January 2013 | Volume 4 | Issue 1

RNI No. APENG/2010/34023
ISSN 2229-5992

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Nanofibrous Alimentary Protein Scaffolds for Enhanced Wound Healing and Aesthetic Dermatology Applications

Of the nearly 37 million annual cases of chronic wounds including skin ulcers, pressure ulcers are the most common ones with an estimated 9 million cases per year[1]. The normal wound healing process generally includes interaction of complex network of signalling systems, leading to the restoration of epidermis and dermis. In human patients, healing skin wounds frequently leave behind disfiguring scar tissue. Moreover, various systemic disease conditions, such as diabetes, impair local tissue repair, resulting in a chronic wound that is difficult to heal (Fig. 1). Chronic wounds, such as diabetic foot ulcers, are responsible for a high rate of morbidity and mortality worldwide and are asubstantial financial burden to the health care industry[2]. Despite the occurrence of a myriad of wound healing products in the market, chronic wounds are a major medical challenge and the wound care market needs constant innovative research efforts to achieve effective measures for their treatment.

Eqalix, Inc. is an emerging technology company in the field of regenerative medicine and is developing a novel concept for the care of difficult to heal wounds: nanofibrous Alimentary Protein Scaffolds (APS), based on food proteins derived from soybean. For manufacturing the APS, purified soy protein is electrospun into sheet-like matrices. As a major advantage, APS are of non-animal/non cadaveric origin and are biocompatible, biodegradable, and non-immunogenic. They also have a virtual unlimited shelf life and are cost-effective. APS are intended as bioactive wound dressings or partial/full thickness skin replacement for non-healing wounds, in the case of severe burns, and other traumatic wounds. Being non-adhesive, APS can also act as a temporary wound covering to promote skin healing following irritation and superficial injury in aesthetic dermatology applications, such as laser ablations.

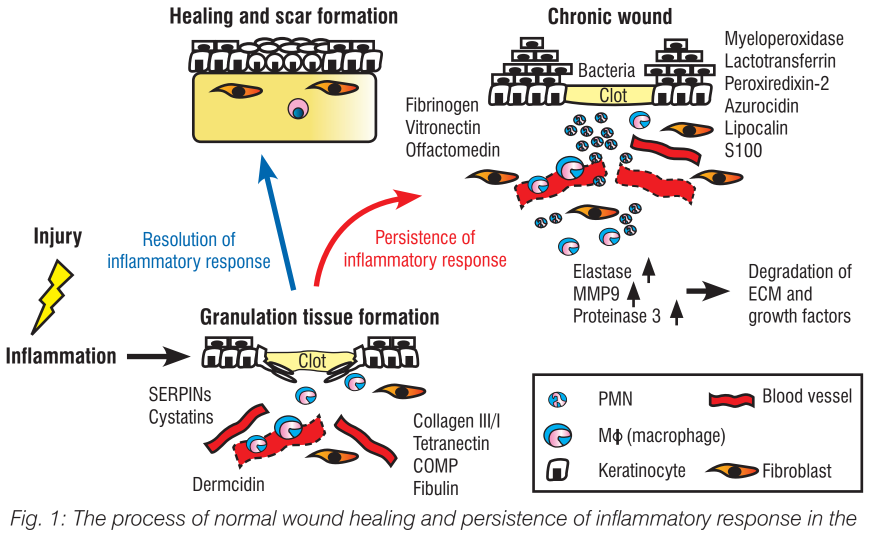

Fig. 1: The process of normal wound healing and persistence of inflammatory response in the case of a chronic wound [Reprinted with permission from S.A. Eming et al., J. Proteome. Res., 9(9) (2010) 4758–4766]

Most of the existing technologies that incorporate cell-based skin substitutes to heal chronic wounds suffer from a number of serious drawbacks: restricted availability, high cost, risk of immune rejection, short shelf life and extended culture periods are some of the prominent shortcomings which limit their clinical success. On the other hand, acellular natural skin substitutes consist of decelluarized extracellular matrix (ECM) of animal origin and thus have a high risk of intrinsic disease transfer and religious/ethical restrictions. Synthetic polymer based skin substitutes lack biodegradation profiles as well as biochemical signals and thus are not able to bridge this need gap.

Of late, plant components have increasingly been studied for various biomedical applications including bioactive scaffold materials. Scaffolds made of plant proteins accelerate the natural healing process and are a promising candidate for skin regeneration and organotypic skin equivalent culture. Among the fabrication techniques, electrospinning is one of the most efficient platform technologies to construct dermal tissue scaffolds as it offers a good degree of control over porosity and fiber size of the mesh resulting in a better cellular migration and infiltration into the scaffold[3]. The first plant protein having been electrospun was wheat gluten[4] and it led to the consideration of numerous plant-derived proteins

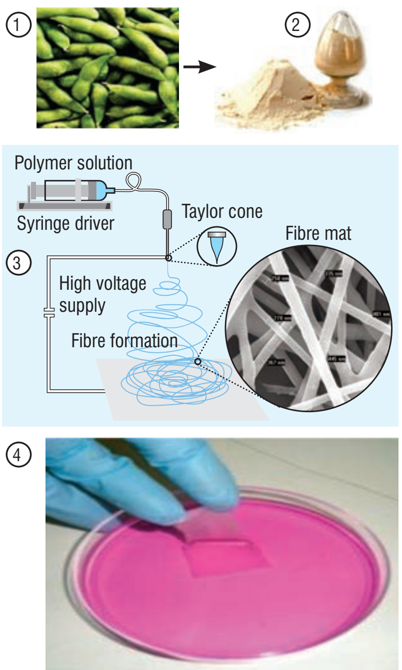

Fig. 2: From soybeans to bioactive scaffolds: Soybeans (1) are the source for alimentary proteins (2) which can be electrospun (3) into elastic APS scaffolds (4) [Image credits: 1: http://www.healingthrufood.com[6], 2: de-in-china.com[7], 3: http://www.centropede.com[8], 4: Dr. Leko Lin/Dr. Peter I. Lelkes, Drexel/Temple University]

for being utilized in nanofibrous scaffolds (Fig. 2).

Soy protein is one of the prominent plant-derived proteins, which may be useful for application in tissue engineering and regeneration. Soy protein with its many bioactive cryptic degradation products is a promising biomaterial candidate for tissue scaffolds. Electrospun soy protein scaffolds support adhesion and proliferation of cultured dermal fibroblasts,. They are resistant to hydrolysis and contain numerous bioactive cryptic peptides and isoflavones, which get metabolized by the body after scaffold degradation and resorption[5].

Eqalix intends to commercialize the APS technology in the near future and has obtained the exclusive license for the IP from Drexel University in Philadelphia (provisional patent application PCT/US 2008/001936). The technology incorporated in these APS does not rely upon the implementation of animal or cadaver tissues or synthetic polymers or stem cells. It represents the second generation of technologies in the area of regenerative medicine that restores the functionality of body's own repair mechanism to heal the damaged tissues. To date, Eqalix's APS for enhanced wound healing have undergone the initial proof-of concept research in animals and show significant promise in enhancing wound healing and skin regeneration in animal models of splinted wounds that normally heal very slowly or do not heal at all (Fig. 3).

The company is planning further validation tests in large animal models, before moving into human studies by the end of the coming year. Initially, the product will be launched under the brand name of DermaSoy™ and will not possess any medical claims. DermaSoy™ will be useful in rejuvenating skin, reducing the duration of healing process and increasing elasticity following cosmetic/aesthetic dermatological procedures. Following validation in initial clinical studies a product line of these APS with medical claims will be launched under the brand name of OmegaSkin™ in next couple of years. OmegaSkin™ will act as a bio-healing system to treat acute and chronic wounds, burns and diabetic foot ulcers.

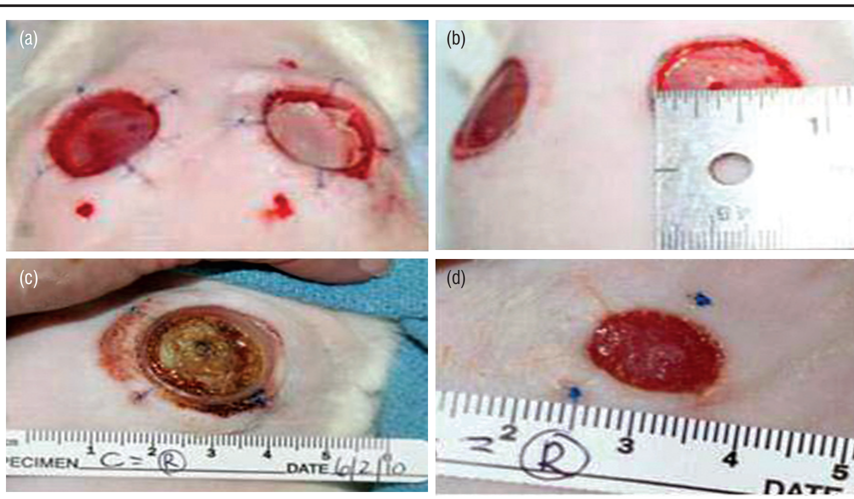

Fig. 3: Splinted wound model in rat: (a) treated with soy scaffold (right) and untreated (left), (b) wounds measure around 0.8 inches, (c) soy scaffold treated wound well on the way to healing after 15 days and (d) untreated wound after 15 days shows no signs of healing [Image courtesy: Dr. Leko Lin/ Dr. Peter I. Lelkes, Drexel/Temple University[9]]

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