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COMPARISON OF PELVIC FLOOR TISSUE-BASED REPAIR PRODUCTS.

Hypothesis / aims of study

To test the tensile strength and suture pull strength of five commercially distributed (USA) pelvic floor repair tissue-based materials.

Study design, materials and methods

A minimum of three lots of product were tested for tensile strength and suture pull strength using a constant rate of elongation tensile testing machine at an independent lab. The samples for tensile strength testing were 0.5 cm x 5 cm. The tensile testing equipment was set up to elongate the samples at a rate of 0.5 inches per minute. The samples were placed between two rubber coated jaws that were a distance of 1 inch apart. Each product was tested in the X and Y axis of the "as received" product. Five tensile tests were conducted in each direction for each lot for a total of 15 tensile tests per axis and 30 tensile tests per material type. The tensile strength was recorded in pounds at the break point of each material. The samples for suture pull through testing were 2 cm x 4 cm. The suture (size 0 monofilament polypropylene (Genzyme)) was placed in the midline of the short axis of the test piece, 0.5 cm from the edge. Five suture pull through tests were conducted on each lot of product for a total of 15 suture pull tests per product type. The suture pull through strength was measured in pounds at the point when the suture was pulled through each material. Each product was hydrated per instruction prior to testing and measured for thickness in the hydrated state. The materials tested included Cytrix® (TEI Biosciences Inc), InteXen® (AMS), Pelvicol® (CR Bard), Repliform® (Boston Scientific) and Suspend® (Mentor).

Results

Chart 1 shows graphical comparisons of the tensile strengths for each material tested in Direction A, Direction B, and Directions A and B combined. In Direction A, the tensile strength for Suspend was weaker than InteXen, Pelvicol, and Repliform. In Direction B, the tensile strength for Suspend was the weakest of the group. InteXen and Repliform were stronger than Cytrix and Pelvicol. When combining the tensile strength data in Directions A and B, Suspend was the weakest of the group. InteXen and Repliform were noted to be stronger than Cytrix.

Chart 2 shows graphical comparisons of the suture pull through strength for each material tested in Direction A, Direction B, and Directions A and B combined. Suture pull through strength in Direction A noted Suspend to be the weakest. Pelvicol and Repliform were stronger than Cytrix, and Repliform was stronger than InteXen. Suture pull through strength in Direction B also noted Suspend to be the weakest, and Cytrix to be weaker than InteXen, Pelvicol, and Repliform. Combining the suture pull through strength in Direction A and B noted that Suspend was the weakest, and Repliform was the strongest. InteXen, Pelvicol, and Repliform were stronger than Cytrix. These comparisons were all noted to be statistically significant based on ANOVA with significance assigned for $P<0.05$.

Interpretation of results

Suspend appears to be the weakest material overall, and Repliform is among the strongest. Suspend and Pelvicol demonstrate the most directionality in tensile strength. Suspend and Cytrix show the least directionality for suture pull through. The data which combines Directions A and B for both the tensile strength and suture pull through strength were obtained by averaging the breaking points in each direction. This data is the most practical because the manufacturers of each material do not specify that one direction is stronger than another, and Direction A or B is unknown to the physician using a particular material.

Concluding message

While this study does demonstrate the strength of some tissue-based repair products over others, there is no evidence to prove that these materials will actually reach their breaking point in vivo.

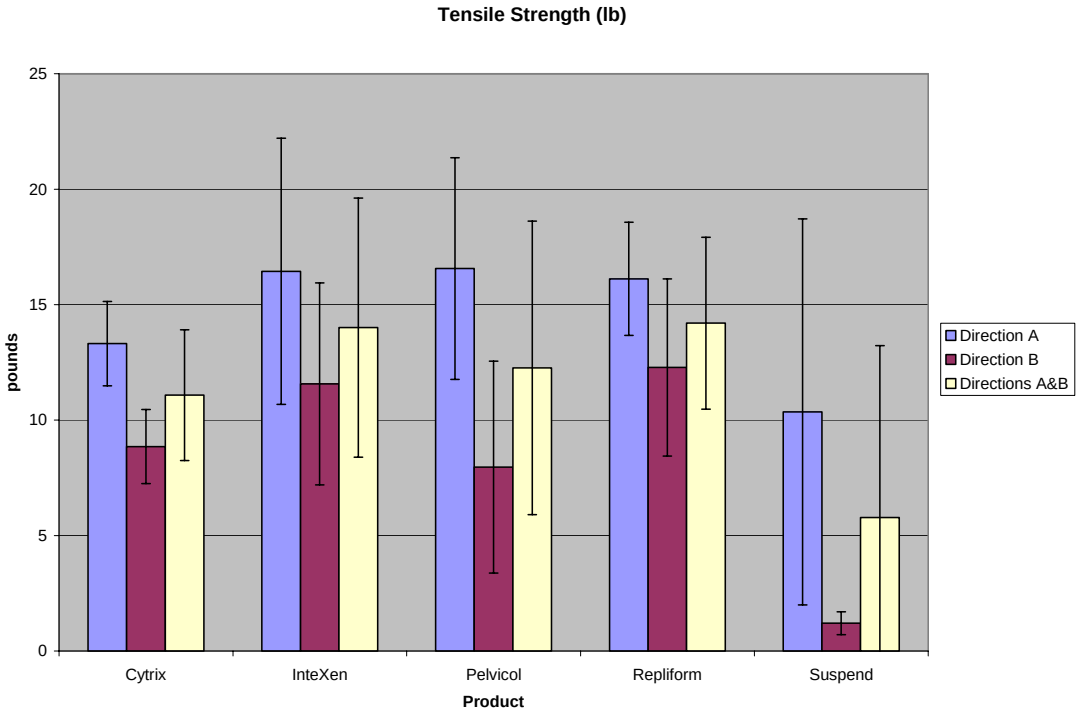

Chart 1

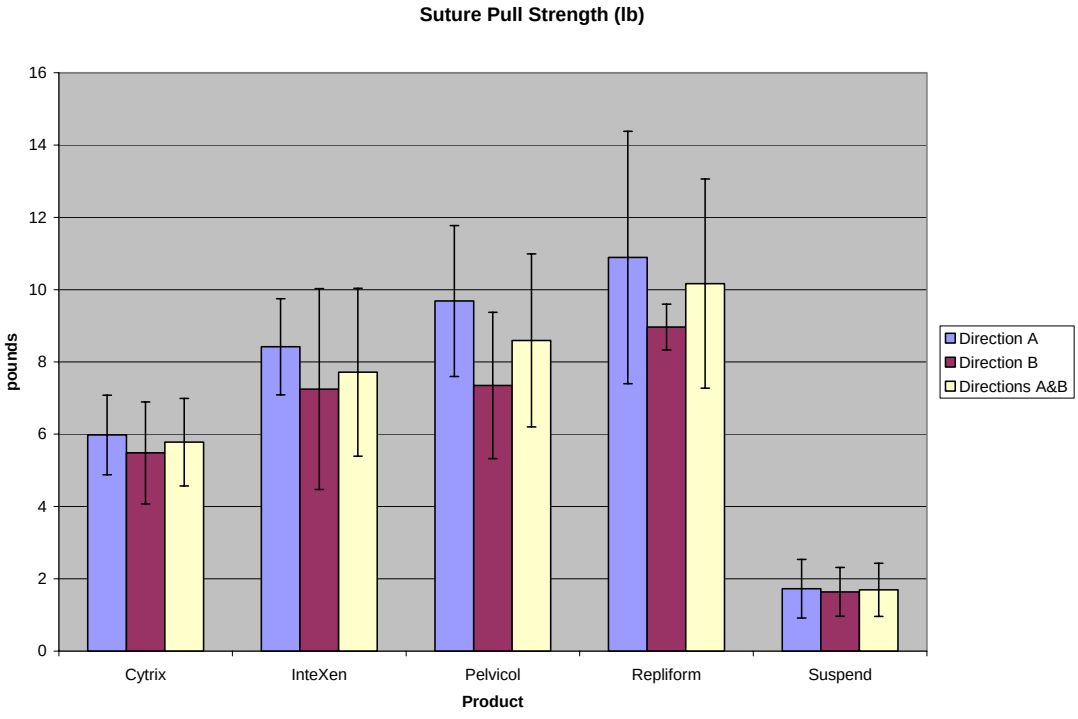

Chart 2

FUNDING: Boston Scientific Corporation