

Study on wound healing after cutaneous lesion and reconstructed Autologous Pigmented Skin Dressing (APSD) in nude mice: GLP-studyJ.C. Lepivert^{1,2}, E. Desnouveau², V. Casoli^{1,2}, M. Cario^{1,3}¹INSERM 1035, France²Hospital Center University De Bordeaux, France³National Reference Center for Rare Skin Disease, France

Authors develop a biological dressing designed for patients presenting chronic wound, burn injury or congenital melanocytic naevus. The reconstructed skin is produced under Good Laboratory Practices (GLP). Subsequently, application of Autologous Pigmented Skin Dressing (APSD) on immunodeficient mouse model demonstrates its harmlessness and functionality with the required safety controls.

Keratinocytes, melanocytes and fibroblasts were extracted from a patient's biopsy and multiplied. On top of the collagen matrix, fibroblasts were seeded to remodel collagen and secondly, keratinocytes and melanocytes were seeded to produce the epidermal layer. APSD was produced in 3 to 5 weeks. From July 2018 to July 2019, 4 groups of 7 mice were implanted. For each group, 6 mice were treated with Test Item and one mouse with collagen matrix alone as control. Defects of 6 cm² on dorsum of mice were done and covered with APSD or matrix alone.

Wound healing, clinical behavior, adverse events, tumor development and mortality signs were checked every day. Groups 1, 3 and 4 healed well. Follow up demonstrated a good integration of APSD with minor retraction and a diffuse pigmentation. Group 2 had skin retraction that increased during weeks. In the control group, wounds did not heal and a complete skin retraction was present. Bioengineered APSD demonstrated enthusiastic results regarding wound healing. It can be easily handled and shipped.

APSD groups healed well except one group for which the quality of cells was initially worse than the others. A clinical trial is planned by mid-2020.