Use of Radiochemically Sterilized, Absorbable Tissue Adhesive for Rabbit Kidney Repair

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Statement of Purpose: The purpose of this study is to explore the application of low-dose radiochemical sterilization method (RCS) to absorbable devices that are known to be unsuited for traditional radiation sterilization.[1,2] A nominal dose of 25 kGy of gamma rays or E-beam is traditionally used and results in the degradation of the polymeric chain which compromises clinically relevant properties of the devices. The RCS protocol entails the use of low-dose gamma radiation or E-beam of about 5-10 kGy in the presence of radiolytically generated formaldehyde gas in a closed, dry package[1,2]. RCS was shown to be effective for sterilizing an absorbable tissue adhesive (Tissuemend II-Sterile) using about 5 kGy. This sterile adhesive was successfully use to repair corneal abrasions and prompted the pursuit of its effectiveness on other soft tissues such as kidney lacerations.

Methods: Tissuemend II-Sterile was supplied by Veterinary Products Laboratories (VPL, Phoenix, AZ.) Prior to sterilization, aliquots of tissue adhesive, contained in sealed polyolefin dispensers, were packaged with Tyvek® (DuPont, Wilmington, DE) pouches containing Celcon® M90 (Ticona, Florence, KY) as a precursor of radiolytically generated formaldehyde. Sterilization was conducted using about 5 kGy of gamma radiation. Sterilized adhesive packages and non-sterile control were tested, as described earlier[3].

Six New Zealand white rabbits were used in three sets of two. For the surgical procedure a single abdominal incision was made exposing the left kidney. For the control animals two ½ cm incisions separated by 1cm of intact tissue was made and adhesive applied to the entire 2cm length. For the experimental animals a 2cm incision was made in the kidney and the edges of the tissue reapproximated using sterile absorbable tissue adhesive, Vicryl suture (Ethicon, Inc., Somerville, NJ) or PDS monofilament suture. The control rabbits served to observe side-by-side the local tissue response of intact and incised tissue to the tissue adhesive. Following post-operative recovery times of 1, 2 or 3 weeks, the animals were euthanized, the kidneys dissected and placed in formalin for histological processing. The specimens were subjected to standard protocol for sectioning and staining[4] and examined by an optical microscope.

Results / Discussion: Surgical procedures were pursued uneventfully and adhesives appeared to adhere within a minute to wound edges. Shortly after, sufficient strength appeared to develop to stabilize adjoined wound edges. Histological micrographs of repaired tissue sections and a control are shown in Figs. 1 through 4. In Fig. 1, the incisions repaired with tissue adhesive appear to elicit a tissue response similar to that repaired with Vicryl suture. In fact, the tissue adhesive appears to result in a higher quality of wound edge approximation compared to Vicryl. Similar tissue response and wound repair quality was observed at 2 weeks as shown in Figure 2. For the 3 week study, the adhesive is compared with PDS monofilament suture, which is normally less reactive than Vicryl, and shows that PDS and adhesive yield a similarly healed wound with comparable quality (Fig.3). Tissue reaction at 3 weeks is practically non-existent and tissues appear to be quite comparable to intact tissue control (Fig. 4.).

Conclusions: RCS-absorbable tissue adhesive Tissuemend II-Sterile is well suited for repairing soft tissue such as these kidney incisions and can be competitive with absorbable sutures.

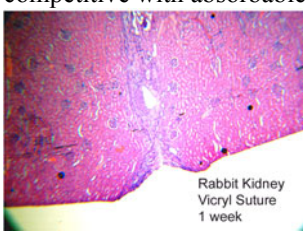

Fig. 1A Rabbit Kidney Vicryl Suture – 1 week

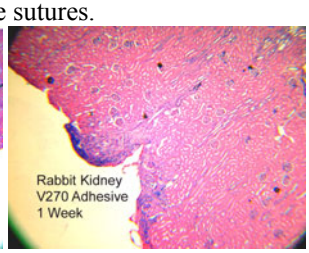

Fig. 1B Rabbit Kidney Adhesive – 1 week

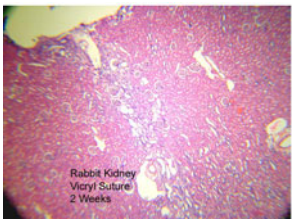

Fig. 2A Rabbit Kidney Vicryl Suture – 2 week

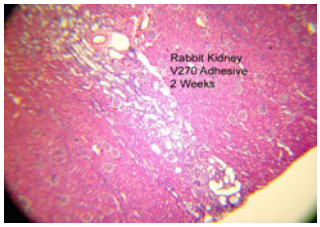

Fig. 2B Rabbit Kidney Adhesive – 2 week

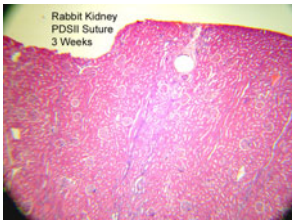

Fig. 3A Rabbit Kidney PDS Suture – 3 week

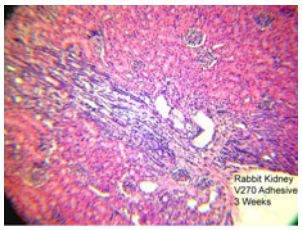

Fig. 3B Rabbit Kidney Adhesive – 3 week

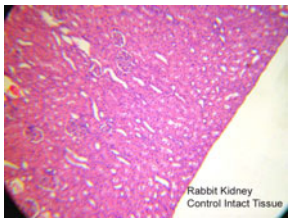

Fig. 4 Rabbit Kidney - Control

References:

1. Shalaby SW et *al*. Nuclear Instrum Methods, B-2003; 208:110.
2. Vaughn MA et *al*. 7th World Biomat Congr, Trans Soc Biomater, 2004; 27:1044.
3. Vaughn MA et *al*. Trans Soc Biomater, 2005; 28: 1045.
4. Matlaga BF. Tissue Preparation. In Biomaterials Evaluation. 2nd Ed (VonRecum AF, Ed), Taylor & Francis, 1999.

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