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(54) Titre : SOIE DENTAIRE AVEC AGENTS CHIMIOTHERAPEUTIQUES
(54) Title: DENTAL FLOSS PROVIDED WITH CHEMOTHERAPY AGENTS

(57) **Abrégé/Abstract:**

Dental floss provided with chemotherapy agents, including wax that is emulsible upon contact with saliva. State of the art dental flosses achieve an efficient release of active agents within the oral environment, by using soluble waxes, but said solution decreases comfort of application since there is a decrease in the levels of sliding and penetration between the teeth, in comparison to the use of insoluble waxes. The use of said emulsible wax allows for an efficient release of the chemotherapy agent through the oral environment - preferably fluoride ions - while maintaining the same levels of sliding and penetration between teeth as are obtained with insoluble wax.

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ABSTRACT

Dental floss provided with chemotherapy agents, including wax that is emulsible upon contact with saliva. State of the art dental flosses achieve an efficient release of active agents 5 within the oral environment, by using soluble waxes, but said solution decreases comfort of application since there is a decrease in the levels of sliding and penetration between the teeth, in comparison to the use of insoluble waxes. The use of said emulsible wax allows for an efficient release of the 10 chemotherapy agent through the oral environment - preferably fluoride ions - while maintaining the same levels of sliding and penetration between teeth as are obtained with insoluble wax.

Title: "DENTAL FLOSS PROVIDED WITH CHEMOTHERAPY AGENTS"

This invention relates to dental waxed textile materials (threads and tapes) that contain chemotherapy agents.

In order to facilitate understanding of this specification, any reference to dental floss should be understood to extend to dental tape, dental thread or any similar materials.

STATE OF THE ART

Various patent documents that illustrate the state of the art relating to this invention are mentioned below:

US Patent 4,548,219 and US Patent 4,638,823 disclose a dental floss containing a stannous fluoride incorporated in the floss by means of a soluble polyethylene glycol wax.

Patent application WO9108716 describes a dental floss in the absence of bonding agents and including a surfactant, a specific silicone type coating and a chemotherapy agent.

Patent application EP 335466 discloses a low friction coefficient polytetrafluoroethylene dental floss containing active agents.

US Patent 3838702 discloses a dental floss provided with a coating of polymer, elastomer, natural or synthetic wax, which contains inorganic particles that act as a polishing agent for the teeth.

US Patent 4029113 mentions a dental floss (and its manufacturing process) provided with natural or synthetic wax

that releases fluorine ions during use.

US Patent 5040554 mentions a dental floss with a wax, soap or detergent bonding agent, as a base for a phenol derivative germicide coating.

5 It should be noted that waxed dental flosses containing active agents are well known in the present state of the art, both for the mechanical removal of food deposits, plates or tartar from the internal spaces between teeth, and for the release of active agents that will act within the oral
10 environment, such as tooth decay prevention, anti-tartar, antibiotic, antimicrobial, anti-inflammatory, antioxidant, antiseptic, anticoagulant, analgesic, anesthetic, desensitization, and flavoring products, among others.

The use of wax (herein construed as actual wax or
15 waxy material of any kind) for impregnation of dental floss is already known, basically as a bonding agent, that is to say, to maintain the threads together, which make up the dental floss. Furthermore the wax acts as a lubricant that provides more comfort when using the dental floss, promoting sliding
20 and penetration of floss between teeth.

During the development of the technology related to the subject matter hereof, wax began to be used as a support for active agents, mainly for products with a fluorine content.

25 It was found that the release of the active agents added to the wax was of inefficient, due to the insoluble nature of waxes used up to then. Soluble waxes then began to be used, such as polyethylene glycol derivative waxes.

It was then found that, in spite of the efficiency
30 in the release of the active agents contained in dental floss having soluble waxes, use became less comfortable, that is to say, with harsher sliding and much harder penetration between teeth, and thus less comfortable for the user.

Such effects were accounted for by a possible in-
35 crease in the coefficient of sliding friction between dental floss and teeth, partially solved by using more noble material, such as polytetrafluoroethylene. However, this entailed a much higher cost for the floss, both as a result of the intrinsic cost of raw material itself, and of the manufacturing

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procedure.

Therefore the need still remains for an improved dental floss that would entirely or partially solve the problems found to date.

5 This present invention aims at eliminating or mitigating the problems found by the present state of the art products, by means of a dental floss provided with an emulsible wax.

10 Unexpectedly, it has been found that such a wax allows for an efficient release of any associated chemotherapy product, while concurrently preserving the comfortable effect assured by dental flosses with insoluble wax, that means, the same sliding and penetration between teeth.

15 Therefore, one of the objects of this invention is a dental floss characterized by comprising wax that is emulsible when in contact with saliva, and containing chemotherapy products, that is to say, the wax is the carrier for the active agents within the oral cavity.

20 Another object of this invention is a dental floss which has improved chemotherapy product release qualities within the oral environment, as well as comfort in use sliding and penetration between teeth.

25 Still another object of this invention is an improved dental floss with improved performance combined with low cost.

According to one aspect of the invention, there is provided dental floss comprising one or more chemotherapy agents and a wax that is emulsible upon contact with saliva,

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wherein said emulsible wax comprises an insoluble wax and at least one surfactant capable of emulsifying said insoluble wax upon contact with saliva.

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The dental floss of this invention is made up of known filamentary materials, such as cotton, silk, nylon, polyethylene, polypropylene, polyester, acrylic fibers, any combination thereof, etc., having characteristics that are also known, such as the number filaments per thread, the amount of twisting applied, tensile strength, etc. These are known parameters for person skilled in the art and do not impose any restrictions on the scope of the invention.

The emulsible wax of the dental floss of this invention may be of any nature, for instance: a combination of insoluble wax with surfactant, preferably taking into account the specific desired use. Some desirable parameters are as follows:

- quality compatible with mouth contact,
- reduced aggression to gums and mouth mucous membrane,
- absence of any accentrated flavor of its own.

Advantageously, the emulsible wax of the invention includes an insoluble wax, preferably beeswax, and at least one, preferably non ionic mild surfactant capable of emulsifying the wax when in contact with saliva.

In a particular case, the emulsible wax of the dental floss of this invention may include, besides beeswax, another insoluble wax, preferably microcrystalline mineral wax.

In a specific embodiment of the invention the emulsible wax has the following formulation (the ranges placed between parentheses indicating the approximate

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percentages by weight of the component with respect to the total weight of the emulsible wax composition):

I - refined beeswax (25-40%)

II - microcrystalline wax (4-10%)

5 III - ethoxylated sorbitan monostearate (23-35%) -
- products such as Nikkol TS by Nikko Corporation,
Japan, are suitable;

IV - glyceryl monostearate (3-10%) -

suitable products include Atmul™ by Imperial
10 Chemical Industries, England, or Imwitor, by Huels America,
USA.

V - ethoxylated glyceryl monostearate (22-38%) -
products such as Cutina™ E-24 of Henkel, Germany,
or Varonic L142 by Sherex, USA, are suitable.

15 Preferably the floss of this invention contains
sodium fluoride as the active agent in the oral cavity,
without excluding any others known to persons skilled in the
art.

The active agent may comprise one or more
20 chemotherapy agents having at least one product with at
least one of the following characteristics: tooth decay
prevention, antitartar, antibiotic, antimicrobial, anti-
inflammatory, antioxidant, antiseptic, anticoagulant,
analgesic, anaesthetic and desensitizing.

25 Chemotherapy agents which impart tooth decay
prevention characteristics may be one or both of sodium
fluoride and stannous fluoride.

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Impregnation with wax of the thread material of the dental floss is made according to a process known in the art, for instance, by dipping the floss into a bath of molten emulsible wax, or any other.

5 An example of a practical embodiment of the invention is given below merely by way of illustration, without this imposing any restriction or limit on the scope of the invention, as defined in the claims.

 Two dental flosses A and B are manufactured
10 pursuant

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to the process described by US Patent 4,029,113, with threads (12 nylon yarns of 78 Dtex per yarn, 23 filaments per yarn and 120 twists/m) impregnated with 20% by weight of, respectively, emulsible wax according to invention (LIPOWAX JDL, Ionquímica, 5 Brazil) and polyethylene glycol (CARBOWAXTM 1450, Union Carbide, United States). Both the emulsible wax and the polyethylene glycol contain a sufficient quantity of sodium fluoride so that an approximate amount of 300 ppm of this matter is obtained in the resulting floss.

10 Subsequent tests showed that:

- both floss A and floss B permit release of equivalent quantities of fluorine within the oral cavity during use;

15 - floss A of the invention is clearly more comfortable to use, that is to say, it has better sliding and penetration properties than floss B which is common to the present state of the art.

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CLAIMS:

1. Dental floss comprising one or more chemotherapy agents and a wax that is emulsible upon contact with saliva, wherein said emulsible wax comprises an insoluble wax and at least one surfactant capable of emulsifying said insoluble wax upon contact with saliva.
2. Dental floss according to claim 1, wherein said insoluble wax is beeswax.
3. Dental floss according to claim 1, wherein said insoluble wax comprises beeswax and an additional insoluble wax.
4. Dental floss according to claim 3, wherein the additional insoluble wax is a microcrystalline wax.
5. Dental floss according to any one of claims 1 to 4, wherein said at least one surfactant is mild, when in contact with a person's gums and mucous membrane of the person's mouth.
6. Dental floss according to any one of claims 1 to 5, wherein said at least one surfactant is non ionic.
7. Dental floss according to claim 1, wherein said emulsible wax comprises:
 - approximately 25% to 40% by weight of refined beeswax;
 - approximately 4% to 10% by weight of microcrystalline wax;
 - approximately 23% to 35% by weight of ethoxylated sorbitan monostearate;

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- approximately 3% to 10% by weight of glyceryl monostearate; and

- approximately 22% to 38% of ethoxylated glyceryl monostearate.

5 8. Dental floss according to any one of claims 1
to 7, wherein said one or more chemotherapy agents comprise
at least one product with at least one of the following
characteristics: tooth decay prevention, antitartar,
antibiotic, antimicrobial, anti-inflammatory, antioxidant,
10 antiseptic, anticoagulant, analgesic, anaesthetic and
desensitizing.

9. Dental floss according to any one of claims 1
to 7, wherein said one or more chemotherapy agents have
tooth decay prevention characteristics.

15 10. Dental floss according to claim 9, wherein said
one or more chemotherapy agents having tooth decay
prevention characteristics are one or both of sodium
fluoride and stannous fluoride.

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