TissuePatchDural™ is a surgical sealant film, specifically designed to reinforce closure of the Dura Mater to achieve a watertight dural closure.

It is a self-adhesive film comprising synthetic polymers that are encountered in everyday surgery. It contains no human, bovine or porcine material.

The device is a multi-laminate consisting of thin films of a commonly used structural polymer, poly(lactide-co-glycolide) and a tissue reactive polymer providing fast and strong chemical bonding of the patch with the underlying biological surface.

It incorporates structural and adhesive absorbable components.

The active component within TissuePatchDural™ is Tissuemed’s proprietary TissueBond™ bioadhesive technology. This bonds the film to proteins on the tissue surface within a minute, providing immediate support and an effective watertight closure during the natural healing process.

It is available in neurosurgery in order to repair dural defects and, consequently, to prevent the postoperative formation of CSF fistulas. Della Puppa in 2010, reported the preliminary experience about the use of such device in 12 selected patients 1).

von der Brelie et al., implanted it in 25 patients who underwent intradural neurosurgical procedures. The indication for use was to adjunctively seal dura mater defects. Intraoperative handling and efficacy, biocompatibility, and postoperative observations/follow-up were analysed. Infectious complications, surgical wound features, and postoperative MRI scans were especially reviewed. The mean follow up period was 4.4 months.

The device provided fast and efficacious sealing of circumscribed dura mater defects within 1 minute in 23 patients (92%). Two of 25 patients developed a postoperative CSF leakage (8%), which may be secondary to particular factors predisposing these patients to CSF leaks. Surgical handling was straightforward. No infectious complications were recorded; furthermore, wound healing was
unremarkable. No clinical evidence of foreign body reactions was observed. In 18 patients, postoperative MRI scans were available which did not show irregularities in any case.

Safe and effective sealing can be accomplished with this bioabsorbable, purely synthetic and thin dural sealant, avoiding the application of foreign biologic material. The product has been shown to be effective in achieving watertight closure of the dura mater and has prevented CSF leakage in 92% of patients treated

A retrospective, single-center, clinical investigation was conducted on 119 patients who underwent elective neurosurgical procedures between January and June 2010. Inclusion criteria included adult patients undergoing clean elective surgeries where a primary watertight closure was not possible. Three groups of patients were considered: 1) infratentorial, 67 cases; 2) supratentorial, 34 cases; and 3) spinal, 18 cases. All these patients received TPD to reinforce dural closure. Preoperative (long-term corticosteroid therapy, previous surgery and radiotherapy), intraoperative (site of procedures and size of dural gap), and postoperative (early and late hydrocephalus) conditions were analyzed as possible risk factors associated with CSF leakage.

The mean follow-up was 7.14 months (range 6-12 months). CSF leak was detected in 11 of 119 cases (9.2%). The presence of pre- and postoperative risk factors was associated with a higher percentage of CSF leakage: 8 of 22 cases (36.3%) vs. 3 of 97 cases (3.1%) (P < 0.0001). All leaks could be conservatively treated and no patient required readmission or second surgery. No TPD-related adverse or allergic effects were observed.

TPD seems to be a safe tool to be used to reinforce dural closure in patients with a high risk of developing CSF leaks

Of 161 patients analyzed, 115 were treated with TPD and 46 with DuraSeal. The post-operative leaks related purely to TPD or DuraSeal failure were recognized in 3 (2.6%) and 5 (10.86%) cases, respectively (P = 0.015). The presence of pre- and post-operative risk factors was associated with an increased incidence of CSF leak in both groups. TPD showed a better control in patients without these risk factors (P = 0.08). The incidence of CSF leak in patients who underwent posterior fossa surgery by craniectomy was statistically lower in TPD group compared to DuraSeal group (3.22% vs 17.8%, respectively; P = 0.008).

TPD seems to be a safe tool for use as an adjunct to standard dural closure in posterior fossa surgery, particularly in patients without pre- or post-operative risk factors, in those who did not develop hydrocephalus, and who underwent craniectomy. The CSF leak rate in TPD group was found to be lower or within the range of the more advanced alternative dural closure strategies, including polyethylene glycol (PEG)-based sealant

Eser et al., aimed to investigate comparative efficacy of a novel absorbable adhesive membrane (TissuePatchDural “TPD”) and a fibrin glue (Tisseel “T”) in reducing CSF leaks after posterior fossa and spinal procedures, and also to identify potential risk factors for CSF leakage.

This is a single-center, retrospective cohort study of 123 consecutive posterior fossa (n=77) and spinal (n=46) surgeries. Patients were grouped based on dural sealants used: 2-group comparison:
TPD (n=56) vs no-TPD (n=67) and 3-group comparison: T only (n=43), TPD only (n=32) vs TPD+T (n=35).

Mean age was 38.9 ±22.2 years (62M, 61F). Baseline characteristics were similar between groups. Neither 2-group (TPD: 10.4% vs no-TPD: 8.9%; p=0.778) nor 3-group (T: 9.3% vs TPD: 6.3% vs TPD+T: 14.3%; p=0.539) comparisons revealed a significant difference in postoperative CSF leakage rates. Multivariate analysis showed that diagnosis (non-tumoral vs tumor) (OR: 5.487; 95% CI: 1.118-26.937; p=0.036); previous surgery (OR: 9.268; 95% CI: 1.911-44.958; p=0.006), postoperative hydrocephalus (OR: 5.456; 95% CI: 1.250-23.821; p=0.024) were independent predictors of postoperative CSF leakage.

TissuePatchDural is a novel dural sealant patch which can be safely used to reinforce dural closure in posterior fossa and spinal surgeries, and its efficacy is comparable to widely used fibrin glue (Tisseel). Non-tumoral pathologies, previous surgery, and postoperative hydrocephalus appear to be independent risk factors for postoperative CSF leakage.

van Doormaal et al., evaluated 9 commonly used dural sealants, including Tachosil (Takeda Inc, Osaka, Japan), Adherus (Hyperbranch Inc, Durham, North Carolina), Duraform (Codman, Raynham, Massachusetts), Tissudura (Baxter, Deerfield, Illinois), Hemopatch (Baxter), TissuePatchDural (Tissuemed, Leeds, United Kingdom), Tisseel (Baxter), Duragen Secure (Integra, Plainsboro, New Jersey), and Duraseal, (Integra). Sealants were tested in 2 novel in Vitro setups using fresh porcine dura: the first tested the acute burst pressure of a sealed 3-mm gap, while the second examined resistance to a pressure wave mimicking intracranial pressure for 72 h.

Adherus showed the highest mean burst pressure (87 ± 47 mmHg) followed by Tachosil (71 ± 16 mmHg) and Duraseal (51 ± 42 mmHg); these were the only 3 sealants showing burst pressures above normal physiological intracranial pressure. In the 72-h setup, only Adherus and Duraseal maintained appropriate sealing for the duration of the experiment. Tachosil released from the dura after 1.4 h (95% confidence interval, -1.8-4.7).

Given the high cost of sealants and the results of this study, they advocate a critical attitude toward sealant application as an adjunct to classic dural closure.

Videos

References


