A SCAFFOLD MATERIAL FOR WOUND CARE COMPRISING DECELLULARIZED FISH SKIN AND A METHOD FOR THE PREPARATION~~AND/OR OTHER TISSUE HEALING APPLICATIONS~~

FIELD

This invention relates to a scaffold material for wound care and/or other tissue healing applications and methods for making the same. The scaffold material comprises a decellularized extracellular matrix from fish skin.

BACKGROUND

A variety of human, animal and synthetic materials are currently described or used in medical procedures to augment, repair, or correct tissue defects.

For example, U.S. Published Patent Application No. 2003/0059460 discloses a hybrid polymer material comprising synthetic and natural polymers that can be used in regenerating living body tissue. The hybrid comprises a cross-linked naturally-occurring polymer and a biodegradation-absorbable synthetic polymer. A series of complicated process steps, however, must be undertaken to produce the hybrid material. In addition, the resulting hybrid material contains synthetic as well as naturally-occurring materials.

U.S. Patent No. 6,541,023 describes the use of porous collagen gels derived from fish skin for use as tissue engineering scaffolds. Preparation of the collagen gels involves grinding the fish skin. Additionally, China Patent No. 1068703 describes a process for preparing fish skin for dressing burn wounds, involving separating fish skin from the fish body and placing the skin in a preservation solution of iodine tincture, ethanol, borneol, sulfadiazine zinc and hydrochloric acid in amounts sufficient to establish a pH value of 2.5-3. However, these products can be difficult to handle as the product of U.S. Patent No. 6,541,023 is in a gel form and the product of China Patent No. 1068703 is stored in a solution.

In addition, a number of extracellular matrix products for medical uses have been derived from human skin (ALLODERM® Regenerative Tissue Matrix (LifeCell)); fetal bovine dermis (PRIMATRIX™ Dermal Repair Scaffold (TEI Biosciences)); porcine urinary bladder (MATRISTEM™ Extracellular Matrix Wound Sheet (Medline Industries, Inc.)); and porcine small intestinal submucosa (OASIS® Wound Matrix (Healthpoint Ltd.)). However, there is a need for improved products and methods to enhance wound healing and tissue repair. The present invention satisfies this need.

SUMMARY

The extracellular matrix (ECM) of vertebrates is a complex structural entity surrounding and supporting cells. ECM is composed of complex mixtures of structural proteins, the most abundant of which is collagen, and other specialized proteins and proteoglycans. The scaffold material described herein is a largely intact acellular scaffold of natural biological ECM components from fish skin. The scaffold can also comprise naturally-occurring lipids from the fish skin. The native three-dimensional structure, composition, and function of the dermal ECM is essentially unaltered, and provides a scaffold to support cell migration, adherence, proliferation, and differentiation, thus facilitating the repair and/or replacement of tissue. The present ~~invention~~disclosure also relates to methods of making and of using the scaffold material.

In one aspect, there is provided a scaffold material comprising intact decellularized fish skin, wherein the scaffold material comprises extracellular matrix material from intact fish skin.

In another aspect, there is provided a method for producing a scaffold material as defined above, comprising: (a) obtaining a fish skin; and (b) decellularizing the fish skin, wherein the scaffold material comprises extracellular matrix material from fish skin.

In yet another aspect, there is provided the use of the scaffold material as defined above in the manufacture of a medicament for treating a wound.

In still another aspect, there is provided the scaffold material as defined above, for use in a method for treating a wound.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an illustrative sample of a decellularized ECM product (scaffold material) made from fish skin in accordance with a process described herein.

Figure 2 shows optical images of scaffold material cross-sections at 100x (2A) and 400x (2B) magnification.

Figure 3 shows scanning electron microscope (SEM) images of scaffold material cross-sections at 300x (3A) and 600x (3B) magnification.

DESCRIPTION

A scaffold material in accordance with this invention is obtained from intact fish skin. An illustrative example showing the appearance of a sample of the scaffold material is shown in Figure 1. Any species of fish, including bony or cartilaginous fish, can be used as the source of the fish skin. For example, the source can be round fish like cod, haddock and catfish; flatfish, like halibut, plaice and sole; salmonids like salmon and trout; scombridaes like tuna; or small fish like herring, anchovies, mackerel and sardines. In certain embodiments the fish skin is obtained from cold-water oily fish and/or fish known to contain high amounts of omega-3 oil. Examples of fish high in omega-3 oil are salmon, pilchards, tuna, herring, cod, sardines, mackerel, sable fish, smelts, whitefish, hoki fish, and some varieties of trout.

The fish skin is removed from the fish before processing. If the fish skin is from a species of fish that has scales, the fish skin should be de-scaled so that a substantial portion of

10. The method of claim 8, wherein decellularizing comprises one or more physical treatment, one or more chemical treatment, one or more enzymatic treatment, or any combination thereof.

11. The method of claim 10, wherein the chemical treatment comprises treating the fish skin with one or more decellularizing agents selected from the group consisting of ionic salts, bases, acids, detergents, oxidizing agents, hypertonic solutions, chelating agents, organic solvents, methionine, cysteine, maleic acid, polymers that bind to DNA, and combinations thereof.

12. The method of claim 10, wherein the enzymatic treatment comprises treating the fish skin with one or more enzyme selected from the group consisting of proteases, endonucleases, and exonucleases.

~~13. A scaffold material produced using the method of any one of claims 8 to 12.~~

13~~14~~. Use of the scaffold material of any one of claims 1 to 7 in the manufacture of a medicament for treating a wound.

14~~15~~. The scaffold material of any one of claims 1 to 7, for use in a method for treating a wound.