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MEDICATED SURGICAL DRESSINGS

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The present invention relates to the manufacture of an improved surgical dressing, and more particularly to a non-dusting medicated surgical dressing that is especially adapted to supply controlled and safe amounts of one of the sulfa compounds directly to a wound where it can be effective in creating or maintaining an antiseptic condition and at the same time can be absorbed into the circulation without producing undesired after effects.

Sulfanilamide and its numerous derivatives and related compounds of high germicidal activity, hereinafter more particularly defined and usually referred to as "sulfa" compounds, in addition to their systemic use by peroral and parenteral administration, have come to be used to some extent by local application in powdered form in wounds and in the surgical operating field. Among such applications, one may especially mention the use of sulfa compounds in powder form in abdominal operations, where the danger of infectious peritonitis has been greatly reduced by the introduction of, say, 5 grams of a sulfa compound at operation. These compounds have likewise been used locally in the treatment of extensive burns and in compound fractures.

The local application of sulfa compounds is accompanied by absorption of the compound, which produces as a side effect the distribution of the drug through the circulation. While this effect is by no means undesirable, the sudden absorption of large quantities introduced in solid form often causes the appearance of the sulfa compound in the blood stream in higher quantities than those considered safe. Anoxemia, liver and kidney damage may result. When the sulfa compound is applied in solid form to certain types of wounds, for instance in pyelonidal cysts, the compound will tend to dissolve rapidly and drain down or away from the wound. The present procedure of dusting the powdered sulfa compound into the wound or field of operation has the further disadvantage that the distribution is not uniform or sufficiently controlled in amount.

I am aware of the earlier use of surgical gauze drenched with ferric chloride for hemostatic purposes or impregnated with iodoform or bismuth subgallate for minor wounds and dressings, but so far as I know no one has previously produced a surgical gauze impregnated with a sulfa compound for use as a medicated surgical dressing. There are several factors that would tend to discourage the use of a sulfa compound in surgical dressings, among which may be mentioned the fact that in order to introduce an effective amount

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of the sulfa compound into the dressing the impregnating solution in which the gauze is immersed must carry a high concentration of the sulfa compound. Since sulfanilamide itself has a relatively low water solubility, only about 0.7% dissolving at room temperature, the amount of the compound that can be introduced into a surgical gauze by means of an aqueous solution is necessarily very limited. If a non-aqueous liquid such as ethyl or methyl alcohol is used, then there is a tendency for the sulfa compound to crystallize out on the fibers of the gauze or other textile material with resultant dusting. Judging by the behavior of various of the water soluble germicides and bacteriostats of the prior art, it was to have been expected that if a relatively water soluble sulfa compound were used instead of the relatively insoluble sulfanilamide, such compound would tend to be dissolved out in sterilizing and after application to various types of draining wounds. A still further deterrent to the use of the sulfa derivatives generally is the tendency of many of them to discolor a textile material when the impregnated textile material is exposed to light and air.

I have found that these apparent obstacles to the use of sulfa compounds in surgical dressings may be overcome in several ways which I will describe below, and it is therefore a principal object of my invention to produce a surgical dressing impregnated with a sulfa compound in an effective amount for direct application to wounds and in other situations where it is desired to effect or maintain antiseptic conditions or to effect direct absorption of the compound into the circulation.

It is a further object to provide a sulfa compound-impregnated surgical dressing which is dry and substantially non-dusting and at the same time retains essentially the feel and flexibility of untreated surgical gauze.

My invention has for a further object a method of impregnating surgical gauze and similar materials with a sulfa compound and the fixing of the compound in the fibers of the textile material so that it will be released in controlled and regulated amounts when the dressing made therefrom is applied to a wound. At the same time the sulfa compound is prevented from being dissolved away by the moisture present in the conventional sterilizing autoclaving treatment.

My invention in certain of its broader aspects is based upon my discovery that the relatively water soluble sulfa compounds, such for example

as various salts formed by reaction of the sulfa compounds with inorganic or organic bases, for example, sodium hydroxide or diethanolamine, when used in a solution of 2½% or higher to impregnate surgical gauze, will be retained within and on the surfaces of the fibers of the textile material to such an extent as to insure a highly satisfactory result when the gauze is used as a surgical dressing. The sulfa compounds retained in the gauze show no tendency to dusting on drying and are not washed out or drained away during the autoclaving treatment.

I have further found that the amount of sulfa compound that may be retained in the gauze may be markedly increased by adding a small amount of a compound having the effect of increasing the viscosity of the solution. This compound should also be selected from those that are inert in respect to the sulfa compound as well as bland in their effect on body tissues or wounds with which they may come in contact on application of the surgical gauze. I have found that methyl cellulose serves very well for this purpose, particularly when the sulfa compound is introduced into the gauze in the form of an aqueous solution. When an alcohol solution is used, ethyl cellulose may be added to bring about the desired viscosity and thereby promote retention of the sulfa compound on the fibers of the gauze or dressing material.

By way of example, I have found that a marked improvement in the ability of surgical gauze to retain sulfa compounds is brought about by adding as little as one part per thousand of methyl cellulose to a relatively concentrated aqueous solution of a sulfa compound. Due to the increased viscosity of the solution it is possible, by merely soaking the gauze and then subjecting it to gentle wringing comparable to that obtained by wringing the gauze in the hands, to obtain an average increase in the weight of the gauze of 200%. Hence if a solution carrying two and one-half parts by weight of the sulfa compound is used to impregnate the gauze, it is possible to insure a minimum saturation of around 5% of the sulfa compound. After the soaking and gentle wringing the moisture or other solvent is removed from the padding by evaporation, as for instance by a current of warm air or the use of a warm light such as an infrared lamp, care being taken, however, not to apply sufficient centrifugal or similar mechanical force to remove the solute as well as the solvent. Slight stiffness at this stage may be eliminated by rubbing and working the gauze. The impregnated gauze may now be sterilized like ordinary surgical gauze which is usually autoclaved for 20 minutes with steam at 20 lbs. per square inch. As is customary with the autoclaving of ordinary gauze, here too additional moisture is removed by evacuating the autoclave during the cooling period. Various grades of methyl cellulose may be used. The particular methyl cellulose used in my work is a product of the Dow Chemical Company of Midland, Michigan, known as Methocel XX High. Methyl cellulose of various other viscosity types may be used with appropriate adjustment of the proportion added so as to insure the desired viscosity in the impregnating solution. Likewise, when ethyl cellulose is used in an alcohol solution or other suitable solvent, the ethyl cellulose will be selected from the various viscosity types available and proportioned in the amount added to the solution to insure the desired ultimate viscosity in the impregnating bath.

I have further found that the tendency of the treated gauze to become discolored during autoclaving can be overcome by using an impregnating solution having a pH value below 9. Such a solution may be obtained, for example, by using sodium "sulfacet" (N¹-acetyl sulfanilamide) as the sulfa derivative. In case the sulfa derivative employed has a higher alkalinity as, for example, one of the more alkaline sodium salts, e. g., the sodium salt of sulfapyridine, the pH of the impregnating solution may be reduced, preferably to between 7 and 8, by adding thereto a suitable proportion of the corresponding free acidic sulfa compound.

By following this procedure I have prepared surgical dressings containing as much as 20% by weight of a sulfa compound without altering the appearance and the mechanical properties of the surgical dressing material before and after sterilization. The following demonstrates that the sulfa compound is not altered by the process, especially by the sterilization:

A course grade surgical gauze was impregnated with sodium "sulfacet" in a 10% solution containing 0.1% of Methocel XX High. After impregnating and drying, the dressing had gained 19% in weight. Sections of the pads so prepared were set aside before and after autoclaving and extracted with water. They contained 10% of "sulfacet" by chemical analysis before autoclaving and 12.0% after autoclaving. Using the same impregnating solution on finer surgical gauze material, there was an increase in weight of about 15% after impregnating and drying, and the impregnated gauze contained 10.8% and 13.1% of "sulfacet" before and after autoclaving, respectively. It will be understood that the apparent increase during autoclaving is due to the more thorough drying resulting from the autoclaving treatment. It will be understood that the impregnation process may be carried on either as a continuous or batch process.

Some of the sulfa drugs have a tendency to turn yellow, especially when exposed to light and air. This may be counteracted by wrapping the impregnated surgical dressing in a light-proof cover, such as colored Cellophane, that will keep out the actinic rays, and by placing the material in evacuated containers. I have also found that the addition of small amounts, e. g., at least about one part to one thousand parts of the sulfa compound, of sodium sulfite to the impregnating bath serves to prevent discoloration.

Contrary to what might have been expected, I have found that when I have used more or less concentrated aqueous solutions of the relatively soluble types of sulfa compounds as, for example, the sodium and diethanolamine salts of N¹-acetyl sulfanilamide, the sulfa compound stays on the fibers of the dressing material and shows no tendency to crystallize and fall off as dust even when stored over considerable periods.

While I prefer to use the relatively water soluble sulfa compounds, it will be understood that the sulfa compounds that are less soluble in water, and more particularly the free acid sulfa compounds, may be used in various non-aqueous solutions, especially in ethyl or methyl alcohol solutions of suitable concentration. When used in such a non-aqueous medium, a binding or controlling agent such as methyl cellulose should be added since otherwise there will be a rather marked tendency for the sulfa drug to crystallize out on the textile material.

Where herein the term "sulfa compound" is

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used in the specification and claims, it is to be understood as including sulfanilamide and its numerous derivatives having germicidal or bacteriostatic properties and produced by substitutions effected either in the ring or in the functional groups, particularly the amide nitrogen, usually referred to as N¹; also germicidally active or bacteriostatic derivatives of these compounds, such as "Prontosil Red," where the amino group N⁴ is replaced for instance by an azo group which is reconverted in the body to —NH₂. I also intend to include within the term "sulfa compound" as used herein those germicidally active or bacteriostatic salts which are formed from the sulfa compounds by reaction with inorganic as well as organic bases, for example, sodium hydroxide or diethanolamine.

It will be understood that where herein I have referred to "surgical gauze" and "surgical dressing material," I mean to include any and all of the textile materials heretofore used for such purposes, such as cotton, wool and the various synthetic fibers. The impregnation treatment may, of course, be applied to the material at any stage in its manufacture or even after it has been completely converted into one of the conventional forms for use as surgical dressings such as gauze, bandages, packing, absorbent cotton and related products.

I claim:

1. A surgical dressing material comprising a dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of a sulfa compound in a proportion at least equalling 5% of the weight of said textile material and a binding agent consisting essentially of a cellulose ether present in an amount sufficient to hold said sulfa compound in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said sulfa compound from the dressing when applied to a wound.

2. A surgical dressing material comprising a dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of a sulfa compound in a proportion between 10 and 20% of the weight of said textile material and a binding agent consisting essentially of a cellulose ether present in an amount sufficient to hold said sulfa compound in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said sulfa compound from the dressing when applied to a wound.

3. A surgical dressing material comprising a

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dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of a sulfa compound in a proportion at least equaling 5% of the weight of said textile material and a binding agent consisting essentially of methyl cellulose in an amount sufficient to hold said sulfa compound in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said sulfa compound from the dressing when applied to a wound.

4. A surgical dressing material comprising a dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of a mixture of an alkaline salt of a sulfa compound and an acid sulfa compound having a pH value of less than 9 when brought into solution in water and said sulfa compound being further associated with a binding agent consisting essentially of a cellulose ether present in an amount sufficient to hold said sulfa compound in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said sulfa compound from the dressing when applied to a wound.

5. A surgical dressing material comprising a dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of sulfanilamide in a proportion at least equaling 5% of the weight of said textile material and a binding agent consisting essentially of a cellulose ether present in an amount sufficient to hold said sulfanilamide in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said sulfanilamide from the dressing when applied to a wound.

6. A surgical dressing material comprising a dry textile material having a feel and flexibility similar to that of untreated surgical gauze and carrying on the fibres thereof an impregnation of a water-soluble salt of N¹-acetyl sulfanilamide in a proportion at least equaling 5% of the weight of said textile material and a binding agent consisting essentially of a cellulose ether present in an amount sufficient to hold said salt in situ in said material without leaching during steam sterilization and substantially without dusting during handling while at the same time permitting gradual absorption of said salt from the dressing when applied to a wound.

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