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Author(s)	Yamaguchi, Shigeru; Terasaka, Shunsuke; Okamoto, Michinari; Ishi, Yukitomo; Motegi, Hiroaki; Kobayashi, Hiroyuki; Houkin, Kiyohiro
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Simplified Dural Reconstruction Procedure Using Biocompatible Polyglycolic Acid

Felt with Autologous Abdominal Fat Grafts after a Transpetrosal Approach

Shigeru Yamaguchi¹, MD, yama-shu@med.hokudai.ac.jp

Shunsuke Terasaka², MD, terasas0727@gmail.com

Michinari Okamoto¹, MD, okamotomichinari@gmail.com

Yukitomo Ishi¹, MD, nekotan0401@hotmail.com

Hiroaki Motegi¹, MD, moccihiro@gmail.com

Hiroyuki Kobayashi², MD, hiro.lausanne@gmail.com

Kiyohiro Houkin¹, MD, houkin@med.hokudai.ac.jp

¹Department of Neurosurgery, Faculty of Medicine, Hokkaido University, Sapporo, Japan

²Department of Neurosurgery, Kashiwaba Neurosurgical Hospital, Sapporo, Japan

Corresponding author: Shigeru Yamaguchi, M.D.

Department of Neurosurgery, Hokkaido University Graduate School of Medicine,

North 15 West 7, Kita-ku, Sapporo 060-8638, JAPAN

Tel: +81-11-706-5987 Fax: +81-11-708-7737

E-mail: yama-shu@med.hokudai.ac.jp

Key Words

Cerebrospinal fluid leakage; Dural reconstruction; Petrosal approach; Polyglycolic acid
felt; Skull base surgery

Short title

Simplified Presigmoid duralplasty

Abstract

Objective: Dural reconstruction after transpetrosal approaches is complicated because complete primary closure of presigmoid dura mater is difficult to achieve. To address this problem, we use biocompatible polyglycolic acid (PGA) felt (Durawave) to reconstruct dural defects. To evaluate the use of PGA felt in dural reconstruction, we compared these results with those after conventional duralplasty using autologous fascia grafts.

Methods: We retrospectively surveyed all cases that involved a transpetrosal approach since 2013. In the conventional procedure, autologous fascia was fixed over the dural defect by using stay sutures; any remaining dead space was obliterated by placing abdominal fat grafts. Since April 2017, we have used PGA felt instead of fascia.

Results: Of the 37 cases identified, 27 were reconstructed according to the conventional procedure; the remaining 10 cases were reconstructed by using PGA felt. Among the 27 conventional cases, 8 experienced cerebrospinal fluid (CSF)-related complications, comprising 3 cases of rhinorrhea and 5 cases of subcutaneous fluid collection; 2 cases (7%) required repair surgeries. Of the 10 surgeries involving PGA felt, 1 patient (10%) developed subcutaneous fluid collection and required repair surgery, whereas the remaining 9 cases had no evidence of CSF leakage. In addition, the median dural reconstruction time when using PGA felt was 9 min, which is significantly shorter than when autologous fascia was used (44 min).

Conclusions: Using PGA felt for presigmoid dura simplifies dural reconstruction because it

obviates the need to suture in a deep field. PGA felt has potential to prevent CSF-related complications after transpetrosal approaches.

Introduction

Transpetrosal approaches—including the anterior transpetrosal, posterior transpetrosal, and combined transpetrosal approaches—are established neurosurgical approaches for the resection of tumors located in the petroclival region, such as schwannoma, meningioma, and epidermoid^{1, 2}. Although a relatively complex neurosurgical technique, opening the pre-sigmoid dura after removing the petrosal bone provides a direct approach for resecting tumors that requires minimal brain retraction. However, achieving a watertight dural closure after tumor resection by using suture only is difficult due to spatial constraints. Postoperative cerebrospinal fluid (CSF) leakage due to incomplete dural closure is one of the greatest risk factors for postoperative morbidity, including meningitis and tension pneumocephalus^{3, 4}.

To address this problem of incomplete closure, various dural substitutes have been used in skull base surgeries⁵⁻¹³. Autologous transplants, including temporal fascia, pericranium flap, and fascia lata, are the most popular materials among neurosurgeons because autografts minimize the likelihood of immunoreactivity and induction of an inflammatory response⁶. In addition, several reports have suggested that vascularized pericranial and temporalis muscle flaps are more reliable than fascia transplants and should be used when possible^{11, 13}. However, to remain in place, these autografts must be sutured to the remnant of dura mater, which is a laborious and messy process during the final surgical phase. Furthermore, for harvesting of graft material, patients often have to endure a second surgical wound¹⁴.

In addition to autologous transplants, several biomaterials and synthetic materials have been reported as potential dural substitutes, including expanded polytetrafluoroethylene sheets⁹, biosynthesized cellulose⁸, collagen matrix (DuraGen)^{5,7}, and nanofibrous synthetic dural patch to remain in place¹⁰. Unlike autologous transplants, these materials present risks for infection, premature material dissolution, and transplantation rejection¹⁵. In contrast, we recently developed a dural substitute consisting of polyglycolic acid (PGA) felt and demonstrated its efficacy and safety for preventing CSF leakage during non-suture dural reconstruction¹⁶. In April 2017, this PGA felt (Durawave) was approved in Japan as an artificial dural substitute. Because this felt is eventually replaced by biological tissues and without any incompatibility¹⁷, this product may be particularly useful for defect sites that are unamenable to direct primary closure, such as presigmoid dural defects. In this study, we retrospectively reviewed consecutive cases of dural reconstruction after a transpetrosal approach at our institution and compared the results after using PGA felt with those using autologous biological tissue, specifically temporal fascia or fascia lata.

Materials and Methods

Study design

This retrospective study was approved by the Institutional Review Board (IRB). Written informed consent about our surgical procedures was obtained from all patients. As this study

was retrospective, informed consent for this report was waived by the IRB. We retrospectively reviewed the operative records since 2013 at our institution and identified 36 cases of tumor resection via transpetrosal approach during this study period. Among these 36 cases, we reviewed the portions of the surgical videos and documents that involved dural reconstruction. These patients were divided into 2 groups according to the dural substitute used: the autologous fascia group comprised cases from January 2013 through March 2017, and the PGA felt (Durawave, Gunze, Osaka, Japan) group included cases since April 2017. All surgeries were performed by a single treatment team led by the senior surgeons (S.Y. and S.T.). Regarding the dural reconstruction procedure, we investigated the time needed for dural closure, defined as the duration from the start of dural closure until packing with abdominal fat graft was complete, and the total amount of fibrin glue (Beriplast P, CSL Behring, King of Prussia, PA, USA, or Bolheal, Kaketsuken, Kumamoto, Japan) used during each operation.

Operative technique of dural reconstruction

The procedure for dural closure through a combined transpetrosal approach has been described in detail previously¹⁸; closure of the presigmoid dura through an anterior or posterior transpetrosal approach is accomplished in the same manner. Before March 2017, fascia lata or temporal fascia was harvested and placed into the dural defect. This tissue was fixed to remaining dura mater by using braided silk suture (4-0 Nurlon; Ethicon, Somerville, NJ, USA)

in a running pattern or by applying an AnastoClip Vessel Closure System (LeMaitre Vascular, Boston, MA, USA) (Fig. 1A–B). Neoveil (Gunze), an absorbable PGA material, was fixed along the suture line by using fibrin glue to augment sealing of the dura; finally free abdominal fat grafts were packed into any remaining dead space (Fig. 1C). Postoperative CSF drainage was performed when surgeons judged that the risk for CSF leakage was high because a watertight ligation between the autologous fascia and remnant of the dura mater was not achieved.

Beginning in April 2017, PGA felt (Durawave) was used instead of autologous fascia in the dural defect site¹⁶. The PGA felt was easily manipulated according to the manufacturer's instructions to conform to the shape and size of the dural defect without suturing (Fig. 1D–E). Free abdominal fat graft was placed along the dural substitute to reinforce the sealing effect and to fill dead space (Fig. 1F). Postoperative CSF drainage was not applied.

Evaluation and management of postoperative CSF leakage

To assess postoperative CSF leakage (represented as rhinorrhea or subcutaneous fluid collection), patients underwent CT or MRI immediately and at 1 day, 1 week, and approximately 1 month after surgery; details regarding the management of CSF leakage were collected. Evaluation of all imaging was conducted independently by institutional neuroradiologists who was blinded to the clinical course. We also screened patients' medical

records for evidence of other postoperative complications, such as surgical site infection and meningitis.

Results

Patient characteristics

We retrospectively identified 37 consecutive patients at our institution who underwent transpetrosal approaches primarily for resection of meningiomas (n = 15) or schwannomas (n = 17) (Table 1). Between 2013 and 2016, 27 cases underwent dural reconstruction by using autologous temporal fascia (n = 22) or fascia lata (n = 5). In addition, 15 of these 27 cases (55.6%) underwent postoperative CSF drainage, mainly lumbar drainage, for approximately 5 days to prevent CSF leakage.

Beginning in 2017, the remaining 10 of the 37 identified cases underwent dural reconstruction using PGA felt. None of these 10 patients received postoperative CSF drainage (Table 1).

Time needed to complete dural reconstruction surgery

The median time to complete dural reconstruction was 44 minutes (range, 23 to 82 minutes) in the autologous fascia group compared with 9 minutes (range, 7 to 15 minutes) in the PGA felt group. The time to achieve dural reconstruction was significantly shorter when using PGA felt

instead of autologous fascia ($P < 0.001$, Wilcoxon rank-sum test) (Fig. 2).

Amount of fibrin glue used

In the autologous fascia group, the transplanted fascia was sprayed until completely covered with fibrin glue as a dural sealant to augment the watertight closure. In the PGA felt group, fibrin glue was used according to the manufacturer's instructions: fibrin glue was sprayed on the central portion of the PGA felt, fibrinogen solution was applied to the dural stump, and then the entire mass of PGA felt was sprayed with fibrin glue to augment the closure. In both groups, the median amount of fibrin glue used was 6 mL; fibrin glue use did not differ significantly between groups ($P = 0.42$, Wilcoxon rank sum test) (Fig. 3).

Postoperative CSF leakage and other complications

In the autologous fascia group, 8 of the 27 cases (29.6%) developed CSF leakage, comprising 5 cases of subcutaneous fluid collection and 3 of CSF rhinorrhea (Table 2). All 5 patients with subcutaneous fluid collection were treated conservatively, and fluid collection resorbed spontaneously within 2 to 4 weeks after surgery. The 3 patients with rhinorrhea initially were treated through lumbar drainage, but 2 of these patients eventually required surgical revision for direct dural repair.

In the PGA felt group, only 1 patient showed subcutaneous fluid collection, which

occurred 1 week after surgery. This patient initially was treated conservatively through direct compression of the wound by using elastic bandage, but fluid collection continued for another 2 weeks. The patient eventually required surgical revision and direct dural repair. During this operation, CSF was observed to leak through a fistula between the PGA felt and the edge of the petrosal bone remnant, suggesting that the CSF leakage was due to graft dehiscence. This fistula was plugged by using a pedicled muscle flap; the patient did well after revision surgery. The frequency of revision surgery was 7.4% (2 of 27 cases) for the autologous fascia group compared with 10% (1 of 10 cases) for the PGA felt group (Table 2); these rates did not differ significantly ($P = 0.62$, Fisher's exact test).

In addition, a single patient in the autologous fascia group had a delayed postoperative complication, comprising an oily transudate from the external auditory canal at approximately 6 months after surgery. The patient was treated conservatively, and the transudate spontaneously resolved over several weeks.

Discussion

Prevention of CSF leakage after petrosal approach

Microscopic surgical techniques have been developing rapidly, and we now frequently achieve adequate resection of skull base tumors without inducing severe neurologic deficits. In particular, transpetrosal approaches are useful for the resection of tumors located in the

prepontine or cerebellopontine cistern. Transpetrosal approaches are widely applicable for diverse tumor types. For example, trigeminal schwannomas and small petroclival meningiomas can be resected through an anterior transpetrosal approach ¹⁹, large vestibular schwannomas through a posterior transpetrosal (translabyrinthine) approach ²⁰, and large petroclival meningiomas through a combined transpetrosal approach ²¹. Given that any transpetrosal approach requires incision of the presigmoid dura, duralplasty after tumor removal is definitively important to minimize the likelihood of postoperative complications and to avoid severe morbidity ²².

Indeed, although a watertight primary dural closure after a reconstruction procedure is ideal, it is seldom achieved after a presigmoid dural incision due to shrinkage of the dura as a result of surgical electrocautery. To circumvent this difficulty, autologous free-fat grafts are widely applied during dural reconstruction of the petrosal region ^{23, 24}. The conventional technique, in which small pieces of fat graft are plugged into the defect between the dura and bone defect, is relatively effective for preventing CSF leakage ^{23, 24}. Although the autologous fat graft is nonvascularized, it retains its volume for years after surgery ²³. A study investigating the fate of component adipocytes after nonvascularized free-fat grafts by using both in vitro and in vivo analyses demonstrated that implanted adipocytes regenerated for a brief time after grafting ²⁵. However, the direct contact between a free fat graft and the CSF confers a risk of postoperative lipoid meningitis ^{24, 26, 27}.

Key results

To avoid directly exposing the CSF to fat grafts, autologous temporal fascia or fascia lata is used as a dural substitute during the reconstruction of a dural defect. Because autologous materials theoretically are devoid of immunogenic effects, many surgeons have preferred them as dural substitutes, and their use markedly decreases the rate of complications after posterior fossa surgeries ⁶. However, the use of autologous fascia or pericranium as a dural substitute requires meticulous direct watertight closure of the dura; consequently, these procedures typically are troublesome and time-consuming during dural reconstruction, particularly in the presigmoid region. In fact, in our case series, the median time to complete duralplasty was 44 minutes (median) in the autologous fascia group. In addition, 5 of the 27 patients in this group needed a second incision in the lateral thigh to harvest fascia lata. The invasiveness of the second incision is an important disadvantage of graft harvesting ²⁸.

In April 2017, PGA felt (Durawave) was approved in Japan as a dural substitute. This biocompatible dural substitute is replaced by biological connective tissue by 1 month after surgery ¹⁷. Eventual replacement by dura mater is a key advantage among the various dural substitutes available ²⁹. A previous multicenter clinical trial demonstrated the efficacy and safety of PGA felt with fibrin glue for filling dural defects ¹⁶. Because no suturing is involved, outcome after dural reconstruction in the presigmoid region by using PGA felt is quite favorable. In our current series, 10 cases comprised dural reconstruction using PGA felt with

abdominal fat grafts. Of note, none of these 10 cases needed postoperative CSF drainage; In addition, only 1 patient required revision surgery due to subcutaneous fluid collection, and none of the remaining 9 patients experienced any dural reconstruction–related complications, such as CSF leakage or postsurgical infection. In recent expert series, the CSF leakage rate after a transpetrosal approach was 5% to 15%^{11,12}. In this context, we consider the CSF leakage rate of our PGA felt group (10%) to be acceptable.

The time to achieve dural closure using PGA felt is significantly shorter than the conventional autograft technique. Because dural reconstruction using PGA felt is technically simple, this refinement has the potential to decrease the operation time and to spare surgeons the burden and stress of having to achieve meticulous dural closure during the last part of a lengthy surgery. Although we initially were concerned that using PGA felt would increase the amount of fibrin glue used during reconstruction, the total amount of fibrin glue in fact did not differ between the autologous fascia group and the PGA felt group in the current series.

Limitations

The single postoperative complication in the PGA felt group involved leakage of CSF through a fistula between the edge of the remnant petrosal bone and the PGA felt. As we reported previously, PGA felt is replaced by biologic connective tissue that extends from the dural stump¹⁷. Therefore, when the contact between the PGA felt and remnant dura mater is insufficient, as in our complication case, connective tissue replacement of the dural substitute

may be incomplete. We consider that complete and consistent connection between the dural stump and PGA felt is a critical element of this dural reconstruction procedure.

PGA felt is a biocompatible material and likely eventually is replaced by biological tissues. However, like other artificial materials, PGA felt poses potential risks of infection, premature material dissolution, and allergic reaction. In this study, although none of our patients experienced any of these potential side effects, the number of cases in which PGA felt was used is quite small; consequently, prolonged monitoring for potential post-operative complications, especially those related to the use of synthetic materials, is warranted.

Conclusions

According to results from this initial retrospective study, we propose that PGA felt is an effective candidate material for use as a dural substitute in transpetrosal approaches and is associated with an acceptable postoperative complication rate. Dural reconstruction using PGA felt in this skull base field is convenient and can reduce the duration of this time-consuming procedure. Assessment of the efficacy and safety of this novel dural reconstruction procedure is warranted.

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Figure Captions

Fig. 1

Dural reconstruction procedures using temporal fascia (A–C) or PGA felt (D–E) after an anterior transpetrosal approach. (A–C) A right anterior transpetrosal approach was used to access a small petroclival meningioma. (A) After tumor resection, (B) temporal fascia was placed on the dural defect and fixed by using suture and surgical clips; (C) the dead space then was packed by using free abdominal fat grafts. (D) A left anterior transpetrosal approach was performed to access a trigeminal schwannoma. (E) PGA felt covering the dural defect was fixed in place by using fibrin glue, and then (F) the dead space was packed with free abdominal fat grafts.

Fig. 2

Comparison of dural reconstruction time between the autologous fascia group and PGA felt group. The median time needed to complete dural closure was 44 minutes for the autologous fascia group compared with 9 minutes for the PGA felt group; the difference between the 2 groups is statistically significant ($P < 0.001$).

Fig. 3

Comparison of the amount of fibrin glue used according to the dural reconstruction procedure.

In both groups, the median amount of fibrin glue used is 6 mL.

Table 1. Patient characteristics

	Autologous fascia group (January 2013–March 2017)	PGA felt group (April 2017–May 2019)
No. of patients	27	10
Male/Female	10/17	5/5
Median age (y, range)	54 (29–72)	51 (21–69)
Approach		
Anterior petrosal	9	2
Posterior petrosal	12	7
Combined petrosal	6	2
Tumor histology		
Meningioma	12	3
Schwannoma	13	4
Other	2	3
Postoperative CSF drainage	15 (55.6%)	0 (0%)

Abbreviations: CSF; cerebrospinal fluid, PGA: polyglycolic acid

Table 2. Postoperative cerebrospinal leakage according to dural reconstruction procedure

	Autologous fascia group (n = 27)	PGA felt group (n = 10)
CSF leakage (overall)	8 (29.6%)	1 (10.0%)
subcutaneous	5	1
rhinorrhea	3	0
Revision surgery	2 (7.4%)	1 (10.0%)

Abbreviations: CSF; cerebrospinal fluid, PGA: polyglycolic acid





