VARIATION BRAIDING TECHNOLOGY BY THE EXAMPLE OF NOVEL STENT STRUCTURES

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Abstract: *Coronary stents are commercially available in many different types and are already successfully used. In case of a stenosis in a bifurcated coronary region, the otherwise usually uncomplicated and safe treatment still causes some problems [1]. In the introduced research project different tubular and bifurcated stent structures have been implemented, using a variation braiding machine, which enables the fully automatic production of complex, if required bifurcated braided structures. Additionally an implanting concept for bifurcated areas has been devised to enable a safe and quick interventional therapy.*

Keywords: *Braiding, stents, bifurcations, complex tubular structures, shape memory.*

1 INTRODUCTION

Technical textiles become more and more important in a wide range of medical applications. From well known simple bandaging, and surgical sewing materials to complex high technical textile structures, which are neccessary to construct functional artifical ligaments, tendons and cartilages [2, 3].

A material construction based on textile technique is especially suitable for products that require a high flexibility and at the same time a suitable amount of stability, such as needed for medical stents [4].

To re-open a morbid narrowed vessel, for a sufficient blood circulation, an interventional treatment is possible. In this case the vessel gets expanded and is additionally supported by an endoluminal vascular implant, a stent [5]. Coronary stents are commercially available in many different types and are already successfully used, but in case of a stenosis in a bifurcated coronary region, the otherwise usually uncomplicated and safe treatment still causes some problems [1].To enable tailor-made solutions, the novel variation braiding technolog has been used to develop new, innovative structures and bifurcations, which have the potential to improve the interventional results.

2 EXPERIMENTAL

2.1 Materials

Stents, especially for the coronary usage require a strong, but at the same time flexible and compressible material [6]. Nowadays there is a big variety of materials in use, from metal-alloys to bioresorbable polymers that dissolves after a certain time. In the here presented research project metal-alloys have been in the focus [7]. Platinum/chromium alloy is a quite new, but already very important material for coronary stents. Caused by its high amount of platinum it is very tough and enables a delicate, but still stable stent construction, which reduces the occurrence frequency of restenosis, but at the same time requires high pressure while implanting the material into the vessel [6].

To increase the material flexibility the super elastic nickel/titanium alloy, so called Nitinol, has been selected for the here introduced research project. Nitinol is a popular material for a big number of different stent systems from several manufacturers, especially because of its shape memorizing effect and its super-elastic properties, combined with a good biocompatibility [8, 9]. While most metallic alloys show a plastic deformation when compressed, Nitinol has the temperature-dependent ability to deform elastic and get back to its original shape, even after a significant deformation. This effect can be explained by different crystal structures in different temperature fields [9].

2.2 Methods

2.2.1 The variation braider

For the research activities a novel variation braiding machine has been used to develop various complex tubular structures. The braiding machine is constructed with 4x4 horn gears arranged in a square and a maximum of 32 carriers. To enable a high structural braiding flexibility the machine is equipped with 24 selectable pneumatic cross sections, 9 core yarn feeders and 16 filler yarn feeders. With this technical features a fully automated pattern change and even the production of a bifurcation is possible without an interruption of the braiding process.

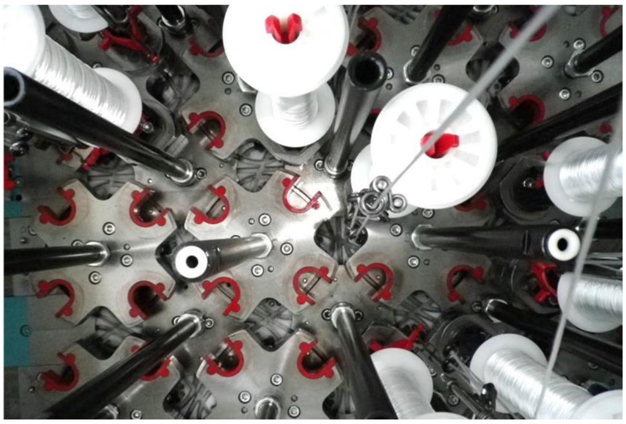

Figure 1 Variation braiding machine with selectable cross sections

2.2.2 *Braiding of technical materials*

The braiding of technical materials like metal or brittle fibers requires a couple of adjustments during the braiding process. The yarn feeding for example has to be as linear as possible to avoid material kinks and the carriers have to be overturned to eliminate material twists and so enable a uniform, intact braid.

By using metallic wires in the production, increased abrasion of the corresponding machine parts might accrue. To reduce this effect, all yarn feeding elements have to be sufficiently adapted.

Figure 2 Multi-branched braids

2.2.3 *Pattern variations*

The used braiding machine has diverse possibilities to create custom structures, which can vary in their pattern, density and overall structure. The technical possibilities enable the production of tubular-square- or flat braids, spiral braids, core/shell braids and combinations of all types. For stent structures different types of tubular braids and interlocking structures can be suitable.

By changing the design of the pattern cycle, carrier movement and the speed of the takedown-wheel, different material densities with varying supporting effects can be achieved. To make the technique even more multifarious, it is possible to bifurcate all types of braids and herby be able to create stent solutions for complex human vessel architectures.

3 RESULTS AND DISCUSSION

Based on the research of human anatomic tube structures and in collaboration with different surgeons, several concepts for customized self-expanding stents have been developed.

In a first step a number of braided tubular net structures have been designed. Caused by the different structures and densities, varying strong supportive effects have been achieved, which made it possible to reinforce different sectors in a disparate degree.

Enhancing these results, bifurcated structures as seen in Figure 3 have been realized to produce a pattern, which might be suitable for bifurcated vessels. A simple bifurcated braided tube usually shows a varying density and even holes in the transition area. These unwanted effects reduce the supportive force in the affected area and might increase the risk of a re-stenosis. To avoid this problem an adjusted pattern has been developed, which creates a homogeneous structure, even in the transition area.

Beside the customized construction of a bifurcated braid, the possible difficulties during the implantation of such a complex stent system have been investigated. The longer the intervention takes to re-open a stenosed vessel, the higher the risk for the patient gets. This made it necessary to think about a suitable and fast implantation technique.

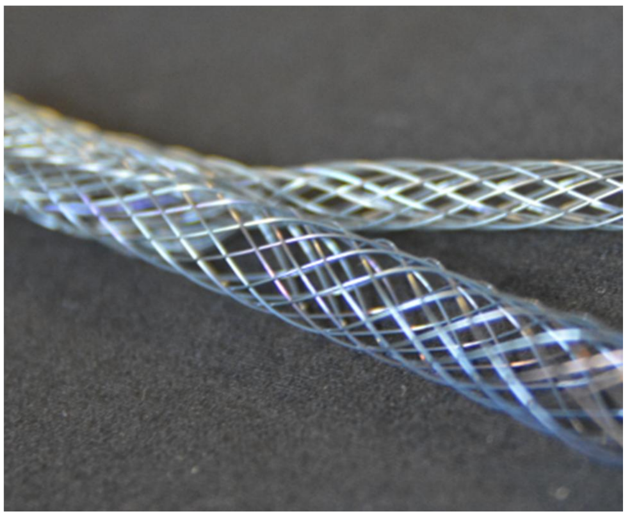

Figure 3 Example for a bifurcated braid

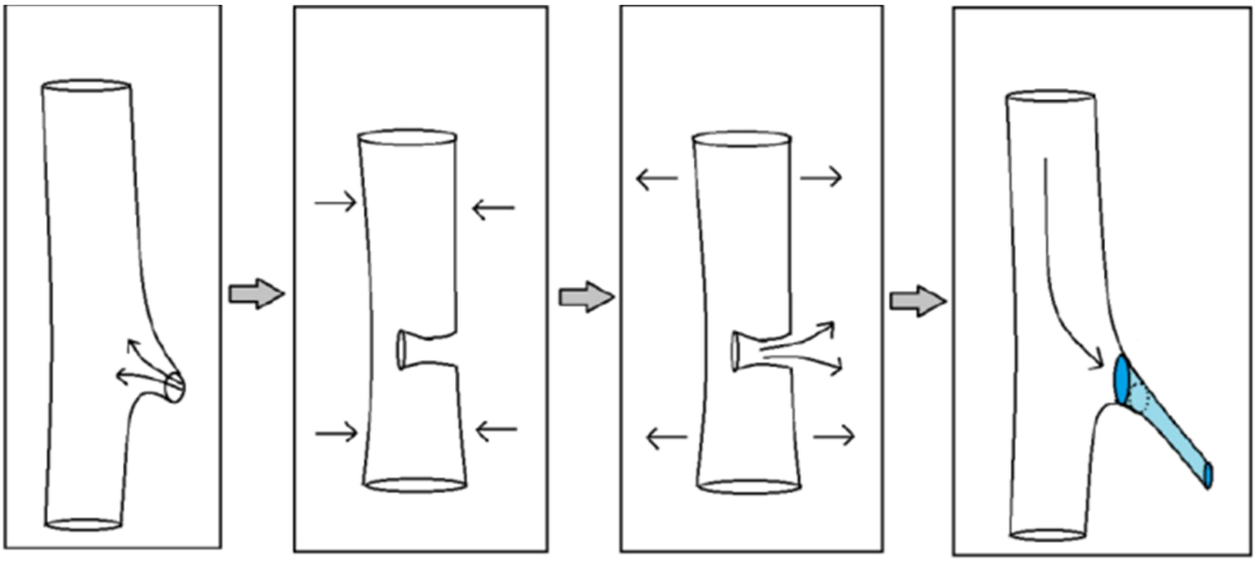

Figure 4 Concept for implantable bifurcated stent

Following these requirement a Y-shaped bifurcated stent structure with one long main stent and a short side stent has been constructed.

Before implanting the stent, the manufactured short side arm can be pulled into the main arm, similar to a bud. Following, the stent gets compressed and implanted into the stenosed area in the vessel. There the stent expands and re-opens the main vessel. Finally the pulled-in side arm gets inflated, to open and support the crossover to the side vessel. To support the side vessel a second simple tube stent gets implanted through the already opened transition area (see Figure 4). This technique might be an applicable solution for complex stenosis, but has still to be tested conscientiously.

4 CONCLUSIONS

Variation braiding technology is highly innovative when it comes to flexible tubular structures. It offers the technical possibilities to create various different bifurcated forms and is so suitable for the development of complex stent structures. In combination with the use of the super elastic nickel/titanium alloy Nitinol, customizable stent solutions have the potential to generate new features for complex anatomical circumstances and should be followed up in future development projects.

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