TITLE OF ARTICLE:
Non-watertight Dural Reconstruction in Meningioma Surgery: Results in 439 Consecutive Patients and a Review of the Literature.
Sade B, Oya S, Lee JH.

SUMMARY:
The article demonstrates the use of DuraGen® Dural Graft Matrix as the sole means of dural closure in meningioma surgery. This retrospective study reviews 439 consecutive meningioma surgeries over a 7-year period performed by one surgeon. The article also reviews different dural reconstruction techniques, with an emphasis on the non-watertight reconstruction of the dura using the dural repair matrix.

RESULTS:
- High efficacy rate observed with DuraGen® Matrix
  - CSF leak rate - 0.4% with a 0% reoperation rate (interpreted as a 99.6% efficacy rate)
- Low rates of graft-related complications observed in this series with DuraGen® Matrix
  - Chemical meningitis, cerebral inflammation, extraaxial reactive fluid collection – 2.3%
  - Bacterial meningitis, osteomyelitis/epidural abscess rate – 0.9%
- In vivo action of DuraGen® Dural Graft Matrix and alternate technologies are reviewed:
  - DuraGen® Dural Graft Matrix is resorbed and replaced by endogenous collagen within 6-8 weeks.
  - Suggests allogenic/cadaveric dura and synthetic grafts may become encapsulated
  - Suggests other collagen xenografts are compact and may limit fibroblast migration/infiltration

<table>
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<tr>
<th>KEY POINTS OF STUDY</th>
<th>IMPORTANCE</th>
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<tbody>
<tr>
<td>High efficacy rate observed</td>
<td>First study demonstrating high efficacy rates of DuraGen® Dural Graft Matrix for non-watertight closure in a large number of patients (99.6% efficacy over 439 patients)</td>
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<td>Low rates of complications observed in the series</td>
<td>Demonstrated low incidence of complications using DuraGen® Dural Graft Matrix</td>
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CALL TO ACTION:
- Position this study with physicians who are currently suturing their dural repairs. These physicians may believe that a “watertight”, sutured dura is the best way to have low CSF leaks. However, this study shows high efficacy and low leakage rates using DuraGen® Dural Graft Matrix.
- Position this study to surgeons performing meningioma procedures. It may be particularly challenging to achieve a “watertight” sutured closure in meningioma surgeries. This study presents clinical data supporting successful use of DuraGen Matrix in meningioma procedures.
- Position this study with existing DuraGen® Dural Graft Matrix users to reinforce they are using an excellent dural graft product by citing that in this recent, large subject study, the product demonstrated both high efficacy and low complication rates. Additionally, it adds to the library of clinical data supporting our product, which greatly exceeds the clinical study information available for competitive collagen based products.

1 CONTRAINDICATION: DuraGen Dural Graft Matrix is not recommended for large defects at the skull base following surgery. Please see instructions for use for complete product information.

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