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[54] **STARCH TYPE GEL SEALS FOR OSTOMY PATIENTS**

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[52] **U.S. Cl.**..... **128/283,** 106/210, 260/233.3 R

[51] **Int. Cl.** **A61f 5/44**

[58] **Field of Search** ..... 128/156, 268, 285, 290, 128/296, 283; 106/210, 214; 260/233.3 A, 233.3 R; 127/32

[56] **References Cited**

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FOREIGN PATENTS OR APPLICATIONS

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Primary Examiner—Charles F. Rosenbaum

[57] **ABSTRACT**

This invention relates to modified starch gel seals for ostomy patients that can be produced in relatively high purity and at low cost, composed essentially of gelatinized starch, with or without a plasticizer such as glycerol or the like and glyoxal. The seal has a low rate of solubility that can be controlled and provides protection for the skin surrounding the stoma. One small size stoma opening in the center of the seal can be stretched and will fit larger size stomas without causing strangulation of the stoma. The gels can also act as a vehicle for medicinals, odor-control materials, or water retardants and can be made of multiple layers to satisfy the various needs of the patient.

8 Claims, No Drawings

STARCH TYPE GEL SEALS FOR OSTOMY PATIENTS

This is a continuation-in-part of my copending application Ser. No. 884,842 filed Dec. 15, 1969, now U.S. Pat. No. 3,667,469, issued Jan. 6, 1972 and constitutes a modification and improvement over the gel seal compositions disclosed in my application Ser. No. 90,368 filed Nov. 17, 1970, now U.S. Pat. No. 3,712,304, issued Jan. 23, 1973.

This invention relates to an improvement in the postoperative care of patients who have submitted to surgical procedures such as colostomy, ileostomy, cecostomy, and the like. This surgery results in an opening in the abdominal wall thus permitting the severed end of the intestine or duct to protrude through the opening. The severed end of the intestine is called a stoma. As the stoma is without the benefit of a sphincter muscle to control discharge, it flows as needed due to gravity and peristalsis. This uncontrolled flow from the stoma is usually entrapped in a pouch or bag secured in place and encompassing the stoma. Many different pouch appliances have been developed for this purpose.

One of the problems common to most patients is excoriated or irritated skin surrounding the stoma which is usually caused by stoma discharge contacting the skin and in some cases can be caused by adhesives and the use of organic solvents.

One effective means for the prevention of skin irritation, skin excoriation, and leakage on clothing and bedding is a gel sealing pad using karaya gum such as disclosed in my prior U.S. Pat. No. 3,302,647 which has proven to be a great benefit to the patients.

However, today the cost of top quality karaya gum is about $1.00 per pound and karaya gel seals cost the patient from twenty cents to fifty cents each. Since some patients require the use of several seals every 24 hours this becomes a substantial financial burden to the patient.

In addition, karaya gum is imported primarily from India to the United States; therefore, political and economic disturbances in India could certainly curtail or even eliminate availability of this gum. Also, karaya gum is subject to many variables and standardization of quality is difficult to be maintained by the gum supplier.

For these and other reasons it becomes important to develop a low cost, effective and improved substitute from materials locally available and to this end the invention contemplates the use of starch and its derivatives in the production of a gel seal of superior characteristics.

The ingredients contemplated by this invention are manufactured in large quantities in the industrial countries and, consequently, the price per pound is quite low, and since the manufacture of the constituents of the improved gel seals are rigidly controlled by accepted chemical standards, the uniformity and high quality of ingredients is maintained.

The invention also contemplates a gel composition formed largely from starch which extends the time that a gel seal can be used by a patient before it dissolves and must be replaced.

An important characteristic of a good gel seal is its tack or ability to adhere to the body of the patient and thus effect a seal and it is therefore desirable also to increase the usable life of the gel seal on a patient without reducing the gel seal's tack or sealing effectiveness or absorption ability. An increase in the percentage of starch in such a gel seal will increase the time required for the seal to dissolve. However, it also increases the hardness of the gel and decreases the tackiness, the sealability, flexibility and elasticity, each of which is undesirable.

I have discovered that the useful life of the gel can be greatly increased by incorporating glyoxal into the composition without the requirement of heat or large volume of water. However, heat can be used to accelerate the process. There is evidence to indicate that chemical crosslinking occurs between the starch and the glyoxal reducing solubility, so the degree of solubility can be in a large measure controlled by varying the percentage of glyoxal. Increasing the percentage of glyoxal will increase the insolubility of the starch gel. However, total insolubility cannot be attained, particularly where plasticizers are employed, as the plasticizers are commonly glycols that are water miscible. In fact, it is not desirable to provide insoluble gel seals. For example, seals of soft rubber have been used in the past and proved unsatisfactory since they are unable to absorb perspiration and fecal discharge that collects between the surface of the rubber and the patient's skin.

According to this invention, a gel seal of the usual shape is molded from a composition formed by mixing starch, and a solution of glyoxal.

Any of the starches commercially available from corn, potatoes, rice, wheat and the like may be used, but proprietary starches such as a starch known as B919 Snow Flake instant stabilizer starch seemed to give excellent results. This is a pre-gelatinized, crosslinked, waxy starch distributed by Corn Industrial, Co. Division of CPC International, Argo, Illinois. Other similar starches marketed by a number of companies under proprietary names have been used with success.

The glyoxal employed is preferably the commercial water soluble form usually containing about 60% water and 40% glyoxal, the suitable form being that distributed by the Union Carbide Company.

It has been noted that a suitable and usable gel seal can be prepared using as little as 9% of starch and 91% of glyoxal and as much as 33.33% of starch and 66.66% of glyoxal. In general seals of such composition have good compressibility, moderate elasticity but rather low flexibility and thus are comparatively rigid. However, they dissolve more slowly thus providing relatively longer use on the patient. Such seals find use for those patients requiring a more rigid gel seal. When these ingredients are mixed in the proportions indicated they appear to undergo a chemical reaction in the nature of crosslinking in the formation of the gel.

However, it has been found that when less than about 65% of glyoxal is employed in a starch-glyoxal mixture a rather hard dough-like product results and therefore, in such compositions as well as with other proportions it is desirable to employ a plasticizer to modify the characteristics of the product. Such plasticizers appear to be inert in the compositions and their function is to modify the physical characteristics of the product.

The plasticizer may be any of a number of liquids, glycerol being preferred though glycols, such as propy-

lene glycol, dextrose, glucose and even corn syrup has been found to be effective.

The addition of plasticizers may be employed in varying amounts to increase or control the flexibility, elasticity, tack, and solubility rate and to control the hardness in the ultimate product.

The addition of glyoxal to a B919Starch and glycerol mixture in proportions suitable to form a gel also appears to undergo a chemical reaction in the nature of crosslinking in the formation of the gel. The gel can be tested for water solubility within an hour after mixing the ingredients. One series of tests for water solubility of a gel without glyoxal and one with glyoxal showed that the gel without glyoxal dissolved in 23 minutes while the gel with glyoxal dissolved in 75 minutes. It was noted that the percentage of glyoxal used with the starch and glycerol is also a factor in producing varying degrees of solubility of the resulting gel.

As previously noted, one important object of the invention was to produce a gel seal having a relatively high degree of insolubility yet retaining the tack or adhesiveness necessary to adhere effectively to the skin of the patient. The method employed for measuring the relative solubility was to place the gel seal in an open wire cage suspended in water held in the mixing jar of a conventional household blender with the blender set at its lowest speed to thereby agitate the water and produce a flow of water past the gel seal. The time required for the seal to dissolve was noted and recorded.

In one series of tests, seals of uniform size were prepared by mixing varying amounts of glyoxal with 3 grams of glycerol to which was added one gram of B919 proprietary starch composition. The composition was poured into molds and the seals were allowed to air dry at normal room temperature of about 70° F. for one hour. The seal containing no glyoxal dissolved in about 20 minutes; that containing 0.05 gram of glyoxal in about 37 minutes; that containing 0.1 gram of glyoxal in about 66 minutes; that with 0.4 gram of glyoxal in about 90 minutes, and that containing 1.0 gram in about 105 minutes. Higher concentrations of glyoxal appeared to result in only a minor increase in the time of solution.

It appears however, that these times will vary somewhat depending upon the specific starch compound employed. It also appears that the time to dissolve increases as the gel ages and when aged at temperatures above normal room temperature.

For example a series of gel seals of uniform size were prepared, one containing 1 gram of B919 Starch and 3 grams of glycerol and a plurality of seals each formed of 1 gram of B919 Starch, 3 grams of glycerol and 0.5 gram of glyoxal. These were placed in an oven and baked at 130° F. The seal without glyoxal was baked for 11 days (268 hours) and was found to dissolve in about 35 minutes. The glyoxal containing seals dissolved in one hour and four minutes when baked 48 hours; one hour and 11 minutes when baked for 72 hours; one hour and 20 minutes when baked for 96 hours and one hour and 32 minutes when baked for 120 hours.

The proportion of ingredients in the gel can be varied rather widely to produce somewhat different characteristics in the seal. For example a composition containing about 22% by weight of B919 proprietary starch, 67% of glycerol and 11% of glyoxal produces a seal having high surface tack, great flexibility and elasticity, good opaque quality, and a fair solubility. This results in a composition pourable into molds.

Starch contents as high as 75% can be employed as for example one containing about 75% of B919 Starch, 12½% of glycerol and 12½% of glyoxal results in a seal having lower surface tack, less flexibility, a lower degree of opaqueness, but a higher degree of insolubility. These gels require handling as dough-like masses and require shaping and cutting to the desired shape.

As a further example of my invention, a gel can be produced having one side of high surface tack which is applied to the skin and the opposite side having no surface tack. These opposing qualities enable ease of handling by the nurse or patient during application to the patient. By employing a tapioco starch such as made by A. E. Staley of Decature, Illinois, designated F4-246 a higher percentage of starch may be employed and yet obtain the desirable liquid pourable characteristic, for example 40% of this starch, 40% glycerol, and 20% glyoxal. In this example the gel is poured into a one face mold, leaving the opposite side open, providing high surface tack on the side against the mold and practically no surface tack on the opposite side thus facilitating handling by the nurse or patient during application to the patient.

The percentage of glyoxal can be varied within rather wide limits to produce different characteristics in the resulting gel seal, particularly as to the rate of solubility.

The percentages given in these examples are not limitations but are for the purpose of illustrating the principles of the invention.

It is sometimes desirable to employ the gel seals as carriers for inclusions such as medication, deordorants and the like. However, I have found that it is advantageous to be able to selectively control the rate of release of the inclusions and to this end I have developed a seal composition and structure enabling such control. For example a composition comprising 1 gram of starch, 3 grams of glycerol and 0.1 gram of hexachlorophene, with or without a small amount of glyoxal to modify the solubility but less than required for maximum insolubility, is poured into a mold to a thickness of about 1/16 inch for example and allowed to gel. Thereafter a composition containing glyoxal in proportion to given maximum insolubility is prepared and poured into the mold on top of the previous layer to a thickness of about 1/16 inch and allowed to gel to thereby produce a seal having a layer of higher solubility containing the antiseptic which may be placed next to the skin and a layer of lower solubility to extend the life of the seal.

In like manner a seal formed of three layers may be produced, each in the region of 1/16 inch thickness, the outer layer placed away from the skin, containing a deordorant composition in the area where the seal is exposed to fecal discharge such as the proprietary deodorants commercially available or on the other hand essential oils, for example lemon oil to mask the odor. The other two layers being layers such as described in the preceding paragraph.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A sealing member for application to a patient's skin in the area around the stoma opening in ostomy conditions comprising a gel-like body composed essen-

tially of gelatinized starch cross-linked with glyoxal, the body having a uniform, homogenous gel throughout the total mass and having a central opening for passage of the patient's stoma, said body having a tacky pressure-sensitive adhesive quality for effecting sealing around the stoma opening.

2. A sealing member as set forth in claim **1** wherein the starch comprises between 9% to 33.33% by weight of the composition.

3. A sealing member as set forth in claim **1** wherein the glyoxal comprises between 66.66% to 91% by weight of the composition.

4. A sealing member as set forth in claim **1** wherein the composition of the gel-like body includes a plasticizer in an amount comprising between about 15% and 65% of the composition.

5. A sealing member as set forth in claim **1** wherein the composition of the gel-like body includes a plasticizer taken from the group comprising glycerol, propylene glycol, dextrose and glucose.

6. A sealing member for application to ostomy patients comprising a gel-like body composed essentially of gelatinized starch and glyoxal, an outer side of said member comprising a layer formed of a gelatinized starch together with a plasticizer and an odor control component.

7. A sealing member for application to ostomy patients comprising a gel-like body composed essentially of gelatinized starch and glyoxal, an outer side of said member comprising a layer formed of a gelatinized starch together with a plasticizer and a medication.

8. A sealing member for application to ostomy patients comprising a gel-like body composed essentially of gelatinized starch and glyoxal, an outer layer on said member formed of a gelatinized starch, and a plasticizer and another layer comprising a gel comprising starch and glyoxal.

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