Clinical Application of Human Acellular Collagen Matrix as a Dural Substitute

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PURPOSE

We investigated retrospectively the clinical use of a human acellular collagen matrix (HACM) for a dura mater substitute. It was previously demonstrated that decellularization and viral/bacterial inactivation improved in vitro/in vivo biocompatibility and safety of this device.

METHODS

HACM was formed from human fascia lata which was chemically and physically treated. One human tissue donor provided 2 fascia lata and then 4 HCAM of 10-50 cm^2. In our study, 130 patients were treated with HACM between 2003 until 2007. Clinical signs and parameters of infection (CRP) and inflammation (White Blood Cell count (WBC) were assessed at: (i) prior, (ii) early (1 week after the operation) and (iii) later (> 1 month) post-implantation. Medical imagery (CT-Scan, MRI) was also achieved.

Statistical methods: The test applied for analysis of contingence tables was χ^2 or Fisher test. To compare means, analysis of variance (ANOVA) test has been run supplemented by the Bonferroni correction or the nonparametric Kruskal-Wallis test. Analysis of repeated measures was performed by using pair t-test or the nonparametric Wilcoxon test.

RESULTS

Among these cases, the ratio male/ female was 63/67 with a mean age of 45.4 years (range: 0.25-84). The average follow-up period was 11.75 $\pm$ 12.10 months (range: 1-44 months). The HACM was applied for cerebral tumours (52.3% of cases); traumatisms (1.5%); malformations (43.8%); neuralgias (2.3%). A range of 10 to 50 cm^2 of HACM was used to cure dura-mater defect. No significant correlation was found between clinical indications and the HACM size. An overall complication of 2.3% was observed in the total follow-up study. HACM leakage was essentially found in malformation indications at pre-operative time. An inflammation was elicited at the early post-implantation time by a significant increase of CRP and WBC in comparison to pre-transplantation (4.90 vs. 0.20; 11.48 vs. 8.77 for CRP and WBC, $p<0.005$, respectively). A complete return to normal values was found after long-term course of implantation ($p<0.005$).

CONCLUSIONS

This study confirms, in a large cohort of patients, that human processed tissue is a fully applicable and safe device to cure dura-mater defect.

REFERENCES

1. Dufrane D, Marchall C, Cornu O et al : Clinical application of a physically and chemically processed human substitute for dura mater. J Neurosurg 98 : 1198-1202, 2003.
2. Dufrane D, Cornu O, Delloye C et al : Physical and clinical processing for a human dura mater substitute. Biomaterials 23 : 2979-2988, 2002.