In situ Deposition of Polymer Sealants via Solution Blow Spinning

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Statement of Purpose: Topical and internal tissue closure is a pervasive challenge in a majority of surgeries and injuries. While conventional suturing is still ubiquitous, clinicians have begun moving towards using tissue sealants to reduce tissue inflammation and scarring, and to improve usability and patient comfort. These desired attributes have led to our investigation into using solution blow spinning for the direct deposition of polymer fiber mats as surgical sealants. Solution blow spinning is a polymer fiber mat fabrication technique that requires only a simple apparatus, a concentrated polymer solution in a volatile solvent, and a high-pressure gas source.[1-3] More importantly, this technique does not have the high voltage and conductivity requirements of electrospinning and does not suffer from a slow deposition rate. These advantages allow for direct deposition on any substrate including use during surgery.

Methods: A commercially available airbrush (Master Airbrush, G222-SET gravitational feed) was used in all studies. Gas flow rate was varied using compressed carbon dioxide. SEM and optical microscopy were used to characterize morphology. Thermal transitions were characterized by DSC. Adhesive testing utilized an Instron mechanical tester with temperature control. Degradation was investigated by molecular weight change (GPC). *In vitro* biocompatibility was investigated with MTS assays. Pilot animal studies were then used to illustrate potential applications.

Results: Through the use of biodegradable polymer blends and solution blow spinning, a method to conformally apply a surgical sealant was developed. Directly deposited fibers of certain polymer blends exhibit thermal responsive behavior at both topical (32°C) and internal (37°C) body temperature. Upon reaching the phase transition, polymer fibers weld together and the majority component becomes plasticized (Figure 1).

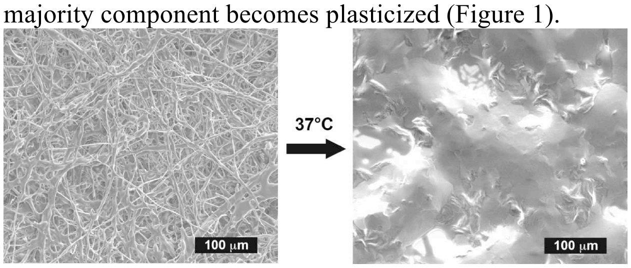

Figure 1. SEM of Polymer blend fiber mat fiber to film transition at 37°C.

In vitro cell viability showed no decrease of the direct deposition of fibers relative to the live control. A pilot animal study illustrated the utility of this technique, generating conformal sealants for liver resection and femoral artery injury. Additionally, when used for an intestinal anastomosis procedure, burst pressure was measured in isolated small bowel segments (Figure 2). An un-protected six suture anastomosis leaked at an average pressure of 2.5 mmHg, while the same anastomosis sealed with blow spun polymer leaked at an average pressure of 23 mmHg. During this procedure, this technique also showed ability to bridge mesenteric defects created during an anastomosis procedure (black arrow Figure 2 (A) and (C)). This is an important feature of this technique because defects are typically closed with sutures that can impair blood supply to the anastomosis, resulting in anastomotic breakdown.

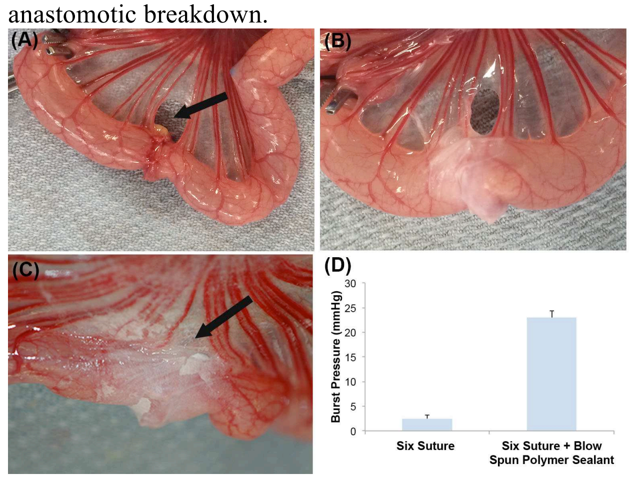

Figure 2. Intestinal anastomosis in pilot non-survival piglet studies. (A) An un-protected six suture anastomosis leaked. (B) Blow spun polymer reinforced anastomosis. (C) Ability to bridge mesenteric defects created during an anastomosis procedure (black arrow (A) and (C)). (D) Differences in burst pressure.

Conclusions: Solution blow spinning offers the ability to generate on-demand conformal polymer mats directly on a wide range of targets, including use during surgery. Using polymers with different mechanical and chemical properties allow for a variety of applications to be investigated. *In vitro* biocompatibility and pilot animal studies demonstrate the potential of this technique. Future studies will focus on operation and recovery outcomes.

References:

(1) Behrens AM, ACS Macro Lett. 2014; 3:249-254.
(2) Tutak W, Biomaterials. 2013; 34(10):2389-2398.
(3) Medeiros E, J. Appl. Polym. Sci. 2009; 113(4):2322−2330.

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