Polyglycolide

Polyglycolide or poly(glycolic acid) (PGA), also spelled as polyglycolic acid, is a biodegradable, thermoplastic polymer and the simplest linear, aliphatic polyester. It can be prepared starting from glycolic acid by means of polycondensation or ring-opening polymerization. PGA has been known since 1954 as a tough fiber-forming polymer. Owing to its hydrolytic instability, however, its use has initially been limited.

Currently polyglycolide and its copolymers (poly(lactic-co-glycolic acid) with lactic acid, poly(glycolide-co-caprolactone) with ε-caprolactone and poly (glycolide-co-trimethylene carbonate) with trimethylene carbonate) are widely used as a material for the synthesis of absorbable sutures and are being evaluated in the biomedical field.

The objective of a 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 [1)].

1)
Terasaka S, Taoka T, Kuroda S, Mikuni N, Nishi T, Nakase H, Fujii Y, Hayashi Y, Murata JI, Kikuta KI, Kuroiwa T, Shimokawa S, Houkin K. 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. J Mater Sci Mater Med. 2017 May;28(5):69. doi: 10.1007/s10856-017-5877-8. Epub 2017 Mar 29. PubMed PMID: 28357687.