AnastomoSEAL – Biopolymeric patches for the treatment of colorectal anastomosis

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Introduction: AnastomoSEAL is a collaborative project co-funded by the European Commission under the 7th Framework Program. AnastomoSEAL, whose extended title is "Development of a resorbable sealing patch for the prevention of anastomotic leakage after colorectal cancer surgical treatment", is a three-year project under the theme "Biomaterials for tissue engineering for age-related cancer and sensory organ diseases". The most frequent post-operative complication of any bowel resection is "Anastomotic Leakage" (AL) which occurs when proper and rapid regeneration of the intestinal tissue does not takes place. The incidence of AL depends on the segment of colon involved and on the kind of operation performed. The rate of AL after rectal surgery varies according to different countries affecting up to 21% of patients and leading to mortality up to 39% of cases. At present, efficient treatments or drugs to prevent the onset of AL are still not available. AnastomoSEAL is focused on responding to the widespread clinical need of preventing AL after colorectal cancer resection. The objective of this project is the development of a bioresorbable biomaterial capable of promoting a safe sealing during the critical period of tissue healing without causing adverse reactions.

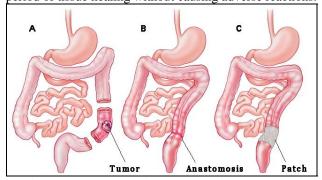


Figure 1. A) Colorectal cancer resection; B) Sutured bowel (anastomosis); C) Sealing of the anastomosis with a biomaterial patch.

The new and innovative product prototypes produced by AnastomoSEAL will fill the unmet need in rapid colorectal anastomosis regeneration and prevention of leakage. The AnastomoSEAL Consortium is composed of 6 partners: 2 Universities (University of Trieste - Italy, University of Maastricht – The Netherlands); 3 SME's (RESCOLL – France, SIGEA – Italy, IMPULS – Poland); and 1 industrial partner (FMC BioPolymer – Norway). The University of Trieste is the project coordinator.



Methods: We aim to design a patch from natural-derived bioresorbable polysaccharides to be inserted by the surgeon after the anastomotic procedure. The patch will be wrapped around the sutured tissue to promote tissue regeneration, to seal the external part of the intestine, and increase early structural integrity thus preventing anastomotic leakage.

Results: Prototypes of the biopolymeric patch (figure 2) have successfully been prepared in a size suitable to be wrapped around the anastomosis site and the formulations for the patches are being continuously improved and optimized. *In vitro*, *ex vivo* and *in vivo* test methods for characterization of the physical and biological properties of the patch are currently being developed. These methods include bioadhesion, mechanical properties, biodegradability/resorbability and biocompatibility.



Figure 2: A prototype of the patch to be wrapped around the anastomosis site.

Conclusions: A biopolymeric patch can be formulated having strength, but also flexibility, adhesion, and bioresorption for application to the colon.

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