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In-vitro and clinical study on a novel synthetic absorbable biomimetic dural substitute

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Introduction: For duraplasty of children, absorbable dural substitutes are demanded as their in-growth heads and non-animal-source materials are recommended to reduce the risk of transmitting disease or immune response. In this study, a new absorbable synthetic dural substitute mainly composed of PLLA has been developed using emerging nano-technology and characterized with mechanical properties and biocompatibility both in vitro and in vivo. The safety and efficacy were evaluated in animal and clinical research.

Methods: The microstructure, mechanical properties, and cytotoxicity were evaluated by SEM scanning, tensile testing, and MTT assay, respectively. Canine model was used for dural defect repair experiment and general and histological observations were performed subsequently. A multi-center, randomized, single-blind, clinical trial was performed in 4 hospitals with 6 months follow-up, 132 patients enrolled, commercially available Ethisorb (Johnson&Johnson) as control.

Results: The new substitute exhibited unique 3D nonwoven microfibers structure with high strength, good conformability, and 100% water-tight, as well as demonstrated good biocompatibility in vitro. In animal study, complete defect closures and no CSF leakage were found. Postoperative local inflammatory response was mild indicating good tissue compatibility. In clinical research, the postoperative CSF non-leakage rate of ReDura was 100% (control: 98.5%), subcutaneous non-exudate rate 93.9% (control: 92.3%), both with no significant difference. The same statistical results was presented on the patient body temperature from 1st to 10th day (P=0.320~0.975) and the scalp wound healing on 10th day (P=0.311), and safety indicators such as incidence of nausea, vomiting, meningeal irritation sign and seizure at each time point (P=0.205~0.971).

Conclusions: The new biomimetic absorbable dural patch was confirmed safe and effective in the animal and clinical research and proved to be an ideal dural alternative substitute. Moreover, updated to the end of 2013, we had over thirty successful cases used on children, no any adverse report received.