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3,491,760

WOUND COVERINGS

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ABSTRACT OF THE DISCLOSURE

A heteroplastic skin, i.e., wound covering comprising a first tanned collagen gel layer containing about 10 to 25 weight percent of a polyol plasticizer and adhered to one surface of the gel layer a second tanned collagen gel layer of substantially the same composition as the first gel layer but having a lower water content than the first gel layer.

This invention relates to wound coverings. It more particularly refers to skin substitutes.

It is known to cover skin defects with various types of "skins." These defects may be wounds, burns, abrasions or the like. Three types of such coverings have been used.

In autotransplantation, a patient's own skin is grafted from another, healthy part of the body onto the injured area. This type of transplantation is generally limited to cases where the wound area is small since to graft larger skin areas would pose problems in that part of the body from which the graft was taken.

In homotransplantation, the skin from one or more other humans, is grafted onto the patient's wound. This type of transplant has usually been unsuccessful over a prolonged period, since the transplanted skin flap generally turns necrotic and is rejected by the patient.

In heterotransplantation, the wound is covered with a "skin" of non-human origin. This replacement skin may be from an animal or it may be of synthetic manufacture. Such heteroplastic skins have been made from foamed or film-form material. They have been made of felted non-woven fabric of many materials. Halogenated olefin polymers, such as polytetrafluoro ethylene, have been used for this purpose. It has often happened in the past that these heteroplastic skins have, similarly to homoplastic skins, become necrotic and been rejected.

Heteroplastic skins, and in fact all skin transplants, must have certain properties in order to be suited to use.

These properties are that:

- (1) The wound covering must not irritate the tissue of the wound site and must be free of antigens towards human tissues.
- (2) The wound covering must be yielding and elastic to ensure that all layers constituting it are in close contact with the surface of the wound and no folds occur under which the sanies could be trapped.
- (3) The wound covering must be suitable for fixation by suturing or sticking to the surrounding hale skin tissue.
- (4) The wound covering must join up with the newly formed granulation tissue and gradually cause reepithelization of the injured tissue.
- (5) The wound covering must lend itself to easy and reliable sterilization, and it must be put on the market ready for use and in a storable state.
- (6) The manufacture of the wound covering must be easy and economical.

In an attempt to provide heteroplastic skins it has been attempted to use collagen films alone or collagen films containing polyamide fibers embedded therein. However,

these foils were not successful because they were either too dry or dried too quickly so that they contracted and formed folds under which secretions from the wound accumulated which were strongly exposed to infections and finally caused rejection of the graft. Moreover, the tender tissue buds of the granulation tissue hit the hard foil and withered.

Accordingly, it was endeavoured to use collagen gel foils made from animal proteins which by their high water content very closely resemble human tissue, consist of the identical base material and make important chemical ingredients available for the growth of granulation tissue.

German specification 1,138,536 discloses a process for the manufacture of clear, viscous gels from eye lenses, wherein the eye lenses are dissolved in acids or alkaline solutions of urea or its derivatives or solutions of salts such as lithium thiocyanate and to cause separation of the gel counter-ions are diffused into the solution, or the gel is separated by electrophoresis or by a simple variation of the pH value.

When gels are manufactured by the process of German specification 1,138,536 from proteins, such as collagen, these gels have in their use as wound coverings the disadvantage that they are not sufficiently elastic, that they dissolve at the body temperature and that they are extremely brittle so that they cannot make perfect contact with the surface of the wound site without wrinkling which produces sanies accumulations which in view of the constant risk of infections sooner or later cause rejection by the body.

Thus, it is apparent that none of the heteroplastic or homoplastic skins previously used, satisfied the above-recited requirements.

It is an object of this invention to provide a novel heteroplastic skin.

It is another object of this invention to provide a process for the production of novel heteroplastic foils.

It is a further object of this invention to provide novel heteroplastic skins suitable for grafting onto human tissues.

Other and additional objects of this invention will become apparent from a consideration of this entire specification including the claims appended hereto.

In accord with and fulfilling these objects, this invention includes, as one of its aspects, the provision of a heteroplastic skin which promotes the formation of granulation tissue by the surface of the wound being covered. This heteroplastic skin is produced by forming it in a suitable nutrient medium so that the skin contains at least some of the tissue building elements of the medium in appropriate molecular size such that these building elements are available to the wound.

The heteroplastic skin according to this invention is prepared by gelling a sol of animal collagen. The collagen sol is prepared in a known manner, foamed, converted to the gel state in the known manner in foam form, tanned and a collagen covering film is adhered to the tanned gel. It is suitable in the practice of this invention to provide at least about 10 weight percent of a plasticizer in the collagen sol which will be incorporated in the collagen foam gel. About 10 to 25 weight percent of plasticizer have been found to be effective with about 20 weight percent being preferred. The plasticizer is suitably a polyol, preferably glycerin. Tanning is suitably accomplished by use of synthetic or vegetable materials as tannins. Physiologically acceptable polyaldehydes such as glutaric dialdehyde and starch polyaldehyde have been found to be quite effective for this purpose.

Improved pliability is achieved by the present invention by imparting a foamy consistency to the gel by injecting air or an inert gas in the form of extremely fine