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DETERMINATION OF RESIDUAL CHEMICAL AGENTS AND BIOLOGICAL AGENTS IN DECELLULARIZED NERVE ALLOGRAFT

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SUMMARY

Introduction: If the gap of injured peripheral nerve is large, surgical treatment using autogenous nerve graft, nerve condiut or allogeneic nerve graft is necessary. Fresh nerve allograft requires immunosuppressive treatment because of the immune response. To prevent the immune response, decellularized nerve graft has recently been developed and used. Chemical and biological agents can be used for decellularization, and the residuals in the graft can elicit an inflammatory response and can cause toxicity. We quantify the residual agents in decellularized nerve allograft treated with the decellularized protocol developed by Zilic et. al. and evaluate its safety. **Materials:** Saphenous nerve and sural nerve were retrieved from the tissue donor(n=7), and decellularized by the modified decellularization method developed by Zilic et al. using SDS, EDTA, aprotinin, DNase, RNase and finally washed. Residual SDS was detected by HPLC ELSD Detector, EDTA was detected by HPLC UV / Vis Detector, and aprotinin, DNase and RNase were quantified by ELISA kit. **Results:** Three batches of retrieved nerves were processed by the SOP of Korea Public Tissue Bank according to the Zilic's method and the residuals was quantified. Residual SDS was not detected, and 0.0007, 0.0006, 0.0002 ug / mg of EDTA was detected in each batch, and 0.004, 0.0021 and 0.0087 ug / mg of DNase was detected and 0.0001, 0.0001 and 0.0005 ug / mg of RNase was detected, and aprotinin was detected by 0.0014, 0.0033, and 0.013 ug / mg. **Discussion & conclusion:** Wilshaw et al. reported that no toxicity was observed if the residual SDS was less than 20 ug / mg in wet tissues, and Keane et al. reported that the lower cytotoxic threshold for SDS was approximately 10 ug / mg dry weight. Residual levels of all agents used for decellularization were far below those standards and the residual levels of these agents weree considered to be safe. Our result was consistent with the that of the protocol for the production of acellular dermal matrix, which has been applied safely to the clinical practices already.