Replacement by Bone." In: Bone Engineering, ed. JE Davies, Em^2 Inc., Toronto, Ont. Canada, Chapter 30, 332-344, 2000).

[0007] The many clinical situations that require extensive complex bone repair and regeneration continue to represent problems without acceptable solutions. The current clinical treatments are compromises that require elaborate and complex autogenous grafting procedures, or they represent imperfect allogeneic or alloplastic treatment options. In all cases these complex bone repair situations require that materials not made for a specific site are fit as well as possible into the defect. It would be desirable to provide new means for printing three dimensional scaffolds composed of osteoconductive biomaterials that have the potential to be custom-fabricated to repair complex defects.

SUMMARY

[0007a] In one aspect, there is provided a tissue repair device or scaffold having a precise porous bone ingrowth structure containing interconnected struts surrounded by a microporous shell.

[0008] Disclosed is a tissue repair device or scaffold having a porous bone ingrowth area containing interconnected struts surrounded by a microporous shell. The microporous shell may function to attach but limit soft tissue ingrowth. At the ends of the tissue repair device or scaffold, the shell may be extended as a guide flange to stabilize the tissue repair device or scaffold between ends of bone, across a bone defect, etc. or the tissue repair device or scaffold may be used to repair a defect of a flat bone. The center of the tissue repair device or scaffold may be empty and may serve as a potential marrow space. The porous ingrowth structure may be infiltrated with a soluble filler or carrier, such as, for example calcium sulfate. This soluble filler or carrier, such as, for example calcium sulfate, may be infiltrated with one or more of an antibiotic, a growth factor, a differentiation factor, a cytokine, a drug, or a combination of these agents. The tissue repair device or scaffold may fit between the cortical bone ends of long bone and conduct healing bone, which arises largely from the endosteal and periosteal surfaces or it may be used at or near a bone defect of, for instance, flat bone. The tissue repair device or scaffold may be stabilized using a modified bone plate or bone screws. The tissue repair device or scaffold may be produced by a three dimensional printing procedure and may be formed of, for instance, an osteoconductive ceramic.

[0015a] In one aspect, there is provided a method for producing a tissue repair device or scaffold useful for promoting bone growth or treating bone fracture, defect or deficiency having a precise porous bone ingrowth region containing interconnected struts surrounded by a microporous shell, comprising:

(a) providing microporous shell that may function to attach but limit soft tissue ingrowth, and

(b) infiltrating the porous ingrowth structure with a soluble filler or carrier.

[0016] Disclosed is a method for producing a tissue repair device or scaffold useful for promoting bone growth or treating bone fracture, defect or deficiency having a porous bone ingrowth area containing interconnected struts surrounded by a microporous shell. The method features (a) providing a microporous shell that may function to attach but limit soft tissue ingrowth, (b) infiltrating a porous ingrowth structure with a soluble filler or carrier, and optionally (c) infiltrating the porous ingrowth structure with one or more of an antibiotic, a growth factor, a differentiation factor, a cytokine, a drug, or a combination of these agents. The soluble filler or carrier may be a filler that attracts osteoclasts, such as, for example calcium phosphate mineral and type I collagen protein. tissue repair device or scaffold useful for promoting bone growth or treating bone fracture, defect or deficiency having a porous bone ingrowth area containing interconnected struts surrounded by a microporous shell may have the features described herein with respect to the aspects and embodiments of thedisclosure.

BRIEF DESCRIPTION OF THE FIGURES

[0017] Figure 1 is a schematic drawing of a tissue repair device or scaffold design that may be used to regenerate a long bone defect, showing its placement and fixation in the defect. The scaffold has a porous bone ingrowth area (A) containing interconnected 250μm cylindrical struts surrounded by a microporous shell (B) to attach but limit soft tissue ingrowth. At the ends of the scaffold, the shell may be extended as a guide flange (C) to stabilize the construct between the bone ends. The center of the scaffold (D) may be left empty as a potential marrow space. The porous ingrowth structure (outlined with dashed line in upper left drawing) may be infiltrated with a soluble filler/carrier (such as calcium sulfate as an example) that may be infiltrated with one or more of antibiotic, growth factors, differentiation factors, cytokines, drugs, or a combination of these agents. The scaffold may fit between the cortical bone ends (E) of the long bone and conduct healing bone, which arises largely from the endosteal and periosteal surfaces (F). The construct may be stabilized using a modified bone plate (G) and bone screws (H).

CLAIMS

What is claimed is:

1. A tissue repair device or scaffold having a precise porous bone ingrowth structure containing interconnected struts surrounded by a microporous shell.

2. A tissue repair device or scaffold according to claim 1 wherein the microporous shell is extended as a guide to stabilize the tissue repair device or scaffold between one or more ends of bone.

3. The tissue repair device or scaffold according to claim 1 having a center defined by an empty space.

4. The tissue repair device or scaffold according to claim 1 wherein the porous ingrowth structure is infiltrated with a soluble filler or carrier.

5. The tissue repair device or scaffold according to claim 4 wherein the soluble filler or carrier is calcium sulfate.

6. The tissue repair device or scaffold according to claim 4 wherein the soluble filler or carrier is infiltrated with one or more of an antibiotic, a growth factor, a differentiation factor, a cytokine, a drug, or a combination thereof.

7. The tissue repair device or scaffold according to claim 1 wherein the struts are from about 100-350 μm diameter.

8. The tissue repair device or scaffold according to claim 1 wherein the struts are within about 2x or substantially the same diameter as bone trabeculae.

18. A method for producing a tissue repair device or scaffold useful for promoting bone growth or treating bone fracture, defect or deficiency having a precise porous bone ingrowth region containing interconnected struts surrounded by a microporous shell, comprising:

(a) providing microporous shell that may function to attach but limit soft tissue ingrowth, and

(b) infiltrating the porous ingrowth structure with a soluble filler or carrier.

19. A method according to claim 18 further comprising (c) infiltrating the porous ingrowth structure with one or more of an antibiotic, a growth factor, a differentiation factors, a cytokine, a drug, or a combination of these agents.