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MICROBIOCIDAL SUTURES CONTAINING QUATERNARY AMMONIUM COMPOUNDS AND METHOD FOR MAKING

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ABSTRACT OF THE DISCLOSURE

A surgical suture having sustained microbiocidal activity is provided by incorporating a microbiocidal quaternary ammonium compound substantially uniformly throughout the body of the suture. The salt is provided in the body of the suture material by utilizing a solvent which swells the suture to permit the salt to penetrate throughout the suture body. On removal of the solvent, the suture returns to its original size.

The present invention relates to materials having microbiocidal properties and methods of making such materials. More particularly, the invention relates to woven and non-woven fabrics of varying weave and mesh sizes having long-lasting microbiocidal activity. Even more particularly, the invention relates to threads, specifically sutures, having substained microbiocidal activity.

In medical practice, and in other fields requiring aseptic techniques, it is frequently necessary or desirable to employ antiseptic or aseptic materials. When employing hard goods, such as surgical instruments, the materials can be rendered free of microorganisms by autoclave and other relatively simple sterilizing techniques. Soft goods, on the other hand, tend to be difficult to thoroughly sterilize and, when sterilized, remain so for relatively short periods of time. Exemplary of such soft goods are fabrics of either synthetic or natural fibers which are fashioned into articles of clothing or into textile products. Surgeons' clothing, gloves and dressings used in surgery are typical of fabric products, or soft goods, which are advantageously antiseptic for long periods of time. Further, there are many scientific operations which must be conducted in an organism-free environment. Fabrics, textiles and soft goods generally used in these and analogous fields should be antiseptic in nature and it is very desirable that such antiseptic or microbiocidal activity be as permanent as possible.

Another material wherein sustained microbiocidal activity would be very beneficial is material used as surgical sutures. Surgical practice requires antiseptic techniques. It is always desirable to maintain as low an infectious probability as possible. For this reason, all materials which come into contact with open wounds are presterilized. In the operating room, effort is made to keep the pathological microbial population at a minimum by scrubbing down the room with antiseptic solutions; by having positive air pressure so that the unclean air currents cannot flow in; by sterilizing the incoming air to the best of one's ability; by having all masks and gowns scrupulously clean, by keeping all outside influences to a minimum; by placing caps, masks and gowns on all personnel; and by sterilizing all objects that come into contact with the surgeon or the patient, such as linens, instruments, sutures and prosthetics.

These factors are intended to start a surgical procedure in the optimal condition. During the procedure there is an inevitable increase in microbial population as the operation progresses. The quantity of airborne bacteria entering the operating room varies directly to the time of exposure. The breathing and talking of personnel, as well as possible "breaks in technique," introduce microorganisms. The patient himself may spread his own bacterial population to the wound site via his blood stream. In essence, there will be a microorganism population and this population will reproduce and increase geometrically in relation to time.

Sterile conditions must be scrupulously maintained in order to keep the microbial population to a minimum. As an additional precaution, all objects which contact a patient should have inherent bactericidal or bacteristatic properties to lend protection for the duration of a procedure. This should apply to coverings (drapes, masks, gowns, and gloves), instruments, sutures and prosthetics and all other modalities which are inherent in the particular procedures.

Sutures are composed of filamentous material. Typical among such materials are silk and Dacron which comprise 80 to 90 percent of all non-absorbable sutures. Almost all the silk and Dacron sutures are braided and therefore, polyfilamentous. The porous structure of the braid aids and abets the growth of microorganisms which are found therein. These microorganisms find their way into the braid by direct extension from the patient's body (endogenous spread) or by contamination from the outside (exogenous spread). However, the end result is the same. Once the infection starts involving the suture, it is almost impossible to cure except by removal of the offending sutures. Obviously, this means that the suture must be "fished out" or an actual reoperation for removal must be performed.

It is clear that endowing sutures with inherent microbiostatic or microbiocidal properties should be highly desirable. This has been realized in the past. There has been a suture impregnated with Aureomycin as an antibiotic which is predominantly effective against gram-negative organisms. However, the biocide is water soluble and the protection of short duration. Short acting biocides could be of help in initial healing, but, as all surgeons know, the wound may apparently heal without complications only to be followed by a wound infection appearing after periods as long as three months. In these infections, the sutures are almost invariably involved.

What is required is microbiocidal activity for as long a duration as possible. Two objects would be achieved:

(1) The suture would provide, over long periods of time, a source of medicament for the immediately surrounding tissues and

(2) The suture itself would be rendered antiseptic for long periods of time.

It is an object of the present invention to provide a method of endowing soft goods, such as fabrics, textiles, threads and films with long-lasting microbiocidal properties and to provide materials having such properties.

These and other objects are achieved according to the present invention by uniformly distributing a microbiocide throughout the body of a fabric or soft goods material. The materials so produced contain a microbiocide so intimately associated with the material as to become, in essence, a part of the material itself such that the microbiocide, which may be highly soluble, is only slowly dissolved out of the material when the material is in contact with a solvent in which the microbiocide is soluble.

The invention will be more fully described in the examples which follow which illustrate a preferred embodiment of the invention.

EXAMPLE I

A Dacron suture was immersed in a solution containing 1% benzalkonium chloride (a mixture of alkyldi-

methylbenzylammonium chlorides) in methyl Cellosolve (2-methoxyethanol). The swelled and saturated thread was then rinsed with water and dried. The suture so prepared was repeatedly contacted with nutrient on a culture plate, but no growth of organism on the nutrient was observed.

EXAMPLE II

A silk suture was immersed in a solution of about 1.5% benzethonium chloride [benzyldimethyl{2-(2-(p-1,1,3,3 - tetramethylbutylphenoxy)ethoxy)ethyl}-ammonium chloride] in water (270 gallons) maintained at about 140° F. The impregnated thread was rinsed with warm water and dried. The suture product was tested as in Example I and the result was the same.

EXAMPLE III

A Dacron suture was immersed in a solution of about 0.5% hexachlorophene [2,2'-methylenebis(3,4,6-trichlorophenol)] in methyl Cellosolve and subsequently rinsed and dried. The suture so prepared was tested as in Example I with similar results.

EXAMPLE IV

One hundred pounds of silk suture was immersed in the following solution, maintained at 140° F., for 1 hour:

Water	gals.	270
Cetalkonium (cetyl dimethyl benzyl ammonium chloride)	lbs.	27

The swelled and saturated thread was then rinsed twice with warm water and dried. The treated suture was tested as in Example I and no organisms were observed on the nutrient.

EXAMPLE V

One hundred pounds of nylon monofilament suture were immersed in the following solution, maintained at 140° F., for 15 minutes:

Water	gals.	200
Glacial acetic acid (to pH 2)	gals.	75
Cetalkonium	lbs.	2

The swelled and saturated thread was then rinsed twice with clear water and dried. The treated suture was tested as in Example I and no organisms were observed on the nutrient.

EXAMPLE VI

One hundred pounds of cotton thread was immersed in the following solution, maintained at 140° F., for 30 minutes:

Water	gals.	300
Glacial acetic acid (to pH of 2 to 3)	lbs.	20
Cetalkonium	lbs.	20

The swelled and saturated thread was then rinsed twice with clear water and dried. The resultant thread was tested as in the previous examples with similar results.

In the foregoing examples, the solvent for the microbiocides is selected to have a swelling effect on the thread or fabric treated. In this manner the fabric is caused to swell such that the microbiocide is thoroughly impregnated into the thread. The thread shrinks back to its original size when the solvent is removed and the microbiocide remains tenaciously in the body of the thread. When the thread is placed in contact with solvent for the microbiocide as, for example, when the thread is contacted with a moist nutrient, the microbiocide tends to remain in the thread resulting in a suture material having sustained microbiocidal activity.

While fabric materials such as threads and sutures have been exemplified, the invention is also applicable to thread derivatives such as fabrics, both woven and non-woven. Surgeons' cotton gloves, for example, could be rendered microbiocidal for long periods of time in accordance with the invention.

Many microbiocides are known and these known materials may be utilized in the present invention by selecting a suitable solvent therefor which solvent acts as a swelling agent as disclosed. Solvents having both polar and non-polar groups appear to be quite advantageous although water and hydrocarbon solvents are suitable.

The treated threads may be rinsed to remove excess solvent and this may be accomplished with a rinse solvent which preferentially removes the solvent and not the microbiocide. After the solvent is removed, either by rinsing or any suitable means, such as evaporation or drying, the thread returns to its original shape or nearly so. The thread is then dried in any convenient manner.

I claim:

1. A surgical suture having sustained microbiocidal activity comprising a sterile suture thread having a microbiocide distributed substantially uniformly throughout said suture, said microbiocide being selected from the group consisting of quarternary ammonium salt microbiocides and hexachlorophene.

2. A surgical suture having sustained microbiocidal activity comprising a polyester thread having a quaternary ammonium salt microbiocide distributed substantially uniformly throughout said thread.

3. A surgical suture having sustained microbiocidal activity comprising a nylon thread having a quaternary ammonium salt microbiocide distributed substantially uniformly throughout said thread.

4. A surgical suture having sustained microbiocidal activity comprising a silk thread having a quaternary ammonium salt microbiocide distributed substantially uniformly throughout said thread.

5. A surgical suture having sustained microbiocidal activity comprising a cotton thread having a quaternary ammonium salt microbiocide distributed substantially uniformly throughout said thread.

6. A method of making an antiseptic suture having sustained microbiocidal activity comprising the steps of contacting a suture with a solution of a microbiocide selected from the group consisting of quaternary ammonium salt microbiocides and hexachlorophene dissolved in solvent for a time sufficient to swell said suture and to substantially uniformly distribute said solution therein, subsequently removing said solvent from said suture to cause the suture to return substantially to its pre-swelled size whereby said microbiocide is retained substantially uniformly distributed throughout said suture.

7. A method as claimed in claim 6 wherein said solvent comprises 2-methoxyethanol and said suture is a polyester.

8. A method as claimed in claim 6 wherein said solvent comprises an aqueous acid solution, and said suture is nylon.

9. A method as claimed in claim 6 wherein said solvent comprises water, and said suture is silk.

10. A method as claimed in claim 6 wherein said solvent comprises an aqueous acid solution, and said suture is cotton.

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