

## **Key Points**

- There are many variations to the basic surgical technique used for Chiari decompression
- One of these involves the selection of the material used for the dural graft
- Options include grafts derived from human cadavers, cows, or the patients themselves
- Recently what are referred to as collagen matrix grafts have become available
- Study compared complication rates and average operating time between a collagen matrix graft (DuraGen) and cadaver grafts
- In general, complication rates were about the same, but surgery with the DuraGen graft didn't take as long
- Other research has shown that grafts taken from the patient may have the lowest complication rates, however this technique can be difficult with children
- 8. Transmitting disease and infection from the donor to the patient is also a consideration in graft selection

### Definitions

**autologous** - refers to something taken from a patient's own body, such as blood or tissue

cadaver - dead human body

**craniectomy** - surgical procedure where part of the skull, or cranium, is removed

**Creutzfeldt-Jakob disease -** a rare disease which causes rapid neurological deterioration and eventual death, similar to Mad Cow disease in cattle

**dura -** thick, outer layer of the covering of the brain and spine

**dural graft -** a patch which is inserted into the dura, effectively making it bigger

# What's In Your Head? Study Compares Dural Graft Materials

March 20, 2006 -- When someone is newly diagnosed with Chiari, they are often surprised to learn that there are many variations to the "standard" Chiari decompression surgery. Indeed, those who seek opinions from several neurosurgeons are likely to find that each surgeon approaches the surgery in their own unique way. Surgical variations include, but are not limited to, how much bone to remove, whether to open the dura, whether to manipulate the cerebellar tonsils, and of interest for this article, what type of material to use for a dural graft.

The dura is the thick, outer layer of the covering of the brain and spinal cord. Most, but not all, Chiari surgeries cut open the dura and insert a patch - or graft - to create more space around the Chiari malformation. Interestingly, thousands of dural grafts are used each year for surgeries other than Chiari. In fact, Chiari surgeries account for a relatively small percentage of the total dural grafts used each year.

Dural grafts have been used for more than a century and have been based on a variety of materials. In the 1800's rubber and gold foil were tried (can you imagine?). These gave way to gelatin products in the first half of the 20th century and silicone later on. Today, surgeons have a variety of graft types to choose from, including those taken from human cadaver (Ed. Note: I have a cadaver graft), bovine material, tissue taken from the patient, and recently, a new generation of specially crafted materials.

These new grafts are referred to as collagen matrices. Collagen is a type of connective tissue which provides structure to body parts and has many advantages as the basis for a graft. Two newer grafts, Duarsis (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.

Given the market forces at work, and the idiosyncratic nature of brain surgery, it is possible that there will never be a true consensus on which material is best suited for Chiari surgeries. However, a recent study from a group at Children's Hospital of Philadelphia, led by Dr. Shabbar Danish, directly compared surgical complications and total operating time of the collagen matrix graft DuraGen to grafts from human cadavers in over 100 Chiari surgeries. They published their results in the January, 2006 issue of the Journal of Neurosurgery.

Their study reviewed the operating results of 56 children who received a DuraGen graft and 45 children who received a human graft. On average, the children were 9 years old and 96 of them had Chiari I, while 5 had Chiari II.

In general, the surgeons used a standard technique for all the surgeries. However, there were variations, such as how large of a laminectomy was performed and whether the cerebellar tonsils were completely removed, depending on what they found during the operation. Their general decompression technique involved removing a trapezoidal piece of bone from the skull between 3cm-4cm in height. The dura was opened in a Y-shape (Ed. Note: there is a webcast video of a pediatric Chiari decompression available at: <u>Surgery Video</u>) and the arachnoid, beneath the dura, was opened as well to expose the cerebellar tonsils. For each patient, the surgeons reduced the size of the tonsils by cauterizing them until there was adequate CSF flow. The dural grafts were put it into place and the incisions were closed. It should be noted that the DuraGen is what is called an overlay graft, and it does not require sutures. In contrast, the human graft requires a water-tight seal, using sutures, with the dura.

The children recovered for 2-4 days in the hospital, were examined one month after surgery, and then at regular intervals after that. For this study, the authors looked at four specific surgical complications:

- 1. Visible pseudomeningoceles, which is when the space which contains CSF bulges, or protrudes, into surrounding tissue
- 2. Any type of wound infection
- 3. Cerebrospinal fluid leak
- 4. Reoperation for any reason

Interestingly, the researchers found a very similar number of complications between the two groups (see Table 1), and the overall complication rate was the same (16%). There were five pseudomeningoceles in each group, one CSF leak in each group, two infections in the DuraGen group, and one infection in the cadaver graft group. Statistically, there were no significant difference in the number or type of complications between the two groups.

There was, however, a significant difference between the average operating time of the two groups. Because the DuraGen graft does not require suturing, surgeries using this graft were more than 30 minutes shorter than surgeries using the cadaver grafts.

**duraplasty -** surgical procedure where the dura is opened and a patch, or graft, is sewn in

**laminectomy -** surgical procedure where bone is removed from one or more vertebra of the spine

**pseudomeningocele** - when the subarachnoid space - where CSF circulates - bulges or extends into surrounding tissue; essentially creates a soft bulge filled with CSF

#### Common Chiari Terms

**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

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

**MRI** - magnetic resonance imaging; large device which uses strong magnetic fields to produce images of soft tissue inside the human body

**syringomyelia (SM)** - neurological condition where a fluid filled cyst forms in the spinal cord

**syrinx** - fluid filled cyst in the spinal cord

#### Source

Sources: Danish SF, Samdani A, Hanna A, Storm P, Sutton L. Experience with acellular human dura and bovine collagen matrix for duraplasty after posterior fossa decompression for Chiari malformations. J Neurosurg. 2006 Jan;104(1 Suppl):16-20.

Update: <u>Creutzfeldt-Jakob</u> disease associated with cadaveric <u>dura mater grafts</u>--Japan, 1979-2003. MMWR Morb Mortal Wkly Rep.

2003 Dec 5;52(48):1179-81.

In discussing their results, the authors point out that the medical literature indicates that autologous grafts, which are taken from the patient's own tissue, appear to involve the least number of complications. In fact, two studies which involved a combined 232 patients reported no surgical complications in using autologous grafts. While autologous grafts do offer advantages, such as eliminating risks of rejection and transmission of infectious agents from the donor, the authors note that it can be difficult to find appropriate tissue in children. Also, some neurosurgeons do not like the idea of creating another wound which will require healing.

For all dural grafts, the spread of a virus or other type of infection from the graft to the patient is a serious concern. Human donors are screened for hepatitis B and C, HIV, and other diseases. Grafts that are derived from cow tissue (such as the collagen matrix DuraGen) are screened for evidence of Mad Cow disease and treated with powerful chemicals to kill viruses.

Unfortunately, the transmission of Creutzfeldt-Jakob disease (CJD), an always fatal neurodegenerative disease in humans similar to Mad Cow, has been documented in cases of human cadaver dural grafts. However, most of these cases occurred in Japan and were traced to a single brand produced before May, 1987.

The Centers For Disease Control in the US (CDC) has issued a number of reports on this topic. According to the CDC, between 1996 - 2003, the Japanese government identified 97 cases of CJD transmitted through a human cadaver dural graft. Of these 97, 93 of the affected patients received their grafts before 1987 and it is likely that the remaining four patients were given grafts produced before 1987. All but 11 of the grafts were traced to a single brand (LYODURA) - the brand could not be identified definitely in the other cases - and this manufacturer changed their procedures in 1987 to reduce the chances of CJD transmission.

While the effects of CJD are catastrophic, it is important to keep the relative risk in perspective. During the time period in question, there were over 100,000 LYODURA grafts used in Japan. Also, that specific brand was never intended to be distributed in the US, and very few have ever been used here. In 1997, a US Food and Drug Administration Advisory Committee recognized that using human cadaver dura carries an inherent risk for transmitting CJD, but went on to recommend that using such grafts be left to the discretion of the neurosurgeons, provided that the grafts are processed using acceptable safety measures. Interestingly, according to the CDC report an estimated 4,500 such dural grafts were distributed in the US in 1997, but after the FDA recommendation this number dropped sharply to only 900 in 2002.

There is no definitive answer as to what type of dural graft is best for Chiari surgeries, and there may never be. It is clear however, that since patients must literally live with the decision, they may want to find out what is being put into their head and why.

# Table 1: Comparison Of Complication Rates & Operating Time Between Human Cadaver & DuraGen Grafts

	DuraGen Graft (56)	Cadaver Graft (45)
Pseudo-meningocele	5	5
Infection	2	1
CSF Leak	1	1
Reoperation	4*	2
Avg. Operating Time (min)	92	129

Notes: \* Includes 3 patients already counted with other complications

#### **Related C&S News Articles:**

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