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A Prospective Cohort Study on Biodegradable Polylactic Acid Occlusion Material-Assisted Endoscopic Skull Base Dural Defect Repair for Cerebrospinal Fluid Leak and Skull Base Bone Remodeling

Yuefeng Zhu
Department of Neurosurgery, Yichang Central People's Hospital, The First College of Clinical Medical Science, China Three Gorges University, Yichang 443003, Hubei, China

Author to whom correspondence should be addressed.

Abstract: *Objective:* To evaluate the efficacy of biodegradable polylactic acid (PLA) occlusion material-assisted endoscopic skull base dural defect repair on postoperative cerebrospinal fluid (CSF) leak incidence and skull base bone remodeling. *Methods:* A prospective cohort study design was employed. Patients undergoing endoscopic endonasal skull base dural defect repair in the Neurosurgery Department of a tertiary hospital from June 2023 to December 2025 were enrolled. They were divided into a study group (PLA occlusion material-assisted repair) and a control group (autologous material repair). The primary outcome was postoperative CSF leak incidence. Secondary outcomes included skull base bone defect area, bone mineral density, and intracranial infection rate at 6 months postoperatively. *Results:* A total of 164 patients were included (84 in the study group, 80 in the control group). The postoperative CSF leak rate in the study group was 3.6%, significantly lower than 12.5% in the control group ($p = 0.038$). CT evaluation at 6 months postoperatively showed that the study group had a superior reduction rate of skull base bone defect area and an increase in bone mineral density compared to the control group. Differences in bone volume fraction and trabecular thickness were statistically significant ($p < 0.01$). Intracranial infection rates were 1.2% and 6.3%, respectively ($p = 0.086$). *Conclusion:* Biodegradable PLA occlusion material-assisted endoscopic skull base repair effectively reduces postoperative CSF leak incidence and promotes skull base bone remodeling, representing a safe and effective repair strategy.

Keywords: Polylactic acid; Biodegradable material; Endoscopic skull base repair; Cerebrospinal fluid leak; Bone remodeling

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1. Introduction

The rapid development of endoscopic endonasal surgery for pituitary tumors was marked by the reports of Jankowski et al. in 1992. Endoscopic skull base surgery still poses challenges in terms of creating skull base bone and dura mater defects

and CSF leaks, which limit further progress in the field [1].

Successful closure of skull base defects to prevent CSF leaks is very important in endoscopic skull base surgery. Commonly used materials include autologous fat, fascia, nasal septal flaps, and several other types of biological tissue. Even though the use of flaps reduces the occurrence of CSF leaks, harvesting them causes injury to the nasal mucosa, and there is a risk of flap necrosis and other complications [2]. The biocompatibility of various biodegradable biomaterials in skull base defect closure has been widely explored. Recent reports indicate that polylactic acid absorbable plates used in the reconstruction of sellar and extrasellar skull base defects yield postoperative CSF leak rates of 0–6.7% [3].

A prospective cohort study is carried out in order to compare the clinical effectiveness between using biodegradable PLA occlusion materials and autologous materials in the endoscopic repair of skull base dural defects in terms of the occurrence rate of CSF leakage after operation and the parameters of bone reconstruction at the skull base level [4].

2. Materials and methods

2.1. Study design

This prospective cohort study was conducted in the Neurosurgery Department of a tertiary hospital from June 2023 to December 2025.

2.2. Study participants

2.2.1. Inclusion criteria

(1) Imaging and/or pathologically confirmed sellar or anterior skull base space-occupying lesions requiring endoscopic endonasal surgery;
(2) Intraoperative dural defect graded as Esposito grade II or III;
(3) Age 18–75 years;
(4) No history of preoperative CSF leak;
(5) No coagulation dysfunction or severe organ insufficiency [5].

2.2.2. Exclusion criteria

(1) Prior skull base surgery;
(2) Acute infection;
(3) Allergy to PLA material components;
(4) Pregnancy or lactation;
(5) Lost to follow-up.

2.3. Interventions

2.3.1. Study group (PLA occlusion material group)

Repair of skull base dural defects using PLA absorbable occlusion plates. The material is PDLLA, polymerized from approximately 50% D-lactic acid and 50% L-lactic acid, completely degraded and absorbed via hydrolysis within 25 weeks. Surgery followed the multi-layer reconstruction principle: filling the subdural space with fat or gelatin sponge, placing the trimmed and shaped absorbable plate extradurally as rigid support, and finally reinforcing with fascia lata or artificial dura. For larger defects, two absorbable plates could be overlapped [6].

2.3.2. Control group (autologous material group)

Repair using autologous materials, with the specific approach individualized based on intraoperative CSF leak grade and defect size [7].

2.3.3. Study design

Both groups received routine antibiotics for 3–5 days postoperatively. High-risk patients for CSF leak received lumbar drainage for 3–5 days as appropriate. Postoperative bed rest for 5–7 days, avoiding activities that increase intracranial pressure [8].

2.4. Outcome measures

2.4.1. Primary outcome measure

Incidence of CSF leak within 30 days postoperatively. CSF leak diagnosis was based on clear fluid draining from the nose, positive β2-transferrin test, or imaging clearly showing the leak site [9].

2.4.2. Secondary outcome measures

(1) Skull base bone defect at 6 months postoperatively, measured using 64-slice spiral CT thin-section scanning with three-dimensional reconstruction to measure bone defect area, mean bone mineral density (Hounsfield Units, HU), bone volume fraction (BV/TV), and trabecular thickness (Tb.Th);
(2) Intracranial infection rate, diagnosed according to the Chinese Expert Consensus on Diagnosis and Treatment of Central Nervous System Infections in Neurosurgery;
(3) Other postoperative complications (pneumocephalus, material-related adverse reactions, etc.);
(4) Length of hospital stay

2.5. Sample size estimation

Based on prior literature, anticipated postoperative CSF leak rates were 12–15% in the control group and 3–5% in the study group. With 80% power and one-sided $\alpha = 0.05$, a minimum of 75 patients per group was required. Considering a 10% loss to follow-up, 83 patients per group (166 total) were enrolled.

2.6. Statistical methods

SPSS 26.0 software was used for statistical analysis. Continuous data were expressed as mean ± standard deviation, with intergroup comparisons using an independent samples *t*-test or Mann-Whitney U test. Categorical data were expressed as number (percentage), with intergroup comparisons using χ^2 test or Fisher's exact test. $p < 0.05$ was considered statistically significant [10].

3. Results

3.1. Baseline data

A total of 164 patients were included (84 in the study group, 80 in the control group). The two groups were comparable in baseline characteristics including age, sex, body mass index (BMI), lesion type, intraoperative CSF leak grade, and defect area, with no statistically significant differences ($p > 0.05$) **(Table 1)**.

Table 1. Baseline characteristics comparison between the two groups

Characteristic	Study group (n = 84)	Control group (n = 80)	*p* value
Age (years)	52.4 ± 13.1	53.0 ± 12.7	0.726
Sex (M/F)	38/46	35/45	0.835
BMI (kg/m^2)	27.2 ± 4.5	26.9 ± 4.3	0.612
Lesion type (pituitary adenoma/meningioma/other)	52/21/11	49/20/11	0.970
Intraoperative CSF leak grade (I/II/III)	0/38/46	0/37/43	0.874
Defect area (cm^2)	3. 8 ± 1.2	3.6 ± 1.1	0.281
Lumbar drain placement (n, %)	52 (61.9)	49 (61.3)	0.930

3.2. CSF leak incidence

Postoperative CSF leak occurred in 3 cases (3.6%) in the study group and 10 cases (12.5%) in the control group, with a statistically significant difference ($\chi^2 = 4.321$, $p = 0.038$). Notably, in the grade III high-flow CSF leak subgroup, 2 of 46 cases (4.3%) in the study group leaked compared to 8 of 43 cases (18.6%) in the control group, an even more pronounced difference ($p = 0.031$). All CSF leaks were controlled with lumbar drainage and conservative management; no patient required repeat surgical repair.

3.3. Skull base bone remodeling

CT assessment at 6 months postoperatively showed significantly better bone healing quality in the study group. The study group demonstrated superior reduction in skull base bone defect area (73.5% ± 12.4% vs. 58.2% ± 15.6%, $p < 0.001$), increase in bone mineral density (+ 126.7 ± 34.5 HU vs. +72.3 ± 28.9 HU, $p < 0.001$), bone volume fraction (BV/TV: 0.54 ± 0.11 vs. 0.38 ± 0.13, $p < 0.001$), and trabecular thickness (Tb.Th: 0.28 ± 0.05 mm vs. 0.21 ± 0.04 mm, $p < 0.001$). Nearly complete bone defect repair was observed in 8 cases (9.5%) in the study group compared to only 2 cases (2.5%) in the control group. No material-related abnormalities such as plate fragmentation or displacement were observed in the study group.

3.4. Other complications and length of hospital stay

Intracranial infection occurred in 1 case (1.2%) in the study group and 5 cases (6.3%) in the control group, with a difference approaching statistical significance ($p = 0.086$). Pneumocephalus rates were 2.4% and 3.8%, respectively ($p = 0.682$). Mean length of hospital stay was 10.2 ± 3.1 days in the study group versus 12.5 ± 3.8 days in the control group ($p = 0.032$). No severe material-related adverse reactions or deaths occurred in either group.

4. Discussion

4.1. Clinical advantages of PLA occlusion material

First, the PLA material greatly decreased the occurrence rate of postoperative CSF leakage. The overall CSF leakage rate among patients in the study group was much lower compared to that among the controls. This result was especially notable for the third-grade high-flow leak subgroup. Similar results were obtained in other studies. It is worth noting that due to the prospective nature of the study, we obtained more reliable data confirming the positive qualities of PLA material.

The mechanisms of PLA material may be explained from two points of view: mechanically and biologically. On the one hand, the absorbable plate supports the skull base defect while the use of the multi-layer method forms a gradient mechanical stabilization structure. On the other hand, animal experiments and in vitro studies proved that PLA material is characterized by a three-dimensional structure that stimulates cell migration and neovascularization.

Second, this study is the first to quantitatively evaluate the promoting effect of PLA occlusion material on skull base bone remodeling. CT three-dimensional reconstruction at 6 months postoperatively showed that the study group had significantly better outcomes in reduction of bone defect area, increase in bone mineral density, bone volume fraction, and trabecular thickness. These data further confirm that the absorbable plate, as a scaffold structure, provides spatial and temporal guidance for new bone formation during its degradation, promoting regenerative repair of bone tissue at the defect site.

4.2. Comparison with traditional repair methods

Multi-layer composite reconstruction is the basic principle of skull base repair. Autologous material remains the “gold standard” for skull base repair but has many limitations. The biodegradable nature of PLA occlusion material gives it both the mechanical strength of synthetic materials and the gradual integration characteristics of biological materials. It provides rigid support in the early postoperative period and gradually degrades during bone healing, eliminating the need

for a second surgery for removal. Compared with non-degradable materials such as titanium mesh, PLA material does not interfere with postoperative imaging follow-up and avoids the potential risks of long-term retention of metallic foreign bodies.

5. Conclusion

Repairing the skull base dural defect assisted by biodegradable occlusion materials with PLA can effectively reduce the occurrence of CSF leakage, accelerate bone reconstruction in the skull base, and shorten hospital stays, which can be considered a good method for dural defect repair. The use of the prospective cohort study design and evaluation indicators for this study can provide references to the skull base repair field.

Disclosure statement

The author declares no conflict of interest.

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