

An innovative skin dressing based on perinatal tissues derivatives for the facilitated skin defects regeneration

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Annotation:

Wound healing is an intricate, well organized and coordinated process with temporal and spatial regulation. All wounds undergo common reparative processes including hemostasis, inflammation, granulation tissue formation, reepithelialisation and scar remodelling. Ability to repair wounds without excessive wound healing is age-dependent. Fetal wound healing is characterized by regeneration of normal dermal architecture. Wound healing in fetal skin defects involves a distinct profile, a lower inflammatory response lower biomechanical stress, an extracellular matrix enriched of hyaluronic acid and type III collagen, and an important role for stem cells. Comprehensive wound management for acute wounds continues to be progressive, accompanied by increased quality of local care provided and increased chances for patient's survival.

Amniotic or amnion membrane (AM) offers alternative for wound management compared with other biological dressings. AM is the innermost, multilayered part of the placenta (thickness is 0.02–0.5 mm), that contributes to the homeostasis of amniotic fluid during pregnancy. After the birth all perinatal tissues are considered as a biological waste. However, unique composition, mechanical (thickness is 0.02–0.5 mm), immunological and regenerative properties of AM make it a valuable tissue for the treatment of chronic wounds and regenerative medicine in general. Positive effects of amniotic membrane on acceleration of wound healing and its quality were reported almost one hundred years ago. More recently, AM has been shown to promote epithelialization, to have antimicrobial effects, to reduce inflammation and fibrosis, to promote neovascularization, and to provide a substrate for cell growth, and functions as a biological bandage. The partial thickness wound healing, however, demands different approach and structure of the dressing material.

The objective of current project is to evaluate regenerative properties (wound reduction and rates of complete healing and epithelization) of the new form (hydrogel) of biologic product, based on human amniotic membrane versus standard treatment procedure of partial-thickness wounds using a porcine model.

Aims of the project

The overall aim of this project is to utilize an innovative concept into a novel biologically-based product on the basis of amniotic membrane for the management of partial-thickness wounds patients.

To reach the aim of the project the following milestones should be reached:

- 1) Characterization and optimization of physico-chemical, biomechanical and stability properties of bio-substitute
- 2) Biocompatibility, cytotoxicity and immunocytological studies with bio-substitute *in-vitro* with fibroblasts and umbilical cord mesenchymal stromal cells. Optimization of the most efficient concentration of the hydrogel *in vitro*
- 3) A proof-of-concept *in vivo* study using porcine model of partial thickness wounds
- 4) Standard operational protocols (SOPs) for future GMP manufacturing