Potential of Biological Material Translocation with Medical Devices

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Statement of Purpose: Single use medical devices are designed to minimize contamination between patients vs. traditional multi-use devices. However, autologous contamination is possible during a surgical procedure since many devices interact with tissue to manipulate, transect, or mobilize an area[1]. Consequently, if the device is further used in other areas of the primary or adjunct surgical site, there exists potential to deposit biological material in new tissue sites. This may include cells (microbial, tumor, etc.), tissue fragments, or other pathogens. Considering gastrointestinal surgery, where small or large intestine may be transected with a surgical stapler that employs a reusable knife, there may be a risk of transferring non-native biological material from the primary anastomotic site to a different tissue location. This may thereby increase the potential to initiate local infection, tumor cell transfer, or immunogenic response. The goal of this study was to demonstrate the feasibility of transferring mammalian and microbial cells from one tissue site to another via a surgical stapler with a reusable knife.

Methods: The transfer of endogenous biological material via surgical stapling was evaluated *in vitro* and *ex vivo* under simulated clinical use conditions. Staplers were configured to be multi-fire, comprised a reusable knife blade and a single use disposable staple cartridge (3.5mm titanium staples). Functional canine small bowel was transected using a prototypical linear surgical stapler (45mm laparoscopic type). Following *in vivo* surgical use, staplers and respective components were evaluated for tissue/cell remnants using scanning electron and fluorescence microscopy, tissue debridement, and further serial stapler firings into sterile gelatin hydrogel disks.

The stapler cartridge, knife, and cutting mechanism were aseptically removed following *in vivo* use, critical-point dried, sputter coated, and evaluated using SEM for tissue and cell fragments. In parallel experiments, stapler components (cartridge, etc.) and gelatin hydrogel disks were labeled post-surgical use with nuclear stains (DAPI/Sytox Green) and imaged under fluorescence.

Microbial evaluations consisted of contaminating the stapler jaws (including knife blade) during stapler firing in a high density *Escherichia coli* or *Staphylococcus aureus* tryptic soy broth of approximately 10^8 colony forming units (CFUs/ml). Following initial contamination, the stapler was transferred and fired in sterile growth medium. Following each firing, the stapler was placed through a brief mechanical (vortex) and energetic (sonication) debridement process to recover and enumerate stapler associated micro-organisms. Five serial firing/debridement steps were conducted.

Results/Discussion: Significant amounts of tissue and cell transfer were observed following transection of canine small bowel. Large tissue fragments were found to adhere to the stapler knife and various components of the cutting mechanism. Further firing of the stapler in sterile medium or serial debridement of the stapler jaws and cutting mechanism, resulted in significant transfer of tissue and cells. Many of the larger tissue fragments exhibited the prototypical multilayer morphology of the small bowel. The tissue architecture, including the villi of mucosa, was evident by fluorescence microscopy. Similar results were obtained following serial firing of the stapler after initial surgical use. Significant microbial transfer was observed through all serial firings (five) and debridement. Following five firing/debridement steps, the stapler knife blade, and cutting mechanisms were found to transfer 10^4 CFUs/ml.

Conclusions: This study focused on feasibility of cell transfer *ex vivo* using surgical staplers. Staplers clamp, join, and ligate tissue. Each of these actions may collect intact tissue or debris. Results suggest that a significant amount of debris appears to be transferred from the ligating portion of the device (knife), since the knife performs a full tissue thickness transection it is possible that luminal contents may adhere to the blade. Thus, reusing the knife to transect a different portion of bowel may transfer that debris. It may be prudent to consider (where it would be appropriate and such a device is available) the use of a surgical stapler that does not reuse components.

References:

1.Garske et al. (2006) *J R Soc Interface*. (Epub ahead of print)