Another proposed solution is a composite osteoimplant described in US2008/0063684. Such an osteoimplant includes a polymer and bone-derived particles. The composite is adapted and constructed to be formable during or immediately prior to implantation and to be set after final surgical placement.

US 7.270.813 describes a method for preparing bone-derived composites, wherein the mineral portion of the bone is treated with a coupling agent before being incorporated into a biocompatible polymeric matrix. The resulting composite may be used as such that or be further processed to form an osteoimplant.

Therefore, there is the need in the field of regenerative bone surgery to find new bone implant matrixes, which have satisfactory characteristics of mechanical resistance and ductility to tridimensional processing.

Summary ~~of Invention~~

Object of the present ~~invention~~disclosure is a matrix for bone implant, comprising a base matrix either treated or to be treated with a mixture containing at least a polymer.

According to one aspect, there is provided a bone implant matrix comprising: a) a base matrix treated with b) a reinforcing mixture as a homogeneous coating,

finely dispersed on the whole surface of the matrix, said reinforcing mixture containing at least a polymer and at least an additional component selected from cell nutrients, cell-growth promoters, cell-adhesion promoters, osteo-inductors, osteo-integrators, "friendliness to cell": a substance, which is able to promote the cell-rooting and the cell growth, by stimulating cell proliferation and tissue integration, wherein the base matrix is a bone demineralised, non-demineralised, acellularized bovine matrix, the polymer of the reinforcing mixture is a biodegradable polyester or co-polymer thereof, the "friendliness to cell" is selected from the group consisting of gelatine, hydrolysed gelatine and wherein the reinforcing mixture is obtained starting from two solutions, each of them made of a soluble polymer, which is the biodegradable polyester or co-polymer thereof, and an agent, which is the gelatine or hydrolysed gelatine, promoting the cell engraftment, growth and proliferation, and the tissue integration, respectively, immiscible to each other, but made partially miscible by adding an alcohol or another proper solvent in each of them; in order to obtain a fine and homogeneous molecular dispersion of the components.

Preferred embodiments of the bone implant matrix are defined in claims 2 to ~~16~~8.

The bone implant matrix object of the present ~~invention~~ disclosure is suitable to be used in the bone reconstructive surgery field in general, in orthopaedics and in particular in the oral surgery, in the maxillo-facial and dental implantology.

It is a further object of the present ~~invention~~ disclosure the use of the bone implant matrix according to claim ~~1~~7~~9~~ and particular embodiments thereof according to claim ~~18-23~~10.

It is a further object of the present ~~invention~~disclosure a method for preparing a bone implant matrix ~~according to claim 24 and its preferred embodiments according to claims 25 and 26~~.

List of figures

Particular embodiments of the invention are described in detail herein below, as a way of example and not limited to, with reference to the attached figures, wherein:

-Figure 1 is an optical microscopy image of the cortical layer of human bone,

-Figure 2 is an optical microscope image of a bovine-derived purified bone,

-Figure 3 is an optical microscope image of a bovine-derived bone reinforced according to a preferred embodiment of the invention,

CLAIMS

1. A bone implant matrix comprising:

a) a base matrix treated with

b) a reinforcing mixture as a homogeneous coating, finely dispersed on the whole surface of the matrix, said reinforcing mixture containing at least a polymer and at least an additional component selected from cell nutrients, cell-growth promoters, cell-adhesion promoters, osteo-inductors, osteo-integrators, "friendliness to cell": a substance, which is able to promote the cell-rooting and the cell growth, by stimulating cell proliferation and tissue integration, wherein the base matrix is a bone demineralised, non-demineralised, acellularized bovine matrix, the polymer of the reinforcing mixture is a biodegradable polyester or co-polymer thereof, the "friendliness to cell" is selected from the group consisting of gelatine, hydrolysed gelatine and wherein the reinforcing mixture is obtained starting from two solutions, each of them made of a soluble polymer, which is the biodegradable polyester or co-polymer thereof, and an agent, which is the gelatine or hydrolysed gelatine, promoting the cell engraftment, growth and proliferation, and the tissue integration, respectively, immiscible to each other, but made partially miscible by adding an alcohol or another proper solvent in each of them; in order to obtain a fine and homogeneous molecular dispersion of the components.

2. A bone implant matrix according to claim 1, wherein the bio-degradable polyester is selected from the group consisting of polylactic acid (PLA), poliglycolic acid (PGA), polycaprolactone (PCL) and co-polymers thereof comprising polycaprolactone-polylactic (PLA/PCL) co-polymers, poly(L-lactide-co-Ɛ-capcolactone) co-polymers, poly(L-lactide), poly(D,L-lactide-co-glycolide), poly(L-lactide-coD,L-lactide), their enantiomers, their co-polymers and mixtures thereof.

3. A bone implant matrix according to claim 1, wherein the reinforcing mixture containing at least a polymer and at least an additional component selected from the group consisting of gelatine, hydrolysed gelatine, wherein the base matrix is a bone non-demineralised, acellularized bovine matrix and the polymer of the reinforcing mixture is a biodegradable polyester or co-polymer thereof selected from the group consisting of polylactic acid (PLA), poliglycolic acid (PGA), polycaprolactone (PCL) and co-polymers thereof comprising polycaprolactone-polylactic (PLA/PCL) co-polymers, poly(L-lactide-co- Ɛ-capco-lactone) co-polymers, poly(L-lactide), poly(D,L-lactide-co-glycolide), poly(L-lactide-coD,L-lactide), their enantiomers, their co-polymers and mixtures thereof.

4. A bone implant matrix according to claim 1, comprising a bovine demineralised bone matrix treated with a reinforcing mixture comprising a biodegradable polyester-based co-polymer and hydrolysed gelatin.

5. A bone implant matrix according to claim 1, comprising a bovine acellularised bone matrix, treated with a reinforcing mixture comprising a biodegradable polyester-based copolymer and hydrolized gelatin.

6. A bone implant matrix according to claim 1, comprising a bovine non-demineralised acellularised bone matrix, treated with a reinforcing mixture comprising a biodegradable polyester-based copolymer and hydrolized gelatin.

7. A bone implant matrix according to claims 4-6, wherein the biodegradable polyester-based copolymer is a polycaprolactone-polylactic copolymer (PLA/PCL).

8. A bone implant matrix according to claims 4-6, wherein the biodegradable polyester-based co-polymer is a poly(L-lactide-co-Ɛ-caprolattone) co-polymer.

9. A bone implant matrix according to claim 1, for use in at least one of the following fields: bone reconstructive surgery, in maxillo-facial bone reconstructive surgery, in oral surgery, dental surgery, orthopaedic surgery and implantology.

10. A bone implant matrix according to claim 1, for use in human or veterinary treatment.

CLAIMS

1. A bone implant matrix comprising:

a) a base matrix treated or to be treated with

b) a reinforcing mixture containing at least a polymer.

2. A bone implant matrix according to claim 1, wherein the base matrix is synthetic, selected from the group consisting of polymeric, metallic, ceramic, bio-ceramic and bio-glass, or natural selected from the group consisting of demineralised bone matrixes, non-demineralised bone matrixes, acellularised bone matrixes, natural polymeric matrixes, mineral matrixes.

3. A bone implant matrix according to claim 1, wherein the base matrix and/or the polymer of the reinforcing mixture is bio-integrable.

4. A bone implant matrix according to claim 2, wherein the base matrix is a bone demineralised or non-demineralised or bone acellularized, bovine or human corpse-derived matrix.

5. A bone implant matrix according to claim 2, wherein the base matrix is polymeric of biocompatible polymers.

6. A bone implant matrix according to claim 1, wherein the polymer of the reinforcing mixture is se-

~~lected from the group consisting of biodegradable~~ polymers, non-biodegradable polymers, co-polymers of biodegradable polymers, co-polymers of non-biodegradable polymers, co-polymers of biodegradable and non-biodegradable polymers.

7. A bone implant matrix according to claim 6, wherein the biodegradable polymer is selected from the group consisting of poly(arylates), poly(acrylates), poly(anhydrides), poli(hydroxyacids), polyesters, poly(orthoesters), polycarbonates, poly(propylene fumarates), poly(amide esters), poly(amide carbonates), polyamides, polyaminoacids, polyacetals, polylactides, polyglycolides, poly(dioxanones), polyhydroxybutyrate, polyhydroxyvalerate, poly vinyl pyrrolidone, polycyanoacrylates, polyurethanes, polyalkylene oxides, polyamino carbonates, polyester amides, polyester imides, polyarylate aminoacids, polycarbonate aminoacids, polysaccharides, poly-ethylene-glycole and tyrosine-based polymers comprising polyarilates, polyacrylates and polycarbonates.

8. A bone implant matrix according to claim 7, wherein the bio-degradable polyester is selected from the group consisting of polylactic acid (PLA), poliglycolic acid (PGA), polycaprolactone (PCL) and

~~co-polymers thereof comprising polycaprolactone~~ polylactic (PLA/PCL) co-polymers, poly(L-lactide-co-ε-capcolactone) co-polymers.

9. A bone implant matrix according to claim 6, wherein the non-biodegradable polymer is selected from the group consisting of polypyrrole, polyaniline, polythiophene and derivates thereof, polystyrene, polyurethanes, polyureas, poly(ethylenevinylacetate), polypropylene, polymethacrilate, polyethylene, poly(ethylene oxide).

10. A bone implant matrix according to claim 6, wherein the polymer is selected from the group consisting of starch, poly(caprolactones), poly(L-lactide), poly(D,L-lactide-co-glycolide), poly(L-lactide-co-D,L-lactide), their enantiomers, their co-polymers and mixtures thereof.

11. A bone implant matrix according to claim 1, wherein the reinforcing mixture comprises an additive selected from the group consisting of cell-nutrients, cell-growth promoters, cell-adhesion promoters, osteo-inductors, osteo-integrators, "friendliness to cell".

12. A bone implant matrix according to claim 11, wherein the "friendliness to cell" is selected from the group consisting of gelatine, hydrolysed gela-

~~tine; glycosaminoglycanes; polysaccharides, agarose,~~ dextrane, chitosane; fibrin, fibrinogen and derivates thereof; collagen of any kind and derivates thereof; hyaluronic acid and derivates thereof; vitamins, comprising vitamin D; soya-isoflavons comprising genestein; drugs, which reduce the bone destruction and stimulate the bone reconstruction comprising strontium ranelate.

13. A bone implant matrix according to claim 1, wherein the reinforcing mixture comprises at least a biodegradable polyester and at least a "friendliness to cell".

14. A bone implant matrix according to claim 1, comprising:

a bovine demineralised bone matrix treated with a reinforcing mixture comprising a biodegradable polyester-based co-polymer and hydrolysed gelatine

or

a bovine acellularised bone matrix, treated with a reinforcing mixture comprising a biodegradable polyester-based copolymer and hydrolized gelatine.

15. A bone implant matrix according to claim 14, wherein the biodegradable polyester-based co-polymer is a polycaprolactone-polylactic copolymer (PLA/PCL).

~~16. A bone implant matrix according to claim 14,~~ wherein the biodegradable polyester-based co-polymer is a poly(L-lactide-co-ε-caprolattone) co-polymer.

17. A bone implant matrix according to claim 1, for use in bone reconstructive surgery.

18. A bone implant matrix according to claim 17, for use in maxillo-facial bone reconstructive surgery.

19. A bone implant matrix according to claim 1, for use in the oral surgery.

20. A bone implant matrix according to claim 1, for human or veterinary use.

21. Use of a bone implant matrix according to claim 1, in bone reconstructive surgery.

22. Use of a bone implant matrix according to claim 21, in maxillo-facial bone reconstructive surgery.

23. Use of a bone implant matrix according to claim 1, in oral surgery.

24. A method for preparing a bone implant matrix, comprising the steps of:

a) preparing a solution of a reinforcing mixture containing at least a polymer,

b) immersing a base matrix into said reinforcing mixture solution,

c) drying and optionally degassing the matrix for removing possible solvent residues;

d) optionally immerse the dried and optionally degassed, again, in said solution of reinforcing matrix.

25. A method for preparing a bone implant matrix according to claim 24, further comprising the post-treatment step selected from heating, conditioning in a inert atmosphere, vacuum degassing.

26. A method for preparing a bone implant matrix according to claim 24, further comprising the steps of:

d) packaging in sterile and inert atmosphere,

e) sterilization.