METHODS FOR APPLICATION OF INTRALUMINAL PHOTOPOLYMERIZED GELS

FIELD OF THE INVENTION

This invention relates to devices and methods for applying photopolymerizable gels to tissue lumens.

BACKGROUND OF THE INVENTION

U.S. Pat. No. 5,213,580, issued May 25, 1993 to Slepian et al., and International Patent Application No. PCT/US89/03593 by Slepian et al., published Mar. 8, 1990 as Publication Number WO 90/01969, both describe a system of endoluminal sealing in which a biodgradable polymer is introduced into the lumen of a blood vessel, positioned at a point of stenosis, and thermally reconfigured to seal and pave the interior of the vessel. International Patent Application No. PCT/US91/01242 by Slepian, published Sep. 5, 1991 as Publication Number WO 91/12846, describes a method for treatment of tubular organs in which a therapeutic agent is introduced into a region of a tissue lumen defined by two expansile members and allowed there to remain for a therapeutically effective period of time.

U.S. Pat. No. 5,410,016, issued Apr. 25, 1995 (Hubbell et al.) and U.S. patent application Ser. No. 08/024,657 (Hubbell et al.) both filed Mar. 1, 1993 disclose a number of photopolymerizable polymers that may be applied to living mammalian tissue, including living soft tissue in order to treat various medical conditions. For example, the polymers may be applied for the prevention of post-operative adhesions, protection of tissue surfaces, the local application of biologically active species, and the controlled release of biologically active agents to achieve local and systemic effects. The materials and conditions of application are selected to enhance desirable properties such as good tissue adherence without adverse tissue reaction, non-toxicity, good biocompatibility, biodegradability, and ease of application or handling.

The compositions that form the polymers generally include a light sensitive polymerization initiator applied as a coating to the tissue surface in a fluent form, such as a liquid. The coated tissue then is exposed to light to polymerize the composition in situ.

Reference is made to the above-identified patent applications for a detailed description of the various polymers, their compositions, manufacture and general use. The disclosures of the above-identified Hubbell et al. applications are incorporated by reference, in their entireties, as part of the disclosure herein.

It is among the general objects of the present invention to provide devices and techniques for effectively and efficiently delivering and applying the liquid compositions (referred to as "prepolymers") to targeted tissue lumens, and then initiating the polymerization reaction in situ.

SUMMARY OF THE INVENTION

The invention includes devices for applying a polymeric material to a surface of a targeted tissue lumen or space, whether natural or induced, within a human or animal patient. The coating is applied as a prepolymer composition which then is irradiated with light, such as actinic light, to initiate and cause polymerization. In one embodiment, adapted for providing a "thick" gel to the interior surface of a lumen, the device comprises a catheter system having proximal and distal occlusion elements, such as radially expandable balloons, to define a treatment space, a molding member positioned between the occlusion elements to mold the prepolymer, and an optical emitter to provide a substantially uniform light field within the treatment space to uniformly polymerize the prepolymer.

In another embodiment, useful for providing a "thin" gel to the surface of a tissue lumen, the device comprises a catheter system having proximal and distal occlusion elements to define a treatment space, and an optical emitter to provide a substantially uniform light field within the treatment space. Unlike the device used for providing a thick gel, in the thin-gel embodiment, a molding member positioned between the occlusion elements is not used.

In still another embodiment, either of the devices described above can have a single occlusion element. In this embodiment, rather than defining the treatment space as that area between proximal and distal occlusion elements, the treatment site is defined as that region extending a short distance from the occlusion element in which light from the emitter, the prepolymer, and an optional photoinitiator, converge. Additionally, for certain applications, the occlusion elements can be eliminated entirely.

It is among the general objects of the invention to provide a device for efficiently and effectively applying polymerizable materials to tissue, including living tissue, and for initiating polymerization of the composition in situ.

A further object of the invention is to provide an apparatus for applying either a thin or thick film of a polymer on a targeted tissue lumen.

Another object of the invention is to provide devices of the type described that are suited particularly, although not exclusively, for use in percutaneous, transluminal surgical applications.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a schematic representation of one embodiment of a device for providing thick polymeric gels on the interior of a body lumen.

FIG. 2 is a cross-sectional view through line 2—2 of FIG. 1 at a region proximal to a proximal occlusion balloon.

FIG. 3 is a cross-sectional view through line 3—3 of FIG. 1 at a region within a molding balloon.

FIG. 4 is a schematic representation of a second embodiment of a device for providing thick polymeric gel on a luminal wall.

FIGS. 5A and 5B are schematic representations of still another embodiment of a device for providing a thick polymeric film on a luminal wall.

FIG. 6 is a schematic representation of an optical emitter catheter.

FIG. 7 is a schematic representation of one embodiment of a device for providing a polymeric barrier layer on a luminal wall.

FIG. 8 is a cross-sectional view through line 8—8 of FIG. 7 at a location proximal to a proximal occlusion balloon.

FIG. 9 is a cross-sectional view through line 9—9 of FIG. 7 across an optical emitter,

FIG. 10 is a schematic representation of a second embodiment of a device for providing a polymeric barrier layer on a luminal wall.