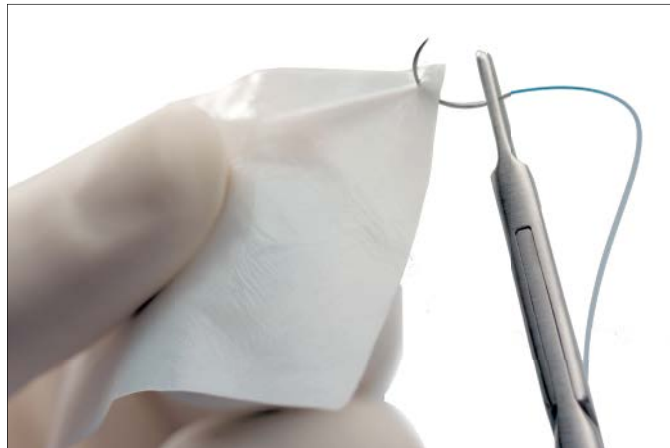


## CASE REPORT

# SYNTHECEL™ DURA REPAIR – DURAL CLOSURE AFTER POSTERIOR FOSSA SURGERY

Marco Lee, MD, PhD, FRCS



## 1. CASE REPORT

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### 1a. Patient Profile

A 23-year-old female with a known family history of neurofibromatosis 2 (NF2) presented to the emergency room with worsening headache, ataxia, dysphagia, diplopia, and numbness on the right side of her face over a period of a month. Hearing bilaterally was also noted to be decreasing over several months but functional.

Her neurological examination revealed decreased right facial sensation in all three divisions of the trigeminal nerve, bilateral 6th cranial nerve palsy, marked nystagmus, and an ataxic gait. The motor and sensory examinations of the upper and lower extremities were normal.

She underwent MRI imaging which confirmed bilateral large cerebello-pontine angle tumors consistent with vestibular schwannomas and the diagnosis of NF2 (Figure 1). As she did not complain of hearing loss up until presentation, she had previously chosen not to be screened for NF2 while knowing that her father had the disease.

Her neurological condition deteriorated rapidly despite steroid treatment, and she was taken to the operating room for surgical resection of the larger and more symptomatic right-sided vestibular schwannoma.

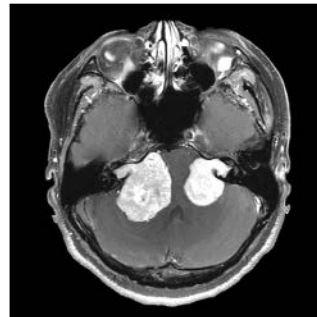


Figure 1

## CASE REPORT

### 1b. Treatment

The patient underwent general anesthesia and she was positioned in the lateral decubitus position with her head fixed in a three-point fixation device, flexed and slightly rotated to expose the right suboccipital area. Neurophysiological electrodes for monitoring of the facial nerve were placed and a retrosigmoid approach to the tumor planned. After a right-sided suboccipital craniotomy was performed, which extended to the foramen magnum and included a C1 hemilaminectomy, a small linear opening was made in the midline at the level of the foramen magnum to allow cerebrospinal fluid (CSF) egress and relaxation of the tense cerebellar dura.

The durotomy was then performed based over the Transverse and Sigmoid sinuses. The tumor was identified and resected under the microscope with facial nerve preservation anatomically and neurophysiologically.

### 1c. Dura Closure

Due to shrinkage of the dura, approximation of the edges was no longer possible and the SYNTHACEL™ Dura Repair graft was used to close the dural defect. A 2 in x 2 in (5.0 cm x 5.0 cm) piece of SYNTHACEL Dura Repair was selected and cut to a suitable size and shape that was then sutured without tension to the native dural edge using a 4-0 nylon suture with a 13 mm tapered needle. The previous small opening of the midline dura was closed primarily using the same suture material.

SYNTHACEL Dura Repair, which in this case was triangular shaped, was first anchored to the native dura at its three points (Figure 2). The graft was then sutured with a continuous 4-0 nylon suture with a 13 mm tapered needle in a clockwise direction starting at the highest point (Figure 3). Just prior to closing the defect completely, the subdural space was filled with warm normal saline and the final stitch performed to complete the duraplasty. A Valsalva maneuver was then performed to check for a watertight closure.

After confirming no leakage of fluid could be seen, the free bone flap was replaced and secured with titanium plates and screws (DePuy Synthes MatrixNEURO™ Cranial Plating System), and the wound was closed in the standard fashion. No wound drain or CSF drainage devices (external ventricular drain, lumbar drain, or ventriculo-peritoneal shunts) were used. A simple adhesive wound dressing was applied without head bandaging.

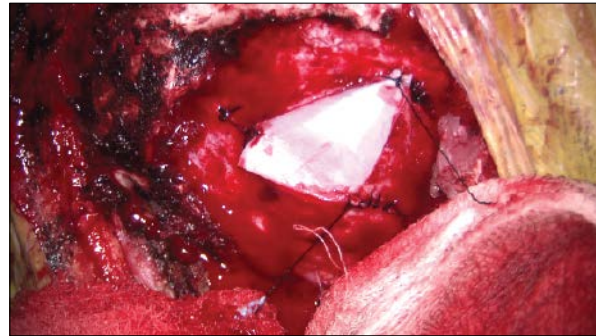


Figure 2

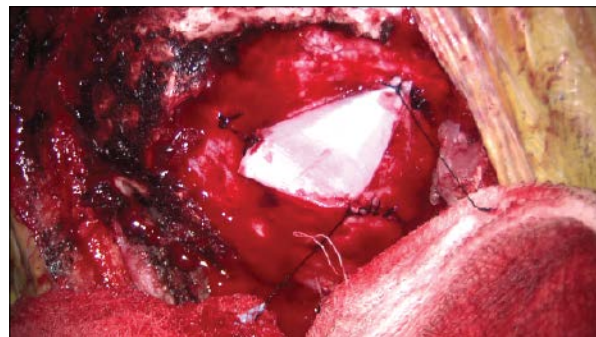


Figure 3

### 1d. Outcome

In the immediate postoperative period, the patient had developed a House-Brackmann grade 4 facial weakness and right deafness. Her other preoperative symptoms improved and by 1 month, her ataxia, dysphagia, and 5th and 6th nerve deficits had completely resolved. Her right facial weakness had improved to House-Brackmann grade 2.

The wound healed well with no evidence of CSF leak or collection. A postoperative MRI scan at 1 month also did not reveal any significant pseudomeningocele (Figure 4). There were no other complications noted, including wound infection and aseptic meningitis.

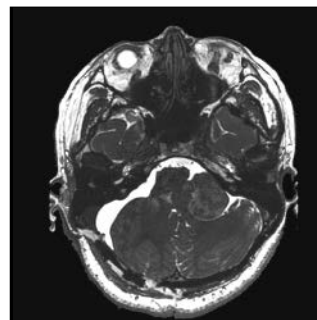


Figure 4

## CASE REPORT

### 1e. Discussion

A CSF leak following cranial surgery is a well known complication (Cosgrove et al, 2007). The problem is particularly prevalent after surgery in the skull base, including the posterior fossa (Moskowitz et al, 2009, Jan Parížek et al, 1998). The surgeries in these locations are often long, and the dura is prone to shrinkage during the prolonged exposure and, sometimes, electrocautery. In many cases, the disease process necessitates excision of the dura.

The dependent position of the skull base and resultant increased CSF pressure also contribute to the increased risk of a postoperative CSF leak at surgical sites such as the one presented here. Failure to achieve a watertight dural closure can result in a multitude of postoperative problems, including pseudomeningocele, wound dehiscence, infection, and aseptic meningitis. Not only can a CSF leak out through the dural defect but lack of the natural barrier can allow blood products and potential pathogens in with subsequent morbidity and, sometimes, mortality.

The choice of material available for dura repair is impressive, but autologously harvested pericranium is often preferred over any other material. However, pericranium is not always readily available, especially in the infratentorial compartment, and some other autologous material, such as fascia lata, necessitates additional incisions at distant sites. The other choices have, until recently, included allografts, xenografts, or synthetic materials.

Whatever dural substitute is used, it should have the basic quality of being durable and act as effective a barrier as dura. This usually necessitates the graft to be suturable and therefore the handling of the material should be qualitatively similar to dura itself. It must, of course, be safe, with minimal immunogenicity.

The dura replacement graft used in this case belongs to an entirely different category and has such dura-like qualities. SYNTHECCEL Dura Repair is made of biosynthesized cellulose and water. It is derived from a naturally forming organism named *Gluconacetobacter xylinus*. (It contains no animal products, such as Bovine tendon, skin, or pericardium.) In the first prospective, randomized, controlled trial undertaken on dural substitutes, SYNTHECCEL Dura Repair was found to be noninferior compared to other commonly available nonautologous dural substitutes, both in its efficacy and safety in a range of cranial cases (Rosen et al, 2011).

The single case presentation here illustrates the usability of SYNTHECCEL Dura Repair to successfully achieve a dura closure in the posterior fossa, one of the more challenging sites for effective dural closures. The strength was found to be excellent.

The malleability of the material also made shaping and handling of the material easy. Particular attention was directed to seeing whether suture holes enlarged, as can occur in dural substitutes while manipulating the graft, and none were seen.

It was also simple to use, with no requirement to soak the sheet prior to use, and the operating room staff did not need to differentiate between sutureable and onlay products since SYNTHECCEL Dura Repair can be used in either way.

Lastly, the fact that it is an entirely biosynthesized cellulose material with no animal product may be attractive to some surgeons and patients. The ease of storage and documentation of a non-animal product may also confer some appeal to hospital administrators.

## 2. SURGEON PROFILE



### Marco Lee, MD, PhD, FRCS

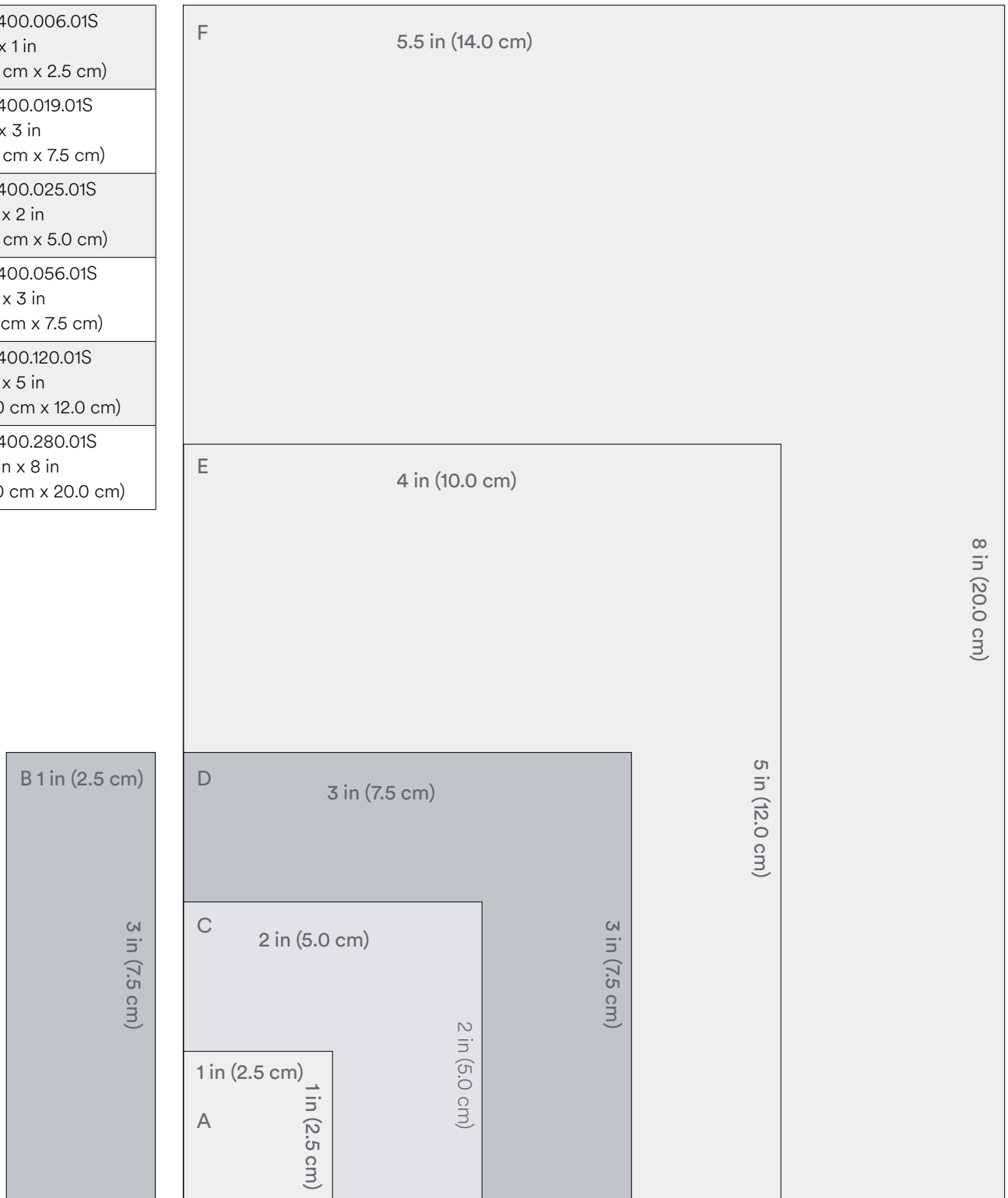
Clinical Associate Professor,  
Neurosurgery,  
Stanford University, Stanford, CA  
Chief of Neurosurgery, Santa Clara Valley  
Medical Center, San Jose, CA

## 3. REFERENCES

- Cosgrove GR, Delashaw JB, Grotenhuis JA, et al. Safety and efficacy of a novel polyethylene glycol hydrogel sealant for watertight dural repair. *J Neurosurg.* 2007;106(1):52-58.
- Moskowitz SI, Liu J, Krishnaney AA. Postoperative complications associated with dural substitutes in suboccipital craniotomies. *Neurosurgery.* 2009;64(suppl 3):ons28-ons34.
- Parížek J, et al. Posterior cranial fossa surgery in 454 children. *Childs Nerv Syst.* 1998;14(9):426-439.
- Rosen CL, Steinberg GK, DeMonte F, et al. Results of the prospective, randomized, multicenter clinical trial evaluating a biosynthesized cellulose graft for repair of dural defects. *Neurosurgery.* 2011;69(5):1093-1104.
- Results from case studies are not predictive of results in other cases. Results in other cases may vary.

## CASE REPORT

<b>A</b>	SC.400.006.01S 1 in x 1 in (2.5 cm x 2.5 cm)
<b>B</b>	SC.400.019.01S 1 in x 3 in (2.5 cm x 7.5 cm)
<b>C</b>	SC.400.025.01S 2 in x 2 in (5.0 cm x 5.0 cm)
<b>D</b>	SC.400.056.01S 3 in x 3 in (7.5 cm x 7.5 cm)
<b>E</b>	SC.400.120.01S 4 in x 5 in (10.0 cm x 12.0 cm)
<b>F</b>	SC.400.280.01S 5.5 in x 8 in (14.0 cm x 20.0 cm)



Images shown are to scale in inches. Products are sold sterile.



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119715-220729 DSUS

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Results from case studies are not predictive of results in other cases. The material contained in this case study reflects the opinions of Dr. Lee and his conclusions based on experience with SYNTHECEL™ Dura Repair, unless otherwise noted.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

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