Original Article

The need in dural graft suturing in Chiari I malformation decompression: A prospective, single-blind, randomized trial comparing sutured and sutureless duraplasty materials

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Abstract

Background: This study compared the use of two commonly utilized dural closure techniques used in augmentation duraplasty for Chiari malformation I (CM I) and evaluated their efficacy and outcome in terms of quality of life assessments.

Methods: This prospective randomized study compared sutureless (DuraGen) and suturable (Dura-Guard) techniques in CM I decompression. Clinical parameters, cost analysis, and SF-36 Quality of Life Questionnaire (QLQ) were utilized to assess outcome.

Results: Thirty-four patients were enrolled. Average age was 38.7 ± 12.2 years (mean $\pm$ SD (Standard Deviation)) and 82% of patients were female. Sixteen patients received DuraGen and 18 Dura-Guard. Age and gender were similar among groups. Postoperative complications did not differ between groups. Operative cost and time were less for DuraGen, whereas hospital stay was less with Dura-Guard, neither was statistically significant. Average QLQ scores at months 1, 2, and 3 improved in both groups. Dura-Guard patients showed greater improvement in quality of life at month 2 ($P < 0.05$) but groups did not differ at final survey. All patient's physical health ($P < 0.005$) and function ($P < 0.005$) were significantly improved. Outcome did not differ between groups and all patients showed significant improvement ($P < 0.05$).

Conclusion: Both techniques are effective in reaching the goals of decompressive surgery for CM I and did not differ in quality of life at final survey. All patients showed significant improvement in physical function, physical health, and outcome following surgery. With all variables being equal the choice of duraplasty material may be based upon surgeon's preference.

Key Words: Chiari malformation, dural substitutes, duraplasty, outcome, posterior fossa

INTRODUCTION

Dura mater may be damaged as a result of trauma, surgery, or tumor involvement and its reconstruction traditionally involved use of harvested autologous membranes like the pericranium, fascia lata, or temporalis fascia. These native collagen grafts are immunologically accepted without rejection and/or reaction and get reconstituted with host

cells and supporting vasculature. Subsequently they are incorporated into host tissue. This biological response to the native tissue remains an ideal to which any other dural substitutes can be compared.[18] Over the past several decades, poor biological performance compared with native tissue has excluded many dural substitutes ranging from metal foils to various synthetic polymer sheets.[9,15-17,22-24] Xenogeneic collagen-based dural graft materials, such as DuraGen (Integra Life Sciences, Plainsboro, NJ, USA) and Dura-Guard (Synovis Surgical, St. Paul, MN, USA), have shown to be favorable alternatives to autografts.[5] These materials are composed of animal collagen tissue processed to remove immunogenic components for improved integration into patient's tissues.

Dura-Guard, derived from processed bovine pericardium, is a strong membranous implant that is sutured to the surrounding dura. DuraGen, in contrast, is a collagen matrix derived from bovine Achilles tendon and is implanted, without suture, as an on-lay graft to cover dural defects. To emphasize, DuraGen does not require suturing to the surrounding dura.[4,8,9,21]

In 1891, Hans Chiari first document 3 rhombencephalic congenital defects that are now classified as Chiari malformation Types I, II, and III.[3] Chiari Malformation I (CM I) is the mildest form of the disease and it is associated with a protrusion, of varying degrees, of the cerebellum through the foramen magnum.[19] Patients with symptomatic CM I tend to experience disequilibrium, dizziness, headaches, neck pain, double vision, difficulty swallowing, slurred speech, and loss of coordination.[20]

This study focuses on posterior fossa decompression for the treatment of CM I and the possible benefits of sutured vs. sutureless duraplasty in a surgery requiring an opening of the dura mater. The efficacy of DuraGen and Dura-Guard as dural substitutes in cranial and spinal surgery has been previously reported. The literature is distinctly sparse, however, on outcome and cost analysis data following posterior cranial fossa augmentation duraplasty utilizing the two dural substitutes.[13] To our knowledge, no one has explored the questions of whether suturing the dural patch is essential for reduction of complications or whether use of sutureless patches correlates with worse clinical outcomes.[8,10,21] To address these questions, we compared outcome, cost, operative and postoperative variables, and rates of complications in patients randomized to either DuraGen or Dura-Guard for dural closure during posterior fossa decompression in patients with CM I.

MATERIALS AND METHODS

Institutional review board and human subject protection
This research was conducted with approval and under the guidance of the University of Illinois at Chicago's (UIC)

Institutional Review Board. The study was listed at www.clinicaltrials.gov as NCT00741858.

All patients scheduled for CM I decompression surgery in the Department of Neurosurgery at our university, who met inclusion criteria and were approved for participation by the treating physician, were approached for enrollment and those who agreed to participate signed written informed consent.

Study subject inclusion and exclusion
Study subjects were included based upon the following criteria: >18 years of age; clinical diagnosis of CM I; radiographic evidence of downward tonsillar herniation by an official independent radiology report; and written informed consent.

The exclusion criteria included the following: Presence of hydrocephalus or previous cerebrospinal fluid (CSF) diversion procedure, such as shunt; prior operation on the posterior cranial fossa; inability to understand the informed consent or unwillingness to participate in the study; inability, at time of consent, to return for follow up evaluations 3 months after the surgery; evidence of spinal dysraphism; allergy or history of allergic reaction to DuraGen, Dura-Guard, or their components; or pregnancy.

Subject randomization and blinding procedures
Subjects were randomized to one of the two techniques, sutureless duraplasty with DuraGen or sutured with Dura-Guard, immediately prior to Chiari decompression surgery. Randomization was 1:1 to DuraGen or Dura-Guard and the subjects were blinded to the results of randomization.

Decompression surgery procedures
Treatment within the study protocol did not deviate from standard practice. Following suboccipital craniectomy and C1 posterior arch excision, dura was opened along with arachnoid membrane to facilitate CSF flow and all visible arachnoid adhesions were released. After an adequate intradural decompression the duraplasty was performed with either DuraGen or Dura-Guard depending on randomization. Dura-Guard patches were sutured to the native dura in a watertight fashion using 4-0 Nurolon running nonlocking suture, whereas DuraGen was placed over the dural opening without any sutures or glue. In most cases, DuraGen was tucked under the native dura. After discharge from the hospital, the patients were seen in the outpatient neurosurgical clinic for suture removal and follow up examinations for the duration of study.

Operative parameters and study follow up procedures
Patients were followed for 3 months postoperatively with the SF-36 Quality of Life Questionnaires (QLQ) and for

specific complication indicators. Complication parameters evaluated were: Presence of pseudomeningocele based on clinical examination and follow up magnetic resonance imaging (MRI); postoperative meningitis (infectious and aseptic), evaluated by clinical symptoms and/or lumbar puncture; development of CSF leak; and postoperative wound infection. We also analyzed duration of surgery (minutes); blood loss (milliliters); length of postoperative hospital stay (days); readmissions and emergency room (ER) visits within 30 days following surgery; and other postoperative complications not included above.

Cost analysis

Total charges were calculated as actual hospital charges incurred from surgery to discharge. Operating cost was calculated as actual hospital charges specified as operating room cost, anesthesia cost and recovery room cost. Each was assessed individually and additively (total operating time cost) for statistical significance. The complication management cost was determined by the cost of treatment of complications occurring after the initial hospital treatment. Among others, it included cost of all readmissions, ER visits and outpatient visits related to any complication of surgery.

SF-36 quality of life grading and evaluation

Symptomatic improvement vs. stabilization vs. worsening was measured by the SF-36 health outcomes survey (Quality Metric, Lincoln, RI, USA) at months 1, 2, and 3 postoperatively. Outcome was evaluated by subject reported response to the month 1, SF-36 questionnaire question #2: "Compared to one year ago, how would you rate your health in general now?" Subjects were also evaluated for outcome via this criterion at their last postoperative, or month 3, questionnaire evaluation. The SF-36 quality of life questionnaire scores resulted in five specific scoring categories.

Scores range from 1 to 100 (1 = very poor and 100 = excellent), and these categories are: physical function, physical role, pain, general health, vitality, social function, emotional role, and mental health. The questionnaire also gives a total physical health and mental health score that ranges from 1 to 100. The total QLQ score was determined by adding the total physical health and mental health scores together (score 1-200). Scores for each specific category, total physical, total mental, and total QLQ score were individually assessed at the three time points (months 1, 2, and 3) and were averaged across all time points for an overall assessment of each parameter.

Outcome

Follow up evaluation was conducted for objective evaluation of outcome and marked as better, same or worse. All patients were examined in person and the questionnaires were filled at the time of follow up visit.

Statistical analysis

The study data was compared relative to randomization to DuraGen or Dura-Guard and conclusions were drawn based on all previously described variables. Study data was also compared at different time points to determine overall efficacy of posterior fossa decompression for CM I.

All statistics were performed with the use of the Statistical Analysis Software (SAS) Version 9.2 (Cary, NC, USA) and Prism 4 (La Jolla, CA, USA) for Windows, Version 4.00, released April 2003. Statistical significance was assumed significant at a P value of <0.05. All parameters were evaluated, relative to each material used, with a Student t-test or with the Mann–Whitney test.

RESULTS

The study was conducted over the period of 2002-2011. Out of more than a 150 CM patients undergoing surgery in our institution, 34 patients met all inclusion and exclusion criteria, agreed to written informed consent, and participated in the study. Sixteen patients were randomized to DuraGen and 18 were randomized to Dura-Guard.

Demographic parameters

No statistical difference was found between the two treatment groups, DuraGen or Dura-Guard, based upon age, average age was 38.7 ± 12.2 years (mean ± SD), or duration of preoperative symptoms, average duration was 37 ± 49 days (mean ± SD). There was no significant difference in gender between the two groups; overall, there were 28 females and 6 males. No statistical difference was found between the two treatment groups on the basis of insurance status, smoking, drug, or alcohol use.

Operative parameters

No significant difference was found between the two treatment groups for operative time, hospital stay, and blood loss during surgery [Table 1]. Average operative time for the entire group was 142 ± 46 minutes (mean ± SD), average hospital stay was 4.5 ± 1.8 days (mean ± SD), and average blood loss was 99 ± 118 mL (mean ± SD). Of interest, the surgical time for Dura-Guard group was 30 minutes longer than in DuraGen (156 vs. 127 minutes, respectively) but the difference was not statistically significant.

Although not specifically measured, the size of craniectomy and extent of C1 posterior arch resection did not differ between the groups as we routinely perform 2.5-3 cm-wide semicircular craniectomy and 2-2.5 cm-wide resection of C1 arch.

Postoperative parameters

No significant difference was found between the two treatment groups for postoperative

complication parameters: Presence of complications, pseudomeningocele, meningitis, CSF leak, other complications, readmissions, or ER visits [Table 1] and no patient had a wound infection. Of the patients studied here 20.6% were readmitted for complications related to the decompression. Of the common complications associated with posterior fossa decompression surgery for CM I: Meningitis occurred in 9% of the patients, pseudomeningocele occurred in 26.5%, CSF leak occurred in 5.9%, and no patients experienced a wound infection. The percentage of all patients that experienced a complication was 41%.

There was a clear difference in incidence of some complications: Meningitis occurred in 1/16 patients with DuraGen group and 2/18 in Dura-Guard, CSF leak happened in 2/16 of DuraGen patients and 0/18 of Dura-Guard, and radiographic pseudomeningocele in 6/16 of DuraGen and 6/18 Dura-Guard patients. None of these differences reached statistical significance [Table 1]. Readmissions were observed in 7/16 DuraGen patients and 0/18 Dura-Guard patients. Comparison of this parameter between two study groups using Mann–Whitney U test resulted in a P value of 0.1807, which was higher than preset level of significance (0.05) and therefore the difference in readmissions was deemed not significant. A larger sample size could provide more conclusive results and may have to be investigated further in the future.

Cost analysis

No significant difference was found between the two treatment groups for total charges, hospital stay cost, postdischarge treatment cost, or operative cost [Table 1]. The average cost for posterior fossa decompression surgery for CM I was $33,851.18 ± $1,808.80 (mean ± standard error of the mean (SEM)).

SF-36 QLQ parameters

No significant difference was found between the two treatment groups, averaged across all time points, for specific QLQ survey parameters: Physical function, physical role, pain, general health, vitality, social function, emotional role, and mental health. Nor was there a significant difference between the two study groups for total physical health, total mental health, or total QLQ score [Table 2]. Dura-Guard patients (80.13 ± 0.86, mean ± SEM) had a significantly greater mean Total QLQ score at month 2 compared with DuraGen patients (67.11 ± 1.19, mean ± SEM) ($P = 0.0384$), however, the difference between the groups for total QLQ score was not significant when comparing months 1 or 3 [Figure 1].

Evaluation of efficacy for all study patients showed a significant improvement in total physical health at month 3 (36.99 ± 0.36, mean ± SEM) compared with month 1 (29.21 ± 0.26, mean ± SEM) ($P = 0.0043$) and

at month 2 (34.32 ± 0.29, mean ± SEM) compared with month 1 [$P = 0.027$, Figure 2a and b]. All study patients also showed a significant improvement in physical function at month 3 (39.98 ± 0.44, mean ± SEM) compared with month 1 (28.09 ± 0.37, mean ± SEM) ($P = 0.0007$) and at month 2 (36.15 ± 0.41, mean ± SEM) compared with month 1 [$P = 0.0153$, Figure 2a and b]. However, patients did not show a significant improvement or difference in scores from months 1 to 3 for total mental health or for the specific QLQ survey parameters physical role, pain, general health, vitality, social function, emotional role, or mental health [Figure 2a].

Table 1: Summary of operative, post operative data and cost analysis for DuraGen vs. Dura-Guard patients

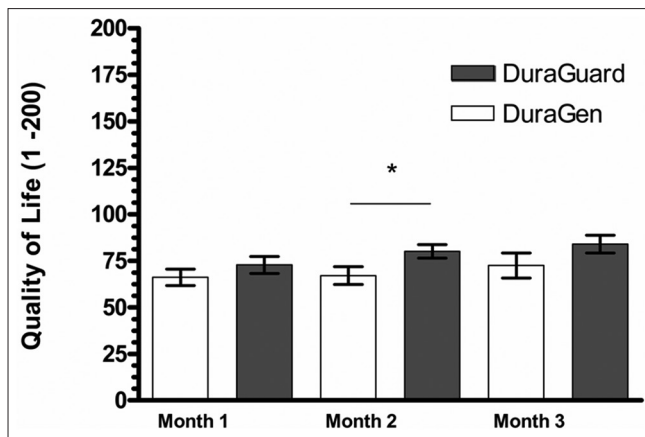| Parameter	DuraGen mean or %	Dura-Guard mean or %	P value
Operative time (minutes), ±SD	126.6±10.91	155.8±10.69	0.0646
Hospital stay (days), ±SD	5.125±0.5391	3.889±0.3120	0.0587
Blood loss (mL), ±SD	87.50±30.24	109.4±27.66	0.5962
Total charges($), ±SEM	36620±2970	31390±2079	0.1613
Hospital stay cost ($), ±SEM	16910±1779	12830±1029	0.0587
Operative cost ($), ±SEM	5919±357.9	6589±282.4	0.1525
Anesthesia time cost ($), ±SEM	1930±219.4	2341±90.28	0.0990
Recovery time cost ($), ±SEM	195.3±108.2	175.8±112.1	0.9013
Total operating time cost ($), ±SEM	8045±512.6	9106±399.8	0.1136
Postdischarge treatment cost ($), ±SEM	8475±4191	4037±4037	0.4515
Radiographic pseudomeningocele	31.25%	22.22%	0.6555
Meningitis	6.25%	11.11%	0.8121
CSF leak	12.50%	0	0.7002
Wound infection	0	0	n/a
Other complications	18.75%	5.5%	0.4994
Presence of complications	56.25%	27.77%	0.1533
Readmissions	37.60%	0	0.1807
Emergency room visits	31.25%	5.55%	0.3088

SEM: Standard error of the mean, SD: Standard deviation, CSF: Cerebrospinal fluid

Table 2: Summary of quality of life questionnaire results for DuraGen vs. Dura-Guard patients

Parameterss	DuraGen mean±SEM	Dura-Guard mean±SEM	P value
Physical health total	31.40±2.008	35.61±1.870	0.1349
Mental health total	39.30±3.265	43.53±2.489	0.3113
Physical function	30.92±2.919	38.16±2.188	0.0570
Pain	31.58±2.771	36.59±2.027	0.1554
General health	38.15±2.647	43.68±2.128	0.1144
Vitality	37.25±2.250	43.53±2.445	0.0680
Social	34.52±3.087	37.27±2.498	0.4945
Emotion	35.04±3.257	36.06±2.576	0.8070
Mental	38.12±3.736	45.55±2.267	0.1014

QLQ: Quality of life questionnaire, SEM: Standard error of the mean

Figure 1: Overall quality of life questionnaire scores at months 1, 2, and 3 for DuraGen and Dura-Guard. Bar graph representing mean ± SEM and * indicates a significant difference, *P* = 0.0384

Figure 2: (a) For all patients, a comparison of all specific QLQ parameters at months 1 and 3 postoperatively (b) For all patients, a comparison of physical function and physical health at questionnaire time points (month 1, 2, and 3). Bar graph representing mean ± SEM, * indicates significance *P* < 0.05, and ** indicates significance *P* < 0.005

Furthermore, study subjects did not show a significant increase in total QLQ score (1-200), which is the result of adding together total mental health (1-100) and total physical health (1–100) from months 1 to 3 postoperatively [Figure 3a].
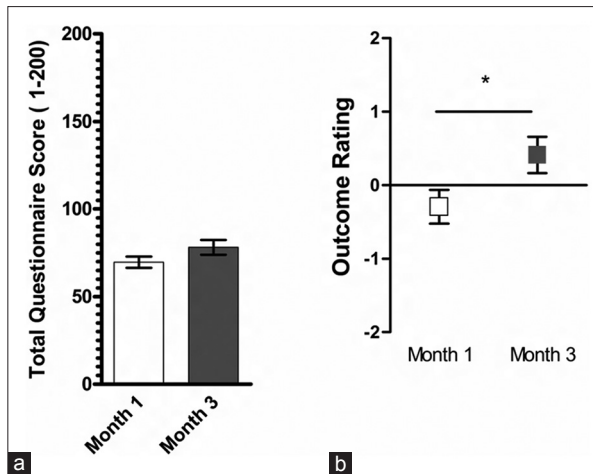
Outcome

No significant difference was observed between groups, DuraGen or Dura-Guard, for outcome evaluations at months 1 and 3. All patients, however, showed a significant improvement in their outcome response "Compared to one year ago how would you rate your health in general now?" between months 1 and 3 (P = 0.0112) [Figure 3b]. A score of '−2' indicates that the subject is considerably worse than one year ago and '+2' indicates the patient is considerably better than one year ago [Figure 3b].

DISCUSSION

The purpose of this study was to determine whether the process of suturing the dural collagen-based graft during posterior fossa decompression in patients with CM I alters the outcome and/or reduces incidence of complications. We also evaluated whether the type of duraplasty, sutureless with DuraGen, or sutured with Dura-Guard, translates into additional cost both during surgery and postoperatively. Furthermore, study data was compared at different time points throughout the clinical course to determine overall efficacy of surgery.

The two study groups, DuraGen and Dura-Guard, exhibited comparable demographic parameters indicating that differences in clinical course could be correlated with randomization to either duraplasty material. Similarly, it has been previously reported that intrinsic patient characteristics (e.g., age, alcohol, drug abuse, duration of symptoms, and smoking) do not affect the efficacy of collagen dural grafts.[8] The higher prevalence
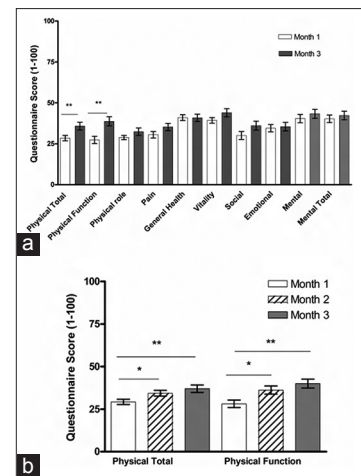
of women with CM I has been previously documented in the literature and again confirmed here within our study population.[13]

We did not find any significant difference in clinical course (operative time, hospital stay, and blood loss during surgery) between sutureless (DuraGen) and suturable (Dura-Guard) [Table 1]. Operative time was less for DuraGen and it appears to be related to the fact that DuraGen is an on-lay graft and does not require suturing time.[4] The difference, however, was not statistically significant (P = 0.06), although it is conceivable that this could become significant with a larger study population.

Hospital stay for Dura-Guard was on average less but not significantly different from DuraGen (P = 0.06). In this case, the lack of a statistically significant difference is not surprising as the postoperative treatment was essentially identical between the two groups. For postoperative parameters, Dura-Guard and DuraGen showed somewhat larger than expected incidence of complications, infections, CSF leaks, pseudomeningocele formation, ER visits, and readmissions. Zerris, *et al*. studied somewhat similar parameters in animal experiments comparing Dura-Guard with DuraGen and none of the animals developed CSF leak, seizures, hemorrhage, hydrocephalus, foreign body reaction, or infection.[25] Dura-Guard in our study had smaller incidences for most postoperative outcome parameters (e.g., CSF leak, ER visits, etc.) and higher for some others (e.g., meningitis) [Table 1], however, this was not significantly different from DuraGen.

The cost analysis portion of our study indicated that there was no significant difference in cost for DuraGen compared with Dura-Guard duraplasty [Table 1]. We postulated that DuraGen, because it does not require

Figure 3: (a) For all patients, Total QLQ score (1–200) results from the addition of the total physical and mental score at months 1 and 3 postoperatively (b) For all patients, the outcome rating at 1 and 3 months postoperatively. Outcome rating corresponds to patient-reported response to the question "Compared to one year ago how would you rate your health in general now?" A score of-2 indicates an answer of "Much worse than one year ago." A score of 0 indicates an answer of "The same as one year ago." A score of 2 indicates an answer of "Much better than one year ago." * indicates significance of <0.05

suturing and suturing time, compared with Dura-Guard would have lower operating room cost, however, we did not find this to be the case. Therefore, the argument that surgeons can reduce cost by avoiding duraplasty, which requires suturing, was not supported by our results as reduction in surgical time did not translate into statistically significant reduction in costs.

Dura-Guard patients compared with DuraGen showed more improvement in quality of life at month 2. However, scores did not significantly differ between groups at the final follow up [Figure 1]. This indicates that Dura-Guard patients may recover more quickly but DuraGen patients reach a comparable quality of life at 3 months postoperatively. The success of the Dura-Guard in clinical setting and possibly the quicker recovery time observed here could be attributed to its ability to be sutured securely in place, which provides an immediate occlusive seal.[4,8,10,11]

Nevertheless, both DuraGen and Dura-Guard patients had comparable results in the QLQ categories of total mental and total physical health [Table 2] and all patients showed significant improvement in outcome from months 1 to 3 [Figure 3b], and most prominently in the categories of total physical health and physical function [Figure 2a and b]. This, in our opinion, indicates the overall effectiveness of both implants and duraplasty techniques in the surgical treatment of CM I.

Interestingly, patients did not show a significant difference between months 1 and 3 for specific QLQ survey parameters physical role, pain, general health,

vitality, social function, emotional role, or mental health [Figure 2a]. Furthermore, study subjects did not show a significant change in total QLQ score from months 1 to 3 following surgical intervention for CM I [Figure 3a]. This indicates that the bulk of improvement following posterior fossa decompression for CM I is related to total physical health and physical function. This may be in part because CM I pathology involves herniation of the cerebellum through the foramen magnum[19] and the cerebellum is primarily responsible for motor function. The cerebellum receives motor input from the cerebral cortex, balance information from the vestibular organs, and sensory information from the spinal cord. Its major function is related to motor learning.[7] The purpose of posterior fossa decompression for CM I is to alleviate overcrowding of rhombencehpalic derivatives (the cerebellum) by creating a larger posterior fossa cavity.[12,14] Thus alleviating the pressure on the cerebellum, caused by a small shallow posterior fossa, results in an improvement in motor function as seen by our SF-36 QLQ results. No specific QLQ survey parameters decreased from months 1 to 3 indicating a stabilization of all other parameters.

It should be noted that one of the limitations of this study was the small sample size and long period of accrual. The National Institutes of Health estimates the prevalence of CM I to be 1 in 1000 individuals and this may or may not include patients that are asymptomatic.[6,13] The low accrual may not be a problem in a larger multi-institutional study that could provide more conclusive results and would further power this analysis. We conclude, however, that the differences in the study variables between dural patches and dural closure technique (DuraGen vs. Dura-Guard) are not statistically significant. Similarly, no difference has been observed in prior studies comparing autologous and nonautologous grafts in duraplasty for Chiari decompression.[1] All patients showed a significant improvement in their response to the question "Compared to one year ago, how would you rate you health in general now?" – The average patient response to this question was "better" indicating treatment efficacy over the time course of the study. Neither DuraGen nor Dura-Guard had a significantly different response to this question. This should alleviate some controversy regarding the effectiveness of posterior fossa decompression for the treatment of CM I.[2]

CONCLUSIONS

Multiple concerns that arise when using autologous collagen implants (inconsistent availability, surgical morbidity at the donor site, and the need for enlargement of original incision or creation of additional incisions) can be addressed by the processed bovine collagen grafts. Both sutureless and suturable xenogeneic dural

substitutes are effective in reaching the goals of posterior fossa decompressive surgery for CM I. Interestingly, with the clinical course of both treatments being statistically similar, surgical time is the only variable that affects the surgeon and shorter surgical time is always preferred by any operating team. Furthermore, shorter surgical time translates into shorter duration of anesthesia and, at least theoretically, should improve outcome and lower the chances of complications. Based on our findings, we conclude that posterior fossa decompression with either duraplasty technique results in an improvement in patients compared with one year prior to surgery, as seen with patient's response to the outcome question, and emphasizes the physical deficits that can be alleviated with treatment. Furthermore, with similar clinical outcomes and comparable costs there is no benefit to the patient for surgeons to take additional effort suturing the dural graft. Ultimately, the choice of duraplasty material may be based upon the surgeon's preference.

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REFERENCES

1. Abla AA, Link T, Fusco D, Wilson DA, Sonntag VK. Comparison of dural grafts in Chiari decompression surgery: Review of the literature. J Craniovertebr Junction Spine 2010;1:29-37.

2. Baisden J. Controversies in Chiari I malformations. Surg Neurol Int 2012;3 Suppl S3:232-7.

3. Chiari H. Concerning alterations in the cerebellum resulting from cerebral hydrocephalus. Pediatr Neurosci 1987;13:3-8.

4. 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;104:16-20.

5. Ellingsworth LR, DeLustro F, Brennan JE, Sawamura S, McPherson J. The human immune response to reconstituted bovine collagen. J Immunol 1986;136:877-82.

6. Fernández AA, Guerrero AI, Martinez MI, Vázquez ME, Fernández JB, Chesa i Octavio E, et al. Malformations of the craniocervical junction (Chiari type I and syringomyelia: Classification, diagnosis, treatment). BMC Musculoskelet Disord 2009;10 Suppl 1:S1.

7. Kandel ER, Schwartz JH, Jessell TM. Principles of Neural Science. 4th ed. New York: McGraw-Hill; 2000.

8. Litvack ZN, West GA, Delashaw JB, Burchiel KJ, Anderson VC. Dural augmentation: Part I-evaluation of collagen matrix allografts for dural defect after craniotomy. Neurosurgery 2009;65:890-7.

9. Maurer PK, McDonald JV. Vicryl (polyglactin 910) mesh as a dural substitute. J Neurosurg 1985;63:448-52.

10. Moskowitz SI, Liu J, Krishnaney AA. Postoperative complications associated with dural substitutes in suboccipital craniotomies. Neurosurgery 2009;64:28-33.

11. Narotam PK, José S, Nathoo N, Taylon C, Vora Y. Collagen matrix (DuraGen) in dural repair: Analysis of a new modified technique. Spine (Phila Pa 1976) 2004;29:2861-9.

12. Narotam PK, van Dellen JR, Bhoola KD. A clinicopathological study of collagen sponge as a dural graft in neurosurgery. J Neurosurg 1995;82:406-12.

13. National Institute of Neurological Disorders and Stroke. NINDS Chiari malformation information page. Available from: http://www.ninds.nih.gov/disorders/chiari. [Last accessed on 2012 Nov 11].

14. Noudel R, Gomis P, Sotoares G, Bazin A, Pierot L, Pruvo J, et al. Posterior fossa volume increase after surgery for Chiari malformation Type I: A quantitative assessment using magnetic resonance imaging and correlations with treatment response. J Neurosurg 2011;115:647-58.

15. Nussbaum CE, Maurer PK, McDonald J. Vicryl (polyglactin 910) mesh as a dural substitute in the presence of pia arachnoid injury. J Neurosurg 1989;71:124-7.

16. Parizek J, Mericka P, Husek Z, Suba P, Spacek J, Nemecek S, et al. Detailed evaluation of 2959 allogeneic and xenogeneic dense connective tissue grafts (fascia lata, pericardium, and dura mater) used in the course of 20 years for duraplasty in neurosurgery. Acta Neurochir (Wien) 1997;139:827-38.

17. Parizek J, Mericka P, Spacek J, Nemecek S, Elias P, Sercl M. Xenogeneic pericardium as a dural substitute in reconstruction of suboccipital dura mater in children. J Neurosurg 1989;70:905-9.

18. Rosen DS, Wollman R, Frim DM. Recurrence of symptoms after Chiari decompression and duraplasty with nonautologous graft material. Pediatr Neurosurg 2003;38:186-90.

19. Siddiqi NH, Das Narla L. Imaging in Chiari I malformation. eMedicine Web site. Available from: http://emedicine.medscape.com/article406849-overview. [Last accessed on 2012 Nov 16].

20. Snyder P. Chiari Malformation and syringomyelia. Radiol Technol 2008;79:555-8.

21. Stendel R, Danne M, Fiss I, Klein I, Schilling A, Hammersen S, et al. Efficacy and safety of a collagen matrix for cranial and spinal dural reconstruction using different fixation techniques. J Neurosurg 2008;109:215-21.

22. Warren WL, Medary MB, Dureza CD, Bellotte JB, Flannagan PP, Oh MY, et al. Dural repair using acellular human dermis: Experience with 200 cases: Technique assessment. Neurosurgery 2006;46:1391-6.

23. Yamada K, Miyamoto S, Nagata I, Kikuchi H, Ikada Y, Iwata H, et al. Development of a dural substitute from synthetic bioabsorbable polymers. J Neurosurg 1997;86:1012-7.

24. Yamada K, Miyamoto S, Takayama M, Nagata I, Hashimoto N, Ikada Y, et al. Clinical application of a new bioabsorbable artificial dura mater. J Neurosurg 2002;96:731-5.

25. Zerris VA, James KS, Roberts JB, Bell E, Heilman CB. Repair of the dura mater with processed collagen devices. J Biomed Mater Res B Appl Biomater 2007;83:580-8.