



(22) Date de dépôt/Filing Date: 2007/09/27
(41) Mise à la disp. pub./Open to Public Insp.: 2008/04/25
(45) Date de délivrance/Issue Date: 2011/01/11
(30) Priorité/Priority: 2006/10/25 (DE10 2006 051 093.3)

(51) Cl.Int./Int.Cl. *A61L 17/00* (2006.01),
A61L 17/12 (2006.01)
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(54) Titre : MATERIEL POUR SUTURE CHIRURGICALE AVEC SURFACE ANTIMICROBIENNE ET PROCESSUS PERMETTANT DE DEPOSER UN REVETEMENT ANTIMICROBIEN SUR LE MATERIEL POUR SUTURE CHIRURGICALE
(54) Title: SURGICAL SUTURE MATERIAL WITH AN ANTIMICROBIAL SURFACE AND PROCESS FOR PROVIDING AN ANTIMICROBIAL COATING ON SURGICAL SUTURE MATERIAL

(57) **Abrégé/Abstract:**

A surgical suture material with an antimicrobial surface is described, the surface exhibiting a coating containing at least one fatty acid, octenidine dichloride and/or dequalinium chloride and optionally oligomeric lactic acid esters. In addition, a process for coating surgical suture material is described which is characterised by the fact that the thread material is wetted with a homogeneous methanolic solution of octenidine dichloride and/or dequalinium chloride and subsequently the methanol is evaporated, a coating forming on the thread surface.



Abstract

A surgical suture material with an antimicrobial surface is described, the surface exhibiting a coating containing at least one fatty acid, octenidine dichloride and/or dequalinium chloride and optionally oligomeric lactic acid esters. In addition , a process for coating surgical suture material is described which is characterised by the fact that the thread material is wetted with a homogeneous methanolic solution of octenidine dichloride and/or dequalinium chloride and subsequently the methanol is evaporated, a coating forming on the thread surface.

Surgical suture material with an antimicrobial surface and process for providing an antimicrobial coating on surgical suture material

The subject matter of the invention consists of a surgical suture material with an antimicrobial coating and a process for providing an antimicrobial coating on surgical suture material.

Surgical suture material can be divided into monofilament and polyfilament threads on the basis of its construction. Polyfilament threads can exhibit a so-called wicking effect. This means that tissue fluid migrates along the thread as a result of capillary action. It is possible for a migration of microbial germs to be associated therewith such that infections may spread along the thread material. It is therefore desirable to provide surgical suture material with a finish in such a way that settling of germs on the thread surface and thus a migration of germs along the thread is effectively prevented.

In the case of resorbable suture materials, polyfilament, braided polyglycolide threads are of particular practical importance. So far, only one polyglycolide-based thread material, marketed by Ethicon, which is coated with the antiseptic triclosan has been available on the market. This antiseptic is a chlorinated biphenyl derivative which has an antiseptic effect on gram-positive bacteria. However, a thread material with a much wider antibacterial effectiveness covering also gram-negative bacteria, yeasts and fungi would be desirable. Polyfilament threads are also commonly used for the group of non-resorbable thread materials. Thus polyfilament surgical steel wire is used in thorax surgery, for example. At present, no commercially marketed non-resorbable suture materials with an antimicrobial finish are known.

Numerous antiseptically effective substances have been known for decades and are in use in the medical field. Apart from water-soluble chlorohexidine salts for dental care, octenidine dichloride solutions sold by Schüle & Mayr under the trade name Octenisept® are widely used in surgery for wound disinfection and surface disinfection. Octenisept is an aqueous alcoholic solution of octenidine dichloride and phenoxyethanol. Octenidine dichloride ((1,1'-(1,10-decane diyl)bis[4-(octylamino)pyridinium] dichloride) is characterised, in comparison with other cationic antiseptics, by the fact that it is doubly positively charged. Octenidine dichloride has a very wide

spectrum of activity and comprises gram-positive and gram-negative bacteria as well as yeasts and fungi. It was developed by Sterling Inc. in 1977.

Dequalinium chloride has a similar structure with, again, two cationic centres.

Dequalinium chloride (1,10-decamethylene bis(4-amino-2-methyl quinolinium) dichloride) was described by Allen & Hanburys in 1957.

Both octenidine dichloride and dequalinium chloride are characterised by a very broad spectrum of activity and a good tolerance with respect to soft tissue, in particular the mucous membrane. Correspondingly, preparations containing octenidine dichloride, for example, have been described for wound and mucous membrane disinfection (DE 101 09 925 A1). However, octenidine dichloride and dequalinium chloride do not exhibit any marked adhesion effect on the surface of common suture material.

The invention is based on the object of developing a surgical suture material which is finished in such a way that it is protected from being colonised by microbes and that the antimicrobial protection covers a wide spectrum of germs. Moreover, an uncomplicated process is to be developed which permits an antimicrobial coating to be applied onto commercial suture material. The process is to be designed in such a way that the suture material is not negatively affected in terms of its structure by the coating process.

Surprisingly enough, it has been found that, by adding at least one fatty acid, it has been possible to cause octenidine dichloride and also dequalinium chloride to adhere to the surfaces of suture material. The antiseptics octenidine dichloride and dequalinium chloride can be applied onto the surfaces of surgical suture material together with the fatty acid(s) acting as adhesion promoter. It follows from this that a coating consisting of a mixture of at least one fatty acid and octenidine dichloride and/or dequalinium chloride is applied onto the surface of the thread.

Preferred fatty acids are lauric acid, palmitic acid and stearic acid. The fatty acids need not necessarily be used as pure substances. It is also possible to use fatty acids contaminated by monofatty acid glycerides, difatty acid glycerides and trifatty acid glycerides. In addition, it is possible to use mixtures of fatty acids and oligomeric lactic acid esters.

The weight ratio of octenidine dichloride or dequalinium chloride to fatty acid is preferably 1 : 0.1 g to 1 : 5, particularly preferably 1 : 1.

The object of the invention is also achieved by a process for coating surgical suture material in the case of which the material is wetted with a homogeneous methanolic solution of octenidine dichloride and/or dequalinium chloride and at least one fatty acid and the methanol is subsequently evaporated, a coating being formed on the thread surface. It is also possible to use mixtures of methanol and other low alcohols such as ethanol, propanol and isopropanol instead of methanol. The advantage of using methanolic solutions is that commonly used polyglycolide threads, polydioxanone threads and poly-epsilon caprolactone co-L-lactide threads are not caused to swell up by the short-term action of methanol and, consequently, the thread structure remains intact.

The invention is illustrated in further detail by the following examples without these limiting the invention.

Example 1:

300 mg of dequalinium chloride (Solmag) and 300 mg of palmitic acid (Fluka) are dissolved in 28.800 g of methanol (Fluka) at room temperature. A clear solution is formed. A piece of braided polyglycolide thread 50 cm in length (USP 2.0) is immersed into this solution. Subsequently, the methanol is allowed to evaporate at room temperature. The coating mass is determined gravimetrically. The coating mass is 0.6 mg.

Example 2:

600 mg of octenidine dichloride (Dishman Pharmaceuticals) and 600 mg of palmitic acid (Fluka) are dissolved in 28.800 g of methanol (Fluka) at room temperature. A clear solution is formed. A piece of braided polyglycolide thread 50 cm in length (USP 2.0) is immersed into this solution. Subsequently, the methanol is allowed to evaporate at room temperature. The coating mass is determined gravimetrically. The coating mass is 1,4 mg.

Claims

1. Surgical suture material with an antimicrobial surface characterised in that the surface exhibits a coating containing
 - at least one fatty acid,
 - octenidine dichloride and/or dequalinium chloride and
 - optionally oligomeric lactic acid esters.
2. Surgical suture material according to claim 1 characterised in that the at least one fatty acid is selected from the group consisting of lauric acid, palmitic acid and stearic acid.
3. Surgical suture material according to claim 1 characterised in that the weight ratio of octenidine dichloride or dequalinium chloride to fatty acid or the sum total of fatty acids is 1.0 : 0.1 to 1.0 : 5.0.
4. Surgical suture material according to claim 3, the weight ratio being 1.0 : 1.0.
5. Process for coating surgical suture material by the steps of
 - wetting the thread material with a homogeneous methanolic solution of octenidine dichloride and/or dequalinium chloride and at least one fatty acid,
 - subsequent evaporation of the methanol.
6. Process according to claim 5, wherein the methanolic solution comprises a mixture of methanol and other low alcohols.
7. Process according to claim 6, wherein the alcohols are selected from the group consisting of ethanol, propanol and isopropanol.