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Cranioplasty Results after the Use of a Polyester Urethane Dural Substitute (Neuro-Patch®) as an Adhesion Prevention Material in Traumatic Decompressive Craniectomy

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Purpose: This study was conducted to investigate the usefulness of a polyester urethane dural substitute (Neuro-Patch®, B. Braun, Boulogne, France) as an anti-adhesion agent in subsequent cranioplasty by analyzing the use of Neuro-Patch® during decompressive craniectomy in traumatic brain injury patients.
Methods: We retrospectively analyzed patients with traumatic brain injury who underwent decompressive craniectomy followed by cranioplasty from January 2015 to December 2018. Patients were analyzed according to whether they received treatment with Neuro-Patch® or not (Neuro-Patch® group, n=71; control group, n=55). Patients' baseline characteristics were analyzed to identify factors that could affect cranioplasty results, including age, sex, hypertension, diabetes mellitus, use of antiplatelet agents or anticoagulant medication, the interval between craniectomy and cranioplasty, and the type of bone used in cranioplasty. The cranioplasty results were analyzed according to the following factors: operation time, blood loss, postoperative hospitalization period, surgical site infection, and revision surgery due to extra-axial hematoma.
Results: No significant difference was found between the two groups regarding patients' baseline characteristics. For the cranioplasty procedures, the operation time (155 vs. 190 minutes, p=0.003), intraoperative blood loss (350 vs. 450 mL, p=0.012), and number of surgical site infections (4 vs. 11 cases, p=0.024) were significantly lower in the Neuro-Patch® group than in the control group.
Conclusions: The use of Neuro-Patch® was associated with a shorter operation time, less blood loss, and a lower number of surgical site infections in subsequent cranioplasties. These results may provide a rationale for prospective studies investigating the efficacy of Neuro-Patch®.

Keywords: Brain injuries, Traumatic; Craniotomy; Tissue adhesions; Intraoperative complications; Dura mater

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INTRODUCTION

Decompressive craniectomy has been established as an effective treatment method for decreasing intracranial hypertension secondary to traumatic brain injury (TBI) [1,2]. Patients who undergo decompressive craniectomy require cranioplasty as a second operation. The surgical complications of craniotomy include dural tear, cerebral injury, surgical site infection (SSI), and extra-axial hematoma [3]. These complications can occur iatrogenically during dissection due to adhesions, and they may be associated with a prolonged operation time and increased blood loss.

Some studies have investigated adhesion prevention materials for use in craniectomy. Various anti-adhesive materials, such as polytetrafluoroethylene dural substitutes, silicone elastomer sheets, and OrthoWrap™ (MAST Biosurgery, San Diego, USA), were studied, and most studies reported that the use of anti-adhesive materials led to a shorter operation time and less blood loss [4-6].

Neuro-Patch® (B. Braun, Boulogne, France) is a fine-fibered microporous sheet manufactured from highly purified polyester urethane. Neuro-Patch® is utilized as a dural substitute in neurosurgery to repair the dura mater. Commonly used anti-adhesion materials and dural substitutes are absorbable and are often either missing or unexpectedly thin when a cranioplasty is performed. In contrast, Neuro-Patch® is non-absorbable and exhibits no deformations, even months after being placed. These features facilitate dissection during cranioplasty. Other non-absorbable materials with surgical applications include silicone elastomer sheets and polytetrafluoroethylene dural substitutes, but the former are mainly used for plastic surgery and are not commonly used in neurosurgery, and the latter are only available in Japan. We have therefore been using Neuro-Patch® at Gil Medical Center because it is available in South Korea and because it is widely used in neurosurgery as an anti-adhesion material during craniectomy. Hence, we investigated the usefulness of Neuro-Patch® as an anti-adhesion agent in subsequent cranioplasty procedures by analyzing its use during decompressive craniectomy in TBI patients.

METHODS

Study population

We retrospectively analyzed patients with TBI who underwent decompressive craniectomy followed by cranioplasty from January 2015 to December 2018. Decompressive craniectomy was performed in patients with acute intractable brain swelling due to the mass effect and increased intracranial pressure secondary to TBI. Cases where surgery was performed due to spontaneous cerebral hemorrhage or a tumor–not trauma–were excluded, as were patients who developed a SSI after craniectomy. Only unilateral hemicraniectomy was included in the study to ensure a unified analysis of surgical methods.

Patients were divided into the Neuro-Patch® group and control group according to whether Neuro-Patch® was used during the craniectomy. The use of Neuro-Patch® was based on the operator's choice. The medical records were reviewed individually.

Data analysis

Patients' baseline characteristics were analyzed for factors that could affect the results of cranioplasty, including age, sex, hypertension, diabetes mellitus, use of antiplatelet agents or anticoagulant medication, the interval between craniectomy and cranioplasty, and the type of bone used in cranioplasty. The cranioplasty results were analyzed for the following factors: operation time, blood loss, postoperative hospitalization period, SSI, and revision surgery due to extra-axial hematoma.

To quantify blood loss, an anesthesiologist measured the amount of fluid, including blood and irrigation fluid, collected through suction during surgery and then subtracted the amount of fluid used for irrigation from the measured volume. Final blood loss levels were also calculated based on the amount of blood on the gauze according to a method proposed by Ali Algadiem et al. [7].

The US Centers for Disease Control and Prevention (CDC) criteria [8] define SSI as an infection within 1 year of surgery if an artificial substance is inserted. However, in this study, SSI was defined as an infection occurring within 6 months of surgery due to the limited availability of 1-year follow-up data.

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Surgical procedures

Decompressive craniectomy

The standard decompressive craniectomy technique that we perform includes bone removal, dural incision, hematoma removal, and duroplasty. In 71 of the 123 patients, Neuro-Patch® was added to the standard procedure to prevent adhesion formation. The dural incision was made in a C-shape or star shape according to the operator's choice, and duroplasty was performed with an artificial dura substitute. After performing the duroplasty, Neuro-Patch® was placed between the dural flap and the galea/temporalis muscle to prevent the formation of adhesions. The subcutaneous tissue and skin were closed in a serial fashion.

Cranioplasty

Cranioplasty was performed roughly 3 months after craniectomy in our study, with an average interval of 110 days. The incision was made following the previous wound, and the skin flap and dura were carefully dissected. In patients in whom Neuro-Patch® had been placed, it was removed after blunt separation of the patch and dura (Fig. 1). Autologous or artificial bone was used, depending on the condition of the stored bone and the operator's choice.

Statistical analysis

Continuous data (e.g., age) were presented as medians and interquartile ranges. Categorical data (e.g., sex) were presented using frequencies and percentages. Continuous variables were compared using the independent *t*-test, and categorical variables were compared using the Fisher exact or Pearson chi-square test. All tests were performed using a statistical significance criterion of α=0.05, analyses were performed in SPSS for Windows version 23.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Over the 4-year study period, 1,115 patients were hospitalized at Gil Medical Center due to TBI. Of them, 187 underwent decompressive craniectomy procedures that satisfied this study's inclusion criteria. Of those 187 patients, 126 subsequently underwent cranioplasty. The remaining 61 either died before cranioplasty (n=42) or were lost to follow-up or did not undergo cranioplasty for reasons other than death (n=19). The 126 patients who underwent cranioplasty were divided into two groups (Neuro-Patch® group, n=71; control group, n=55). The median age of the patients was 51 years (interquartile range, 40 to 60 years), with a sex distribution of 39 (31.0%) female patients and 87 (69.0%) male patients.

Through a comparison of baseline characteristics, we analyzed factors that could affect cranioplasty. There was no significant difference with regard to age, sex, and history of hypertension or diabetes. Furthermore, there was no significant difference in the use of antiplatelet or anticoagulant medication that could increase the bleeding tendency. The interval between the craniectomy and cranioplasty, and the type of bone used in cranioplasty, were analyzed as factors that could potentially affect the risk of infection or adhesion; there was no significant be-

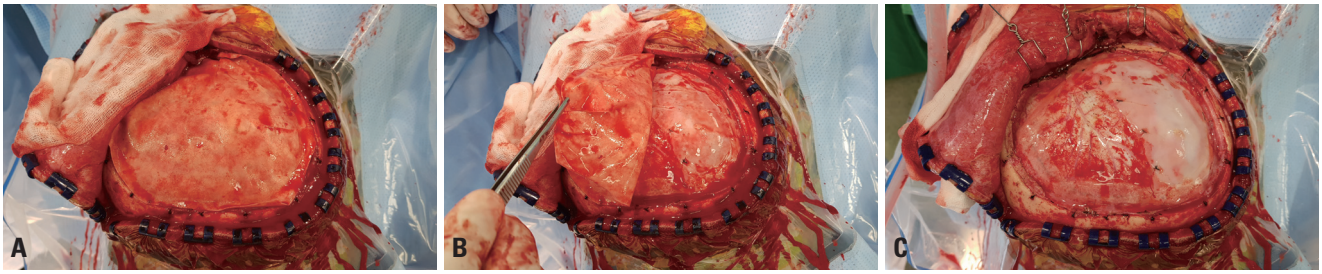

Fig. 1. Operative findings of a polyester urethane dural substitute (Neuro-Patch®, B. Braun, Boulogne, France) in cranioplasty. (A) Neuro-Patch® on the dura after being detached from the galea and the temporalis muscle. (B) Separation of Neuro-Patch® from the dura. (C) Findings after removing the Neuro-Patch®.

tween-group difference according to either of those two factors (Table 1).

The cranioplasty results of the two groups were analyzed according to surgical factors that could be affected by the degree of adhesion. The operation time was significantly shorter in the Neuro-Patch® group than in the control group. Moreover, the blood loss was 350 mL in the Neuro-Patch® group, which was significantly less than the blood loss of 450 mL in the control group. The combined number of SSIs in both groups was 15 (11.9%). The Neuro-Patch® group had 4 cases and the control group had 11 cases. There was no significant difference with regard to the postoperative hospitalization period or revision surgery due to an extra-axial hematoma (Table 2).

DISCUSSION

Relatively common complications of cranioplasty after decompressive craniectomy for patients with TBI include dural or brain injury due to peridural fibrosis and additional soft tissue remnants under the bone flap [3,5]. Moreover, increased adhesion formation makes the dissection of the dura more difficult and time-consuming, which results in a greater amount of blood loss, a longer duration of the operation, and increased frustration for the surgeon [9].

Various methods and anti-adhesive materials have been used to reduce dural adhesions after craniectomy. A polytetrafluoroethylene dural substitute [5], silicone elastomer sheets [4,10], sodium hyaluronate/carboxymethylcellulose (Seprafilm®, Sanofi Genzyme, Cambridge, MA,

Table 1. Baseline characteristics of the Neuro-Patch® and control groups

	Neuro-Patch® group (n=71)	Control group (n=55)	*p*-value
Age (years)	52 (43-61)	51 (37-60)	0.662
Sex (female)	18 (25.4)	21 (38.2)	0.122
Hypertension	22 (31.0)	14 (25.5)	0.495
Diabetes mellitus	6 (8.5)	4 (7.3)	1.000
Antiplatelet agents of anticoagulant medication	9 (12.7)	5 (9.1)	0.525
Interval between craniectomy and cranioplasty (days)	109 (86-196)	110 (78-134)	0.155
Bone type used in cranioplasty			0.201
Autologous bone	16 (22.5)	18 (32.7)	
Artificial bone	55 (77.5)	37 (67.3)	

Values are presented as median value (interquartile range) or number (%).
Neuro-Patch® is a product of B. Braun (Boulogne, France).
Statistically significant differences ($p<0.05$).

Table 2. Cranioplasty results of the Neuro-Patch® and control groups

	Neuro-Patch® group (n=71)	Control group (n=55)	*p*-value
Operation time (minutes)	155 (140-185)	190 (155-220)	0.003[a]
Blood loss (mL)	350 (150-500)	450 (350-600)	0.012[a]
Postoperative hospitalization period (days)	13 (12-18)	14 (11-23)	0.273
Surgical site infection	4 (5.6)	11 (20)	0.024[a]
Revision surgery due to extra-axial hematoma	2 (2.8)	4 (7.3)	0.403

Values are presented as median value (interquartile range) or number (%).
Neuro-Patch® is a product of B. Braun (Boulogne, France).
[a]Statistically significant differences ($p<0.05$).

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USA) [9,11], an anti-adhesive film (Orthowrap™) [6], and an expanded polytetrafluoroethylene membrane [12] have all been used as barriers to prevent adhesions, and have shown promising results in terms of decreasing the total cranioplasty time and amount of blood loss.

We used Neuro-Patch®, a non-absorbable synthetic dural substitute composed of polyester urethane, as an anti-adhesion agent. Neuro-Patch® is a dural substitute, but it was used for adhesion prevention by placing it between the dura and scalp; it was not used during duroplasty. The surgical findings of the patients who underwent cranioplasty with Neuro-Patch® show that almost no adhesions formed between the Neuro-Patch® and the dura, as it was easily detached by blunt dissection with the fingers. Although some adhesion formation was observed between the Neuro-Patch® and the galea, it could be removed by hand without special tools. In the patients who did not receive Neuro-Patch®, the majority of the surgical time was spent on careful dissection to prevent dural tearing and temporalis muscle injury due to adhesion formation between the dura and the galea. In our study, the short time required for dissection in the Neuro-Patch® group shortened the overall operation time, which led to less bleeding from the galea and muscle due to fewer adhesions; additionally, the shorter operation time resulted in less overall blood loss.

We believe that the reduced bleeding and shortened operation time due to easier dissections are the primary advantages of using Neuro-Patch®. Another advantage of using Neuro-Patch® is that its high tensile strength as a non-absorbable material can provide protection against complications, such as dural tearing and brain cortex injuries, that may occur during dissection.

Neuro-Patch® also has some disadvantages. It has been reported that the use of Neuro-Patch® during craniectomy may increase the risk of certain postoperative complications, such as extra-axial hematoma [13]. Theoretical principles suggest that Neuro-Patch®, as a foreign body, should also increase the risk of infection, including SSI, and Malliti et al. [14] reported that Neuro-Patch® may yield a higher rate of SSI in patients with trauma. However, we found that the patients who received Neuro-Patch® actually had a lower rate of SSI. Previously reported risk factors for SSI after neurosurgical procedures include cerebrospinal fluid leakage, multiple operations, operation times longer than 4 hours, higher classes in the American Society of Anesthesiologists (ASA) system, clean-contaminated or dirty wounds, and lower levels of surgeon experience [15-18]. Furthermore, the CDC guidelines indicate that longer durations of anesthesia and surgery are associated with an increased risk of SSI [19]. Based on these reports, we suspect that the Neuro-Patch® group's relatively low SSI rate resulted from the group's shorter operation times and lower bleeding levels.

A previous report described the use of Neuro-Patch® during decompressive craniectomy. Huang et al. [13] reported that there was no difference in surgical time and blood loss when using Neuro-Patch® in cranioplasty compared to the control group. In that study, however, duroplasty was not performed during craniectomy. Instead, Neuro-Patch® was placed on the exposed brain tissue in the Neuro-Patch® group, and hemostatic materials were placed on the exposed brain tissue in the control group. Therefore, we suggest that careful dissection between the dura and the Neuro-Patch® was necessary in those patients because dural defects remained present during cranioplasty; therefore, the effects of Neuro-Patch® on shortening the operation time and reducing blood loss may have been small. If Neuro-Patch® is applied without creating a dural defect through duroplasty during craniectomy, rapid dissection can be achieved during cranioplasty.

This study has some limitations. The data were analyzed retrospectively. A prospective study would be more meaningful, but such studies can be difficult to perform because it is not easy to obtain informed consent from patients and guardians when emergency craniectomy is required. Craniectomy and cranioplasty were performed by several surgeons, rather than by one. Because the operator's skill has a large effect on factors such as the operation time and blood loss, data from a single operator would have yielded more accurate results; nevertheless, we used data from several surgeons to strike an acceptable balance in terms of the study size, which would have been dramatically reduced by restricting the analysis to a single operator's data. The number of SSIs was low in the Neuro-Patch® group, but there was no further analysis of these results. The operation time and amount of blood loss may

have had a significant impact, but many other causes may affect SSIs. Thus, multivariable analysis including various factors is necessary. In South Korea's health insurance system, Neuro-Patch® is designated as a dural substitute and cannot be used as an anti-adhesion substance. In the past, more than two dural substitutes were available. However, due to increased medical expenses, only one has been used in recent years. Therefore, Neuro-Patch® cannot be used as an additional anti-adhesion substance to prevent adhesion after duroplasty using artificial dura. Our study findings suggest that the use of Neuro-Patch® in decompressive craniectomy has several advantages; therefore, we propose that the relevant medical policies should be supplemented.

Despite these limitations, the results of this study may provide useful information for the prevention of adhesions during craniectomy. In addition to the Neuro-Patch® used in this study, several anti-adhesion substances used in previous studies can provide numerous benefits, such as a shorter operation time and less blood loss during cranioplasty.

CONCLUSIONS

Neuro-Patch® is a useful material for preventing postoperative adhesions after decompressive craniectomy in TBI patients. The use of Neuro-Patch® was associated with a shorter operation time, less blood loss, and a reduced risk of SSI in subsequent cranioplasties. These results may provide a rationale for prospective studies.

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