HYDROGEL ADHESIVE FOR ATTACHING MEDICAL DEVICE TO PATIENT

This application is a continuation-in-part of application Ser. No. 08/222,729 filed Apr. 4, 1994, now U.S. Pat. No. 5,474,065.

FIELD OF THE INVENTION

The present invention relates to a biocompatible adhesive which adheres to wet skin. The adhesive may be used as an adhesive for wound care dressings, diaphoretic electrodes, vaginal drug therapies, and ostomy attachment appliances. More particularly, the invention relates to an electrically conductive biocompatible adhesive and biomedical sensing means, which utilize the adhesive, such as a fetal pulse oximeter and a non-invasive fetal probe which adhere to the skin of a fetus during labor and delivery.

BACKGROUND OF THE INVENTION

There is a need for a biocompatible adhesive which adheres to wet skin. Generally such an adhesive would be useful for use in attaching products which require or which would benefit from an adhesive with wet tack properties. Examples of such products are wound care dressings, diaphoretic electrodes, vaginal drug therapies, and ostomy attachment appliances.

Other applications requiring secure attachment means in a wet environment could also utilize such an adhesive. For example, such an adhesive would also be a useful alternative to securely attach equipment for biometric monitoring of fetal parameters (physical and chemical) intrautero during labor. During labor and delivery, the well-being of the fetus must be carefully monitored. The procedure of monitoring the fetus allows the clinician to assess the health of the fetus, detect fetal stress, and provide appropriate treatment. Many internal devices and methods are used to directly monitor and record such fetal parameters as heart rate, blood gas composition, and pH levels during labor and delivery. These direct monitoring procedures require a secure attachment of the sensor to the tissue of the fetus and commonly use sharpened wires in the form of spiral wires or hooks as the securing means. Examples of devices which evaluate the well being of the fetus by measuring fetal parameters are a fetal spiral electrode and a fetal pulse oximeter.

A fetal spiral electrode directly monitors fetal heart rate during labor using fetal scalp electrodes, such as those manufactured by Graphic Controls Corporation, having a sharpened helical wire for the secure attachment of the sensor. The wire penetrates the fetal tissue. Vacuum systems, inflatable balloons, and glue have been used to secure sensors to fetal skin. Active vacuum systems such as those described in U.S. Pat. No. 5,345,935 are bulky and are easily dislodged during labor. In addition, these systems restrict maternal mobility. Inflated balloons increase intrauterine pressure and the balloon may restrict fetal movement and maternal mobility. Prior art glues either do not adhere in a wet environment or, for adhesives such as the cyanoacrylates ("super glue"), aggressively bond the sensor to the skin so that removal requires cutting of the sensor from the tissue.

Fetal pulse oximetry is used to monitor the oxygen saturation in fetal tissue during labor and is described in German Patent Application Number P4304693.2 to Gerhard Rall and Reinhold Knitza. A fetal pulse oximeter is fixed to the fetal scalp by a sharpened helix wire similar to a fetal scalp electrode. This fetal pulse oximeter would be improved by the use of an attachment means which fixes the sensor to the fetal tissue without trauma. In addition, the wire attachment may affect the blood flow to the tissue at the site of attachment and therefore give an erroneous indication of fetal well being. A non-.invasive attachment means would be preferred.

Other diagnostic equipment, although not invasive, could also benefit from an adhesive having improved wet tack properties. For example, a transcutaneous fetal blood gas analysis for oxygen and carbon dioxide levels attaches sensors to a fetus by vacuum and "super glue" adhesives. Problems experienced with these sensors include bulky vacuum systems which cause the sensor to dislodge and also trauma to the skin by the cyanoacrylate adhesives. Other prior art pressure-sensitive adhesives, such as those used for self-adhesive bandages, cannot be readily utilized for such an application as they are hydrophobic and will not adhere to wet surfaces such as fetal skin.

Glue fixation of a transcutaneous pCO_2 electrode for fetal monitoring has been described by S. Schmidt, "Glue fixation of the $tcPco_2$ electrode for fetal monitoring," Journal Perinatal Medicine, 15(4), 377 (1987). Glue fixation to a fetus is difficult to achieve. It requires sufficient dilation and careful preparation of the attachment site. The electrode often becomes detached during use and may need to be reapplied. In addition, trauma to the skin during removal of a sensor attached by glue is possible. If the sensor is not completely sealed to the tissue, air leakage under the seal will cause an erroneous indication of oxygen and carbon dioxide levels. A biocompatible adhesive hydrogel with wet adhesive properties would be preferred as the attachment means.

An adhesive with wet tack properties could also be used far the attachment of sensors in the oral cavity. U.S. Pat. No. 5,139,023 discloses a non-invasive blood glucose sensor which attaches to the epithelial membrane. Bioadhesive hydrogels such as cellulose and cellulose derivatives, CARBOPOL polymer and gelatin are utilized as the attachment means. These materials are not sufficiently adhesive or stable, however, to allow a durable attachment. In addition, bioadhesives such as the polycarbophil resins available from B. F. Goodrich under the trademark NOVEON have been used for vaginal drug therapies. These materials may not have the adhesive properties or durability required for long term application.

To overcome the shortcomings of prior art attachment means, a new hydrogel with wet adhesive properties is provided.

SUMMARY OF THE INVENTION

The present invention provides a biocompatible hydrogel adhesive which adheres to wet tissue. The use of an alcoholamine such as diisopropanolamine provides these unexpected and unique wet tack properties. Additionally, the use of a polyol which contains hydroxyl groups, such as glycerine, and a diamine is found to provide a hydrogel having wet adhesive properties and longer shelf life. Preferably, the hydrogel adhesive can be used as an attachment means in conjunction with a biomedical detection or monitoring means. The adhesive may be used to attach a sensor on the skin of an intrautero fetus and to monitor the well being of the fetus during labor and delivery. The hydrogel having wet adhesive properties permits the attachment of a sensor or sensors onto wet tissue. Preferably, the biocompatible adhesive of the present invention is used to attach a fetal probe securely to a fetus in a non-invasive manner.

In addition, the adhesive can be used as an attachment means for a drug delivery therapy or prosthetic device. The