partially hydrate a section of the porous material at the interface between materials; b) drying the gel to bond the materials together; and c) crosslinking the collagens in the bonding layers. The fabricated biomaterial obtained combines a porous collagen based material, which may be mineralized [0042], [0048], and a mechanically strong non-porous collagen-based material, thus providing a scaffold for regeneration of load-bearing tissues (notably meniscus, articular cartilage, tendons and ligaments), which has both porosity and mechanical strength, i.e. is able to resist compressional and tensional forces. Nothing is disclosed on the resistance to bending moments of that combined biomaterial or on the composition of the mineralized porous collagen-based material.

US 2014/0193477 teaches that in the fabrication of collagen mats from soluble collagen stretching the collagen prior to its crosslinking increases its mechanical strength, in particular the ultimate tensile strength (UTS), stiffness and elastic modulus (Young's modulus) (see in particular [0109], [0110]).

Langdon, Shari E et al., Biomaterials 1998, 20(2),137-153 CODEN and Chachra, Debbie et al., Biomaterials 1996, 17(19), 1865-1875 CODEN, disclose that stretching a pericardium derived membrane prior to its crosslinking increases its tensile strength and stiffness.

SUMMARY

In one aspect, the present invention refers to a resorbable crosslinked form stable membrane for use in the oral cavity which comprises a composite layer of collagen material and inorganic ceramic particles containing 1.5 to 3.5 weight parts of inorganic ceramic for 1 weight part of collagen material, sandwiched between two layers of elastic pretensed collagen material, wherein the elastic pretensed collagen material is a collagen material that has been stretched such as to be in the linear/elastic region of the stress-strain curve, the collagen material comprising 50-100 % (w/w) collagen and 0-50 % (w/w) elastin.

In another aspect, the present invention refers to a process for preparing a crosslinked resorbable crosslinked form stable membrane of any of claims 1 to 12 comprising the steps of:

(a) Preparing a composite layer of inorganic ceramic particles and collagen material, optionally crosslinking that composite layer,

(b) Assembling and glueing the composite layer of collagen material and inorganic ceramic particles between two layers of collagen material submitted to tensioning leading to a stretching of the collagen material in the linear region of the stress-strain curve, thereby giving a composite layer of collagen material and inorganic ceramic particles sandwiched between two layers of elastic pretensed collagen material , and

(c) Crosslinking that composite layer of collagen material and inorganic ceramic particles sandwiched between two layers of elastic pretensed collagen material, followed by a hydrophilic making treatment.

The objective of the present invention is to provide a resorbable form stable membrane for use in the oral cavity, apt to resist to pressure, shear forces and bending moments such as to support bone formation, bone regeneration, bone repair and/or bone replacement at a non-containing bony defect site, notably in horizontal or vertical augmentations in the maxilla or mandible, which does not have the above drawbacks.

The objective is attained by the invention as defined in the appended claims.

The invention provides a resorbable crosslinked form stable membrane for use in the oral cavity which comprises a composite layer of collagen material and

CLAIMS

1. A resorbable crosslinked form stable membrane for use in the oral cavity which comprises a composite layer of collagen material and inorganic ceramic particles containing 1.5 to 3.5 weight parts of inorganic ceramic for 1 weight part of collagen material, sandwiched between two layers of elastic pretensed collagen material, wherein the elastic pretensed collagen material is a collagen material that has been stretched such as to be in the linear/elastic region of the stress-strain curve, the collagen material comprising 50-100 % (w/w) collagen and 0-50 % (w/w) elastin.

2. The resorbable crosslinked form stable membrane according to claim 1 wherein the composite layer of collagen material and inorganic ceramic particles contains 2.0 to 3.0 weight parts of inorganic ceramic for 1 weight part of collagen material.

3. The resorbable crosslinked form stable membrane according to claim 1 or 2 wherein the collagen material comprises 70-90 % (w/w) collagen and 10-30 % (w/w) elastin.

4. The resorbable crosslinked form stable membrane according to any of claims 1 to 3 wherein the collagen material is derived from tissues of natural origin selected from the group of mammalian peritoneum or pericardium membrane, placenta membrane, small intestine submucosa (SIS), dermis, dura mater, ligaments, tendons, diaphragm (e.g. Thoracic diaphragm), omentum and fascie of muscles or organs.

5. The resorbable crosslinked form stable membrane according to any of claims 1 to 3 wherein the collagen material is derived from a porcine, bovine or equine peritoneum or pericardium membrane, small intestine mucosa (SIS) or muscle fascie.

6. The resorbable crosslinked form stable membrane according to any of claim 1 to 4 wherein the elastic pretensed collagen material has an elastic modulus of 2 to 150 MPa.

7. The resorbable crosslinked form stable membrane according to any of claims 1 to 4 wherein one of the layers of the elastic pretensed collagen material includes holes of 5 to 500 μm.

8. The resorbable crosslinked form stable membrane according to any of claims 1 to 7, wherein the inorganic mineral particles have a size of 150 to 500 μm.

9. The resorbable crosslinked form stable membrane according to any of claims 1 to 8, wherein the inorganic ceramic is hydroxyapatite.

10. The resorbable crosslinked form stable membrane according to any of claims 1 to 9, wherein the inorganic ceramic is hydroxyapatite bone mineral.

11. The resorbable crosslinked form stable membrane according to any of claims 1 to 10, which is chemically crosslinked.

12. The resorbable crosslinked form stable membrane according to any of claims 1 to 10, which is crosslinked by dehydrothermal treatment DHT.

13. A process for preparing a crosslinked resorbable crosslinked form stable membrane of any of claims 1 to 12 comprising the steps of:

(a) Preparing a composite layer of inorganic ceramic particles and collagen material, optionally crosslinking that composite layer,

(b) Assembling and glueing the composite layer of collagen material and inorganic ceramic particles between two layers of collagen material submitted to tensioning leading to a stretching of the collagen material in the linear region of the stress-strain curve, thereby giving a composite layer of collagen material and inorganic ceramic particles sandwiched between two layers of elastic pretensed collagen material , and

(c) Crosslinking that composite layer of collagen material and inorganic ceramic particles sandwiched between two layers of elastic pretensed collagen material, followed by a hydrophilic making treatment.

14. The method of claim 13 wherein the hydrophilic making treatment comprises immersing the crosslinked composite layer of collagen material and inorganic ceramic particles sandwiched between two layers of elastic pretensed collagen material into a sodium chloride solution.

15. The resorbable crosslinked form stable membrane of any of claims 1 to 12 for use as an implant to support bone formation, bone regeneration, bone repair and/or bone replacement at a non-containing dental bony defect site in a human or animal.