

DEVICE FOR TREATING FINE SUPERFICIAL FACIAL LINES

This application is a continuation of application Ser. No. 07/677,403, filed Mar. 29, 1991, now abandoned.

TECHNICAL FIELD

This invention is in the field of plastic surgery/dermatology and relates specifically to correcting fine superficial facial lines such as those around the eyes by injecting aqueous suspensions of particulate biomaterials, such as collagen, intradermally at the site of the lines.

BACKGROUND

Injectable forms of purified atelopeptide collagen have been commercially available for many years for soft tissue augmentation. Daniels et al., U.S. Pat. No. 3,949,073, initiated the development of these materials. They describe an injectable solution of atelopeptide which when injected forms a fibrillar collagen implant. Forms of this material are now commercially available from Collagen Corporation (Palo Alto, Calif.) under the trademark ZYDERM®. ZYDERM® collagen implant is prepackaged in a one cc syringe (Medical Molding Co. of America) fitted with a 30 gauge needle.

U.S. Pat. No. 4,488,911 assigned to Collagen Corporation describe a method for preparing purified atelopeptide collagen in solution (CIS). Native collagen, typically of bovine origin, is extracted from tissue in dilute aqueous acid and then digested with a protease such as pepsin, trypsin or PRONASE® to remove the telopeptides from the ends of the collagen molecules. Atelopeptide collagen fibers may be reconstituted from CIS by raising the pH of the solution.

U.S. Pat. No. 4,582,640, also assigned to Collagen Corporation, describes a crosslinked form of atelopeptide fibrillar collagen. An injectable suspension of this crosslinked material is available commercially from Collagen Corporation under the trademark ZYPLAST®. This product is prepackaged in a syringe in the same manner as the ZYDERM® product.

U.S. Pat. No. 4,642,117, also assigned to Collagen Corporation, describes a method for reducing the viscosity of reconstituted CIS by passing the reconstituted fibers through a fine mesh screen.

ZYDERM® and ZYPLAST® collagen implants have enjoyed great commercial success and are used to treat a large variety of soft tissue anomalies. However, physicians have found one type of skin contour, fine superficial facial lines, particularly those about the eyes, (i.e., crows' feet) difficult to treat with these products. Specifically, physicians questioned about such treatment indicated inter alia that (1) they had negative experiences in using prior products due to lumpiness or beading of the injectate, (2) the nature of the skin surrounding the eye increased the possibility of the injection causing trauma or bruising of the area and (3) the treatment required greater control or precision than that which is achievable with these prior products.

Applicants addressed these shortcomings and found that a greatly improved product for treating fine superficial facial lines was achievable through a combination of modifying both the syringe and the injectate.

DISCLOSURE OF THE INVENTION

Accordingly, one aspect of the present invention is a method for correcting fine superficial facial lines comprising injecting an aqueous suspension of a particulate biomaterial at a concentration of 10 to 50 mg/ml wherein the suspension displays an extrusion plot in which there is a smooth substantially linear increase in force up to a substantially constant force in the range of 5 to 30 newtons intradermally at the site of the lines from a syringe having a 31 to 33 gauge needle.

Another aspect of the invention is a device for use in correcting fine superficial facial lines comprising:

(a) a syringe having a barrel fitted with a fine gauge needle, the needle having a gauge in the range of 31 and 33 inclusive;

(b) an aqueous suspension of a particulate biomaterial contained within the barrel, particulate biomaterial having a concentration in the suspension being in the range of 10 to 50 mg/ml, the particulate biomaterial further being comprised of fibrils of uniform size whereby the uniform size of the fibrils results in improved flow characteristics and enhanced extrudability of the suspension through the fine gauge needle such that the suspension displays an extrusion plot in which there is a smooth substantially linear increase in force up to a substantially constant force in the range of 5 to 30 newtons.

MODES FOR CARRYING OUT THE INVENTION

A. Definitions

The term "atelopeptide" collagen refers to collagen which has been treated to remove the immunogenic terminal portions. Typically, collagen is treated with acid to swell the fibers, and the swollen fibers digested with a suitable protease (e.g., trypsin) to remove the terminal portions. The product is soluble in acidic solutions (e.g., about pH 2.0).

The term "reconstituted atelopeptide collagen" refers to uncrosslinked collagen which has been precipitated into a fibrillar form somewhat resembling the triple-helical form of collagen in its natural state. Thus, reconstituted atelopeptide collagen morphologically resembles native collagen, but omits the immunogenic telopeptide regions of the protein.

The term "precipitated" fibrillar atelopeptide collagen refers to uncrosslinked collagen which has been reconstituted into fibrillar form by precipitation from acidic solution.

The phrase "fine superficial facial lines" intends shallow linear depressions in the facial skin that are typically associated with aging or repeated flexing of the skin. They are most commonly found in crows' feet (at the outer edges of the eyes), vertical lines above the upper lips, and around the mouth.

The term "particulate" biomaterial intends materials that are particulate in form (e.g., fibrous or nonfibrous bodies) that are medically acceptable for implantation within humans for augmenting soft tissue. Examples of biomaterials that have been used or proposed for such use are fibrillar noncrosslinked atelopeptide collagen, crosslinked fibrillar atelopeptide collagen, gelatin beads, beads of natural or synthetic polymers such as polytetrafluoroethylene (TEFLON® polymer), silicone rubber, and various hydrogels such as polyacrylonitrile-polyacrylamide hydrogels. Fibrillar non-