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〈教育セミナー〉

皮膚機能の新展開

再生医療製品として開発された自家培養表皮の有効性と安全性の評価

井家益和

Efficacy and Safety of First Tissue-Engineered Cellular Product, Autologous Cultured Epidermis

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Abstract

Regenerative medicine, which achieves a recovery of dysfunction of tissues and organs, might be the main stream of the medical care in this century. We had developed the first tissue-engineered cellular product, JACE®, which received Japanese government approval in October 2007. This product is the autologous cultured epidermis using 3T3-J2 feeder layer system, known as Green's technique, and is grafted for serious burns. By isolating keratinocytes from a few cm^2 biopsy and culturing them, the keratinocyte sheets measuring about 10% of the body surface area can be produced in two weeks, or they cover the entire surface of body in 3–4 weeks. On the development of the autologous cultured epidermis product, the characteristics were investigated and lots of data relating to the safety and efficacy were collected. All type and amount of cells except keratinocyto were determined in the cultivation process. And the residual volume of bovine-serum albumin and feeder cells in keratinocyte sheet were analyzed for the selection of shipping inspections. Karyotype analysis, colony formation test in soft agar gels and transplantation test in nude mice were also performed to prove the absence of transform and tumorigenicity in the final product. To negate product contamination, the bacterial sterility, the endotoxin detection and the mycoplasma negative examination must be performed. In addition, several characteristics, including morphology and proliferative potential of keratinocytes must be evaluated. The 3T3-J2 cell banks are safely controlled and all raw agents and materials are inspected in GMP facilities. This cellular product has been covered by health insurance and is being followed up by post-marketing surveillance study since January 2009.

Key words: autologous cultured epidermis, JACE, feeder layer, cellular product, regenerative medicine.