Purpose: A proof of concept study to determine if swine small intestine submucosa (SIS) can be used to create a suture that will perform comparably to commercial chromic gut sutures for dermal wound healing.

Background: This is a report of the final phase of a project to develop an alternative biologic graft and suture material for a variety of surgical applications. SIS is a minimally invasive and readily available in resource-poor settings of the developing world. The rationale is to provide instruction for the preparation of an inexpensive, plentiful and functional material that can be harvested from locally raised animals, when prepared in the fresh state with the flexibility to be adapted for placement in a variety of procedures.

Methods and Materials: Two groups of 4 rats each received a 5mm, mid-dermal, full-thickness, skin wound. Closure was effected in one group using commercial chromic gut, and with swine intestinal submucosa (SIS) sutures in the other. SIS sutures were prepared from fresh swine jejunum following removal of the serosal and mucosal layers. The resulting strips comparable to 3.0 sutures, then threaded onto a 4-0 reverse cutting needle and sterilized in a 10% gentamycin solution. The animals were euthanized at 21 days post-surgery, and tissue samples excised, fixed, sectioned, and stained with Feulgen’s reagent for examination by light microscopy. The following parameters were compared between groups using a Fisher Exact Test or Student’s t-test: fibroblast presence, infiltration of native tissue into the suture material, organization of collagen, vasculature, and granulation tissue.

Results: All animals showed full wound closure at day 21 with no significant differences between the SIS and Chromic Gut groups in any measured parameter.

Discussion: The results warrant further examination of SIS as a suture material. As the production of low cost, commercially available, absorbable suture materials is phasing out in favor of the production of more expensive synthetic sutures, third world nations are left with fewer wound closure option. SIS sutures could provide a cost effective alternative.

Background
One of the most notable trends in the resource-poors settings of the developing world is the increased number of traumatic injuries combined with treatment constraint that are often related to the availability of medical materials (Singal, 2003). Furthermore, 80% of the world’s population resides in these locales and studies have shown that it may be counterproductive to train surgeons from the developing world in the developed world, when there are locally available options for treatment where modern conventional resources are unavailable (Eyer-Brook, 1986). An alternative would be to train physicians in their home countries based on the availability of the technology and resources available. Dedicated surgeons, for example, face situations where the need for graft and suture material is pressing but an alternative is either not available or prohibitively expensive. This is the primary rationale for this clinical study to provide information concerning the preparation of a plentiful and functional material that can be harvested from locally raised animals, safely prepared in the fresh state, with the flexibility to be adapted for placement in a variety of procedures. Hopefully, the significance of this work lies beyond these preliminary studies.

Hypothesis & Objectives
A. There was no difference in healing between wounds sutured with commercial chromic gut and those sutured with SIS.
B. There was a significant difference in healing between wounds sutured with commercial chromic gut sutures Group I and those sutured with SIS sutures Group II.

Objectives
I. To demonstrate that cost effective SIS sutures can be prepared on site from fresh swine intestine that are comparable in strength and performance to 3-0 commercial chromic gut sutures.
II. To demonstrate that SIS sutures can be placed for dermal tissue repair to effect healing comparable to repair using commercial chromic gut.

Infiltration of Native Tissue into Suture Material

Fibroblasts: Fibroblasts were counted in a 2.01 by 2.01 sampling square superimposed on micrographic fields at 10X. The average number of fibroblasts per animal calculated, and compared using a Student’s t-test. The t statistic=0.07, P value=0.95, therefore, not significant at the P=0.05 level.

Vascularity & Collagen Organization: No differences in vascularity were found between the SIS and chromic gut groups. None of the tissue sections in the area of the wound containing suture materials had any evidence of vascular infiltration in either group. The degree of organized collagen in tissue from both types of repairs was similar with comparable arrangements of parallel collagen fibrils.

Summary of Results: No statistically significant differences were found between SIS and chromic gut sutures in all evaluated parameters of healing. It appears that SIS sutures performed as well as commercially available chromic gut suture material and supported the Null Hypothesis (H0) for this study.

Conclusion & Discussions

After evaluating samples grossly and by light microscopy, no statistically significant differences were found between SIS and chromic gut sutures. A pack of 12 SIS sutures in any of the evaluated experimental groups, which is consistent with expectations at this stage of wound healing (day 21).

Fibroblasts produce collagen, providing structure to healing wounds. They are the predominant cell type during the proliferative phase. Since no statistically significant difference in their presence was found between the SIS and chromic gut, it can be inferred that both groups were at similar stages of healing with similar tensile strength.

Neutrophils: Contamination to wounds results in increased inflammatory response and tissue destruction as the immune system clears infection (Clark, 1991). As neutrophil infiltration has resolved within the first few days. The lack of identifiable neutrophil invasion seems to indicate normal tissue healing, without a prolonged immune response in either group. None of the evaluated experimental groups showed significant neutrophil infiltration.

Cost Effectiveness: While keeping costs low is important, it is also vital to create a suture that is sterile. The use of gentamycin as a stabilizing solution allows SIS sutures to be stored safely over time. Gentamycin sulfate is commercially available for $8 per milliliter. Several milliliters of solution can be used to sterilize a batch of several sutures. Utilizing a reusable suture needle also keeps costs low when compared to their disposable counterparts which can be purchased for $51.99. Sterile water, dry heat, ethylene oxide or by irradiation according to internationally accepted standards (Center for Disease Control and Prevention, 2004).

Conclusions: The number of traumatic wounds in resource poor locales make even small differences in treatment options significant in the reduction of post-operative complications. The availability of new materials that translate into improved health for a substantial number of individuals and significant savings of cost and health services resources.