Collagen matrix duraplasty for cranial and spinal surgery: a clinical and imaging study

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Object. The repair of dural defects is controversial in contemporary neurosurgery. To date, collagen-based products remain a continued area of interest in the development of dural grafts. The authors conducted a prospective case–control study in which they evaluated collagen matrix in the repair of dural defects following cranial and spinal surgery by using specific clinical and magnetic resonance (MR) imaging outcome measures.

Methods. Enrolled in the study were 79 patients, 36 male (45.6%) and 43 female (54.4%), with a mean age of 53 ± 15.8 years. The pathological diagnosis was brain tumor in 49 cases (62%), vascular conditions in 16 (20.2%), degenerative spine in 10 (12.7%), trauma in two (2.5%), and other in two (2.5%). Most of the patients underwent supraorbital craniotomy (57; 72.2%), whereas 11 patients (13.9%) each underwent posterior fossa and spinal surgery. Sixty-three patients (79.7%) completed the study, which included clinical and MR imaging evaluations at 3 months postsurgery. There were no cerebrospinal fluid (CSF) leaks or delayed hemorrhages. The neurosurgical wound infection rate was 3.8%: superficial wound infection in two cases and deep infection and brain abscess in one case (recurrent brain tumor following radiation therapy).

Among the 63 patients in whom 3-month postsurgery imaging data were available, asymptomatic small pseudomeningoceles were detected on MR imaging in two (3.2%); a minor subgaleal fluid collection, which resolved spontaneously, was apparent in another patient (1.6%). Nonspecific dural enhancement was demonstrated on images obtained in seven patients (11.1%), and asymptomatic spinal epidural enhancement was observed on images obtained in two of three patients who had undergone lumbar laminectomy for spinal stenosis.

Conclusions. When used as a dural onlay graft, collagen matrix had a 100% CSF containment rate but might be associated with occult radiological abnormalities.

Key Words • collagen matrix • dural graft • duraplasty • spine

Neurological and spine surgeons not infrequently must use dural grafts when primary closure cannot be achieved because of dural retraction and shrinkage, which can occur with the coagulation of bleeding points on the dura mater, with expansion of the craniovertebral junction (Chiari malformations), when the dura must be left open to accommodate brain swelling (for example, decompressive craniectomy), or when the dura must be excised because of neoplastic infiltration. Interest in the repair of dural defects has increased to minimize or prevent postoperative meningocerebral adhesions and seizures; thus, many synthetic materials and processed membranes have been tested. Many were abandoned because of complications, namely, excessive tissue reaction and inflammation, host tissue encapsulation and fibrosis, and/or delayed hemorrhage. Although autologous grafts have been commonly used, collagen as a dural replacement material was utilized as early as 1965. Collagen is known to be chemotactic with regard to fibroblasts and promotes rapid recolonization of the collagen implant by the host. A collagen sponge, derived from bovine flexor tendons, has been shown to have excellent wet strength, is pliable, and molds easily to the brain surface. We have reported on our previous experience with a collagen sponge in cranial, spinal, and posterior fossa surgery for duraplasty. The current prospective study was undertaken to evaluate the safety, clinical efficacy, and neuroimaging characteristics of collagen matrix when used as a dural substitute in dural repair.

Clinical Material and Methods

A prospective case–control clinical and imaging-based study was conducted at three sites. Institutional review board approval and informed consent were obtained at each of the investigative sites: Health Sciences Center, General Hospital, Winnipeg, Canada; Winnipeg Children’s Hospital, Winnipeg, Manitoba, Canada.
Winipeg, Canada; and Hamilton Health Sciences Corporation, Hamilton, Canada. Patients undergoing cranial and spinal surgery in which a dural graft was necessary, as determined by the attending surgeon, were entered into the study. The inclusion criteria were cranial or spinal surgery in which a dural graft was appropriate; posterior fossa surgery; brain swelling during surgery or if anticipated in the postoperative period; decompressive craniotomy for acute brain swelling (that is, infarcts); laminectomy resulting in pinhole leaks or tears in the spinal dura; and repair of spinal dura after tumor resection.

The preoperative clinical laboratory tests included a complete electrolyte panel, liver function tests, blood lipid profile, full blood count with differential, prothrombin time, partial thromboplastin time, and urinalysis, and the results were compared with data obtained 3 months postsurgery. All patients underwent MR imaging or CT, depending on the emergency nature of the surgery and/or the patient’s condition. All patients were classified into five distinct categories, according to their potential for suffering sepsis, which was indicated by the level of contamination present at the time of surgery. Clinical, surgical, and Outcome Information

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The most common pathological diagnosis was brain tumor, accounting for 49 patients (62%), whereas vascular conditions occurred in 16 (20.2%) and degenerative spinal disorders in 10 (12.7%; Table 2). Most of the patients (57 [72.2%] of 79) underwent supratentorial craniotomy, whereas 11 patients (13.9%) each underwent posterior fossa surgery and spinal surgery. Clinical laboratory test results (mean values) revealed no significant difference between the preoperative data compared with the findings obtained at 3 months postsurgery.

Successful closure of the dura with no graft failure was achieved in all 79 patients (100%). Large dural defects requiring collagen matrix for dural repair were encountered mainly in the cranial surgeries (85.3%), whereas smaller defects (pinhole and < 1 cm) occurred predominantly in spinal surgery (63.6%; Table 3). Closed suction wound drainage was used in 28 (35.4%) of 79 patients. There was no delayed hemorrhage related to the use of collagen matrix.

Infectious Complications

Most of the cases (32 cases [40.5%]) were classified as “clean,” whereas nine cases (11.4%) were classified as “clean with foreign body.” Among the 34 cases in the “clean, contaminated” group, foreign bodies had entered 13 (38.2%) during or just before surgery. A single case was classified as “dirty.” Neurosurgical wound infections were recorded in three patients (3.8%; Table 2). One of these patients, a 53-year-old man in the clean, contaminated group, underwent craniotomy for removal of a brain tumor with a large dural defect requiring collagen matrix for dural repair. Although he suffered a mild superficial wound (scalp) infection, he was successfully treated using intravenous cloxacillin despite no organism isolation. A second patient, a 71-year-old man whose case had been typed as contaminated, also had a mild superficial wound infection following a craniotomy for evacuation of a spontaneous intracerebral hematoma. He was treated empirically with intravenous amoxicillin; no organism was isolated from the wound. The third patient, a 36-year-old man, underwent a clean craniotomy for resection of a recurrent brain tumor. On Day 14 postsurgery, a wound infection (Staphylococcus aureus) was detected and treated with intravenous cloxacillin. This patient underwent additional procedures to remove an osteitic bone flap on postoperative Day 22 and again on Day 32 to drain a brain abscess. He had a poor Karnofsky Performance Scale score, mostly due to his primary brain tumor.

<table>
<thead>
<tr>
<th>Table 1: Preexisting neurological history, conditions, and surgery in 52 patients</th>
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<tbody>
<tr>
<td>Previous Neurological Condition</td>
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<tr>
<td>---------------------------------</td>
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<tr>
<td>past trauma</td>
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<tr>
<td>tumor</td>
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<tr>
<td>epilepsy</td>
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<tr>
<td>acute seizure disorder</td>
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<tr>
<td>previous dural repair</td>
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<tr>
<td>craniotomy</td>
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<tr>
<td>bur holes</td>
</tr>
<tr>
<td>spinal surgery</td>
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<tr>
<td>ventricular drain (preop insertion &lt; 24 hrs)</td>
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<tr>
<td>other</td>
</tr>
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Results

Clinical, Surgical, and Outcome Information

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and he did not complete the 3-month postsurgery MR imaging and clinical evaluations.

Another 16 (20.3%) of 79 patients had the following extracranial infections: chest, eight patients; urinary tract, six patients; other, two patients; combined chest and urinary tract infection, one patient; repeated urinary tract infection, one patient.

**Imaging Evaluation**

Gadolinium-enhanced MR images at 3 months postsurgery could be obtained in only 63 patients (79.7%; Fig. 1 and Table 4). Asymptomatic but radiologically apparent pseudomeningoceles were documented in two patients (2.5%). One of these patients was a 46-year-old man who had undergone a posterior fossa craniectomy for clipping of a cerebral aneurysm (Fig. 1B) and whose 3-month postoperative MR imaging study demonstrated a 3-cm incidental pseudomeningocele. A second patient underwent a lumbar laminectomy for spinal stenosis. A small (<1 cm) incidental durotomy occurred at the time of surgery. This patient had an uneventful recovery. The 3-month MR image was suspicious for a possible pseudomeningocele. There was no CSF leakage, bogginess, or swelling over the surgical site in either of these patients. In both of them, the attendant surgeon had used closed suction wound drainage.

Subdural fluid collections were detected under craniotomy sites in two patients that had undergone craniotomy (for clipping of a cerebral aneurysm and for a subacute subdural hematoma; Fig. 1C). Closed suction wound drainage systems were used in both patients. An asymptomatic, small subgaleal fluid collection was seen in one patient who had undergone craniotomy for excision of a brain tumor without additional treatment. No closed suction wound drainage system was used in this patient. Among three patients who had undergone lumbar laminectomy for spinal stenosis, 3-month postsurgical MR imaging studies revealed epidural enhancement in two asymptomatic and one symptomatic patient (Fig. 1D). This latter patient was a 76-year-old woman who had a failed–back surgery syndrome after repeated decompression and pedicle screw fixation and who had presented with persistent posterior thigh pain without any clinical or radiological features of arachnoiditis.

**TABLE 3**

<table>
<thead>
<tr>
<th>Size of Defect</th>
<th>Cranial Surgery</th>
<th>Spinal Surgery</th>
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<tbody>
<tr>
<td>pinhole</td>
<td>1 (1.5)</td>
<td>2 (18.2)</td>
</tr>
<tr>
<td>small (&lt;1 cm)</td>
<td>3 (4.4)</td>
<td>5 (45.5)</td>
</tr>
<tr>
<td>medium (1–2 cm)</td>
<td>6 (8.8)</td>
<td>3 (27.3)</td>
</tr>
<tr>
<td>large (&gt;2 cm)</td>
<td>58 (85.3)</td>
<td>1 (9.1)</td>
</tr>
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</table>

**Failure to Complete 3-Month Clinical and Imaging Evaluations**

Sixteen (20.3%) of 79 patients did not complete the study and/or did not undergo the clinical and Gd-enhanced MR imaging evaluations 3 months after surgery. Seven deaths (8.9%) were recorded, five of which were due to preexisting malignancies; one patient died of systemic septic sequence after hip surgery, whereas another patient died of unknown causes. An additional three patients with brain tumors had low postoperative Karnofsky Performance Scale scores and were considered too ill to undergo the MR imaging study at 3 months postsurgery. Another six patients did not undergo the 3-month postsurgical MR imaging study for the following reasons: lost to follow up (one patient); voluntary patient withdrawal (one patient); contrast media–related allergy (one patient), failure to administer imaging study (one patient), claustrophobia (one patient), and study site closure (one patient).

**Discussion**

The optimal method of dural closure and/or repair remains a contentious issue with diverse opinions in contemporary neurosurgery. Nonetheless, one surgical paradigm has remained constant, that is, reconstruction of the anatomical barriers that house the brain after surgery. Some surgeons advocate watertight dural closure, and if dural loss or the inability for complete closure exists, nonporous grafts are then sutured in place to reconstitute the integrity of the dura and thus prevent CSF leakage. However, there is doubt as to whether a watertight closure is indeed achieved in the majority of these cases. When grafts have been used, fibroblasts appear to make use of the holes made by the suturing needle to make a repair. During the past 75 years, it has become clear that watertight dural closures may not prevent CSF leaks.

To the best of our knowledge, in 1978 James R. van Dellen (Department of Neurosurgery, Baragwanath Hospital, Johannesburg, South Africa) first introduced the collagen sponge into neurosurgical clinical practice as a dural onlay graft (personal communication, 1988). Extensive clinical experience has been gained over the past 20 years, and the use of the collagen sponge has been experimentally examined and clinically evaluated in various neurosurgical cases with a variety of pathological entities. Collagen matrix,
evolved from a collagen sponge, has an optimized pore size for fibroblast ingrowth and enhances natural biological healing by its 3D matrix structure, thereby encouraging dural repair through the matrix instead of encapsulation, which can occur with synthetic grafts.

The present multicenter case–control study was prospectively conducted to evaluate the safety and efficacy of collagen matrix for duraplasty in general neurosurgical and spinal procedures while incorporating a wide range of disease processes— from tumors to vascular disorders and degenerative spinal cases. In addition to the clinical observations, our Gd-enhanced MR imaging–based data revealed potential and/or occult complications that were clinically apparent, as in 15 (23.8%) of 63 patients at the 3-month postsurgical evaluation.

An important property of any dural graft is its ability to prevent the formation of CSF fistulae or leaks. Collagen matrix was effective in repairing the dural defect in 100% of patients, completely in more than 98% of patients, with no graft failures. Collagen matrix was almost uniformly successful in dural repair for supratentorial surgery, which accounted for the majority of the procedures.

Fig. 1. Three-month postsurgical MR images. A: Sagittal MR image showing a posterior fossa craniectomy for meningioma removal and repair of the dura with a collagen matrix graft. B: Sagittal T₁-weighted MR image demonstrating a pseudomeningocele in an asymptomatic patient who had undergone a posterior fossa craniectomy for clipping of an aneurysm. C: Axial T₂-weighted MR image revealing a small, localized collection below the bone flap in an asymptomatic patient after a craniotomy for a subacute subdural hematoma. D: Sagittal Gd-enhanced T₁-weighted MR image exhibiting epidural granulation tissue in an asymptomatic patient who underwent lumbar decompression for stenosis and required collagen matrix duraplasty for a small dural tear. E: Axial T₁-weighted Gd-enhanced MR image showing dural enhancement in an asymptomatic patient after a craniotomy for clipping of an aneurysm.
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performed (72.2%) in the present study, and is ideal for supratentorial convexity surgery for which there is minimal or no hydrostatic pressure on the graft. These results are evidenced by the low complication rate, that is, the infection rate: three (3.8%) of the 79 patients enrolled in the study, three (4.8%) of the 63 patients who completed the study, and three (5.3%) of the 57 cranial cases. A greater challenge for a dural graft involves the posterior fossa, for which complication rates of up to 34% have been noted.26,27,38,40,42,47,50 Vanaclocha and Saiz-Sapena50 described their frustration in dealing with posterior fossa duraplasty while using cadaveric dura. They reported a 15.8% CSF leakage rate and a 46% clinical rate of pseudomeningoceles that required repeated treatments and up to 1 year to resolve. Even in the context of synthetic dural grafts and seemingly watertight closure, pseudomeningoceles can occur. In our previous experience with a collagen sponge, a 4.8% CSF leakage rate was observed.26,38 Based on our current experience, collagen matrix is suitable for use in the posterior fossa as it can be easily cut to the shape of the dural defect and applied as an onlay graft without the inconvenience and time-consuming process of suturing. It also provides a low-pressure absorptive surface for fluid resorption and thereby creating an initial chemical seal (fibrin and blood products), which closes the CSF space within the first 4 to 8 hours of surgery. Fibroblast proliferation begins at 3 to 4 days and is fully established at 14 days postsurgery.28 The closed suction wound drain provides a negative pressure of up to 8 mm Hg, thereby removing any fluid accumulations and allowing for the approximation of the underlying tissues to obliterate the dead space. In the present study, 13.9% of the patients underwent posterior fossa surgery, and in contrast to other reported study data, neither CSF leaks nor clinical pseudomeningoceles were observed. The only recorded anomaly was the radiologically apparent 3-cm pseudomeningocele at the 3-month MR imaging evaluation in a patient who had undergone a posterior fossa craniotomy.

Subdural fluid collections were detected under craniotomy bone flaps in two patients (one case involving aneurysm clipping; and the other, a subacute subdural hematoma). Postoperative fluid collections under an intact surgical wound could represent CSF, an organizing blood clot, or a seroma and could manifest clinically as boggy swelling, especially over the posterior fossa and spine. Overall, these complications have been reported in 2 to 13% of duraplasties,17,21,24,38,40,42,47,50 However, incidental pseudomeningoceles or pseudocysts often have been observed in clinically asymptomatic patients on follow-up CT or MR imaging studies. Despite undertaking watertight dural closure, Parizek and colleagues40 reported a clinical pseudomeningocele rate of 2.3%. The current study included only two patients (2.5%) with clinically asymptomatic but radiologically apparent pseudomeningoceles, and a third patient had a minor, clinically insignificant subgaleal fluid collection that spontaneously resolved with time. After spine surgery, a symptomatic incidental seroma was detected on an MR image obtained in only one patient. Collagen matrix, when used as an onlay graft, had a 100% closure rate. These findings are similar to our recently reported data on spinal dural repair.56

The risk of postoperative wound infection is particularly important and has been used as a barometer of the efficacy of a dural graft in resisting infection and in serving as a barrier to the spread of sepsis, which is particularly important given that collagen matrix is porous. In the present study, specific criteria were used to place patients into five categories according to their propensity to incur an infection, as previously described.7,18,30,38,40,43 The overall neurosurgical wound sepsis rate was 3.8% (three patients). Two patients had a superficial wound infection that responded to antibiotic agents, whereas one patient who had undergone recurrent surgery for a malignant glioma after radiotherapy had a deep suppurative infection (brain abscess). This subgroup has a higher risk of infection: 10%.39 Further case type analysis was not required because of the low infection rate. Our current experience is highly comparable with our previous experience with a collagen sponge, when the neurosurgical wound infection rate after craniotomy was 6.1%.38 These results are similar to the reported experience with other materials used for duraplasty procedures, for example, Lyodura 3, 6, and 11%, as cited by others.32,34 Therefore, our current evaluation of collagen matrix confirms that dural grafts do not unduly influence neurosurgical wound infections.21,38–41

Delayed subdural hemorrhage with neural compression has been notoriously related to silastic dural grafts. These grafts undergo encapsulation and neomembrane formation together with hemorrhage from neocapillaries.1,4,19,24,25 This complication was not observed with collagen matrix because, as with a collagen sponge, dural repair occurs through the graft matrix without encapsulation or neomembrane formation.

An 11.1% (seven of 63 patients) dural enhancement rate was recorded in the present study, which is much lower than that in other reports.8,40,41 Abnormal dural enhancement has been observed in 50 to 99% of patients undergoing surgery and may be due to a nonspecific inflammatory process or chemical arachnoiditis caused by bleeding in the subarachnoid space at the time of surgery. This enhancement can persist in 50% of patients at 1 to 2 years from surgery; therefore, dural enhancement was not considered pathological.8,26,27,31,45

Epidural fibrosis may not always correlate with clinical symptoms; consider, for example, previously reported data revealing that up to 20% of asymptomatic patients demonstrate some epidural fibrosis at 6 weeks from surgery.8,11,13,16,28,29,40,49,51 Similarly, in two of the asymptomatic patients in the present study, mild epidural fibrosis apparent on 3-month postsurgery MR images was not regarded as pathological. In a third patient, however, the possibility of moderate epidural scarring in the production of symptoms could not be conclusively ruled out. In contrast, in experimental studies conducted in 1995, Jimmin49 showed that a collagen sponge limited the adhesions to the dura and prevented scar formation.

An ideal dural substitute should have the following char-

**TABLE 4**

**Magnetic resonance imaging findings at 3 months postsurgery in 63 patients**

<table>
<thead>
<tr>
<th>Finding</th>
<th>No. of Patients (%)</th>
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<tbody>
<tr>
<td>pseudomeningocele</td>
<td>2 (3.2)</td>
</tr>
<tr>
<td>subdural collection (below graft)</td>
<td>2 (3.2)</td>
</tr>
<tr>
<td>subgaleal collection</td>
<td>1 (1.6)</td>
</tr>
<tr>
<td>dural enhancement</td>
<td>7 (11.1)</td>
</tr>
<tr>
<td>epidural enhancement (spine)</td>
<td>3 (4.8)</td>
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acteristics: induce as little inflammatory and/or immunogenic response as possible; produce little or no adhesions to the underlying brain; prevent CSF leakage; and be resistant to infection, nontoxic, free of any complications, and cost-effective. In 1995, Ernestus and colleagues reported a graft complication or failure rate of 13% in more than 2000 patients who had undergone both cadaveric (Lyodura) and autogenous (fascia lata) grafts over a 3-year period. This rate was lowered to 6.3% with the use of synthetic grafts. In contrast, in 1997 Parizek and colleagues revealed a 7.3% complication rate in patients who had undergone various forms of duraplasty. The authors of that study recorded two radiologically demonstrated pseudomeningoceles (2.5%), one radiologically proven subgaleal seroma (1.2%), and three neurosurgical wound infections (3.8%), thus making an overall complication rate of 7.6%. This rate is similar to that in the present study and supports our past experience in that a watertight dural closure is not mandatory in most dural repairs and does not lead to increased complications.

Conclusions

In this prospective study we used both clinical and specific MR imaging criteria to evaluate collagen matrix as a dural substitute. Collagen matrix has fulfilled the major requirements for a dural graft as it was able to prevent CSF leakage from surgical wounds in 100% of the patients; was safe, having no systemic effects; did not induce an inflammatory response or produce any adhesions to the underlying brain, as evidenced by MR imaging data; was resistant to infection, with wound infection rates comparable to those with other dural grafts; and was easy to use, needing no sutures, and thereby decreasing operating room time.

Disclosure

Dr. Narotam is a consultant for Integra Life Sciences (Plainsboro, NJ).

References

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