COMPARISON OF DEEP WOUND INFECTION RATES USING A SYNTHETIC DURAL SUBSTITUTE (NEURO-PATCH) OR PERICRANIUM GRAFT FOR DURAL CLOSURE: A CLINICAL REVIEW OF 1 YEAR

Miriam Malliti, Pharm.D.
Department of Pharmacy, Sainte-Anne Hospital, Paris, France

Philippe Page, M.D.
Department of Neurosurgery, Sainte-Anne Hospital, Paris, France

Charles Gury, M.D., Pharm.D.
Department of Pharmacy, Sainte-Anne Hospital, Paris, France

Eric Chomette, M.D.
Department of Medical Information, Sainte-Anne Hospital, Paris, France

François Nataf, M.D.
Department of Neurosurgery, Sainte-Anne Hospital, Paris, France

François-Xavier Roux, M.D.
Department of Neurosurgery, Sainte-Anne Hospital, Paris, France

Reprint requests:
Philippe Page, M.D., Department of Neurosurgery, Sainte-Anne Hospital, 1 rue Cabanis, 75014 Paris, France.
Email: page@chsa.broca.inserm.fr

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OBJECTIVE: The need to repair dural defects has prompted the use of dura mater substitutes. Many synthetic materials have been used for dural closure. Neuro-Patch (B. Braun Médical S.A., Boulogne, France) is a nonabsorbable microporous fleece composed of polyester urethane that has been approved for human use by the European Union since 1995. To the best of our knowledge, no clinical series with Neuro-Patch have been published thus far, particularly with regard to septic complications. The aim of our study was to compare the safety of Neuro-Patch with that of pericranium graft with regard to postoperative wound infections.

METHODS: This is a retrospective study of 1 year's experience including all patients who underwent dural plasty with a Neuro-Patch (n = 61) or pericranium graft (n = 63). The follow-up period was at least 12 months after surgery. Before wound infection rates in the two groups were compared, factors suspected of being risks for neurosurgical site infection were evaluated.

RESULTS: Patient characteristics (mean age, neurological diagnosis), surgical procedures, prophylactic antibiotics, and risk factors for surgical infections (including duration of surgery, emergency, contaminated operations, and external cerebrospinal fluid drainage) were similar in the Neuro-Patch and pericranium groups. Deep wound infection rates in the Neuro-Patch and pericranium groups were 15 and 5%, respectively ($P = 0.06$), and cerebrospinal fluid leaks were significantly more frequent in the Neuro-Patch group (13 versus 1.6%, $P < 0.05$).

CONCLUSION: The results of our investigations show that Neuro-Patch raised the risk of wound infection, as do foreign materials implanted in the body. Synthetic dural grafts should be reserved for when autologous grafts are not sufficient or possible. An extensive prospective multicenter randomized trial is needed to confirm our results.

KEY WORDS: Dural substitute, Neuro-Patch, Pericranium graft, Postsurgical site infections

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Neurosurgeons are often confronted with the problem of a closure of a dural defect in their surgical work. Many materials have been used as dural grafts over the years. The goal in using a dural substitute is to achieve a watertight closure, to prevent infection, and to provide a surface along which the "neodura" can be generated (18). Autologous grafts harvested from temporalis fascia, pericranium, or fascia lata remain the dural substitutes most widely used because they do not induce immunological or severe inflammatory reactions (18, 20). However, sufficient quantities may not always be available, and a second skin incision is required for harvesting fascia lata (7). Therefore, synthetic materials, such as polyester urethane (Neuro-Patch; B. Braun, Boulogne, France), expanded polytetrafluoroethylene (Preclude; Gore & Associates, Evry, France), and polyglactin 910-polydioxane (Ethisorb DuraPatch; Johnson & Johnson Medical, Issy-les-Moulineaux, France), have been used as a dural substitute. However, synthetic non-

resorbable materials could lead to an immediate problem of infection, as do other implanted foreign bodies, and late hemorrhagic and fibrotic reactions are also described (2, 12, 13).

Neuro-Patch is a nonabsorbable microporous fleece composed of cleaned aliphatic polyester urethane, available in France since 1995 and used in our institution since that date. This material is approved for human use by the European Union. Neuro-Patch was introduced after the distribution of Lyodura (B. Braun), a human cadaveric dura, was discontinued because of its reported association with Creutzfeldt-Jakob disease (5, 9, 19). To the best of our knowledge, no clinical series with Neuro-Patch have been published thus far, particularly with regard to septic complications. The aim of our study was to compare postoperative wound infection rates and cerebrospinal fluid (CSF) leakage with the use of Neuro-Patch or pericranium. Before comparing wound infection rates with Neuro-Patch and pericranium, factors suspected as contributing to risks for neurosurgical site infection from previous studies (4, 6) were evaluated in the two groups of patients. We also attempted an economic study, calculating the cost of deep wound infections observed.

PATIENTS AND METHODS

This retrospective study concerned all patients who underwent dural plasty with Neuro-Patch or pericranium graft between January and December 2000 in our neurosurgical department. The choice between synthetic and autologous graft material depended on operative situation and individual surgeon preference. Neuro-Patch was used only when necessary, depending on local surgical circumstances. The follow-up period was at least 12 months after surgery or until death for patients who survived less than 12 months. An infection was considered nosocomial if it occurred during the 12 months after the intervention when medical devices were implanted, according to the guidelines of the French Committee, Centre de Coordination de la Lutte contre les Infections Nosocomiales Paris Nord (1). Data were collected for each patient on standardized forms and included age, sex, neurological diagnosis, site of surgery (supratentorial or infratentorial), Glasgow Coma Scale score at admission, previous neurosurgery within 3 months before surgery, scheduled or emergency surgery, Altemeier's wound classification (clean, clean-contaminated, contaminated, and dirty-infected), length of surgery, and presence of external or internal CSF drainage. Type and duration of prophylactic antibiotics were noted. In the postoperative period, early subsequent surgery (e.g., for postoperative hematoma), CSF leakage, and wound infection (type, time of onset, and responsible microorganisms) were registered.

Surgical site infections were classified according to the guidelines of the French Committee, Centre de Coordination de la Lutte contre les Infections Nosocomiales Paris Nord (1), as follows: 1) scalp or superficial infection (not recorded in this study); 2) bone flap osteitis (either a surgical diagnosis of osteitis or fever with local signs and discharge and a positive blood culture or a suggestive x-ray); 3) meningitis-ventriculitis (either a Gram stain and/or CSF culture demonstrating a microorganism or CSF leukocytosis with increased protein concentration and decreased glucose concentration, associated with fever and nuchal rigidity and antibiotic treatment prescribed by the attending clinician); and 4) brain abscess and empyema (either a microorganism isolated from brain tissue or subdural space, or a surgical diagnosis of brain abscess, or fever with altered mental status, and/or focal neurological deficit and suggestive computed tomographic scan, with antibiotic treatment prescribed by the clinician).

For all patients, protocols for infection surveillance were the same (check of temperature at least three times per day and examination of scar every 2 d), and we recorded the same criteria for infections for all patients. To evaluate the cost of deep wound infections observed, hospital stay attributable to infection and antibiotherapy administered were identified.

Statistical Analysis

Data were expressed as mean ± standard deviation. Student's t test was used for quantitative variables and the χ^2 test for categorical variables. All probability values were two-sided, and a value of $P < 0.05$ was considered statistically significant.

Patient Characteristics

During the 12-month study period, 564 intracranial procedures were performed, and dural plasty using Neuro-Patch or pericranium graft was performed on 61 and 63 patients, respectively. Patient characteristics in the two groups are presented in *Table 1*. Mean age and neurological diagnosis were similar in the Neuro-Patch and the pericranium groups. Neurological diagnoses essentially included brain tumors (80 and 65% in the Neuro-Patch and pericranium groups, respectively, $P = 0.06$). Malignant tumors affected 44 and 38% of patients in the Neuro-Patch and pericranium groups, respectively.

Surgical Procedures

Scheduled operations accounted for 56 patients in the Neuro-Patch group and 60 patients in the pericranium group. Surgery was classified as clean for 53 patients in the Neuro-Patch group and 51 patients in the pericranium group, as clean-contaminated for 7 patients in the Neuro-Patch group and 9 patients in the pericranium group, as contaminated for 1 patient in the Neuro-Patch group, and as dirty for 3 patients in the pericranium group. The site of surgery was primarily supratentorial in both groups (64 and 94% in the Neuro-Patch and pericranium groups, respectively). There was no statistical difference between the two groups for Altemeier's classification, which is considered a main risk factor for postoperative infections.

Prophylactic Antibiotics

Perioperative antibiotic prophylaxis according to standard procedures of our neurosurgical department was given in

TABLE 1. Characteristics of patients receiving Neuro-Patch or pericranium for dural closure[a]

	Neuro-Patch (n = 61)	Pericranium (n = 63)	*P*
Age (yr), mean	52 ± 14	50 ± 14	NS
Sex ratio, M/F	27/34	39/24	0.049
Surgical procedures			NS
Meningioma	16	12	
Glioblastoma	5	4	
Glioma	6	3	
Medulloblastoma	1	1	
Ependymoma	1	0	
Craniopharyngioma	1	0	
Metastasis	9	8	
Hemangioblastoma	3	1	
Neuroma	2	1	
Hypophysis adenoma	1	3	
Ethmoid bone	3	5	
Chondrosarcoma	0	1	
Non-Hodgkin's lymphoma	0	1	
Cavernoma	1	1	
Vascular surgery	4	10	
Cranial trauma	2	4	
Other procedures[b]	6	8	

[a] NS, not significant.
[b] Epileptic surgery, Chiari syndrome.

nearly all patients (clean surgery, cloxacillin; clean-contaminated surgery, cefazolin; contaminated surgery, amoxicillin-clavulanic acid for 48 h). Against our protocols, two patients receiving Neuro-Patch and one patient receiving a dural closure with pericranium were given no antibiotic medication before surgery, with no medical reason stated.

Risk Factors for Surgical Infections in the Neuro-Patch and Pericranium Groups

Factors suspected as risks for neurosurgical site infection from previous studies (4, 6) were evaluated in the two groups of patients. Patient-related risk factors for surgical site infections (including a Glasgow Coma Scale score at admission of <8 or a recent neurosurgical procedure), surgical procedure-related risk factors (including no antibiotherapy prophylaxis, a surgical duration of longer than 4 h, emergency surgery, operations classified as contaminated or dirty-infected, external CSF drainage, and postoperative CSF leakage), and post-surgical radiation therapy are presented in *Table 2*. The frequencies of neurosurgical site infection risk factors were similar between the Neuro-Patch and pericranium groups except for CSF leaks, which were more frequent in patients receiving Neuro-Patch. The frequencies of diabetes, previous cytotoxic chemotherapy, and antimicrobial therapy within the month preceding surgery were similar in the two groups.

TABLE 2. Risk factors for neurosurgical site infections in the Neuro-Patch and pericranium groups[a]

Risk factors	Neuro-Patch (n = 61)	Pericranium (n = 63)	*P*
Previous neurosurgery[b]	5	4	NS
GCS score <8	6	2	NS
Emergency surgery	5	3	NS
Wound classification >2	1	3	NS
Surgery >4 h	17	20	NS
External CSF drainage	7	5	NS
No antibiotic prophylaxis	2	1	NS
CSF leakage	8	1	<0.05
Subsequent operation	1	1	NS
Radiation therapy	17	18	NS

[a] GCS, Glasgow Coma Scale; CSF, cerebrospinal fluid; NS, not significant. Wound classification >2, contaminated and dirty-infected surgery.
[b] Within 90 days before surgery.

RESULTS

Deep Wound Infection Rates

Deep wound infection (meningitis, abscess, osteitis, empyema) rates in the Neuro-Patch and pericranium groups were 15% (9 of 61 patients; 95% confidence interval [CI], 6–24%) and 5% (3 of 63 patients; 95% CI, 0.5–10%) (χ^2 test, $P = 0.06$), respectively. The deep wound infection rate in the pericranium group was similar to the mean incidence of deep wound infection after craniotomy in our neurosurgical department (5.5% in the year 2000). Deep wound infection incidence in the Neuro-Patch group was significantly higher than the mean rate after craniotomy (15 versus 5.5%, $P < 0.05$) (*Fig. 1*).

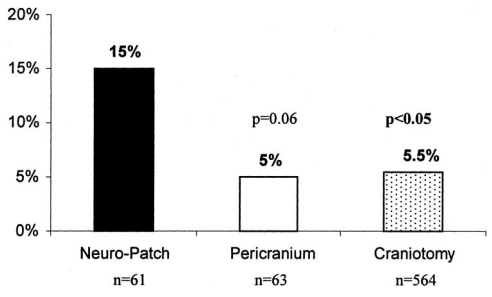

FIGURE 1. *Bar graph showing incidence of deep wound infections in patients receiving Neuro-Patch or pericranium graft for dural closure.*

Deep wound infections recorded in the Neuro-Patch group were meningitis (n = 6), osteitis (n = 1), and empyema (n = 2), and in the pericranium group, meningitis (n = 1) and empyema (n = 2). The median delays between surgery and the onset of infection were 18 days (range, 9–76 d) and 16 days (range, 2–25 d) in the Neuro-Patch and pericranium groups, respectively (*Fig. 2*). *Staphylococcus aureus* was the main organism responsible for deep wound infections, with a large proportion being methicillin-resistant. Other organisms responsible for the infections were Gram-negative bacilli (*Haemophilus influenzae, Klebsiella pneumoniae*) or *Propionibacterium acnes*. In the infected Neuro-Patch subgroup, one patient harboring a malignant glioma and empyema died 4 months after neurosurgery despite receiving antibiotic therapy for 68 days and removal of the synthetic dural plasty.

CSF leaks were significantly more frequent in the Neuro-Patch group (8 of 61 patients) than in the pericranium group (1 of 63 patients). In the pericranium group, only one patient experienced a CSF leakage, and this patient did not have a deep wound infection. Of the eight patients with CSF leakage in the Neuro-Patch group, one-half had a deep wound infection. In addition, of the nine infected patients in the Neuro-Patch group, four had a CSF leakage.

Treatment and Cost of Deep Wound Infections

Removal of Neuro-Patch plasty was necessary for five of the nine infected patients in the Neuro-Patch group. Patients were treated with a mean of three antibiotics, essentially fosfomycin, vancomycin, or ceftriaxone, during a mean of 33 ± 19 days. The mean cost of antibiotic therapy administered in our hospital was evaluated as $1507 per patient. Hospital stay related to deep wound infection was estimated at 30 ± 20 days per patient, with 13 ± 10 days in the intensive care department and 17 ± 13 days in the neurosurgery department. Mean costs related to hospital stay were evaluated as $27,523 per infected patient (*Table 3*).

TABLE 3. Cost of hospital stay related to deep wound infection

	Daily cost ($)	Mean hospital stay related to deep wound infection per patient (d)	Cost per patient ($)
Hospitalization in intensive care unit	1003	13	13,039
Hospitalization in neurosurgery department	852	17	14,484
Mean cost per patient			27,523

DISCUSSION

To the best of our knowledge, this is the first study comparing wound infection rates for Neuro-Patch, a synthetic dural substitute, with autologous pericranium grafts harvested at the operation site for dural closure after a neurosurgical procedure. This study compares 61 patients who received Neuro-Patch as a dural substitute and 63 patients who received a pericranium graft. Surgical procedures and risk factors for neurosurgical site infections were similar in the Neuro-Patch and pericranium groups. Deep wound infection rates observed in the Neuro-Patch and pericranium groups were 15 and 5%, respectively ($P = 0.06$). CSF leakage was significantly more frequent with Neuro-Patch than pericranium grafts (13 versus 1.6%). The results of our investigation indicates that Neuro-Patch increases the risk of wound infection, as do all other foreign materials implanted in the body.

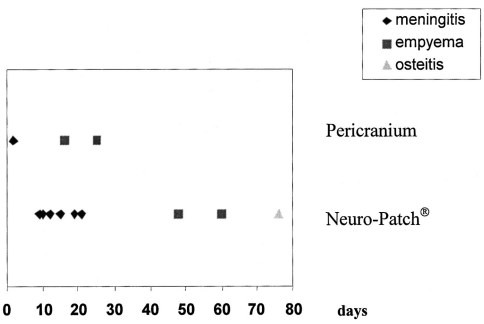

FIGURE 2. *Plot showing delay and site of infections observed in the Neuro-Patch and pericranium groups.*

Infection rates with Neuro-Patch are significantly higher than mean wound infection rates in our neurosurgical department (5.5%). This synthetic dural plasty also increases infection rates compared with autologous pericranium dural substitute, with a difference that did not achieve statistical significance in our study because of the small size of our groups. Otherwise, infection rate differences are not explained by differences in either patient characteristics or surgical procedures. Finally, because risk factors were the same in the two groups, they cannot explain the higher infection rate with Neuro-Patch. Generation of the "neodura" and fusion between tissues are probably slower with Neuro-Patch and could explain the more frequent CSF leakages observed with Neuro-Patch. According to the results of Raul et al. (11), CSF leaks are probably caused by a tear in the dura mater occurring during Neuro-Patch implantation and by the surgical suture. This tear would be related to the elastic properties of Neuro-Patch, which can exert traction on surgical sutures, explaining the increase of postoperative CSF leaks compared with the pericranium group (11).

The safety of synthetic dural grafts against septic complications has been reported in a few studies and concerned materials such as expanded polytetrafluoroethylene (8) or Vicryl (Ethicon, Inc., Somerville, NJ) (3, 14, 16, 17). Infection rates related in those studies, evaluated in groups of 63 to 429 patients, were approximately 0 to 4% (3, 14, 16, 17). Van Calenbergh et al. (15) reported an infection

rate with expanded polytetrafluoroethylene of approximately 1.4%. With Vicryl-polydioxanone, Von Wild (17) and Verheggen et al. (16) cited rates of 4 and 0%, respectively. With Vicryl-collagen, the infection rate reported was approximately 2.6% (14). Therefore, infection rates with these synthetic dural substitutes are not higher than mean infection rates in neurosurgery. Because prosthetic materials vary with respect to their infectivity (8, 10), could the higher infection rate with Neuro-Patch be explained by the material or its texture? In the recently published study by Raul et al. (11), however, in the 70 patients receiving Neuro-Patch for dural closure, three infections requiring the withdrawal of the substitute were observed, and nine radiological CSF leakages occurred with no exteriorized leakage.

The results of our study have had repercussions on the neurosurgical work of our practice, leading us to use, as often as possible, autologous dural grafts rather than Neuro-Patch; synthetic dural grafts are reserved for use when autologous grafts are not sufficient or possible. This study was performed retrospectively using information obtained from medical records. A prospective study with more patients would have allowed for more detailed data collection, notably about wound infection risk factors. An extensive prospective multicenter randomized trial is needed to confirm these results.

CONCLUSION

The results of our investigations show that Neuro-Patch raises the risk of wound infection, as do other foreign materials implanted in the body. In fact, since these results have been known, i.e., for 12 months, we have tried to use Neuro-Patch as infrequently as possible, considering the risk of infection to be too high.

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COMMENTS

Malliti et al. address an important issue in neurosurgery that has not been formally studied in a scientific manner: whether or not it is better to use a pericranial graft or a synthetic dural substitute for dural closure. The two major concerns to neurosurgeons that are addressed in the article are which material is more likely to leak cerebrospinal fluid (CSF) after the repair, and whether there is a higher incidence of infection with one material than the other. As most neurosurgical residents are taught during their training, there is no substitute for a patient's own natural tissues for dural closure if these tissues are accessible. This study shows in a convincing manner that both CSF leakage and deep wound infections are statistically more common when a synthetic dural substitute is used instead of pericranium. The two comparison groups are very well matched in all respects, including the type of malignant brain tumors that were present in each group and whether or not those patients with complications had received adjuvant radiation therapy. The authors even performed a cost-effectiveness analysis that addressed the added cost of diagnosing and treating a postoperative infection. It should be noted that dural substitutes are more costly than pericranium even if no postoperative complication is encountered. At a time when physicians are attempting to curtail the rising cost of medicine, complication avoidance is one of the most financially prudent ways to lower medical costs. One question that is not answered in this study and that would require a much larger clinical trial is whether this particular dural substitute has a complication risk profile comparable to that of other synthetic dural replacements. Given the statistical results of this trial, it would be expected that if two dural substitutes were

compared with pericranium, one substitute might prove to be better than the other synthetic material, but both would prove to be inferior to pericranium.

Walter A. Hall
Minneapolis, Minnesota

The authors report what is essentially a process improvement project for their practice. This is a very important activity that all neurosurgical practices should engage in on a regular basis. It is very logical for the authors to follow their own recommendation. There are important reasons, however, to be cautious in generalizing these conclusions to other practices. I will attempt to elucidate these reasons further by answering questions that should be asked of any report comparing the likelihood of harm (in this case, infection) in two or more groups of patients (1).

1. Are the results valid?
   a. Did the investigators demonstrate similarity in all known determinants of outcome or adjust for such differences in the analysis? Their *Table 2* presents the data in this regard. There is a noticeable difference in sex ratio, reflected in a 4:3 ratio of meningiomas between the Neuro-Patch (B. Braun Médical S.A., Boulogne, France) and pericranium groups. There is a predominance of CSF leaks in the Neuro-Patch group, a factor known to predispose to wound infection. Only very simple analyses have been used, which do not attempt to adjust for these differences between the groups. Therefore, we cannot determine whether Neuro-Patch increases the risk of infection independently of the fact that its use was associated with an increase in CSF leak. We also cannot tell whether the increase in CSF leak may have been related to the increased number of meningiomas in the Neuro-Patch group (the resection of the dural attachment of a meningioma, particularly at the cranial base, may increase the likelihood of CSF leak). The net effect is that we cannot determine whether we should avoid using Neuro-Patch or change our technique for preventing CSF leak.
   b. Were exposed patients equally likely to be identified in the study groups? Because the data were collected retrospectively, involved several surgeons, and used a definition of infection that included subjective assessments in the absence of positive cultures, we do not know, and cannot assume, that infection was sought with the same intensity in all of the patients. It is not unreasonable to propose that, because the surgeons knew which patients received Neuro-Patch and were developing a suspicion that it might promote infection, they were more likely to identify infection in the Neuro-Patch patients. We are all familiar with the differences in interpretation of possible clinical infections by different surgeons and have no reason to expect that such differences do not exist among the surgeons treating these patients.
   c. Were outcomes measured in the same way in the groups being compared? This was addressed in the previous paragraph.
   d. Was follow-up complete? Yes, for the purposes of the article (the authors set a limit of 12 mo after surgery and state that all patients were followed up for 12 mo or until death).
2. What are the results?
   a. How strong is the association between exposure and outcome? The absolute risk reduction (not adjusted for covariates such as sex or CSF leak) attributed to using pericranium rather than Neuro-Patch is 10% (range, 5–15%). The authors do not provide an estimate of the adjusted risk reduction.
   b. How precise is the estimate of risk? The confidence intervals around the risk estimates range from 6 to 24% for the Neuro-Patch group and 0.5 to 10% for the pericranium group.
3. Are the results applicable to patient care?
   a. Is the patient population to which the results are applicable clearly described? This is an area of difficulty with single-institution studies. It is easy to assume that all series of neurosurgical patients are similar, but referral patterns, ethnic variations, and differences in diagnostic and surgical practice, among other things, may make for substantial differences between the patients reported on and those in the reader's practice. This can be assessed only if the patient population is very carefully described, and even then, the extrapolation is uncertain.
   b. Was the duration of follow-up sufficient? Yes, for these purposes.

To restate the original comment, the authors have engaged in an important and useful exercise, but the results are directly applicable only to their own practice. It would be inappropriate to generalize these results to other practices. It would be appropriate, however, to perform a similar analysis in one's own practice and change practice on the basis of those results. To produce data that would be broadly generalizable and appropriate to use as the basis for widespread changes in practice, a more formal and carefully designed study would be required.

Stephen J. Haines
Minneapolis, Minnesota

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An easily available and reasonably priced synthetic dural substitute would be of great benefit to patients who need to have dural repair. An ideal material has not yet been found. The authors report that 56 patients who had repair with a microporous fleece made of polyester urethane had a higher infection rate than 60 patients who had repair using pericranium.

Robert G. Grossman
Houston, Texas