Evaluating the Efficacy and Pitfalls of G-Patch: A Synthetic Fabric Patch for Duroplasty - A Retrospective Single Institute Study

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Abstract

Introduction: The use of synthetic materials for duraplasty has been a topic of considerable interest in neurosurgery. Synthetic grafts offer several advantages over autologous tissue, including reduced operative time, decreased morbidity, and consistent availability..
Material & Methods: This is a retrospective study and analyzed data from patients who underwent duraplasty with G-Patch at a single institute. All the patients under inclusion criteria, data were collected from the hospital records, physical and digital records. Inclusion Criteria were all patients who underwent surgery and dura were closed using Gpatch and availability of complete medical records and follow-up data.
Results: A total of 48 patients were included in this study. Most of the patients were males 68.75% (33) and 31.25%(15) females. The mean (SD) age of the population was 32.48 (20.05) years. Almost 69% (33) had traumatic brain injury where 31% (15) had non-traumatic indications for surgery. Three patients 6.25% had post-operative complications. Two patients had post-operative wound infection, and one patient had wound infection with dehiscence. None of the patients had seizure, bleeding seroma, CSF leak or any signs of foreign body reactions.
Conclusion: G-Patch appears to be safe and biocompatible, efficient, and practical option for dural closure in both traumatic and non-traumatic neurosurgical cases.

Keywords: Gpatch, Duroplasty, Synthetic fabric patch, Dural defects, Craniectomy

Introduction

Duroplasty, the surgical repair of the dura mater, is a critical procedure in neurosurgery aimed at addressing defects that can arise from traumatic brain injuries, surgical interventions, or congenital anomalies. The integrity of the dura mater is paramount in protecting the brain and spinal cord from external insults and maintaining cerebrospinal fluid (CSF) dynamics.[1]

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Traditional methods of dural repair have utilized autologous tissue grafts; however, these can be associated with donor site morbidity and limited availability.[2] Consequently, synthetic materials have emerged as viable alternatives for dural repair

One such material is G-Patch, a synthetic fabric patch made from polypropylene. G-Patch offers a promising solution to the challenges posed by autologous grafts.[3] It has gained attention for its biocompatibility, ease of handling, and low cost.[4] Synthetic grafts offer several advantages over autologous tissue, including reduced operative time, decreased morbidity, and consistent availability.[3]

However, its efficacy and potential pitfalls have not been comprehensively evaluated in clinical practice. Understanding its performance in real-world scenarios is crucial for optimizing surgical outcomes and advancing neurosurgical techniques.
Research by Schuss et al. (2012) demonstrated the effectiveness of synthetic materials in dural repair, highlighting their low complication rates and satisfactory integration with native tissue.[5] Similarly, Reddy et al. (2014) conducted a comparative study of various duraplasty materials and found that synthetic grafts, including polypropylene, had fewer infection rates and better handling characteristics compared to autologous grafts.[6]
However, the use of synthetic materials is not without challenges. Studies have reported instances of foreign body reactions, infections, and delayed wound healing associated with synthetic grafts. For example, a case report by Sapkota

and Karn (2021) described an extradural abscess following polypropylene duraplasty, underscoring the potential for severe complications.[7] Furthermore, Sarkar et al. (2023) conducted a comparative analysis and noted that while synthetic patches had fewer immediate complications, there was a need for vigilant postoperative monitoring to mitigate risks of delayed complications.[8]

This literature review underscores the importance of comprehensive evaluation of synthetic materials like G-Patch in clinical practice. The objective of this study is to evaluate the efficacy and identify the pitfalls associated with G-Patch in duraplasty. This will be achieved through a retrospective analysis of clinical data from patients who underwent duraplasty by examining patient outcomes, complications, and long-term effectiveness. This study aims to provide valuable insights into the use of G-Patch in dural repair.

Materials & Methods

This retrospective observational study analyzed data from patients who underwent duraplasty with G-Patch at National Medical College and Teaching Hospital between 2022 and 2024. After Ethical clearance (Ref. F-NMC/705/080-081) from the institutional review committee all the patients under inclusion criteria, data were collected from the hospital records, digital and physical. The study included demographic information (age, gender), indication for duraplasty, surgical details (technique, duration), postoperative complications (infection, implant failure, etc.), incidence of CSF leaks. Inclusion Criteria were all patients who underwent surgery and dura were closed using Gpatch and availability of complete medical records and follow-up data. Exclusion Criteria were patients with incomplete medical records, lost follow up and comorbidities like diabetes, hypertension and any immune modifying drugs or disease

Result

A total of 48 patients met our criteria and were included in this study. Most of the patients were males 68.75% (33) and 31.25%(15) females. The mean (SD) age of the population was 32.48 (20.05) years. Almost 69% (33) had traumatic brain injury where 31% (15) had non-traumatic indications for surgery. Three patients 6.25% had post-operative complications. Two patients had post-operative wound infection, and one patient had wound infection with dehiscence. None of the patients had seizure, bleeding seroma, CSF leak or any signs of foreign body reactions. The average duration of surgery was 244 minutes.

Table 1 Gender distribution

Gender	Frequency	Percentage
Male	33	68.75
Female	15	31.25

Table 2 Age Distributions

Age Group	Age Range	Number of Patients	Percentage
Pediatric	0-16	8	16.67%
Young Adult	17-50	23	47.91%
Older Adult	51-85	17	35.42%

Table 3 Distribution of surgical indications

Brain injury	Frequency	Percentage
Traumatic brain injury	33	68.75
Non traumatic brain injury	15	31.25

Table 4 Diagnostic Category

Diagnosis	Count	Percentage
Acute Subdural Hematoma (ASDH)	19	39.58%
Intracerebral Hemorrhage (ICH)	10	20.83%
Contusions	10	20.83%
SOL (Space Occupying Lesion)	4	8.33%
Depressed Fractures	4	8.33%
Others (e.g. Abscess)	1	2.08%

Table 5 Frequency of different Complications

Complication	Frequency	Percentage
Bleeding/ seroma	0	0
CSF Leakage	0	0
Infection	2	4.16
Signs of foreign body reaction	0	0
Seizure	0	0
Infection with Wound Gape	1	2.04

Discussion:

A total of three patients presented with long term complications, where they presented with graft rejection and delayed infection of the graft. One patient had presented with a collection under cranioplasty which was sterile on culture therefore we believed it was a case of graft rejection. Similarly, two patients had post-operative surgical site infection and were presented after 1 month of surgery where abscess collection was found below the patch and the other in space between the subgaleal and the graft. Both had graft removal and treated with antibiotics and later discharged. Hence, complication rate was only 6%, which is similar to any other surgical site infection rate for any surgical procedures.[9] In contrast to Pandit et al, in their study autologous vs dural substitutes in traumatic brain injury where they have reported to 16% wound infection with Gpatch and CSF leak 8%, wound gape in 12%.[3] However, none of our subjects had CSF leak and only one patient (2.04%) had

wound gape, it was the among the same subjects with post-operative infections, which we believe was wound dehiscence due to surgical site infection. Gosh et al, in his comparative study has described subcutaneous collection of CSF in synthetic fabric patch graft made of polypropylene.[10] In our series, none of the patients experienced subgaleal CSF collection. This may be due to our institutional practice of placing subgaleal drains post-craniectomy for 2–3 days, which likely prevents fluid accumulation and improves wound healing. Postoperative complications presenting patients had diagnosis of ASDH, one with hemorrhagic stroke and the other had traumatic contusion. This could be only the fact that majority of the patients in this study were diagnosed with acute subdural hematoma (39.58%) followed by spontaneous ICH (20.83%) and brain contusion (20.83%). Though we believe that pattern of intracranial bleed doesn't affect infection rate however, scott et al demonstrated that severity of head injury does increase risk of infection.[11] And all our infected patients had moderate to severe injury at the time of presentation.

Usually, it takes 1.5 hours to 5 hours depending on aim of the surgery for craniectomy.[12] In this study the average duration of surgery was 240 mins, where minimal timing was 120min and maximum up to 360 mins. Since this was a retrospective analysis, precise surgical times from incision to closure were unavailable; instead, operative duration was recorded as total time spent in the operating room, including anesthesia, preparation, and draping. Various autologous grafts pericranium, fascia lata and temporalis fascia can be utilized for dural repair. Typically dura closure with autologous graft such as pericranium and fascia lata extends operative time, surgical trauma and may be limited to poor availability at the harvest.[17] On an average allogenic materials take 92 to 128 mins for suturing.[18] Therefore utilizing synthetic Gpatch graft for dura closure reduces time of surgery and saves energy of the surgeons.

Currently there is no standardized technique of Gpatch placement therefore, its applications largely depends on surgeons' preference. Though there can be various techniques of placing the synthetic graft, inlay (under the dura), onlay (over the dura) or sometimes edge to edges suturing as in duroplasty. In all cases in this study, the G-Patch was placed onlay and secured with one or two stay sutures to prevent dislodgement during closure. No cases of CSF leak, skin erosion, or graft-related inflammation were reported, supporting the safety and reliability of this technique.

In this study gender distribution was male 68.75% (33) and females were 31.25% (15). This result may be only due to the fact that many of the patients had traumatic head injury 68.75% (33) and only fewer patients 31.25% (15) were non-traumatic. Various studies have already showed male predominance in traumatic head injury.[14, 15] Interestingly all three cases that had post-operative complications were males. But only sex as a risk factor for graft rejection cannot be verified independently here. This will require a large, controlled study to verify sex as a risk factor for graft infection or rejection. However, sex rather being a contributing factor, various other factors such as immunity status, severity of injury, surgical techniques, diabetes, nutritional status and environmental factors can be contributing factors for graft rejection.[21]

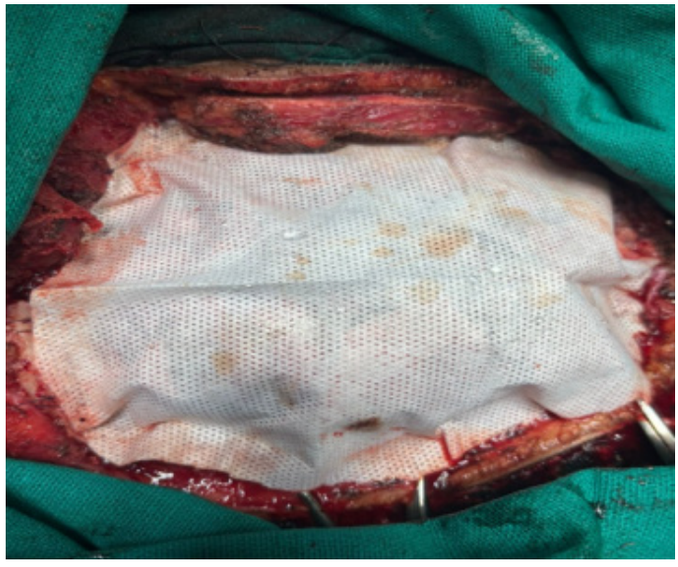

Figure 1: A case of spontaneous ICH , decompressive craniectomy and evacuation of hematoma with Gpatch dural closure

Elderly patients are often susceptible to SSI infection due to immunosenescence.[19,20] But here all patients with complications are younger therefore, age being a contributing factor can be ruled out. A total of 8 (16.67%) cases were pediatric patients (<16), 23 (47.91%) younger (>17 and <50) and 17 (35.41%) were older (51 and above), where the range of age distribution was 5-85 years. Here complications was higher in younger patients, this may be the fact that subjects with traumatic indications for surgery were higher and where trauma is more common in adults than other age group.[14, 15]

In this study majority of cases were traumatic origins (acute subdural hematoma (ASDH), contusion and depressed fractures) i.e. 68.75% (33) and only 31.25% (15) had non-traumatic and were categorized as neoplasm, abscess, hemorrhagic stroke (ICH). One with complication was diagnosed with stroke that makes 6.67% non-traumatic, whereas the other two had traumatic hematoma making a 6.06% total traumatic entity. Almost 2/3rd of the patients in this study had traumatic indications for surgery. Hence, graft rejection in traumatic cases was higher, merely coincidence as trauma patients also outnumbered. 8.33% of the patients had depressed fracture where the patch had been used when the severed dura couldn't be repaired and none of them had even CSF (cerebrospinal fluid) leak nor had any subgalea CSF collection.

Conclusion:

The lower complication rate has proved Gpatch to be safe and biocompatible for duroplasty. Despite the absence of standardized placement techniques, onlay application with minimal suturing proved effective, with no CSF leaks or inflammatory complications. G-Patch was particularly

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