with the intention to learn more about the range of fiber grades that can be used with such equipment for medical applications. Then, we examined the smallest achievable and reliable structural changes that still could be measured. Different fibers of the Dyneema Purity® fiber family (*i.e.* Dyneema Purity® SGX 55, 110 and 440 dtex fiber as well as the VG 110 dtex fiber) were successfully processed with an excellent outcome. There was no tearing of the yarn during the actual braiding process and the manipulation of the switches to guide the bobbin carriers to their programmed positions executed flawlessly. For the unbranched portions of the structure, as well as for the two legs after the first branch, we obtained highly reproducible textile constructions with a resolution of 0.5 mm, for both the Dyneema Purity® SGX 55 dtex fiber and the SGX 110 dtex fiber. For example, an eyelet could have a length of 2.5 mm, 5 times that of 0.5 mm, and the unbranched structure in between could measure 4 mm, 8 times that of 0.5 mm.

These very positive results, using the braided loop as the key design feature for a new interface led to a new platform named the “IMPLANTABLE HOLDING DEVICE”.

Applications

This new Implantable Holding Device platform technology is intended to be particularly useful in the fixation of an auto- or allograft material used to reconstruct a torn ligament or tendon. In a representative example, the braided textile structure, comprises a flexible loop member braided to form bifurcating and converging portions, which define the eyelets used to adjust the loop size. The loop ends connect through attachment elements to a support member configured to lie against a bone (Figure 2). The structure, positioned using sutures, functions as support to keep, for example, a graft substitute for a torn ACL in place.

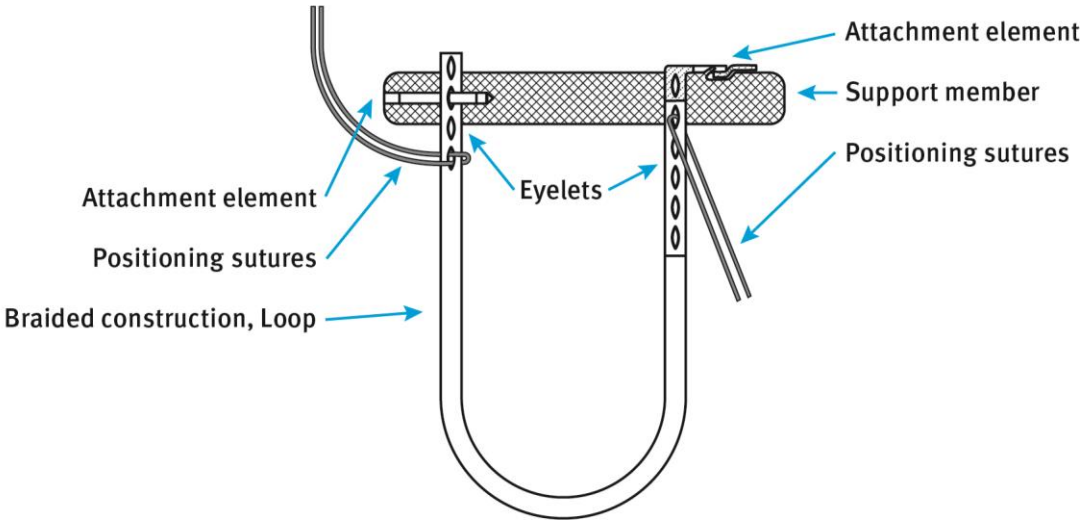

Figure 2: Example of the fixation concept applied to ligament reconstruction

This new platform technology offers many opportunities due to the similarities of placement, not only for ACL reconstructions that are not part of the bone tendon bone (BTB) technique, but also for Syndesmosis or Acromioclavicular joint injuries. The interface of soft tissue to hard tissue is one type of injury that is addressed with this Implantable Holding Device platform technology. The use for pure bone to bone fixation is another promising area where this platform technology could be helpful to solve clinical needs. Additional uses such as sternal closure and cerclage-like applications, where metal cables are often used, unwanted presence of metal debris is still an unsolved clinical need when cutting is required. A textile based solution, which can be made using this new technology, eliminates the issues associated with metal.

"DSM is extremely pleased to be partnered with Meister on this new technology development. This technology enables an improved generation of surgical products for the most intricate medical procedures to truly help patients." said Carola Hansen, Director of Product Management, Polyethylenes, DSM Biomedical.

"After an intensive period of development, Meister is pleased to introduce this new platform technology that will help medical device companies to develop novel devices and surgical procedures. Meister sees the potential of the innovation in sports medicine, orthopaedic and spinal application and is looking for partnership with medical device companies to explore new applications." said Marcel Meister, CEO, Meister & Cie AG.

Quality is a key value at DSM
Quality is critical in our business and we're committed to providing products that comply with all applicable regulatory requirements. In 2017, we received the Medical Device Single Auditing Program (MDSAP) Certificate. Years of experience and a high level of expertise have given DSM a comprehensive understanding of how the body reacts to foreign materials placed inside it. This enables us to design materials that are compatible with the body's physiology. For DSM, the definition of quality includes a thorough understanding of the rigorous requirements for medical devices and the assurance that our materials will help manufacturers develop devices that sustain, restore or repair. Our commitment is demonstrated through our high-quality materials and their ongoing use in products that benefit millions of people worldwide. We comply with all applicable regulatory requirements, like the ISO 13485:2003 quality standards. Material Master Files for many of our products have been submitted to the FDA and appropriate agencies in Europe.

R&D and Quality Management of Meister & Cie AG
Meister & Cie AG is a 148-year-old Switzerland-based textile processor which has a quality management system certified to ISO 9001 and ISO 13485 standards. Based on the Medical Device Directive (Medizinprodukterichtlinie 93/42/EWG), Meister & Cie AG employs a complete product development process, ranging from the proof of concept via different stages (including design transfer) to an initial product batch, which provides a strong basis for MDC customers to get their CE marking and FDA approval. The risk management process of Meister & Cie AG is a constant part of the product development process and the following serial production. It is compliant with EN ISO 14971:2012 (Anwendung des Risikomanagements auf Medizinprodukte). Its long history in the production of braided textiles and a profound understanding and ability of modifying machines to customer needs are two main pillars of Meister's success in the product development process, from a proof of concept to a serial production.