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## KNOT INTEGRITY AS A FUNCTION OF SUTURE EXPIRATION DATE

### Hypothesis / aims of study

The United States Food and Drug Administration sets a five year expiration date for storage of synthetic absorbable suture. To test the integrity of knots tied using an expired suture and non-expired suture using four different suture materials.

### Study design, materials and methods

The four types of dated suture were tied with chromic catgut, polyglactin 910, coated polyester, or polydioxanone. A total of 149 knots were tied including both absorbable and non-absorbable synthetic sutures. We compared the knots using a tensiometer until the suture broke or untied.

### Results

All the suture packs were inspected for intact packaging and no humidity was observed inside the foil packs. Seventy one sutures came from non-expired packets, and 78 came from expired suture packets. The mean tension at failure was 76.0 N (SD = 36.2 N) for expired sutures and 84.9 N (SD = 35.2 N) for non-expired sutures. An independent samples t-test comparing the two knot groups revealed that this difference was not statistically significant. However, since each suture packet was used to tie multiple knots, we wanted to account for the clustering of knots according to suture packet that each of them came from. In order to control for the suture packet, we used a univariate ANOVA to test the difference in tension at breaking point between expired and non-expired with suture packet as a covariate. Consistent with the uncontrolled finding (i.e., the above t-test) the ANOVA revealed no statistically significant difference between expired and non-expired sutures.

### Interpretation of results

There is no statistically significant difference in tensile strength between the expired and non-expired sutures tested in the laboratory environment. The most significant issue in evaluating an expired suture is patient safety. The expiration date on a suture product represents the time through which satisfactory stability studies have been carried out. As such studies are continued, the expiration date may be extended.

### Concluding message

Suture may occasionally expire prior to implantation and despite having the same tensile strength in the lab. While practically suture may be used past the expiration date, it is unlikely that this will be seen as appropriate practice in the eyes of a patient or litigator.

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