

Projekttitle: AnaMag - Development of an automatically produced, degradable anastomosis stent for visceral surgery

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Mission Statement

The creation of a suture connection (anastomosis) serves to restore the continuity of tubular structures, for example in the gastrointestinal tract. A leakage of these connections (anastomosis insufficiency) is considered one of the most serious clinical complications. In the area of the oesophagus, for example, up to 35% of patients develop insufficiencies within the first 10 days after surgery. This leads to an increase in mortality by a factor of 3 and a 2-4 times longer hospital stay. In addition to various surgical, interventional and drug measures, endoscopic stent implantation for sealing the suture in case of an insufficiency offers a minimally invasive treatment approach with good success rates, especially with regard to sepsis control. In the management of complications of insufficient suture connections, coated, non-resorbable stents are used, which must be changed and explanted at regular intervals until complete healing. In addition to the additional patient load, explantation can lead to a renewed rupture of the anastomosis. The treatment of an insufficient suture is complex, cost-intensive and risky, and there are currently hardly any suitable preventive measures available. The aim of this project is the development and validation of an atraumatic, coated and resorbable anastomosis stent for primary prophylactic use. The oesophagus and the bile duct are chosen as an example of application due to the complexity of the suture connections with complication or insufficiency rates of 20-30%. The selection of the application sites also reflects the different geometric requirements for stents in the human body. The diameter of a stent for the esophagus is 2-3 cm, whereas the diameter of a biliary duct stent is 5-6 mm. This allows the transferability of the development results from large-lumen to small-lumen applications to be investigated directly. Advantages of the anastomosis stent to be developed are the reduction of the occurring insufficiencies by prophylactic use, a broad applicability for all patients and the exclusion of a long-term or recurring burden of the patient by the degradability. In the medium term, the novel anastomosis stent will lead to a reduction of insufficiencies and the associated consequences for patients and the health care system. To achieve this goal, a wire-based, atraumatic, coated stent made of resorbable magnesium (Mg) wire and the necessary automated manufacturing process will be developed in this project. The braided structure supports the interface under mechanical stress. The stent structure is coated on both sides with an electrospun silk fibroin membrane to ensure a seal at the interface. Silk fibroin is characterized by high mechanical strength and compatibility with the human body. The complete system of stent and coating must be completely resorbed within 6-8 weeks to prevent migration

of the stent or stenosis, perforation or inflammation of the suture. Automating the stent fabrication process has the advantage that production costs can be reduced and the reproducibility of the fabrication process can be significantly increased compared to manual fabrication.

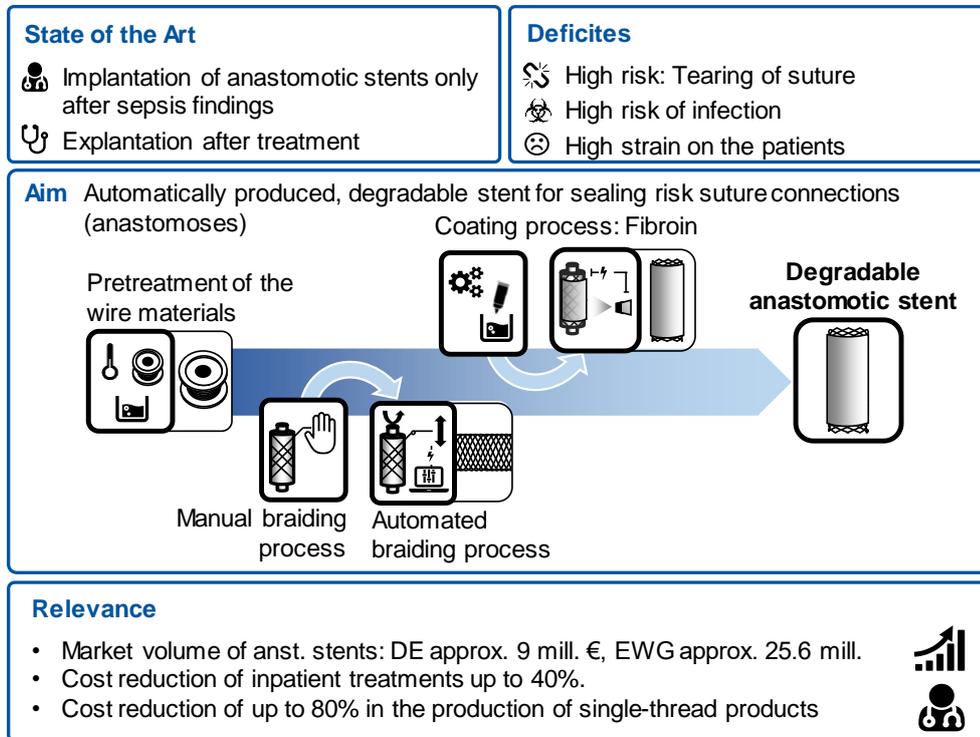


Figure 1: Mission Bild Project AnaMag

In this project, the degradation rate of the magnesium alloy will be adjusted to the above-mentioned time period by a special ceramization process (Meotec). The atraumatic stent structure will be produced manually in the first step by means of single thread braiding (gold standard) (ITA). The single thread stent (EFS) offers the advantage of high radial load capacity with low wall thickness, good dynamic behaviour and individual adjustability of the implants in a flexible manufacturing process. The main disadvantage of the procedure is the high proportion of labour costs in the finished product, as the manufacturing process is currently completely manual. In order to reduce the share of labor costs and thus the manufacturing costs of anastomotic stents by up to 90 % and to enable a competitive production in Germany, the automation of the single thread braiding process of Mg wires is investigated in this project in parallel to the stent and a corresponding system technology is implemented (ITA, Steeger, Feinmechanik Mehr). The prototype of a degradable anastomosis stent developed in this project will be validated with respect to the planned functions (degradation, sealing, heating) (UKA).

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