

## Key Points

1. Several types of dural graft materials are available today, including grafts taken from the patient, cadavers, cows, collagen, and synthetic
2. Multi-center study looked at the safety and efficacy of 59 patients using Durasis graft
3. Found very favorable complication rates, including no CSF leaks in 32 Chiari surgeries
4. Efficacy of graft averaged a score of 4.8 out of 5 and was considered successful in every patient
5. Surgeons rated the handling of the material as excellent
6. Research presented at CC Symposium showed that graft choice may be a matter of surgeon preference

## Definitions

**aneurysm** - a bulge in the wall of an artery due to an inherent weakness

**collagen** - found in connective tissue and acts as an important support structure for cells

**CSF leak** - complication where CSF is not totally enclosed beneath the dura and leaks out

**dura** - thicker, outer covering of the brain/spinal cord

**dural patch** - material, such as from a cow, collagen, or the patient which is sewn into an opening in the dura

**duraplasty** - surgical technique where a patch is sewn into the dura

**cerebellar tonsils** - portion of the cerebellum located at the bottom, so named because of their shape

**cerebellum** - part of the brain located at the bottom of the skull, near the opening to the spinal area; important for muscle control, movement, and balance

## New Dural Patch Found To Be Safe And Effective

**September 30, 2007** -- While the debate over whether it is even necessary to open the dura as part of a Chiari decompression rages on, advances in the types of materials that can be used for dural grafts continues. In fact, today's surgeons, and patients, have an array of dural patch options, including:

**From the Patient** - Many surgeons have begun to use tissue from the patient's own body for the dural graft. The tissue can be taken from a number of different places and has the advantage of eliminating any type of immune response to the graft. Some people also believe that this type of graft reduces the chance of infection. The downside, of course, is that there is another surgical site which needs to heal and may cause additional pain.

**Cadaver** - Very popular a number of years ago, grafts from cadavers are being used less today because of safety concerns. Cadaver grafts can be made either from dural tissue directly or the pericardium, which is the membrane around the heart.

**Cow** - Bovine grafts, such as DuraGuard (Synovis), are taken from the animal's pericardium.

**Collagen** - Several manufacturers have recently come out with a new class of products known as collagen matrices. Collagen is a type of connective tissue which provides structure to body parts and has several advantages as the basis for a graft. Two of these grafts, Durasis (Cook Biotech) and DuraGen (Integra Lifesciences) both utilize animal collagen to form pliable, easy to work with grafts, which are actually absorbed by the body's tissue over a short period of time.

**Synthetic** - Dural grafts can also be made from completely synthetic materials, such as Gore-Tex.

With so many options, what do surgeons look for when they choose a dural graft? An ideal dural substitute must be both safe and effective, meaning that it should be pliable, easy to suture, able to hold a watertight seal to prevent CSF leaks, integrate quickly into the natural tissue of the body and result in minimal complications. While this sounds like a tall order, a publication in the June, 2007 issue of the Journal of Neurosurgery by Dr. Bejjani of the University of Pittsburgh and Dr. Zabramski of the Barrow Neurological Institute indicates that a newer graft, Durasis is a strong candidate.

Bejjani and Zabramski reported the results of a multi-center trial of the dural substitute in 59 patients treated for a variety of reasons, including Chiari, tumors, and tethered cords (see Table 1). According to Cook Biotech, the manufacturer, Durasis "utilizes Cook's innovative Small Intestinal Submucosa (SIS) technology, a collagen biomatrix that supports regrowth of host tissue. SIS is a natural biomaterial harvested from pig small intestine and developed into strong, sterile, pliable sheets that provide a rich environment for cell attachment and tissue growth. Durasis takes on the cellular characteristics of surrounding dural tissue while it serves as a scaffold on which human tissue grows. As the biomaterial is replaced with cells, the scaffold is no longer needed and it is absorbed by the body. The result is a tissue that looks and functions very much like the tissue it replaced."

To evaluate the safety and efficacy of Durasis, surgeons at several centers carefully tracked its use and rated its effectiveness on a 5 point scale, ease of use on a 4 point scale, and looked for complications due to the graft at several points in time after surgery.

For the 59 patients in the study, the overall complication rate was fairly low with the only problems being 1 CSF leaks (1.7%) and 2 infections (3.4%). To compare this with other materials, the authors selected 10 published studies which reported complications from a variety of dural graft types and comprised over 1800 patients. The combined complication rates from the 10 studies was 5.2% for CSF leaks and 5.0% for infections. It should be noted that there no CSF leaks for the 32 Chiari surgeries using Durasis.

In terms of efficacy, Durasis scored an average of 4.8 on a 5 point scale and the graft was considered successful in all 59 cases. In addition, the surgeons rated the material as excellent in handling issues, such as strength and ease of suturing.

While these results indicate that Durasis appears to be a good dural patch, it is important to keep in mind that there are other good options as well and not every surgeon is going to switch to using Durasis. It is also important to keep in mind that this study was funded by Cook Biotech as part of the FDA approval process.

In fact, research presented at the 2007 UIC/Conquer Chiari Research Symposium by Dr. Konstantin Slavin (UIC) indicated that it may not matter what material is used. Dr. Slavin presented the results of a randomized prospective study of 25 patients which compared two well-known graft products. One of the grafts required sutures to be put into place, while the other one did not.

The grafts were evaluated on clinical outcome, complication rates, length of hospital stay and time in surgery. Interestingly, there was no difference between the two grafts for outcome, complication rates, or length of

**cerebrospinal fluid (CSF)** - clear liquid in the brain and spinal cord, acts as a shock absorber

**Chiari malformation I** - condition where the cerebellar tonsils are displaced out of the skull area into the spinal area, causing compression of brain tissue and disruption of CSF flow

**decompression surgery** - general term used for any of several surgical techniques employed to create more space around a Chiari malformation and to relieve compression

### Source

**Source:** Bejjani GK, Zabramski J; Durasis Study Group. Safety and efficacy of the porcine small intestinal submucosa dural substitute: results of a prospective multicenter study and literature review. J Neurosurg. 2007 Jun;106(6):1028-33.

hospital stay. The good news is that today's Chiari surgeons and patients have more choices for dural grafts than in the past and that their safety and effectiveness is improving.

**Table 1**  
**Surgical Procedures Used In Study (59 Total Patients)**

Procedure	# of Patients
Chiari I	32
Tumor	18
Tethered Cord	3
Aneurysm	3
Other	3

**Table 2**  
**Complication Rates, Durasis vs Medical Literature Reports**

	Durasis	Literature
<b>CSF Leak</b>	1.7%	5.2%
<b>Infection</b>	3.4%	5.0%

**Note:** The Literature rates comprise the combined complication rates of 10 published studies of various graft materials (selected by the authors) involving over 1800 patients

### Related C&S News Articles:

[Does the type of dural graft material matter?](#)

[Do You Know What's In Your Head? Study Compares Dural Graft Materials](#)

[Cook Biotech Discusses Their New Dural Substitute Product, Durasis](#)

[Home](#) | [About Us](#) | [Email](#) | [Donate](#) | [Get Involved](#) | [Privacy Policy](#)

**Disclaimer:** This publication is intended for informational purposes only and may or may not apply to you. The editor and publisher are not doctors and are not engaged in providing medical advice. Always consult a qualified professional for medical care. This publication does not endorse any doctors, procedures, or products.

© 2003-2020 C&S Patient Education Foundation