

METHODS FOR DETECTING DEHYDRATION OF A BIOMEDICAL HYDROGEL

DESCRIPTION OF THE INVENTION

This invention relates to methods for detecting a state of relative dehydration, hydration or "dry out" in biomedical polymers. More particularly, this invention relates to methods for visually identifying whether a polymeric, preferably conductive, hydrogel or gel has lost certain desirable characteristics, such as conductivity or transmissivity to sound, as a result of loss of water.

BACKGROUND OF THE INVENTION

Biomedical polymers, hydrogels or gels are a relatively recent development which has had a substantial impact on the biomedical technology. These synthetic, polymeric materials have been used at the interface between various biomedical devices, e.g., electrocardiogram (ECG) electrodes, TENS electrodes, electrosurgery return pads, iontophoresis electrodes, ultrasound electrodes, wound dressings or coverings and skin or surface of an organ. They have largely supplanted naturally-occurring polymers such as karaya gum and guar which were the biomedical materials of choice before development of synthetic hydrogels. As has been described in the literature, synthetic biomedical polymers are a significant advance over their naturally-occurring counterparts in that the properties of the synthetic materials are more controllable, less expensive and more uniform. Given that these materials are used in medical and biomedical applications, the importance of controllability and uniformity of their properties is readily apparent.

Synthetic biopolymers, such as conductive, polymeric hydrogels or gels, do have one significant drawback in that upon storage, these materials tend to lose some of their water content (i.e., they tend to dehydrate or "dry out"). Since these materials normally conduct electricity city (and in some cases, sound), the loss of water tends to adversely effect a very important characteristic. Prior to this invention, there was no easy way for the user of a biomedical device having a polymeric hydrogel in a working surface or skin-contacting surface thereof to tell whether the hydrogel had been dehydrated to the point of significantly altering its properties (e.g., conductivity) short of applying the biomedical device to the patient and testing it. This invention provides an easy, visual method for detecting whether biomedical gels or hydrogels have lost an excessive amount of water so as to reduce their conductivity (to electricity or sound) and stability so as to not be suitable for the purpose intended.

BRIEF SUMMARY OF THE INVENTION

Briefly, in one aspect, this invention is a visual method for detecting a state of relative dehydration (or hydration) of a gel on a skin contacting or working surface of a biomedical device comprising the steps of selecting a weakly acid or a weakly basic, pH sensitive indicator; preparing the gel by incorporating the selected indicator therein, thereby producing a gel having a first color indicating adequate hydration; applying the colored gel to a working or skin-contacting surface of the biomedical device; and shortly before using the biomedical device, visually comparing the color of the

gel shortly before application with its first prepared color to determine the state of hydration of the gel.

In a preferred practice of this invention, the gel is prepared by mixing the indicator with the other raw materials, e.g., polymer powders, used to produce the polymeric gel prior to subsequent processing. It is within the contemplation of the invention that the indicator could be mixed with already polymerized gel.

In another preferred practice, a portion of the gel is covered, e.g., with a piece of transparent film which restricts the evaporation of water from the covered portion of the gel. The covered portion of the gel is then compared with the uncovered gel shortly before using the biomedical device. The covered gel tends to remain adequately hydrated, thus providing a good comparison "patch" or test area for comparison with uncovered electrode gel when hydration (or dehydration) state is later examined.

Preferred indicators are any skin-contact grade coloring having the requisite chemical characteristics specifically including sensitivity to changes in pH. Such preferred indicators are generally selected from the group consisting of Food, Drug and Cosmetic (FD&C) Blue #1, FD&C Blue #2, FD&C Green #3, D&C Green #8 or D&C Red #27.

"Biomedical device" as the term is used herein, is to be very broadly construed to mean essentially any device which is attached to the skin of a patient. Wound dressings, large area bandages and ultrasound interface pads, as well as TENS electrodes, ECG electrodes and iontophoresis devices are specifically contemplated.

"Working surface" or "skin-contacting surface", as the term is used herein, is intended to mean that portion (or the entirety) of a biomedical device which is adhered to the skin or the surface of an organ by means of a polymeric adhesive or biomedical adhesive.

"Biomedical polymer", as the term is used herein, is intended to mean essentially any water-containing, preferably conductive, preferably polymeric, material used to fix a biomedical device to a patient's skin or to the surface of an organ for the purpose of monitoring or controlling biological or electrical phenomenon.

Compositions with which the present invention may be employed are generally any hydrogel composition where the presence (or absence) of a given quantity or concentration of water is important to the gels' characteristics. U.S. Pat. No. 4,391,278 to Cahalan et al, the teaching of which is incorporated by reference herein, describes an acrylate-based material, viz., 2-acrylamido-2-methylpropanesulfonic acid (or its salts) which would be particularly useful as the gel material for the practice of this invention.

Canadian Pat. No. 1,181,582, the teaching of which is incorporated by reference herein, describes another electrically conductive adhesive comprised of an interpenetrating copolymer network of a stated composition, humectant and water. The hydrogel composition of this Canadian patent also would be useful in the practice of this invention.

Another preferred gel composition useful in the practice of the present invention is described in commonly owned, pending U.S. patent application Ser. No. 679,653, now U.S. Pat. No. 4,593,053, "Hydrophilic Pressure Sensitive Biomedical Adhesive Composition" in the name of Allan H. Jevne, Brett R. Vegoe, Carolann M. Holmblad and Patrick T. Cahalan. The '653 patent application discloses a skin-compatible, hydrophilic adhesive composition comprising 25 to 50 weight