



## COMPARATIVE ANALYSIS OF DUROPLASTY TECHNIQUES IN DECOMPRESSIVE CRANIECTOMY FOR TRAUMATIC BRAIN INJURY

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### ABSTRACT

#### Background and Objective

At present, there is no consensus regarding the most optimal dural substitute to use for duroplasty in primary decompressive craniectomy for traumatic brain injury (TBI). The author's objective was to conduct a retrospective analysis comparing 2 techniques of duroplasty: duroplasty using Regenerative Dural Repair Patch -ReDura (RD group) with G patch (GP group). G patch is designed to repair defects in soft tissues & re-enforcement of soft tissues such as Durameter, Peritoneal pleura etc. The patch is made of Poly Propylene (same as Prolene Mesh). G-Patch-2 is made of High Density Polyethylene. Each Pack contains one patch.

#### Methods

From July 2022 to September 2024, 120 craniotomies were done for TBI. Out of these, 20 received vascularized galea pericranium and 100 received synthetic dural graft for dural augmentation either Redura or G-Patch. For analysis, 30 from each group (RD/GP) were taken. The primary outcome was extended Glasgow Outcome Scale (GOS-E) measured at 3 months after injury. Secondary outcomes included were incidence of surgical complications (neurosurgical site infections, and hemorrhagic and hydrodynamic complications), surgical time, days in intensive care unit, hospital length of stay, hospital mortality.

#### Results

The primary outcome GOS-E at 3 months was worse in the GP group than in the RD group. Post-op complications were evaluated as shown in Table below. The frequencies of haematoma and brain abscess were recorded. Out of 60 patients who underwent PDC, 7 got hematoma and 2 got brain abscess.

#### Conclusion

In this retrospective study, adults who underwent DUROPLASTY for TBI using ReDura were associated with significantly lower rates of postoperative hematoma ( $p = 0.0105$ ) compared to those

using G-Patch. However, no statistically significant difference was found in brain abscess rates ( $p = 0.4915$ ) or GOS-E functional outcomes ( $p = 0.5506$ ) at 3 months. Further prospective, larger-scale studies are recommended to confirm these findings.

**Keywords:** TB I, G PATCH, Re Dura.

## INTRODUCTION

Decompressive craniectomy (DC), usually performed worldwide to treat severe traumatic brain injury (TBI), is a surgical procedure in which part of the skull is removed to allow the brain to swell. The efficacy of the procedure in improving patient outcomes is still controversial. The European Brain Injury Consortium (EBIC) and Brain Trauma Foundation (BTF) guidelines for severe TBIs refer to DC as a second-tier therapy for refractory intracranial hypertension that does not respond to conventional therapeutic measures.<sup>(1,2)</sup>

The traumatic space occupying lesions may cause mass effect leading to raised intracranial pressure and corresponding neurological symptoms and signs (eg, deterioration in consciousness levels, pupillary abnormalities, and motor weakness). Presence of traumatic intracranial hematoma with mass effect and corresponding neurological sign and symptoms constitutes indication for surgical removal of intracranial hematoma.<sup>(3,4)</sup>

Even after surgical decompression of a mass lesion in many patients, cerebral edema may persist, and increased intracranial pressure is expected during the postoperative period. To prevent postsurgery raised intracranial pressure, expansile duroplasty is preferred with synthetic or autologous material, and large bone section of skull is also removed. This is referred to as primary decompressive craniectomy (PDC).<sup>(5)</sup>

Many options are available for dural graft viz. pericranium nonvascularized or vascularized, fascia lata, collagen matrix, bovine pericardium, and synthetic dural substitutes. At present, there is no consensus on most optimal dural substitute to use for duroplasty in PDC. For many years, we have been using both vascularized pericranium and synthetic dural substitute (G patch) for duroplasty in PDC and then ReDura recently. Here, we revisited our techniques and conducted this retrospective study to analyze the outcomes in these two synthetic dural substitutes.

## AIMS AND OBJECTIVES

To compare 2 techniques of duroplasty: duroplasty using Regenerative Dural Repair Patch - ReDura (RD group) with G patch (GP group).

## MATERIALS & METHODS

This study was a retrospective analysis of a single-center database including consecutive cases of PDC performed for TBI from July 2022 to September 2024. A neurosurgery unit headed by a senior neurosurgeon operated/supervised all cases.

The study population comprised all patients ranging in age from 18 to 60 years who had nonpenetrating TBI with an abnormal computerized tomography (CT) scan showing post-traumatic intracranial hematoma with mass effect and corresponding neurological signs. All patients underwent surgery for decompressive craniectomy with or without hematoma evacuation. Patients were initially treated at our tertiary care teaching hospital or referred as a secondary transport from a different hospital. In all cases, written informed consent was taken from next of kin/guardian as appropriate.

### Exclusion criteria

1. Age <18 years or >60 years.
2. Bone flap size less than 15 cm.
3. History of previous craniotomy for other brain lesions.
4. Posterior fossa craniectomy.
5. Significant nonbrain injuries.

6. If other body organ surgery was simultaneously performed.
7. Bilateral nonreactive pupil and glasgow coma scale (GCS) = 3.
8. Lack of documentation of surgical technique in operation records.
9. Death in first 24 hours after surgery.

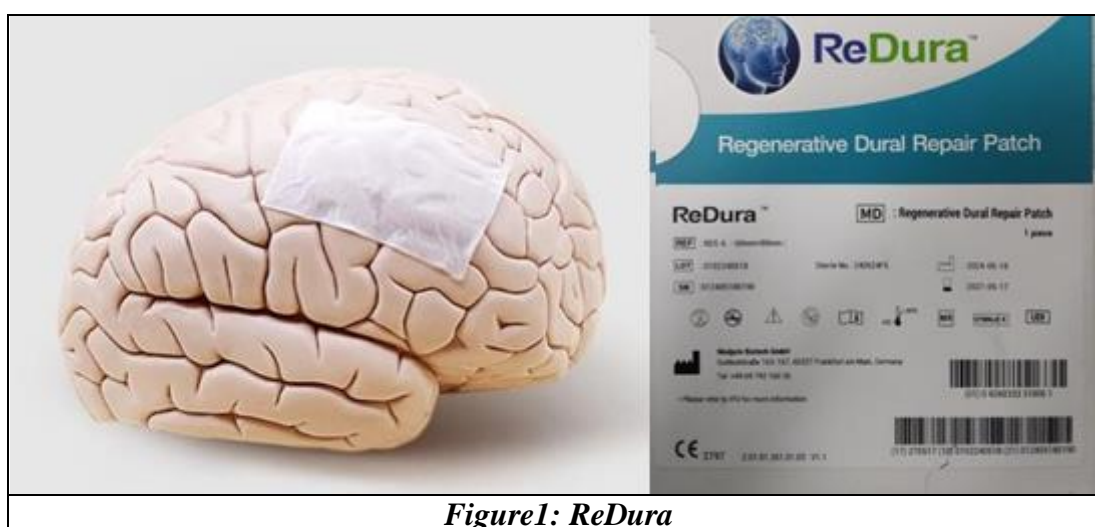
### Treatment Procedures

For craniotomies to evacuate traumatic mass lesion, the need for PDC was anticipated preoperatively and duroplasty was done either by using G-Patch or ReDuRa (Figures 1 and 2 respectively). Usually, the side with greater lesion volume or cerebral edema was chosen. After surgery, patients were monitored daily from date of surgery until discharge from hospital or death.

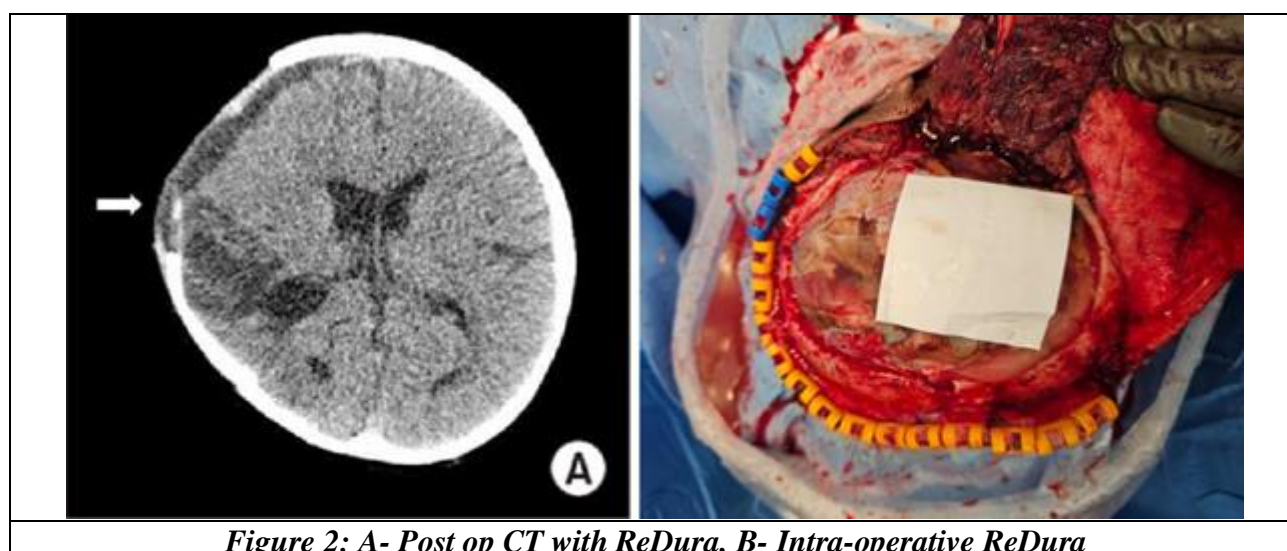
### ReDura™ Synthetic Dural Substitute

FDA approved degradable material poly-L-lactic acid (PLA)

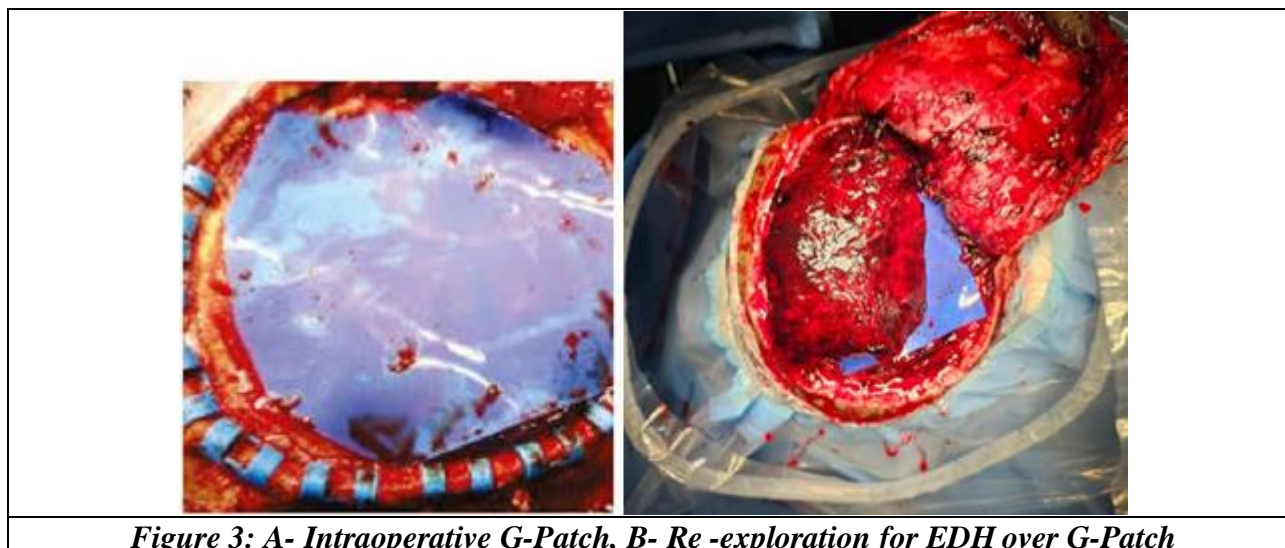
Outstanding efficacy and safety for the dural defect repair



*Figure1: ReDura*



*Figure 2: A- Post op CT with ReDura, B- Intra-operative ReDura*



**Figure 3: A- Intraoperative G-Patch, B- Re-exploration for EDH over G-Patch**

### Assessment and data collection

All the data were collected from the medical files and image records of hospital. Functional outcome measures were evaluated during post discharge follow-up hospital visit/telephone questionnaire completed by the patient or the caregiver.

The database comprised clinical characteristics of the case including post resuscitation GCS score on admission and during treatment, initial CT findings, therapeutic interventions, and complications. Postoperative CT scan was performed in all patients within 48 hours after craniectomy. All the patients were followed up at the hospital visit/telephone for different time periods

### Outcome measures

The functional outcome was analyzed using extended Glasgow Outcome Scale (GOS-E) as described in case file/hospital visit records/telephone questionnaire at 3 months after injury.

GOS-E scale measures global outcome, including functional status, independence, and participation in relevant societal roles. The GOS-E extends the five categories of the GOS into eight states: (1) Death, (2) Vegetative State, (3) Lower Severe Disability, (4) Upper Severe Disability, (5) Lower Moderate Disability, (6) Upper Moderate Disability, (7) Lower Good Recovery, and (8) Upper Good Recovery.

Post-op outcomes measured were incidence of surgical complications (neurosurgical site infection, and hemorrhagic complications), and GOS-E at 3 months

### Data analysis

The data were analyzed using SPSS Version 21.0 (Chicago, IL, USA) and represented as numbers and percentages. Demographic and clinical data were analyzed using the chi-squared test. Qualitative variables were compared using the Fisher chi-square test. Statistical significance was set at  $p < 0.05$

### RESULTS

The primary outcome GOS-E at 3 months was worse in the GP group than in the RD group. Post- op complications were evaluated as shown in Table below. The frequencies of haematoma and brain abscess were recorded. Out of 60 patients who underwent PDC ,7 got hematoma and 2 got brain abscess.

	GP GROUP	RD GROUP
POST-OP HEMATOMA P VALUE = 0.0105	7	0
BRAIN ABSCESS P VALUE= 0.4915	2	0
GOS-E P VALUE= 0.5506	5 GOT 1 SCORE 3 GOT 2 SCORE 4 GOT 3 SCORE 8 GOT 5 SCORE 5 GOT 7 SCORE 5 GOT 8 SCORE	3 GOT 1 SCORE 2 GOT 2 SCORE 5 GOT 3 SCORE 6 GOT 5 SCORE 6 GOT 7 SCORE 8 GOT 8 SCORE

## DISCUSSION

Most of the studies compare autologous vs. Non autologous grafts. To the best of our knowledge, this study is one of the rare studies in comparing two types of synthetic dural substitute in PDC for TBI. One possible explanation for better outcome in the RD group than in the GP group is that ReDuRa has biomimic properties, and is like Native Extracellular matrix and hence is more nonimmunogenic, and acts as a natural barrier between the underlying brain and the overlying scalp. In contrast G-Patch has a lower chance of being accepted by the body when sandwiched between the brain and scalp. Major disadvantages cited to ReDuRa are that they are more expensive and smaller in size as compared to G-Patch. Post - operative Subgaleal collections and subdural collections are also noted in G-Patch group.

## LIMITATIONS OF THE STUDY

The authors acknowledge many limitations of this study that are inherent to retrospective and nonrandomized assessment. First, there is potential for selection bias based on surgeon practice. The resulting sample size is relatively small with 30 in each group.

The small sample size can be attributed to the stringent inclusion and exclusion criteria implemented to minimize confounding factors viz. extremes of age, polytrauma patients with significant nonbrain injury and preexisting neurological disorders, small craniectomy size less than 15 cm, and significant percentage of Exclusions.

## CONCLUSION

In this retrospective study, adults who underwent DUROPLASTY for TBI using ReDura were associated with significantly lower rates of postoperative hematoma ( $p = 0.0105$ ) compared to those using G-Patch. However, no statistically significant difference was found in brain abscess rates ( $p = 0.4915$ ) or GOS-E functional outcomes ( $p = 0.5506$ ) at 3 months. Further prospective, larger-scale studies are recommended to confirm these findings.

## DISCLOSURES

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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