WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: WO 97/31586 (11) International Publication Number: A61C 8/00 **A1** (43) International Publication Date: 4 September 1997 (04.09.97)

(21) International Application Number: PCT/US97/03167 (81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL,

US

08/609,870

(22) International Filing Date: 28 February 1997 (28.02.97)

(30) Priority Data:

1 March 1996 (01.03.96)

(71)(72) Applicant and Inventor: ROBINSON, Dane, Q. [US/US]; 2103 East Southern Avenue, Tempe, AZ 85282 (US).

(74) Agents: LECHTER, Michael, A. et al.; Squire, Sanders & Dempsey L.L.P., Suite 2700, Two Renaissance Square, 40 North Central Avenue, Phoenix, AZ 85004-4424 (US).

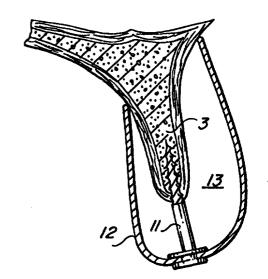
Published

With international search report.

(54) Title: METHOD AND APPARATUS FOR GROWING JAW BONE UTILIZING A GUIDED-TISSUE REGENERATION PLATE SUPPORT AND FIXATION SYSTEM

(57) Abstract

This invention is a method and apparatus for growing jaw bone (3) in an isolated and protected space (13) free from tissue impingement, occlusal loading, chewing forces or muscular pressure between the periosteum and the jaw bone (3). The space (13) is created by first placing either a dental implant (17) or a tenting-type support screw (11) into the jaw bone. A guided tissue regeneration plate (12), preferably made of titanium, is either snapped onto the head of the support screw (11) or held in place by a specialized and modified healing screw (19) of a dental implant (17). The plate (12) is then bent and molded into the proper shape. The pliable, moldable plate (12) is supported by the dental implant (17) or support screw (11) giving a precise space (13) below its surface to grow bone. The plate (12) can be solid or perforated. porous or nonporous.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic	SD	Sudan
CF	Central African Republic		of Korea	SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

WO 97/31586

PCT/US97/03167 1

Title:

METHOD AND APPARATUS FOR GROWING JAW BONE UTILIZING A GUIDED-TISSUE REGENERATION PLATE SUPPORT AND FIXATION **SYSTEM**

5

10

15

FIELD OF THE INVENTION

This invention relates to the art of dentistry and, more particularly, to a method and devices thereof which relate to the surgical placement of endosseous dental implants in the maxillary or mandibular jaw bone. Still more specifically, this invention relates to the growing of jaw bone in order to obtain adequate volume of osseous structure by using a thin titanium bone plate which is mated to an underlying support bone screw or to a dental implant.

BACKGROUND OF THE INVENTION

The successful placement of endosseous dental implants has been well documented for over 30 years; however, the success of these endosseous dental implants has been limited by the quality and quantity of existing bone a given patient would present with. Due to the destructive nature of dentures to the underlying jaw bone as well as the fact that bone that is not internally stimulated by tooth roots will atrophy, the amount of bone in many people is very limited for the placement of dental implants, especially for those who have been missing teeth for an extended period of time.

20

Bone grafting has become an essential element for the successful treatment of those who do not have enough bone for dental implants. As viable methods, blocks of hip bone have been affixed to the jaw and freeze-dried demineralized bone protein has been used as a stimulant to cause the patient's bone cells to become active and lay down new bone onto the existing bone areas and into the new bone graft areas. Through experience and research, it has become evident that, for bone grafting to be successful, it must be given an isolated space to grow, protected from muscular pressure, tissue impingement and chewing forces. In order to create this space, many approaches have been proposed. For example, both Syers (U.S. Patent #5,297,563) and Magnusson et al (U.S. Patent #4,961,707) teach the use of a fabriclike membrane which is used over a bony defect. Although this barrier creates an isolated space from the invasion of epithelial cells into the bony defect or bone graft area, it does not create a protected space from chewing forces or tissue pressure.

30

35

25

Morgan (U.S. Patent #5,380,328) teaches the use of a composite perforated titanium mesh layered with polytetrafluoraethylene (PTFE or Teflon®) fibers. Even though this approach would be feasible for creating a protected space in order to grow bone, it has some severe limitations. This material requires the placement of peripheral bone screws into the edges of the meshed piece in order to create a direct fixation of the titanium mesh to the jaw bone and then bowing-up or tenting-up the center area in order to create the protected space. Often, it would not be feasible to place the peripheral bone screws in the peripheral areas for fear of damage to the inferior alveolar nerves or sinus penetration

or damage to nearby tooth roots. The protrusion of these screws above the mesh is also of concern as potentially causing a tissue irritation complication with this given procedure. Furthermore, the difficulty of forming the exact amount of tenting desired with this material is inherently very difficult to control. Additionally, the removal of this material is complicated by the need to surgically dissect much deeper to locate the peripheral screws. This technique would also be expensive and time consuming to emplace due to the need for multiple screws to secure a single mesh.

On the other hand, as will become more apparent below, the guided-tissue regeneration plate support and fixation system contemplated in accordance with the subject invention obtains the ability to place a single screw in the center of the bone graft area, thereby facilitating the selection of a screw height that allows for an exact amount of tenting, thus giving the support where it is needed most. Placement and removal of this device is greatly simplified due to the fact that peripheral screws are not required. The head of the screw ends up being mostly under the plate, thus preventing any concern about screw-head irritation or protrusion. Furthermore, concern about damage to neighboring peripheral structures is eliminated. In general, a much more simplified and cost effective method, apparatus and result are achieved.

OBJECTS OF THE INVENTION

5

10

15

20

25

30

35

It is therefore a broad object of my invention to provide an improved dental implant system.

It is a more specific object of my invention o provide an improved dental implant system which is relatively inexpensive to fabricate and use.

In another aspect, it is an object of my invention to provide a dental implant system which is relatively easy to use and to obtain high quality results.

SUMMARY OF THE INVENTION

Briefly, these and other objects of the invention are achieved by a method of growing additional maxillary or mandibular bone in areas of atrophy and by the use of a related device to accomplish the task. A pliable guided-tissue regeneration plate, which holds it shape after being bent, is employed as a mating component to a support screw or a dental implant and is secured to the jaw structure by fixation of the guided-tissue regeneration plate at a predetermined distance above or away from the surface of the bone to the support screw or dental implant in order to create a supported and protected space between the underside of the gum tissue and the bone which is free from muscular and chewing pressure in order to promote bone growth. The guided-tissue regeneration plate support and fixation system can be mated with a support screw or screws which are tenting screws designed to be mated with and then become intimately a part of the guided-tissue regeneration plate in order to grow bone in the space created by the guided-tissue regeneration plate system prior to implant placement. Additionally, the guided-tissue regeneration plate system can be utilized during implant placement by creating space adjacent to a dehisced implant by fixation of the guided-tissue regeneration plate directly to the implant

10

15

20

25

30

35

in order to grow bone height or width. A guided-tissue regeneration plate according to the present invention can also be used by affixing it to an existing dental implant that has been previously placed and has undergone bone loss in order to regenerate new bone. The guided-tissue regeneration plate support and fixation system is adapted to be surgically removed after the bone has grown under its surface at a later uncovering or implant placement surgery.

DESCRIPTION OF THE DRAWING

The subject matter of the invention is particularly pointed out and distinctly claimed in the concluding portion of the specification. The invention, however, both as to organization and method of operation, may best be understood by reference to the following description taken in conjunction with the subjoined claims and the accompanying drawing of which:

- FIG. 1 illustrates a bony ridge that has undergone substantial loss;
- FIG. 2 depicts a cross-section of a maxillary midline area of an edentulous ridge showing the original size prior to bone loss;
- FIG. 3 shows the surrounding tissue first reflected away from the bony ridge to expose the ridge in its entirety;
- FIG. 4 depicts the mating of a guided-tissue regeneration plate component of the invention to a support screw component of a snap-fit embodiment;
 - FIG. 5 shows bone graft material packed beneath the plate and against the existing bony ridge;
- FIG. 6 shows how the bony ridge appears after the guided-tissue regeneration plate support and fixation system has been removed to expose the new bony ridge;
 - FIG. 7 depicts the placement of a large implant into the new bony ridge;
 - FIG. 8 shows the placement of an implant into an atrophic bony ridge;
- FIG. 9 depicts the installation of a guided-tissue regeneration plate using a screw supplied by an implant manufacturer;
 - FIG. 10 illustrates the final result of the process shown progressively in FIGs. 8, 9 and 10;
- FIG. 11 illustrates the manner in which the guided-tissue regeneration plate can be snapattached over a modified healing screw made to internally thread into a dental implant;
 - FIG. 12 depicts a non-perforated embodiment of the guided-tissue regeneration plate;
- FIG. 13 illustrates a snap configured support screw ready to receive a guided-tissue regeneration plate;
 - FIG. 14 depicts the guided-tissue regeneration plate over the snap configured support screw after the edges have been bent down to create a space below the guided-tissue regeneration plate;
 - FIG. 15 illustrates a perforated version of the guided-tissue regeneration plate;
- FIG. 16 depicts a guided-tissue regeneration plate being secured to a guided-tissue regeneration plate support screw by a small set screw; and

FIG. 17 illustrates the manner in which an exemplary healing screw of the sort typically supplied by a dental implant manufacturer can be employed to secure the guided-tissue regeneration plate to a dental implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

5

10

15

20

25

30

35

The described invention relates to a method of growing jaw bone and to the related guided-tissue regeneration plate support and fixation system by which an isolated and protected space free from tissue impingement, occlusal loading, chewing forces, or muscular pressure is created between the periosteum and the jaw bone. This space is created by first placing either a dental implant or a guided-tissue regeneration plate support and fixation system tenting-type support screw into the jaw bone and then coupling the guided-tissue regeneration plate to the support screw.

The presently preferred embodiment of the support screws, preferably made out of (but not limited to) titanium, are thin shafted screws with a relatively high ratio between the greater diameter to the minor diameter of the threads to give the maximum bite and hold into the bone. Preferably, this ratio is at least two. The head of the tenting-type support screw is placed above or away from the bone a suitable distance of the space created in order to grow bone. The screw head is configured to receive the guided-tissue regeneration plate, thus allowing for most of the head to be either in or under the guided-tissue regeneration plate after it is engaged into a receiver cap of the head.

In another contemplated embodiment of the support screws, the head of the support screw is internally axially threaded or is provided with a threaded or non-threaded well allowing for a pin with a small head resembling a micro thumbtack to extend through the guided-tissue regeneration plate into the well and snap or thread into place, thereby securing the guided-tissue regeneration plate to the head of the tenting-type support screw. The support screw is preferably fabricated to be very sharp at its tip which includes a self-starting flute in order to facilitate self-threading for facilitating placement.

The guided-tissue regeneration plate is preferably made of thin titanium sheet metal having a peripheral thickness of around 5 to 10 thousandths of an inch. This thickness allows for the material to be thin enough to be bent into shape, but rigid enough to hold its shape after being bent and molded. The present material of choice is Grade 1 titanium which is the fully annealed form of titanium advantageously characterized in that it will not spring back after being bent.

The plates are fabricated with a precise aperture proximate the center or wherever needed in order to allow for a precise union and mating to the support screw or receiver cap of the healing screw of a dental implant, thus giving a secure fixation, by indirect means, to the jaw bone. The central area of the guided-tissue regeneration plate is preferably thicker in order to provide more support and rigidity than the peripheral region. The combination of the support screw and the thicker area of the plate near the center prevents the guided-tissue regeneration plate from caving-in in the area where maximum support is needed when overlying pressure, such as muscular pressure, chewing forces, or any other

premature loading onto the guided-tissue regeneration plate support and fixation system, is later applied.

The guided-tissue regeneration plate can optionally be perforated to allow for better overlying tissue healing as well as to promote the exchange of nutrients and blood supply between the bone graft and the overlying tissue. Generally, the central, thicker, more supportive area is not perforated to obtain more support. Typically, the number and size of the perforations is less concentrated than the amount of solid space to create a more supportive plate at a thinner dimension. If a completely imperforate barrier is desired to isolate all transfer of unwanted epithelial cells into the bone graft area, then the guided-tissue regeneration plate is fabricated imperforate except for the generally centrally disposed aperture for fixing the plate to its support screw.

10

5

However, if a temporary period of isolation from epithelial cells is desired to create a membrane barrier from epithelial cells for a limited period of time which allows for the exchange of nutrients, ions, and tissue fluid or perhaps blood supply, then a resorbable barrier such as vicryl, collagen, resorbable hydroxyapatite crystals or GuidorTM can be applied to the under or over side of the guided-tissue regeneration plate to seal the perforations, then resorbing a limited time later after the system is installed.

15

If a non-resorbable semi-permeable result is desired, then the perforations can be covered by applying a suitable material such as PTFE fibers. After a period of several months have passed, the entire system is removed and then the implants are either simultaneously placed during this surgery or uncovered by placing healing caps into the implants. If the only desired effect is to create a better ridge for the stabilization of a denture, then the system may be left in place indefinitely.

20

Having now discussed the fundamentals of the present invention, attention is invited to the several FIGs. for an alternative and clarifying disclosure as the discussion proceeds.

FIG. 1 shows an exemplary existing midline cross-section of a maxillary edentulous ridge which has undergone substantial bone loss. For orientation purposes, landmarks can be identified by the palatal bone 1, the floor of the nose 2, the bony ridge 3, and the gum tissue 4.

25

FIG. 2 depicts a cross-section of a maxillary midline area of an edentulous ridge showing the original size prior to bone loss (the gum tissue is not shown in this view).. Reference is taken to the marrow space 5, the cortical bone 6 and the current size of the ridge 7 after bone loss and to the area of the original size 8 of the ridge prior to atrophy or bone loss.

30

Referring now to FIG. 3, in order to place a guided-tissue regeneration plate support and fixation system according to the present invention, the tissue is first reflected away from the bony ridge to expose the ridge in its entirety. The palatal gum tissue 9 is reflected 9, the facial gum tissue 10 is reflected, and a guided-tissue regeneration plate support screw 11 is placed into the bony ridge.

35

FIG. 4 depicts the mating of the guided-tissue regeneration plate 12 to a guided-tissue regeneration support screw 11 of the snap-fit embodiment. (The gum tissue is not shown.) The space

10

15

20

25

30

35

13 is the area where new bone will grow, the space having been created by the guided-tissue regeneration plate support and fixation system of the invention. The guided-tissue regeneration plate support screw 11 is placed into the bony ridge 3. After the guided-tissue regeneration plate 12 is affixed to the guided-tissue regeneration plate support screw 11 by snapping it in place, the plate is molded into shape by bending the edges down as shown.

As shown in FIG. 5, once the guided-tissue regeneration plate 12 has been molded into place, then bone graft material 14 is packed beneath the plate 12 and against the existing bony ridge 3. After a period of approximately four-to-eight months, a new bony ridge will form within the space created by the guided-tissue regeneration plate support and fixation system. (Gum tissue not shown.)

Thus, FIG. 6 shows how the bony ridge appears after the guided-tissue regeneration plate support and fixation system has been removed to expose the new bony ridge 15. A small hole 16 remains after the removal of the guided-tissue regeneration plate support screw. (Gum tissue not shown.)

FIG. 7 depicts the placement of a large implant 17 into the new bony ridge. A tooth can be attached to the implant later.

FIG. 8 shows the placement of an implant 17 into an atrophic bony ridge 3. In this environment, the implant is not fully encased in bone resulting in an exposed area 18 of the implant outside the confines of the existing bone 3.

FIG. 9 depicts the installation of a guided-tissue regeneration plate 12 by inserting the healing screw 19 supplied by the implant manufacturer which can be used in place of a tenting-type support screw to mate the guided-tissue regeneration plate 12 directly to the implant 17. This screw 19 extends through the aperture of the guided-tissue regeneration plate 12 and is thus used instead of the snap-type embodiment previously described. The space 13 created by the guided-tissue regeneration plate 12 is filled with bone graft material, thus covering the exposed portion of the dental implant 18 which is out of the confines of the existing resorbed bony ridge 3.

FIG. 10 illustrates the final result of the process shown progressively in FIGs. 8, 9, 10 after the removal of the guided-tissue regeneration plate (not shown) by revealing that the dental implant 17 is now covered with new bone 20 that has grown around the dental implant after four-to-eight months of healing time and the subsequent removal of the guided-tissue regeneration plate system. As will be apparent to those skilled in the art, after the removal of the guided-tissue regeneration plate, a post has been placed into the dental implant 17 as normal followed by a crown or tooth 22 which is secured to the post in the well known manner.

FIG. 11 illustrates the manner in which the guided-tissue regeneration plate 12 can be snapattached over a modified healing screw 23 made to internally thread into a dental implant 17. The modified healing screw 23 has a receiver cap 24 adapted to receive the generally centrally disposed

10

15

20

25

aperture in the guided-tissue regeneration plate 12.

FIG. 12 depicts a non-perforated embodiment 30 of the guided-tissue regeneration plate, particularly illustrating the generally central aperture 31 by which the guided-tissue regeneration plate may be secured using a screw as previously described.

FIG. 13 depicts the snap configured support screw 11 ready to receive the guided-tissue regeneration plate 30 through the aperture 31. Attention is also directed to the cross-section of the guided-tissue regeneration plate 30 which includes a relatively thick central region 32 and a thinner peripheral region 33 as previously described.

FIG. 14 depicts the mating of the guided-tissue regeneration plate 30 over the snap configured support screw 11 after the edges have been bent down to create the space below the guided-tissue regeneration plate.

FIG. 15 illustrates a perforated version 35 of the guided-tissue regeneration plate which allows for blood supply to pass freely through the plate. Note the generally centrally disposed aperture 25.

FIG. 16 depicts a guided-tissue regeneration plate 35 being secured to a guided-tissue regeneration plate support screw 26 by a small set screw 27 which is placed through the aperture 25 in the guided-tissue regeneration plate and into the support screw 26 which has an internally threaded, axially oriented blind hole 36 in its top.

FIG. 17 illustrates the manner in which an exemplary healing screw 19 of the sort typically supplied by a dental implant manufacturer can be employed to secure the guided-tissue regeneration plate 12 to the dental implant 17.

Thus, while the principles of the invention have now been made clear in an illustrative embodiment, there will be immediately obvious to those skilled in the art many modifications of structure, arrangements, proportions, the elements, materials, and components, used in the practice of the invention which are particularly adapted for specific environments and operating requirements without departing from those principles.

WHAT IS CLAIMED IS:

5

10

15

20

25

30

35

- 1. A method of growing bone in order to increase the volume of the bony ridge of the maxilla or mandible by creating a protected and supported space between the underside of the gum tissue and the jaw bone which is protected from outside chewing forces, muscular or tissue pressure, or any other premature loading by utilizing a guided-tissue regeneration plate support and fixation system, which method comprises:
 - A) fixing a support medium to the jaw bone;
 - B) securing a guided-tissue regeneration plate to the jaw bone, which guided-tissue regeneration plate is a pliable, easily bendable and moldable, but keeps its shape and is rigid after molded, biocompatible, substantially thin plate which is designed to be received by and intimately attached to the support medium;
 - C) tenting the guided-tissue regeneration plate to establish a protected space for bone growth; and D) waiting for bone to grow in the protected space.
- 2. The method of Claim 1 in which the support medium is a substantially thin bone screw with its head acting as a receiver cap configured to receive and to be intimately mated with the guided-tissue regeneration plate while at the same time supporting and securing the guided-tissue regeneration plate in a tenting fashion a predetermined distance from the bony ridge.
- 3. The method of Claim 1 in which the support means is a support screw which is a modified healing screw inserted into a dental implant configured to receive and to be intimately mated with the guided-tissue regeneration plate while at the same time supporting and securing the guided-tissue regeneration plate in a tenting fashion a predetermined distance from the bony ridge.
- 4. The method of Claim 1 in which the support medium is a dental implant which is capable of receiving the guided-tissue regeneration plate while at the same time supporting and securing the guided-tissue regeneration plate in a tenting fashion a designated distance from the bony ridge by inserting the healing screw supplied with the dental implant through the guided-tissue regeneration plate and fixing the healing screw to the dental implant.
- 5. The method of Claim 1 in which the guided-tissue regeneration plate and the support medium are made of bio-compatible material selected from the group including titanium, chromium cobalt alloy and Teflon-coated surgical steel.
 - 6. The method of Claim 1 in which the guided-tissue regeneration plate is solid except for a

generally centrally disposed aperture for receiving the support medium.

7. The method of Claim 1 in which the guided-tissue regeneration plate is perforated.

5

8. The method of Claim 1 in which the guided-tissue regeneration plate is perforated and then coated with a resorbable, bio-compatible material for the purpose of creating a temporary guided-tissue regeneration plate barrier to prevent migration of epithelial cells below its surface yet allow blood supply and/or nutrients to pass through said resorbable barrier.

10

9. The method of Claim 1 in which the guided-tissue regeneration plate is covered with a semi-permeable, non-resorbable, bio-compatible material to allow for nutrient supply transfer but prohibit epithelial cell migration below the guided-tissue regeneration plate.

15

10. The method of Claim 1 in which the guided-tissue regeneration plate has a generally centrally located aperture for the purpose of intimate attachment and direct fixation to the tenting-type support medium, thereby creating an indirect fixation of the guided-tissue regeneration plate to the jaw bone and a direct fixation of the support medium to the jaw bone.

20

11. The method of Claim 1 in which the guided-tissue regeneration plate is stiffer and more rigid in the region proximate the attachment aperture and more pliable toward the periphery to facilitate adequate support adjacent the attachment aperture which is coupled to the underlying support medium while achieving adequate flexibility and moldability in the peripheral areas.

25

12. The method of Claim 10 in which the aperture is at least fifty thousandths of an inch in diameter in order to be large enough to receive the shaft of a healing screw supplied with a dental implant through said aperture.

13. The method of Claim 2 in which the support medium is a tenting-type bone screw configured with a snap undercut area on the head of the screw in order to receive and securely retain the guided-tissue regeneration plate.

30

35

14. The method off Claim 2 in which the support medium is a tenting-type bone screw fabricated with an internally threaded aperture on its head to receive an additional micro screw in order to receive the guided-tissue regeneration plate and micro fastening screw.

15. The method of Claim 3 in which the support medium is a modified healing screw inserted into a dental implant is configured with a snap undercut area on the head of the screw in order to receive and securely retain the guided-tissue regeneration plate.

5

10

15

20

- 16. The method of Claim 3 in which the support medium is a modified healing screw inserted into a dental implant fabricated with an internally threaded aperture in its head to receive an additional micro screw in order to receive the guided-tissue regeneration plate and micro screw.
- 17. The method of Claim 2 in which the support medium is a tenting-type bone screw fabricated with a countersunk aperture on its head to receive a micro tack in order to receive the guidedtissue regeneration plate and micro tack.
 - 18. The method of Claim 3 in which the support medium is a modified healing cap fabricated with a countersunk aperture on its head to receive an additional micro tack in order to receive the guided-tissue regeneration plate and micro tack.
 - 19. The method of Claim 18 in which the micro tack is permanently attached to the guidedtissue regeneration plate.
- 20. The method of Claim 2 in which the tenting type support screw is sharply pointed with a cutting flute at its tip to allow for self-threading.
- 21. The method of Claim 2 in which the tenting type support screw has a major/minor diameter ratio of its threads that is at least two in order to facilitate secure anchorage to the bone.

25

22. The method of Claim 2 in which the tenting type support screw has a portion of the shaft near its head that is not threaded in order to create a stop and seat as the screw threads into the bone to facilitate better anchorage of the support screw representing the amount of predetermined distance from the bone the guided-tissue regeneration plate will be fixed and tented.

30

35

23. Apparatus for use in conjunction with the practice of a method of growing bone in order to increase the volume of the bony ridge of the maxilla or mandible by creating a protected and supported space between the underside of the gum tissue and the jaw bone which is protected from outside chewing forces, muscular or tissue pressure, or any other premature loading, which apparatus comprises:

A) a plate support medium adapted to be affixed to a jaw bone; and

5

10

15

20

25

30

35

B) a guided-tissue regeneration plate fabricated from a bio-compatible, pliable, easily bendable material which retains its shape and is rigid after molding, said guided-tissue regeneration plate incorporating an aperture dimensioned and configured to intimately receive said support medium such that said guided-tissue regeneration plate is directly supported by said support medium and indirectly supported by the jaw bone.

24. The apparatus of Claim 23 in which said support medium is a substantially thin bone screw with its head acting as a receiver cap configured to receive and to be intimately mated with said guided-tissue regeneration plate while at the same time supporting and securing said guided-tissue regeneration plate in a tenting fashion a predetermined distance from the bony ridge.

25. The apparatus of Claim 23 in which said support means is a support screw which is a modified healing screw inserted into a dental implant configured to receive and to be intimately mated with said guided-tissue regeneration plate while at the same time supporting and securing said guided-tissue regeneration plate in a tenting fashion a predetermined distance from the bony ridge.

26. The apparatus of Claim 23 in which said support medium is a dental implant which is capable of receiving said guided-tissue regeneration plate while at the same time supporting and securing said guided-tissue regeneration plate in a tenting fashion a designated distance from the bony ridge by inserting a healing screw supplied with the dental implant through said guided-tissue regeneration plate and fixing said healing screw to said dental implant.

27. The apparatus of Claim 23 in which said guided-tissue regeneration plate and said support medium are made of bio-compatible material selected from the group including titanium, chromium cobalt alloy and Teflon-coated surgical steel.

28. The apparatus of Claim 23 in which said guided-tissue regeneration plate is solid except for a generally centrally disposed aperture for receiving said support medium.

29. The apparatus of Claim 23 in which said guided-tissue regeneration plate is perforated.

30. The apparatus of Claim 23 in which said guided-tissue regeneration plate is perforated and then coated with a resorbable, bio-compatible material for the purpose of creating a temporary guided-tissue regeneration plate barrier to prevent migration of epithelial cells below its surface yet allow blood

10

15

20

25

30

35

supply and/or nutrients to pass through the said resorbable barrier.

- 31. The apparatus of Claim 23 in which said guided-tissue regeneration plate is covered with a semi-permeable, non-resorbable, bio-compatible material to allow for nutrient supply transfer but prohibit epithelial cell migration below said guided-tissue regeneration plate.
- 32. The apparatus of Claim 23 in which said guided-tissue regeneration plate has a generally centrally located aperture for the purpose of intimate attachment and direct fixation to said tenting-type support medium, thereby creating an indirect fixation of said guided-tissue regeneration plate to the jaw bone and a direct fixation of said support medium to the jaw bone.
- 33. The apparatus of Claim 23 in which said guided-tissue regeneration plate is stiffer and more rigid in the region proximate the attachment aperture and more pliable toward the periphery to facilitate adequate support adjacent said attachment aperture which is coupled to said underlying support medium while achieving adequate flexibility and moldability in said peripheral areas.
- 34. The apparatus of Claim 33 in which said aperture is at least fifty thousandths of an inch in diameter in order to be large enough to receive the shaft of a healing screw supplied with a dental implant through said aperture.
- 35. The apparatus of Claim 24 in which said support medium is a tenting-type bone screw configured with a snap undercut area on the head of said screw in order to receive and securely retain said guided-tissue regeneration plate.
- 36. The apparatus off Claim 24 in which said support medium is a tenting-type bone screw fabricated with an internally threaded aperture on its head to receive an additional micro screw in order to receive said guided-tissue regeneration plate and micro fastening screw.
- 37. The apparatus of Claim 25 in which said support medium is a modified healing screw inserted into a dental implant is configured with a snap undercut area on the head of said screw in order to receive and securely retain said guided-tissue regeneration plate.
- 38. The apparatus of Claim 25 in which said support medium is a modified healing screw inserted into a dental implant fabricated with an internally threaded aperture in its head to receive an additional micro screw in order to receive said guided-tissue regeneration plate and micro screw.

39. The apparatus of Claim 24 in which said support medium is a tenting-type bone screw fabricated with a countersunk aperture on its head to receive a micro tack in order to receive said guided-tissue regeneration plate and micro tack.

5

40. The apparatus of Claim 25 in which said support medium is a modified healing cap fabricated with a countersunk aperture on its head to receive an additional micro tack in order to receive said guided-tissue regeneration plate and micro tack.

10

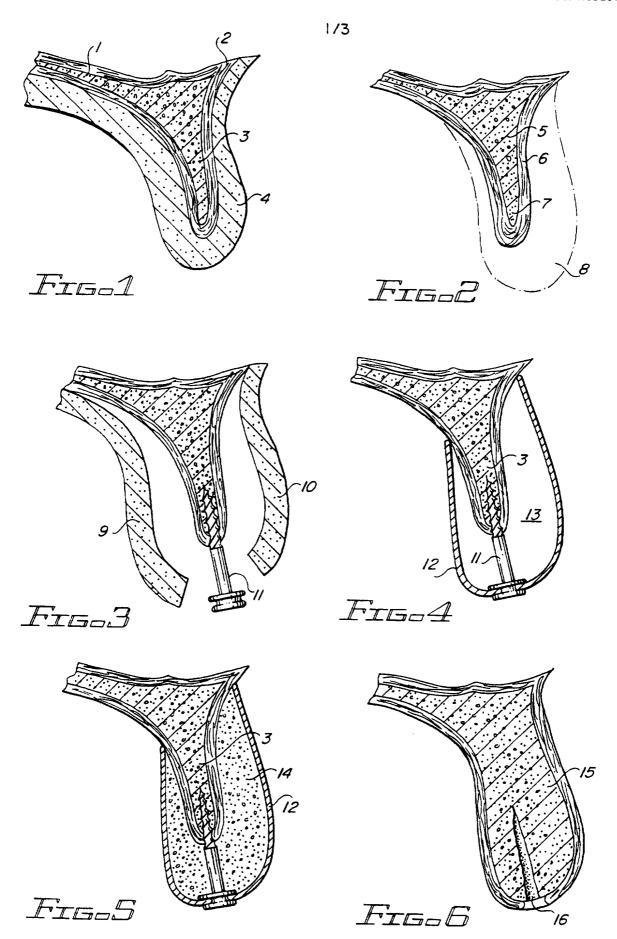
- 41. The apparatus of Claim 40 in which said micro tack is permanently attached to said guided-tissue regeneration plate.
- 42. The apparatus of Claim 24 in which said tenting type support screw is sharply pointed with a cutting flute at its tip to allow for self-threading.

15

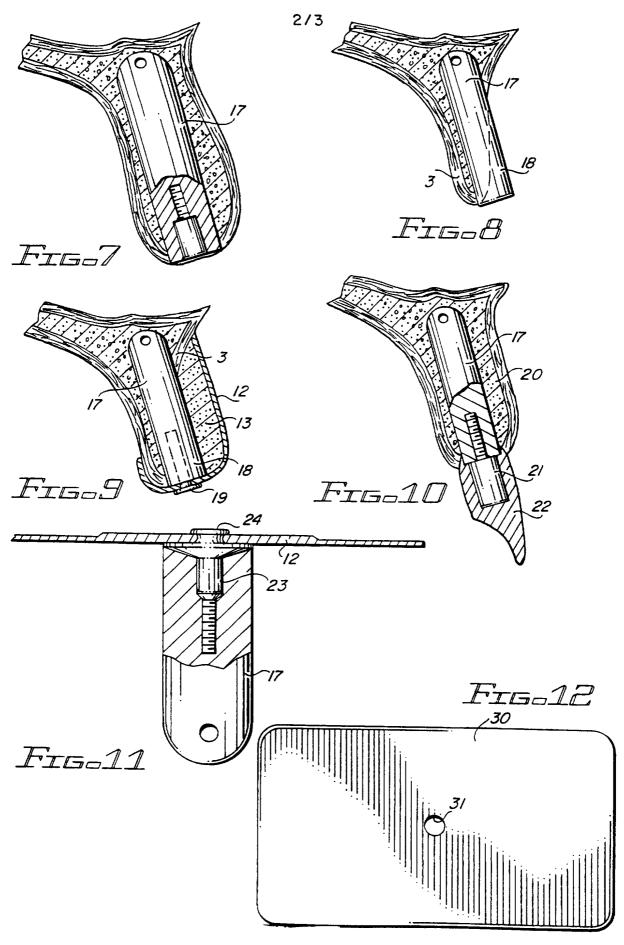
43. The apparatus of Claim 24 in which said tenting type support screw has a major/minor diameter ratio of its threads that is at least two in order to facilitate secure anchorage to the bone.

20

44. The method of Claim 24 in which said tenting type support screw has a portion of the shaft near its head that is not threaded in order to create a stop and seat as said screw threads into the bone to facilitate better anchorage of said support screw representing the amount of predetermined distance from the bone said guided-tissue regeneration plate will be fixed and tented.

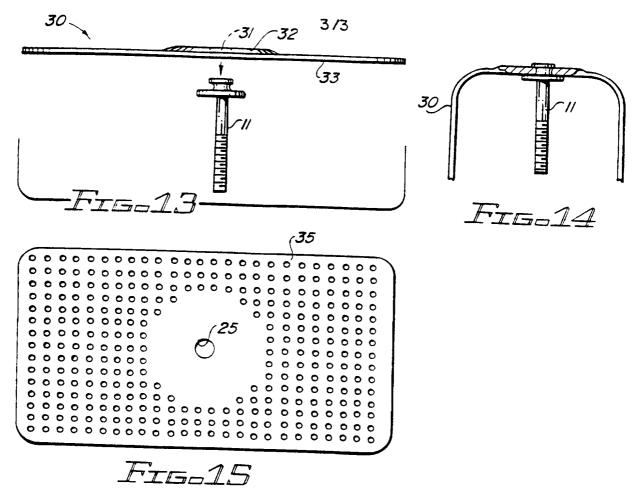


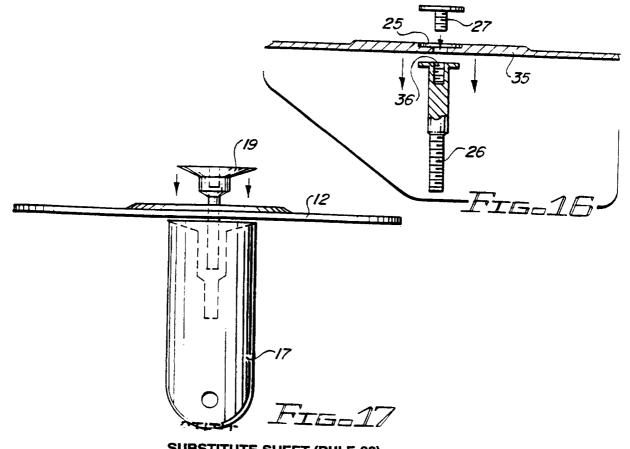
SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

WO 97/31586





SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/03167

	SSIFICATION OF SUBJECT MATTER :A61C 8/00	
US CL	:433/173, 215; 623/16	
	to International Patent Classification (IPC) or to both national classification and IPC	
	LDS SEARCHED	
	ocumentation scarched (classification system followed by classification symbols)	
0.3. :	433/167, 173, 174, 215; 606/53, 69, 70; 623/16	
Documentat	tion searched other than minimum documentation to the extent that such documents are included	in the fields searched
Electronic o	data base consulted during the international search (name of data base and, where practicable	, search terms used)
C. DOC	CUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 88/03391 A (LUNDGREN) 19 May 1988, pages 1-7.	1-5, 7-10, 14,
 Y		16, 23-27, 29-
τ .		32, 36
		6, 11-13, 15,
		22, 28, 33-35,
		37-44
Y	US 4,863,383 A (GRAFELMANN) 05 September 1989,	20, 42
	Abstract.	, ·· -
y	US 5,071,351 A (GREEN, JR. et al) 10 December 1991,	16 20
	Abstract.	16, 38
X Furth	er documents are listed in the continuation of Box C. See patent family annex.	
-	cial categories of cited documents: "T" later document published after the inte	mational filing date or priority
to t	ument defining the general state of the art which is not considered se of particular relevance date and not in conflict with the application principle or theory underlying the investment of the conflict with the application of the conflict with the conflict with the application of the conflict with the ap	antion
	tier document published on or after the international filing date "X" document of particular relevance; the considered novel or cannot be considered novel or cannot be considered.	claimed invention cannot be ed to involve an inventive step
cite	d to establish the publication date of another citation or other	
document referring to an oral disclosure, use, exhibition or other combined with one or more other such		step when the document is documenta such combination
P° doc	being obvious to a person skilled in the uncent published prior to the international filing date but later than *&* document member of the same patent if	e art
	actual completion of the international search Date of mailing of the international search	
21 MAY 1		•
lame and ma	ailing address of the ISA/US	
Commission Box PCT	er of Patents and Trademarks	Lucier
washington, acsimile No	/	
	A/210 (second sheet)(July 1992)*	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/03167

C (Continua	tion). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relev	ant passages	Relevant to claim No
X Y	VO 94/03121 A (LUNDGREN) 17 February 1994, page 16, lines 5-32.		1-4, 7-12, 14, 17, 18, 22-26, 29-34, 36, 39, 40, 44
			5, 6, 13, 15, 16, 19-21, 27, 28, 35, 37, 38, 41-43
X Y	US 5,372,503 A (ELIA) 13 December 1994, Figs. 1 a	nd 10.	1-4, 6, 7, 9, 10, 12, 13, 15, 17- 19, 22-26, 28-30, 32, 35, 37, 39- 41, 44
			5, 8, 11, 14, 16, 20, 21, 27, 31, 33, 34, 36, 38, 42, 43