Efficacy and safety of non-suture dural closure using a novel dural substitute consisting of polyglycolic acid felt and fibrin glue to prevent cerebrospinal fluid leakage-A non-controlled, open-label, multicenter clinical trial-.

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Abstract:

Abstract: The objective of this study is to evaluate the efficacy and safety of non-suture dural closure using a novel dural substitute (GM111) consisting of polyglycolic acid felt with a fibrin-glue-coated area commensurate in size with the dural defect. This was a non-controlled, open-label, multicenter clinical trial. The efficacy evaluation endpoints were (1) GM111's intra-operative capability to close dural defects and (2) prevention of cerebrospinal fluid (CSF) leakage and subcutaneous CSF retention throughout the postoperative period (evaluated by diagnostic imaging). Patients meeting the following three preoperative and two intra-operative selection criteria were enrolled: (1) between 12 and <75 years of age; (2) the dura is surmised to be defective and in need of reconstruction; (3) informed written consent was obtained from the patient; (4) the surgical wound is class 1; and (5) the size of duraplasty is >=0.2 cm² to <100 cm². Sixty patients were enrolled. The craniotomy site was supratentorial in 77.2%, infratentorial in 12.3% and sellar in 10.5%. The GM111 prosthesis size ranged from 0.24 to 42 cm². To evaluate the efficacy, intra-operative closure was confirmed by Valsalva's maneuver, water infusion, etc., in all patients. CSF leakage and subcutaneous CSF retention throughout the postoperative period were found in four patients. Adverse events for which a causal relationship with GM111 could not be ruled out occurred in 8.8% of the patients. There were no instances of postoperative infection due to

GM111. GM111 showed good closure capability and safety when used for non-suture dural closure.

Graphical Abstract: [InlineMediaObject not available: see fulltext.]