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Craniomaxillofacial

# DuraMatrix® Suturable Value Analysis Brief

## Description of Product:

DuraMatrix Suturable is a white, nonfriable, conformable, resorbable, collagen membrane consisting of highly purified collagen derived from bovine dermis. The product is intended for use as a dura substitute for the repair of dura mater.

## Value Proposition:

DuraMatrix Suturable is a third generation of DuraMatrix product designed to include the desired handling characteristics with high comformability. It has a rapid 1 minute hydration time and can be cut in the dry or hydrated state[1].The product utilizes crosslinking technology in order to control the in vivo resorption & degradation profile, control handling characteristics, and enhance mechanical strength[1]. Below you will find a summary of the mechanical and in vivo testing completed on the product.

## Suture Pull Out Strength[1]:

DuraMatrix Suturable shows significantly higher suture pull out strength that permits it to be firmly anchored to surrounding tissue with minimal risk of membrane tear or detachment.

| Product | Suture Pull Out Strength |
|---|---|
| DuraMatrix Suturable | 20.40 ± 1.54 N |
| Durepair | 11.67 ± 4.12 N |

## Implant Resorption and New Collagen Formation[2]:

The total resorption time, defined as ≤ 5% implant remaining, is approximately 38-40 weeks for DuraMatrix Suturable compared to 20-22 weeks for Durepair. The application of DuraMatrix Suturable appeared to potentially prevent CSF leakage.

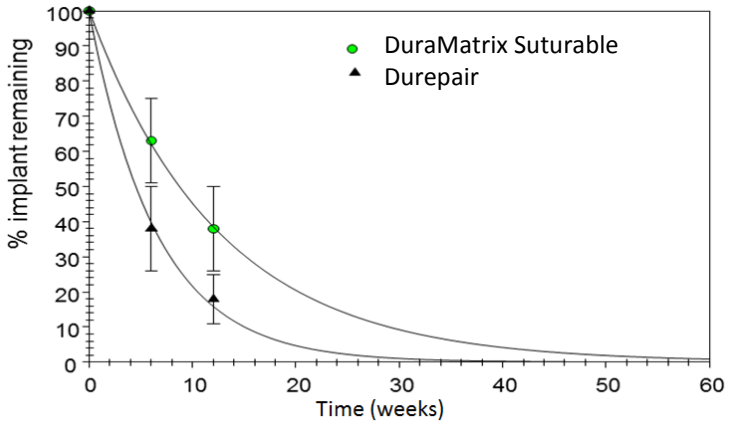


Figure1: Percent Implant Remaining of DuraMatrix Suturable vs. Durepair.

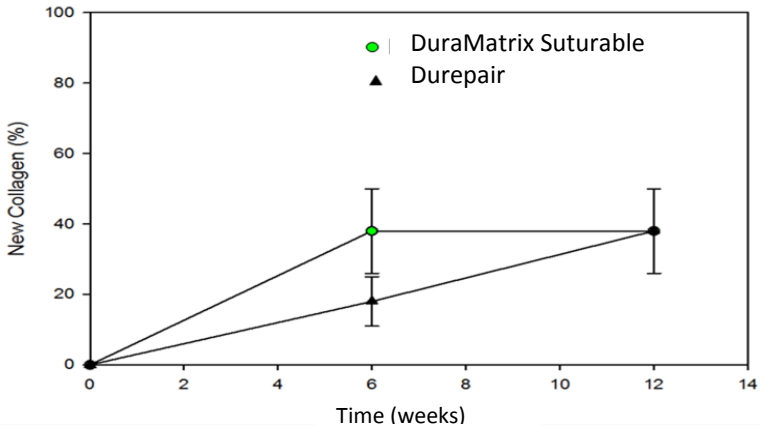


Figure 2. Percent New Collagen Formation of DuraMatrix Suturable and Durepair.

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1: Collagen Matrix Internal Testing
2: In vivo evaluation of resorption in a rabbit duraplasty model. Data on file.