Experience with acellular human dura and bovine collagen matrix for duraplasty after posterior fossa decompression for Chiari malformations

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Object. Posterior fossa decompression with duraplasty is routinely used for the treatment of Chiari malformations. It has been traditionally believed that this procedure requires a watertight seal with primary closure of the dura with either pericranium or allograft. In this study, the authors evaluated two synthetic dural substitutes in this patient population for feasibility of use and identification of perioperative morbidity.

Methods. The authors evaluated 56 patients who underwent duraplasty with a synthetic collagen matrix (DuraGen) after suboccipital craniectomy and C-1 laminectomy, and 45 patients in whom the dural closure involved acellular human dermis (AlloDerm). Patients in both groups were assessed for the presence of a pseudomeningocele, wound infection, cerebrospinal fluid (CSF) leak, and the need for repeated operation either for wound revision or the placement of a ventriculoperitoneal shunt. Operative times for which DuraGen duraplasty was used were compared with those for AlloDerm closure.

In the DuraGen group, complications included five pseudomeningoceles (8.9%), two wound infections (3.6%), one CSF leak (1.8%), and four repeated operations (three shunt revisions and one reexploration; 7.1%) in nine patients. In the AlloDerm group, there were five pseudomeningoceles (11.1%), one wound infection (2.2%), one CSF leak (2.2%), and two repeated operations (two shunt revisions; 4.4%) in seven patients. The operative time associated with DuraGen was significantly shorter than that of duraplasty that required closure with sutures (92 minutes compared with 128 minutes, p < 0.01).

Conclusions. The synthetic dural substitutes DuraGen and AlloDerm provide a suitable alternative duraplasty with comparable complication rates. DuraGen requires a significantly shorter operative time than AlloDerm.

KEY WORDS • Chiari malformation • posterior fossa surgery • dural substitute • duraplasty • DuraGen • AlloDerm • pediatric neurosurgery

CHIARI malformations are associated with a small posterior fossa.20,24 Surgical management must address this anatomical abnormality, which usually requires dural enlargement. Traditionally, a watertight dural closure was considered imperative to minimize the risks of CSF fistulas, infections, hindbrain herniation, cortical scarring, and adhesions.25 Numerous materials have been advocated for achieving this watertight duraplasty, including autologous, allograft, xenograft, and synthetic materials.3,4,9,17,21,22,25 Despite several decades of experimentation and investigation of a wide range of materials, no consensus has been reached on the ideal dural substitute.

DuraGen (Integra Neuroscience, Plainsboro, NJ) is a type I collagen matrix graft manufactured from bovine Achilles tendon. It is an onlay graft that does not require sutures. We report the results in a consecutive series of 56 patients in whom this collagen matrix was used for duraplasty after posterior fossa decompression for the treatment of CMs. We compared this group with patients in whom closure was performed with an acellular human dermis allograft, AlloDerm (LifeCell Corp., Branchburg, NJ), in terms of complications and operative time. In addition we reviewed the complication rates associated with various duraplasty procedures reported in the literature. The goal of this study was to determine whether DuraGen could yield complication rates comparable to duraplasty with a watertight dural closure, while significantly reducing the operative time.

Clinical Material and Methods

Patient Population

A retrospective review of the surgical records from the Division of Neurosurgery, Children’s Hospital of Philadelphia between January 2002 and September 2004 was performed. A total of 56 patients with surgically treated CM Types I and II were identified. All patients who underwent
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posterior fossa decompression and duraplasty with collagen matrix graft were included in this study, regardless of associated conditions or previous operations. The AlloDerm group consisted of 45 patients treated for CMs prior to the introduction of collagen matrix grafts in our institute.

All patients were treated in the inpatient service of the Children’s Hospital of Philadelphia. Preoperative imaging studies included an MR image of the complete neuraxis in all patients. The ventricular size was evaluated and if hydrocephalus was seen, a ventriculoperitoneal shunt was placed prior to posterior fossa decompression.

Surgical Procedure and Follow Up

A standard approach to the surgical procedure was used in each patient. Variables included the extent of the laminectomy and the need for tonsillar resection. The patient was placed prone in a Mayfield headrest. A midline incision was made, exposing the occipital bone inferior to the inion and the posterior arch of C-1. The craniectomy included the whole posterior rim of the foramen magnum and extended superiorly approximately 3 to 4 cm. The piece of bone that was removed was trapezoidal, in that the superior width was slightly larger than at the foramen magnum. The dura was opened in a Y-type fashion, the arachnoid was opened, and the tonsils were identified. In each case, the tonsils were reduced in size using bipolar cautery. When this strategy did not produce spontaneous CSF flow from the fourth ventricle, the caudal portion of one or both tonsils was resected. Decompression was considered adequate when spontaneous CSF flow was visualized. A collagen matrix graft was cut to the size of the craniectomy and placed on top of the dural defect. The collagen matrix was irrigated to promote conformity to the cerebellar surface and dural edges (Fig. 1). The incision was closed in multiple layers, and skin closure was performed with a running 4-0 Monocryl suture. No drains were placed.

In the AlloDerm group, acellular cadaveric dermal matrix was used to perform the duraplasty. The dermal matrix was cut to size and sutured to the dural edges with 4-0 nylon suture material to obtain a watertight closure. All other aspects of the procedure were identical.

Patients routinely recovered in the pediatric intensive care unit. Antibiotic agents were given for the first 24 hours postoperatively. Steroid drugs were not given, and no drains were used. The duration of hospital stay for most patients was 2 to 4 days. Patients were followed up at 1 month postoperatively, and then at routine intervals thereafter. Postoperative imaging was not obtained unless clinically indicated.

Both groups were evaluated for surgical complications. The specific complications analyzed included the following: 1) clinically evident pseudomeningocele; 2) wound infection; 3) CSF leak; and 4) the need for repeated operation for any reason. A clinically evident pseudomeningocele was defined as any protuberance that was bothersome to the patients or parents, and that was either painful or cosmetically unacceptable. When information on surgical complications was incomplete, patients were telephoned to evaluate their postoperative course. All patients eventually experienced clinical improvement. Only patients who did not experience clinical improvement were further evaluated using MR imaging. As a result, the effect of surgery on syringes with either of these techniques was not evaluated. The operative times were recorded based on the perioperative anesthesia reports for both groups.

Statistical Analysis

For statistical analysis, the complication rates were compared for significance between the two groups using chi-square analysis. Operative times between the two groups were compared using an unpaired t-test.

Results

Patient Characteristics

A total of 101 children were treated for CM at the Children’s Hospital of Philadelphia during the study; 96 children had CM Type I and five had Type II. DuraGen duraplasty was performed in 56 children, whereas AlloDerm was used in 45 children. There was a slight female preponderance: 55 girls (55%) and 46 boys (45%). Ages at presentation ranged from 1 to 19 years (mean 9 years). The follow-up period ranged from 1 to 24 months (mean 10 months).

Postoperative Complications

A chi-square analysis revealed no significance in the rates of complications between the collagen matrix graft and allo-graft group.

DuraGen Group. Clinically evident pseudomeningoceles were diagnosed in five patients (8.9%). Three of the patients complained that the pseudomeningocele was cosmetically displeasing, but did not complain of pain or tenderness at the incision site. One patient had a “fluctuating” pseudomeningocele that worsened at nighttime, in the recumbent position, and during episodes of crying. A shunt was placed in one patient in an attempt to treat the pseudomeningocele, but the size of the pseudomeningocele did not decrease postoperatively.

Two patients (3.6%) had postoperative wound infections. One patient presented 4 weeks after surgery with symptoms of meningitis and a superficial wound dehiscence. The patient was given intravenous antibiotic agents against Staph-

Fig. 1. Intraoperative photograph after application of DuraGen.
Staphylococcus epidermidis and dressing changes to the wound. The other patient presented with a superficial dehiscence and serosanguineous drainage from the wound. This patient underwent wound exploration and revision. No evidence of a CSF fistula was found at the time of surgery. Three weeks later, the patient presented with S. aureus meningitis, which was treated with intravenous antibiotic agents. Whether either of these infections was directly related to the use of DuraGen was unclear. One patient (1.8%) presented 1 week after surgery with increased irritability and decreased oral intake. A head CT scan revealed prominent ventricles at that time. A CSF leak developed, which was treated with a ventriculostomy. Once cultures were determined to be negative, the shunt was internalized. The patient had a persistent CSF leak after shunt placement, at which time the wound was oversewn at the bedside. Four patients (7%) required operations after their initial decompression. Three of these patients have been described earlier. The fourth patient presented 1 week after surgery with headaches, nausea, and vomiting. A head CT scan revealed hydrocephalus, and a shunt was placed. All four patients recovered without further complications.

**AlloDerm Group.** Five patients (11.1%) presented with clinically evident pseudomeningoceles. Three patients complained that the pseudomeningocele was cosmetically unacceptable, but denied any pain, tenderness, or fluctuations. One patient (2.2%) presented with an associated superficial wound infection that was treated with dry dressing changes and oral antibiotic agents. Another patient presented with a CSF leak that was treated definitively with a lumbar drain. Two patients (4.4%) had intractable headaches postoperatively, and were found to have hydrocephalus. Both patients underwent ventriculoperitoneal shunt placement and experienced complete resolution of symptoms.

**Operative Time**

The mean operative time for the 56 patients who underwent duraplasty with collagen matrix graft was 92 ± 24 minutes (standard deviation; median 92 minutes). For the 45 consecutive patients who underwent allograft duraplasty prior to the introduction of the collagen matrix graft, the mean operative time was 129 ± 45 minutes (standard deviation; median 120 minutes). Analysis using an unpaired t-test revealed statistical significance with alpha set at a probability value less than 0.01.

**Discussion**

In this paper we demonstrated the use of a synthetic collagen matrix and acellular human dermal graft after posterior fossa decompression for CM. The complication rates were similar between the groups, although the operative time was significantly shorter in the DuraGen group. To date, we have not observed any specific graft-related complications.

The surgical technique of posterior fossa decompression for CM varies. The operative considerations include extent of bone removal including the C-1 arch, dura opening, and extent of intradural manipulation. With respect to the dura, most surgeons open it with or without the use of intraoperative ultrasonography. Recently, the technique of dural scoring has been reported with encouraging results; however, the case numbers remain small. Thus, we continue to open the dura in all of our patients to definitively expand the subarachnoid space at the craniocervical junction.

We chose to evaluate only complications that could be directly attributed to or associated with the type of closure. These are the perioperative problems that are the most practical to consider, because they mandate further care and additional invasive procedures. These complications might have occurred at similar rates regardless of the type of duraplasty used, as is evidenced by the morbidity rate attributable to leaving the dura open. Indeed, the complication rates were found to be similar between the AlloDerm and DuraGen groups.

A variety of materials have been used for duraplasty. Of note, although most surgeons advocate dural closure to decrease the risk of CSF leak, cortical scarring, and aseptic meningitis, some report good results without performing any dural closure. The ideal material would be available in abundance, relatively inexpensive, easy to handle, nonimmunogenic, and biodegradable. Materials that had been used include rubber and gold foil in the late 1800s, gelatin products in the mid-1900s, and synthetics such as silicone in the 1980s. Silastic dural grafts have an increased incidence of hemorrhage associated with their use, even years after implantation. Although many investigators have examined the use of various duraplasty techniques in the posterior fossa, most have not associated specific complications with the type of dural closure. Data from studies in which the authors have noted complications as a result of the closure are summarized in Table 1 and are compared with the findings in the present study.

Analysis of laboratory studies indicates that AlloDerm is completely incorporated by 3 weeks and is characterized by intense fibroblast invasion and organized collagen formation. Neovascularization and neoepithelialization have also been documented after AlloDerm implantation in clinicohistological studies. Collagen fibers are shown to be thickened immediately after rehydration of the collagen matrix graft. Fibroblast proliferation within the matrix is evident within 2 weeks. Two months postimplantation, the trabecular framework of the graft is filled with endogenous collagen. Because incorporation of both acellular cadaveric and collagen matrix grafts seems to take at least 2 to 3 weeks as indicated by laboratory studies, the grafts cannot be relied on to prevent CSF leakage through the wound during the perioperative period. Furthermore, in our experience the development of hydrocephalus after dura closure is a strong determinant of whether CSF transit through the wound will occur, regardless of wound integrity.

Concern remains regarding transmission of infectious agents whenever synthetic or human products are used. Blood samples from each skin donor of acellular human dermis are screened for hepatitis B and C, human immunodeficiency virus types 1 and 2, human T-cell leukemia virus types I and II, and syphilis. The collagen matrix graft is classified as a class IV material, which means there is no detectable infectivity for bovine spongiform encephalopathy. Furthermore, a sodium hydroxide treatment method is used that has been shown to inactivate several viral strains, including human immunodeficiency virus. The transmission of Creutzfeldt–Jakob disease has been documented in cases in which cadaveric dura mater grafts have been used, and this infection remains a major potential risk that needs to be considered.
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TABLE 1  
Literature review of complications associated with type of duraplasty*

<table>
<thead>
<tr>
<th>Authors &amp; Year</th>
<th>Graft Material</th>
<th>Total</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fischer, 1995; Vanaclocha &amp; Saiz-Sapena, 1997</td>
<td>pericranium</td>
<td>32</td>
<td>0</td>
</tr>
<tr>
<td>Kosnik, 1998</td>
<td>ligamentum nuchae</td>
<td>200</td>
<td>0†</td>
</tr>
<tr>
<td>Parizek, et al., 1989, 1994; Filippi, et al., 2001</td>
<td>xenogeneic pericardium</td>
<td>74</td>
<td>1†</td>
</tr>
<tr>
<td>present study</td>
<td>DuraGen</td>
<td>56</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>AlloDerm</td>
<td>45</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>w/ Wound Infection</th>
<th>w/ Pseudo-meningocoele</th>
<th>w/ CSF Leak</th>
<th>w/ Repeated Op</th>
<th>Overall Morbidity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fischer, 1995; Vanaclocha &amp; Saiz-Sapena, 1997</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kosnik, 1998</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Parizek, et al., 1989, 1994; Filippi, et al., 2001</td>
<td>0†</td>
<td>1†</td>
<td>0†</td>
<td>NC</td>
<td>9/56 (16)</td>
</tr>
<tr>
<td>present study</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>7/45 (16)</td>
<td></td>
</tr>
</tbody>
</table>

* NC = not calculated, due to lack of reported complications; NR = not reported.
† Some studies did not report specific complications.

Autologous pericranium appears to be associated with the lowest rate of complications. It is nonimmunogenic, inexpensive, with decreased incidence of CSF leaks and wound infection.12 In children, however, harvesting sufficient pericranium from the posterior fossa region can be difficult. Although ligamentum nuchae has been used without any reported associated morbidity, this material would have to be validated in a prospective, blinded trial. In addition, ligamentum nuchae would be just as difficult to harvest as pericranium. The harvesting of pericranium or ligamentum nuchae has an associated learning curve, which, once overcome, may not be an important factor in determining closure technique. The apparent lower morbidity and reduced cost may offset the increased operative time and may be a more favorable alternative for dural closure in the posterior fossa.

We do not routinely obtain postoperative images in patients with CM. In patients who do undergo postoperative MR imaging, however, we have observed an expanded subarachnoid space at the craniocervical junction.

Limitations of our study include sample size (56 patients) and mean follow-up period (10 months). In addition, a more suitable control would have been comparison of both groups with the use of pericranial or other autologous closure technique. This limitation notwithstanding, after using DuraGen we have observed a complication rate lower than or comparable to that of other materials.

In our series, we have effectively used an onlay collagen matrix graft for duraplasty following posterior fossa decompression. Because no suturing was required, the operative time was significantly shortened. Operative times for patients receiving a collagen matrix graft compared with sutured allograft patch were a mean of 37 minutes shorter (p < 0.01). This difference would be intuitively greater in patients who undergo harvesting of pericranium.

We are not stating that DuraGen in some way alleviates the Chiari syndrome, but that the material is a suitable alternative for a duraplasty. In addition, we chose to analyze patients with CM only to limit the amount of variability in the operative procedure, and because most of these children are otherwise healthy. Furthermore, a randomized clinical trial using a larger sample size comparing collagen matrix graft with other means of duraplasty is needed to further assess its utility.

Conclusions

The use of both AlloDerm and DuraGen for duraplasty in the posterior fossa is associated with moderate morbidity. Although the associated complications did not result in any long-term clinical deficit, they sometimes lengthened the postoperative recovery. Both AlloDerm and DuraGen can be used safely without excessive risk to the patient if the surgeon is willing to accept the overall rate of morbidity.

Disclaimer

None of the authors has any financial interest in the materials or methods used, nor in any of the manufacturers mentioned in this report.

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