ISSN: 2643-4474

Khandpur et al. Neurosurg Cases Rev 2019, 2:018
DOI: 10.23937/2643-4474/1710018
Volume 2 | Issue 1
Open Access

Neurosurgery - Cases and Reviews

CASE SERIES

Clinical Performance of a Novel Fully Synthetic Dura Substitute

Umang Khandpur*, BS, Wilson Z Ray, MD and Matthew R MacEwan, PhD

Department of Neurosurgery, Washington University School of Medicine, USA

***Corresponding author:** *Umang Khandpur, BS, Department of Neurosurgery, Washington University School of Medicine, 660 S. Euclid Ave, St. Louis, MO. 63110, USA, Tel: (314)-362-7733*

Abstract

Background: Despite the range of available dura substitutes, limitations such as harvest site morbidity and graft degradation still exist. As such, there is a need for an optimized dura substitute with superior safety and mechanical properties than currently available products.

Methods: A retrospective case series was performed to evaluate the efficacy of a novel, fully synthetic dura substitute. Clinical outcomes (e.g. infectious, reoperation rates, cerebrospinal fluid leak) and surgeon experiences with the dura substitute intraoperatively were collected. All methods were approved by the Institutional Review Board at Washington University School of Medicine.

Conclusion: This study explored the clinical performance of a fully synthetic nanofabricated dura substitute. Case analysis demonstrated none required reoperation or had clinical evidence of CSF leakage, pseudomeningocele, or meningeal disease after surgery. Results from the physician survey indicated that this dura substitute offered benefits in tensile strength appropriate for a variety of neurosurgical procedures.

Keywords

Cerafix, Synthetic, Non-biologic, Dura substitute, Neurosurgery

Introduction

Dural substitutes are routinely used in neurosurgical procedures that require disruption of the dura mater to access deeper tissue [1]. A repertoire of materials is available to repair these defects including autograft, xenograft, and recently non-biologic synthetics. Despite this diversity, limitations exist in using autograft (e.g. poor availability and harvest site morbidity) or xenograft (e.g. foreign body inflammatory reactions and graft degradation) [2,3]. Exploration and optimization of the safety and mechanical properties of synthetic grafts may overcome the shortcomings of other graft options.

Cerafix® Dura Substitute (Acera Surgical, Inc., St. Louis, MO) is a unique non-biologic dura substitute produced via nanofiber electrospinning which provides impressive strength, handling, and suturability while mollifying local inflammation [4,5]. This biodegradable poly (lactic-*co*-glycolic acid)/polydioxanonematerial is synthesized into a form that mimics native extracellular matrix to improve tissue in growth, neoduralization, and watertight closure. In preclinical testing, Cerafix® demonstrated effective repair of induced dural defects and successful prevention of cerebrospinal fluid leakage without infection or damage to underlying cortical tissue [5]. Compared to DuraMatrix™ (Stryker, Inc., Kalamazoo, MI), a popular collagen-based dura substitute from bovine dermis or calcaneal tendon, Cerafix® exhibited increased neoduralization, fewer cortical adhesions, and less inflammation/fibrosis in a rabbit duraplasty model [5]. Compared to DuraGen Plus™ (Integra LifeSciences, Inc., Plainsboro, NJ), another commercially available xenogenic dura substitute, Cerafix® demonstrated superior tensile and burst strengths [6].

In this study, we performed a retrospective case series to evaluate the efficacy of a novel, fully synthetic dura substitute currently in clinical use within neurosurgical operating facilities at Barnes Jewish Hospital/Washington University School of Medicine. The clinical outcomes and surgeon experiences of these cases confirm that Cerafix® Dura Substitute is a superior option in the arsenal of available dura substitutes for neurosurgery.

Case Descriptions

Data on three unique individuals who underwent

Citation: Khandpur U, Ray WZ, MacEwan MR (2019) Clinical Performance of a Novel Fully Synthetic Dura Substitute. Neurosurg Cases Rev 2:018. doi.org/10.23937/2643-4474/1710018

Accepted: June 15, 2019; **Published:** June 17, 2019

Table 1: Surgeon responses regarding the use of Cerafix® Dura Substitute.

Survey Item	Count
Traditional Product(s)[a]	
DuraMatrix®	4
DuraGen®	3
AlloDerm™	3
Bovine pericardium	2
Cerafix® Handling vs. Traditional Product(s)[a]	
Easier	5
Same	2
Harder	0
Cerafix® Benefits[a]	
Non-biologic	5
Tensile strength	4
Fully resorbable	1
Non-sided	1
Preparation time	1
Suitable Procedures/Locations for Cerafix®[a]	
Supratentorial	5
Skull base/Endoscopic	3
Infratentorial/Posterior fossa	3
Spinal	3
Any dural defect	2
Will you use Cerafix® for future cases?[b]	
Yes	5
No	0
Could Cerafix® replace your current product(s)?[b]	
Yes	5
No	0

[a]Multiple answers were acceptable for this question; [b]Only one answer was acceptable for this question.

neurosurgery in May 2017 were collected via medical record review. Data points included patient age, patient sex, preoperative medical history, imaging findings, primary diagnosis, and postoperative clinical outcomes i.e. incidence of cerebrospinal fluid (CSF) leakage, persistent fluid collection, infection, and reoperation within three months of the surgery. Surgeon experiences with the synthetic dura substitute were documented immediately following respective procedures. Responses were quantified and are reported in Table 1. All methods were approved by the institutional review board (IRB) at Washington University School of Medicine.

Case 1

A 63-year-old man with hypertension, hyperlipidemia, and a solitary pulmonary nodule presented with two to three weeks of declining fine motor skills and morning headaches. The patient had 1-pack per day smoking history. Physical examination was unremarkable, but brain MRI revealed an enhancing mass in the right parietal lobe with large surrounding edema extending into right frontal and temporal lobes as well as along the right internal capsule. There was also approximately 5 mm of leftward midline shift.

He underwent a right frontotemporal craniotomy with microsurgical resection of the tumor. After resection, the dura was reapproximated with nylon sutures. A patch of Cerafix® Dura Substitute was sewn in place followed by an onlay of Cerafix® over the durotomy line sealed with Tisseel™ fibrin sealant. Postoperative imagingshowed expected postsurgical changes including resolution of midline shift without hydrocephalus. At 3-month follow up, the patient had no evidence of CSF leakage, pseudomeningocele, or meningitis.

Case 2

A 57-year-old man with dementia presented with confusion and decreased level of consciousness after a forward fall and subsequent forehead trauma. Medical history was significant for pituitary adenoma status post resection and radiotherapy with secondary adrenal insufficiency, hypothyroidism, and hypogonadism. During physical examination, he was unable to hold conversation or follow commands. Noncontrast head CT revealed a 7-mm thick subdural hematoma (SDH) overlying the right cerebral convexity.

Craniotomy for hematoma evacuation was performed. After copious irrigation, the dura was repaired via interrupted nylon sutures above which a piece of Cerafix® Dura Substitute was placed and fixed to the bone flap via central tack-up sutures. Postoperative head CT showed interval evolution of the SDH and reduced midline shift with some effacement of the right lateral ventricle. The patient expired one month later from respiratory failure and underlying endocrinopathy. No clinical evidence of CSF leakage or infection was noted before then.

Case 3

A 66-year-old man with history of a fourth ventricle ependymoma status post-resection and chemoradiotherapy presented with weeks of worsening diplopia, episodic confusion, and overall visual decline. Physical examination revealed inducible diplopia on extreme lateral gaze bilaterally. Preoperative imaging demonstrated a trilobed peripherally enhancing irregular mass in the left temporooccipital region with central necrosis and associated diffusion restriction. Extension to the splenium was also noted.

The patient underwent craniotomy and microsurgical resection of the left occipital mass later determined to be glioblastoma multiforme. Dura defects were closed using Vicryl® (Ethicon, Inc., Bridgewater, NJ) sutures and an onlay of Cerafix® Dura Substitute. Postoperative MRI showed T1 hyperintensity in the resection

cavity consistent with residual blood products. There was patchy enhancement in the splenium suspicious for residual tumor. At 3-month follow up, the patient had completed chemotherapy and craniospinal radiation. Symptomatically, he had returned to neurological baseline although brain MRI continued to show marginal enhancement of the resection cavity concerning for tumor progression. He had no persistent fluid collections, CSF leaks, or clinical signs of infection over this period.

Conclusions

In their review of available dural grafting materials, Berjano, et al. proposed characteristics of the ideal dura substitute: watertight closure, low antigenicity/tissue toxicity, free from potential risk of infection, easy handling, and availability [7]. Although options for substitutes exist, they are mostly limited to autogenic and xenogenic materials with poor availability, risk of disease transmission, or higher antigenicity.

Autografts are obtained from pericranial tissue or tendinous fascia lata. Although they do not elicit significant inflammation, their use is limited by host site morbidity and larger dural defect areas [5]. Allografts from cadaveric dura are more available but portend serious risk of infection [8,9]. Xenografts from native bovine or porcine tissues offer a similar feel to human dura as well as robust cellular infiltration and angiogenesis [3,5]. However, graft degradation is known to occur prematurely resulting in weak tissue over the dural defect [3,5]. The tradeoff between mechanical properties and resorption ability in addition to the risk of zoonosis and allergic reactions restricts their routine application [3,10]. Effectiveness of other synthetic grafts (e.g. Preclude™ and Ethisorb™ dura substitutes) is limited to preclinical testing where they often do not uphold similar mechanical properties [11].

This study explored the clinical performance of a fully synthetic nanofabricated dura substitute to optimize critical dura substitute properties. Analysis of patient outcomes showed that none required reoperation or had clinical evidence of CSF leakage, pseudomeningocele, or meningeal pathology. The median length of hospital stay after surgery was 4 days. While this dura substitute was examined in the adult population, its utility could be expanded to include pediatric cases as well. Further studies are required. Results from the physician survey indicated that Cerafix® was mostly easier to use, offered benefits in tensile strength, and appropriate for a range of surgical procedures/locations (Table 1) [12]. These clinical observations and surgeon experiences support the use of Cerafix® Dura Substitute in the neurosurgical arena.

Disclosures

WZ Ray is a consultant for Depuy/Synthes and Globus Spine. He has grant support from the Department of Defense and National Institutes of Health. MR MacEwan has equity interest in Acera Surgical, Inc. All other authors have no competing interests to declare.

References

1. Narotam PK, Quao F, Nathoo N (2009) Collagen matrix duraplasty for posterior fossa surgery: Evaluation of surgical technique in 52 adult patients. Clinical article. J Neurosurg 111: 380-386.
2. Dufrane D, Marchal C, Cornu O, Raftopoulos C, Delloye C (2003) Clinical application of a physically and chemically processed human substitute for dura mater. J Neurosurg 98: 1198-1202.
3. Zerris V, James K, Robert J, Bell E, Heilman C (2007) Repair of the dura mater with processed collagen devices. J Biomed Mater Res B Appl Biomater 83: 580-588.
4. Xie J, MacEwan MR, Ray WZ, Liu W, Siewe DY, et al. (2010) Radially aligned, electrospun nanofibers as dural substitutes for wound closure and tissue regeneration applications. ACS Nano 4: 5027-5036.
5. MacEwan MR, Kovacs T, Osbun J, Ray W (2018) Comparative analysis of a fully-synthetic nanofabricated dura substitute and bovine collagen dura substitute in a large animal model of dural repair. Interdiscip Neurosurg 13: 145-150.
6. (2017) Data on file at Acera Surgical, Inc. See Cerafix IFU and FDA 510k 161278. EDS-50013.
7. Berjano R, Vinas FC, Dujovny M (1999) A review of dural substitutes used in neurosurgery. Crit Rev Neurosurg 9: 217-222.
8. Martinez-Lage JF, Poza M, Sola J, Tortosa JG, Brown P, et al. (1994) Accidental transmission of Creutzfeldt-Jakob disease by dural cadaveric grafts. J Neurol Neurosurg Psychiatry 57: 1091-1094.
9. Thadani V, Penar PL, Partington J, Kalb R, Janssen R, et al. (1988) Creutzfeldt-Jakob disease probably acquired from a cadaveric dura mater graft: Case report. J Neurosurg 69: 766-769.
10. Martinez-Lage JF, Rabano A, Bermejo J, Martinez Perez M, Guerrero MC, et al. (2005) Creutzfeldt-Jakob disease acquired via a dural graft: Failure of therapy with quinacrine and chlorpromazine. Surg Neurol 64: 542-545.
11. Barbolt TA, Odin M, Leger M, Kangas L, Hoiste J, et al. (2001) Biocompatibility evaluation of dura mater substitutes in an animal model. Neurol Res 23: 813-820.
12. Schmalz P, Griessenauer C, Ogilvy CS, Thomas AJ (2018) Use of an Absorbable Synthetic Polymer Dural Substitute for Repair of Dural Defects: A technical note. Cureus 10: e2127.