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## Study on wound healing after cutaneous lesion and reconstructed autologous pigmented skin dressing (APSD) in nude mice: GLP-study

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Authors develop a process of *in vitro* skin reconstruction from locally anesthetised patient's biopsies. This process is oriented though applications with patient presenting cutaneous defect as chronic wounds, burn injuries or congenital melanocytic nevus. One step of this development process is reconstructed skin production under Good Laboratory Practices (GLP). Subsequently, application of Autologous Pigmented Skin Dressing (APSD) on immunodeficient mouse model, demonstrates its harmlessness and functionality with required sanitary characteristics. Clinical results will be presented in this paper.

**Materials and methods:** This technology consists in reconstructing autologous pigmented skin on a collagen matrix such as Integra™ or Matriderm®. Skin from breast reductions was taken from the operating room and managed to the French Blood Establishment (FBE). Keratinocytes, Melanocytes and fibroblasts were extract from the biopsy harvested on patient himself and cultured for cells amplifications. On top of the collagen matrix, fibroblasts were seeded to remodel collagen and after this step, keratinocytes and melanocytes were seeded to produce the epidermal layer. APSD were produced in 3-5 weeks. The APSD (Test Item approximately 6 cm<sup>2</sup>) and its culture media was provided by truck at 18-20°C to testing facility (about 500 km). Testing facility stored under a 37°C, 5% CO<sub>2</sub> humidified atmosphere for up to 24 hours. From the Operating room to mice coverage, skin, cells and reconstructed skin were identified and traceable. 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 or two mice with collagen matrix alone as control. Under general anesthesia defects (3x2 cm) on dorsum of mice was done and covered with APSD or collagen matrix alone. This study was conducted according to GLP and EMEA EMEA/CHMP/410869/2006 31/07/2007) guideline. Wound

healing, clinical behavior, any symptom, tumor development, and mortality sign were notice every day. Weight, food and water consumption were notice every week.

**Results:** 1 mouse did not survive to surgery. Groups 1, 3 and 4 healed well. Follow up demonstrated, a good integration of APSD with minor retraction and a diffuse pigmentation. Group 2 healed with multiples milimetric wounds, and during the healing process, skin retraction appeared which increased with weeks. All collagen matrixes (control group) didn't heal and made complete skin retraction for skin closure. Except one mice which had a nice APSD but loss of weight leading to sacrificed, the other mice grew up, drank and ate normally

**Discussion:** Bioengineered APSD demonstrated enthusiastic results regarding wound healing. Reconstructed skin could be easily handled and shipped far from the reconstructed area. APSD were simply immersed in cultured medium. APSD groups healed well except for one batch for which the quality of cells seeded was bad leading to thin APSD.

**Conclusion:** Next step will be the clinical trail. The first selected patients, which will be treated with the autologous-pigmented skin dressing, could have chronic wounds that could not be close with traditional treatment as patients with bad general condition. Phase 1 could be done in 2020 and time to market calculated for 2025.

### Speaker Biography

Jean Christophe Lepivert is currently working as a consultant in University Hospital of Bordeaux, Bordeaux, France. He is also the head of burn surgery unit. His research interest lies in plastic, reconstructive and aesthetic surgery, burns, etc., He also has various research publications in the international journals.

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