COLLAGEN HYDROGEL FOR PROMOTING EPITHELIAL CELL GROWTH AND ARTIFICIAL LENS USING THE SAME

This application is a continuation of application Ser. No. 06/920,031, filed Oct. 16, 1986, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a collagen-hydrogel material which contains a collagen-hydrogel for promoting epithelial cell growth and which is adapted to be used to fabricate artificial lens or contact lens which promotes healing of corneal epithelium during implantation and more particularly to a collagen-hydrogel biomedical material that is formed of a polymerized hydrophilic monomer which is gelled and crosslinked to form a polymeric meshwork in the presence of and anchoring macromolcules formed of a constituent of ground tissue capable of promoting and sustaining epithelial cell growth and wherein an artificial lens, formed of the collagen-hydrogel for promoting epithelial cell growth and positioned over the pupillary zone of the eye contiguous Bowman's membrane having a selected portion of corneal epithelium removed therefrom, promotes epithelial cell growth enabling corneal epithelium to attach to and cover the artificial lens to implant the same in the eye between Bowman's membrane and a new layer of epithelial cells forming corneal epithelium.

2. Description of the Prior Art

Before beginning a description of the prior art, it would be helpful, in understanding the teachings of this invention, to define certain of the key terms that are used in the teachings of this invention.

Collagen, in its broadest sense, is a natural protein which serves as the ground substance or adhesive substance between cells in living tissue. It is well known in the art that collagen, as a substrate material, is capable of promoting cell adhesion and growth. Other proteins are also known to be capable of supporting cell growth of at least certain cell lines. In the present invention, the preferred source of collagen, as a natural protein, is derived from animal sources.

It is also known that other macromolecules, that is a molecule formed of a constituent of a ground substance of tissue, can support cell growth. Typical of such macromolecules, in addition to collagen, are mucopulysaccnarides or fibronectin, which constituents of ground substances of tissue are capable of promoting cell growth.

One class of synthetic materials which have found wide application as biomaterials is the class known as hydrogels. The term "hydrogel" refers to a broad class of polymeric materials which are swollen extensively in water, but which do not dissolve in water. Generally, hydrogels are formed by polymerizing a hydrophilic monomer in an aqueous solution under conditions where the polymer becomes crosslinked so that a three dimensional polymer network is formed which is sufficient to gel the solution.

Hydrogels are described in more detail in Hoffman, D. S., "Polymers in Medicine and Surgery," Plenum Press, New York, pp 33–44 (1974).

Hydrogels have many desirable properties for biomedical applications. For example, they can be made nontoxic and compatible with tissue. In addition, they are usually highly permeable to water, ions and small molecules. As is noted herein below, despite these favorable qualities, hydrogels have been found, in general, to be unsuitable as substrates for cell attachment and growth.

With the benefit of the above described descriptions and definitions, the known prior art will now be addressed.

It is known in the art to utilize a procedure known as epikeratophakia for the correction of aphakia and high myopia in a human eye (hereinafter referred to as the "Epikeratophakia Procedure"). In the Epikeratophakia Procedure, human corneal tissue is used and the corneal tissue is mechanically machined or polished to a specific lens power to form a corneal tissue lens. The corneal tissue lens is then sutured to the anterior surface of the cornea in the pupillary zone of the eye in order to change the refractive power of the eye. The specific procedure used for suturing the machined or polished corneal tissue lens to the eye requires that a portion of corneal epithelium be removed to expose a portion of Bowman's membrane and corneal tissue lens then be placed directly upon Bowman's membrane. During the healing process, corneal tissue lens is covered by epithelial cells which form the cornea epithelium implanting corneal tissue lens between Bowman's membrane and corneal epithelium. This procedure depends on the availability of human cornea tissue.

It is also known in the art to use frozen human corneal tissue, which is ground to a lenticular power, to form a corneal tissue lens and to suture the same to corneal stroma of a human eye to change the refractive power of the eye. This procedure is known as the keratomileusis and is described in a published article captioned "Keratophakia and Keratomikusis—Clinical Results" which appeared in August 1981, Volume 88, No. 8, at pages 709–715 of *American Academy of Ophtalmology* by Swinger, Casmir and Barraquer, Jose' (the "Swinger/Barraquer Publication").

It is also known in the art to use collagen-hydroxyethylmethacrylate hydrogels as substrates for promoting cell growth in tissue culture. The material used for the hydrogel is known as collagen-hydroxyeythylmethacrylic, and referred to as a HEMA hydrogel, which was prepared in the presence of an aqueous solution of native collagen. The resulting transparent hydrogel containing collagen was evaluated as substrata for growth of various cell lines in tissue culture. The preparation and use of collagen-hydroxyethylmethacrylate hydrogels for promoting cell growth in tissue culture is described in a article entitled USE A COLLAGEN-HYDROXYETHYLMETHACRYLATE HYDROGEL FOR CELL GROWTH which appeared in Volume 77, Number 4, April 1980 at pages 2064–2068 of the Proceedings of the National Academy of Science, United States of America, wherein the authors were Linda Civerchia-Perez (the inventor herein), Barbara Faris, Gary La Pointe, John Beldekas, Howard Leibowitz and Carl Franzblau (the "Civerchia Publication"). The Civerchia Publication disclosed that the collagen-hydroxyethylmethacrylate hydrogels for promoting cell growth in tissue culture were prepared by polymerizing monomeric hydroxyethylmethacylate in the presence of various concentrations of soluble native collagen. The resulting transparent hydrogels were used as substrate for growth of IMR-90 human embryonic lung fibroblasts. It was determined from these experiments that the growth of IMR 90 human embryonic lung fibroblasts was dose dependent upon the amount of