

**APPARATUS AND METHOD FOR LOCAL
APPLICATION OF POLYMERIC MATERIAL
TO TISSUE**

This application is a continuation of application Ser. No. PCT/US94/03115, filed Mar. 23, 1994, which is a continuation-in-part of U.S. Ser. No. 08/036,128, filed Mar. 23, 1993, now abandoned.

FIELD OF THE INVENTION

This invention relates to devices and techniques for applying therapeutic polymeric material to living tissue.

BACKGROUND OF THE INVENTION

A number of photopolymerizable hydrogel polymers that may be applied to mammalian tissue, including soft, living tissue, in order to treat various medical conditions are disclosed in the following U.S. patent applications:

U.S. patent application Ser. No. 843,485 filed Feb. 28, 1992 (Hubbell et al.) and a continuation-in-part thereof, Ser. No. 08/022,687 filed Mar. 1, 1993,

U.S. patent application Ser. No. 07/870,540 filed Feb. 28, 1992 (Hubbell et al.) and a continuation-in-part thereof, Ser. No. 08/024,657 filed Mar. 1, 1993.

The hydrogels disclosed in the foregoing applications may be applied to living tissue, for example, for the prevention of post-operative adhesions, the 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. They also may be used as temporary or long-term tissue adhesives or as materials for filling voids in biological materials. 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 when desired, and ease of application or handling.

The composition that will form the polymerized hydrogel may include a light sensitive polymerization initiator and is applied to the tissue surface in fluent form, as a liquid. The coated tissue then is exposed to light to polymerize the composition and render it non-fluent, in situ. The light is selected to be of an appropriate wavelength to efficiently initiate or sustain the polymerization and is of an appropriate intensity to achieve the polymerization within the desired time.

Reference is made to the above-identified patent applications for a detailed description of various hydrogels usable in this invention, their compositions, manufacture and general use. The disclosures of the above-identified applications are incorporated by reference as part of the disclosure herein.

SUMMARY OF THE INVENTION

The invention includes devices for applying a polymeric material to a surface of targeted tissue within a patient. The coating is applied as a predetermined volume of prepolymer composition which, after application, is irradiated with light to initiate and cause polymerization or gellation. The device includes a reservoir for the prepolymer liquid and an outlet adapted to eject the liquid onto the tissue surface in a predetermined pattern. A pumping arrangement is provided to cause transfer of a predetermined volume of prepolymer liquid stored in a reservoir to the outlet and for ejecting the liquid from the outlet. The outlet is arranged to cause the

liquid to be emitted to form a predetermined pattern. The device also includes means for activating the fluent prepolymer liquid to render it non-fluent. The activating means may be a form of light that may be generated locally or conducted through an optical fiber from an external light source. The device has an optical emission aperture at its distal end and is arranged in association with the prepolymer outlet to direct light emission in the same direction. Operation of the various components of the system may be controlled by a microprocessor.

In one specific embodiment of the invention, the device is gas-powered and has an emission nozzle for the prepolymer liquid at its distal end. The nozzle arrangement is adapted to develop a low pressure emission of gas (e.g., CO₂) and a lumen is provided in the device and to communicate the gas to the nozzle from a source of pressurized gas. The outlet nozzle is arranged so that, while gas is being emitted, a bolus of prepolymer liquid injected into the gas stream will cause the liquid to form a desired pattern, as in a divergent spray. The device also includes an optical fiber having an emission aperture at the end of the device, adjacent to the outlet nozzle. After the prepolymer liquid has been applied to the tissue, the activating light is applied to render the liquid to a non-fluent state.

In another embodiment, the fluent prepolymer liquid is subjected to a sudden controlled pulse of high pressure to force a predetermined volume of the liquid through the delivery outlet. The arrangement includes a variable volume reservoir (e.g., a syringe) for the liquid that is operated rapidly and under a force adequate to develop sufficient pressure to emit the liquid from the outlet and deposit it on the tissue in a desired pattern. In this embodiment, the reservoir is mounted in a device that includes a driver element engageable with a movable part of the reservoir. The driver element is movable in predetermined increments to reduce the reservoir volume in sudden, controlled, forceful pulses to cause the ejection of the predetermined volume of liquid from the outlet. The device may include a spray nozzle at the outlet, with the driving system being sufficient to develop sufficient pressure, and pulse characteristics to cause the desired spray pattern. The device also may include an optical system to irradiate the applied liquid with light to activate the material.

The driving element may be powered by a self-contained power source such as a relatively high compression spring associated with a trigger mechanism that enables the spring first to be cocked (compressed) and then fired (released) to provide the driving force for the driver element.

In another aspect of the invention means are provided to facilitate positioning of the distal, emission end of the device with respect to the target tissue.

It is among the general objects of the invention to provide devices and techniques for efficiently and effectively applying a fluent polymerizable material (referred to as a "prepolymer") to targeted tissue, including living tissue, and for effecting polymerization of the fluent prepolymer composition in situ to a non-fluent state.

Another object of the invention is to provide a device of the type described in which the device applies a predetermined volume of the material for each operating cycle.

A further object of the invention is to apply the polymerizable material in a thin film sprayed on the targeted tissue.

An additional object of the invention is to provide means for determining the position of the distal end of the device from the tissue to be coated, and to facilitate aiming the device to control the thickness and location of the coating.