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(54) **METHOD AND APPARATUS FOR PERFORMING RIDGE AUGMENTATION**

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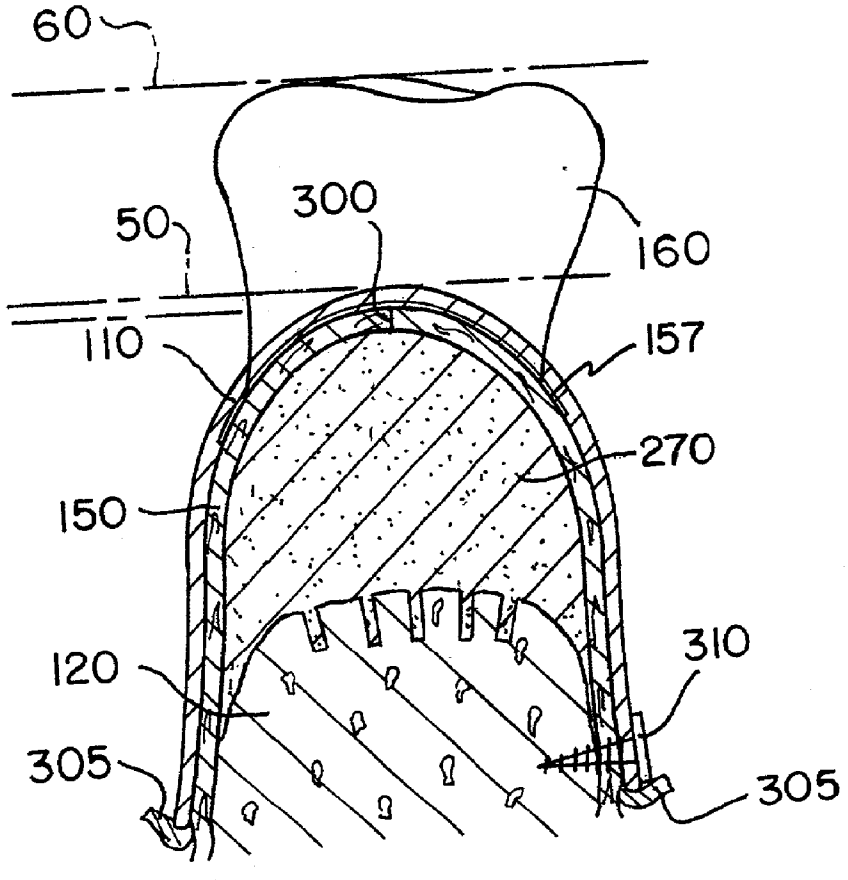
(52) **U.S. Cl.** **433/173**; 433/172; 433/215

(57) **ABSTRACT**

A method and apparatus for augmenting an endentulous alveolar ridge of a patient comprises the steps of (1) making a provisional denture-stent with a hollow space on the underside to account for the width, height and extent of the desired augmentation; (2) making an incision in, and reflecting, the gingiva where the augmentation is desired; (3) inserting bone graft material on the cortical plate; (4) suturing the gingiva; and (5) inserting the provisional stent over the bone graft material.



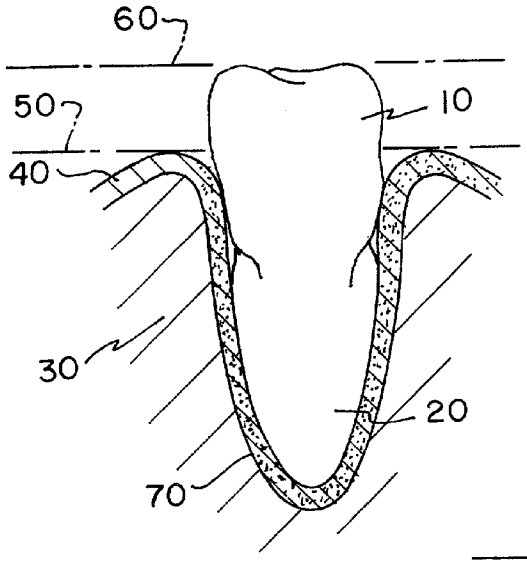


FIG. 1
PRIOR ART

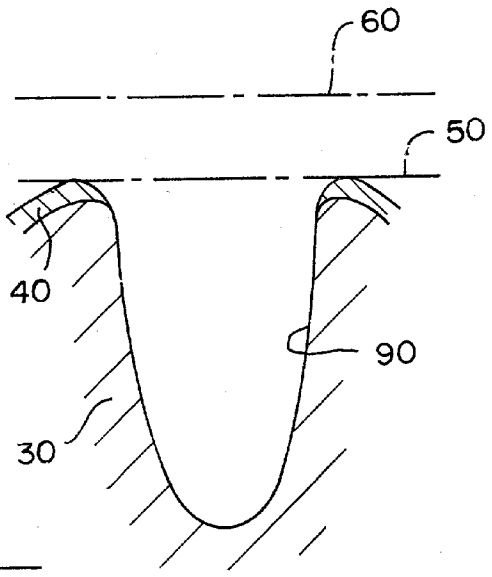


FIG. 2
PRIOR ART

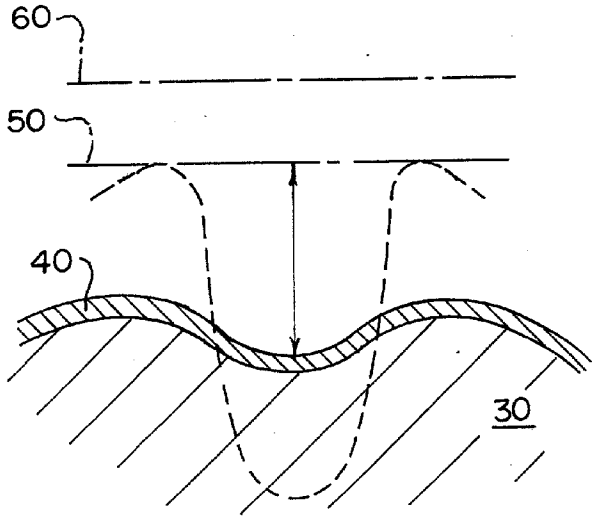
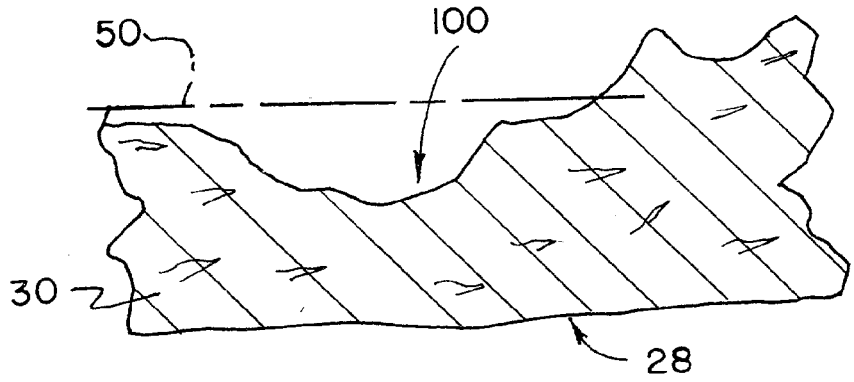


FIG. 3
PRIOR ART

FIG. 4a



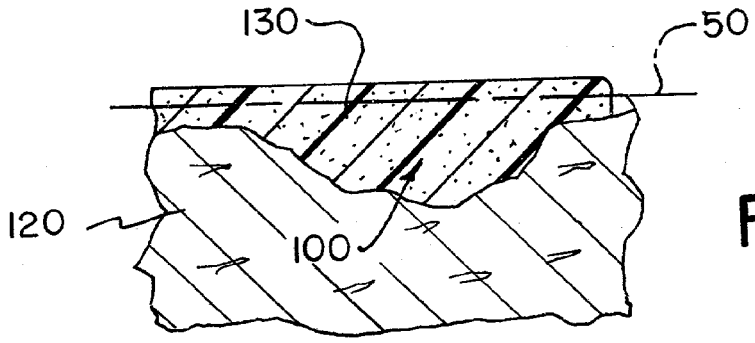


FIG. 4b

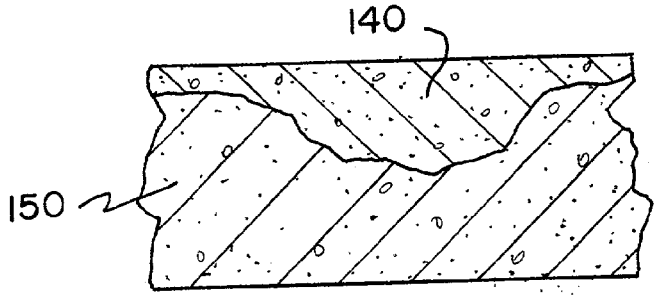


FIG. 4c

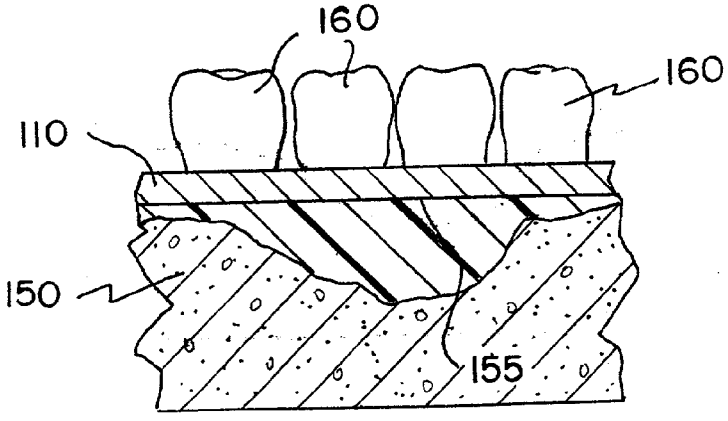


FIG. 4d

FIG. 4e

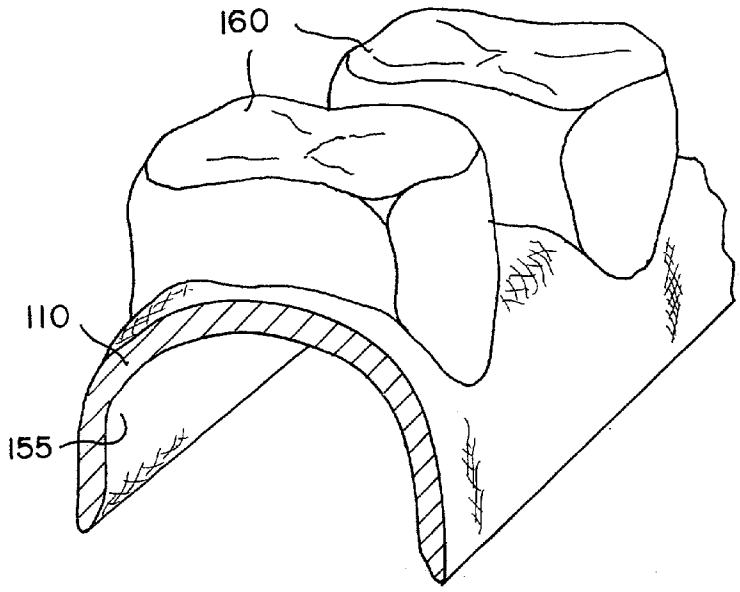
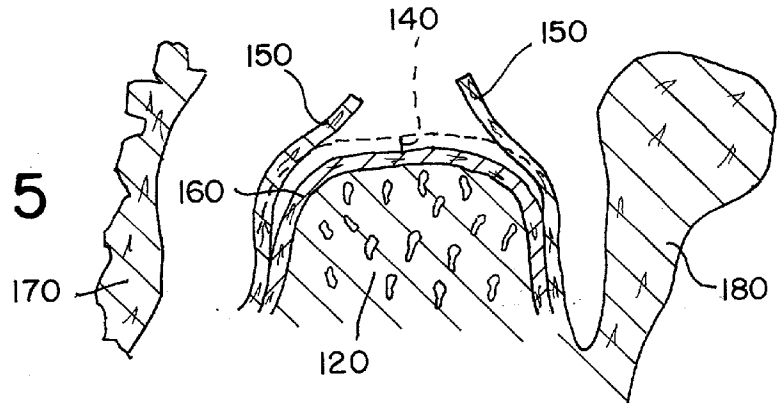


FIG. 5



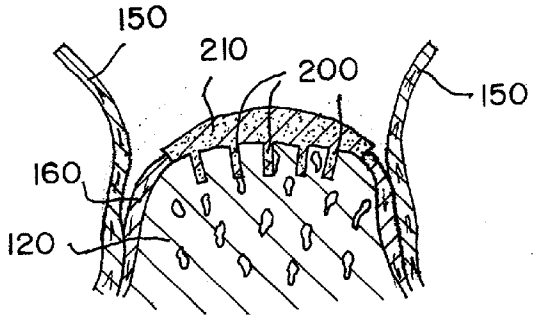


FIG. 6

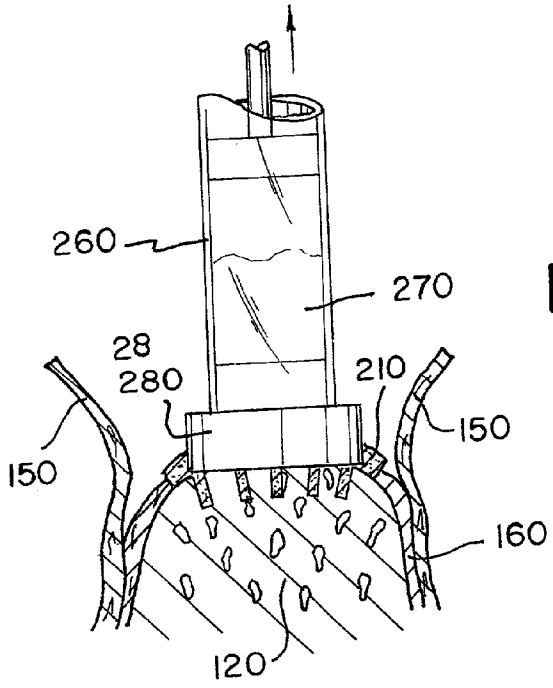


FIG. 7

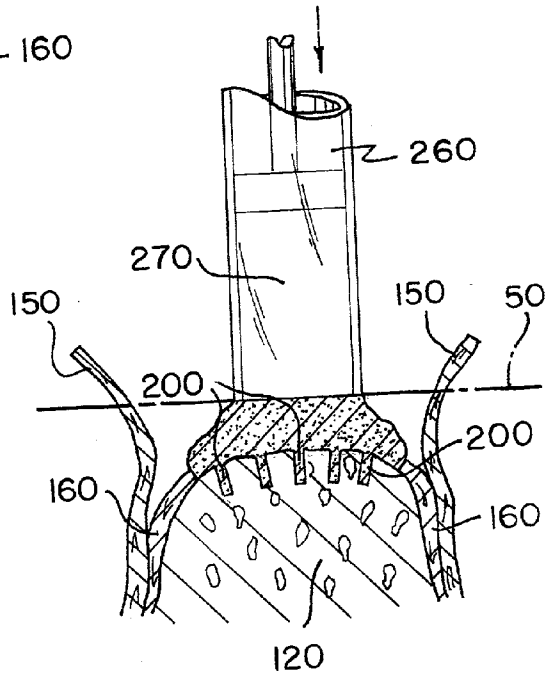


FIG. 8

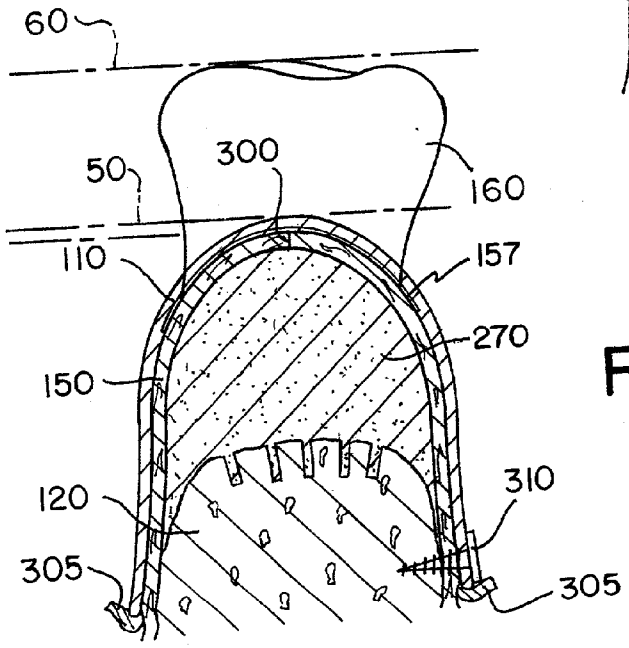


FIG. 9

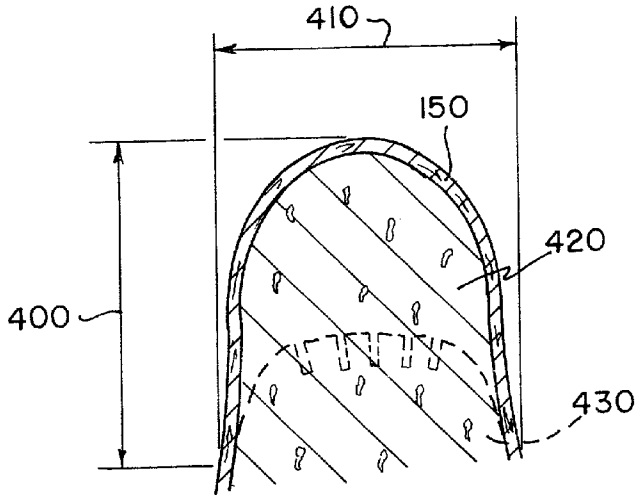


FIG. 10

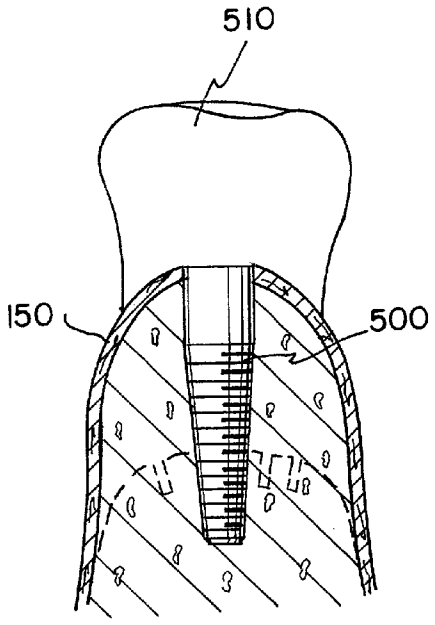


FIG. 11

METHOD AND APPARATUS FOR PERFORMING RIDGE AUGMENTATION

[0001] This application is a continuation of application Ser. No. 09/449,879, filed Nov. 30, 1999, now U.S. Pat. No. _____, issued _____, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to dental surgical procedures in general and, more particularly, to a method and apparatus for augmenting a patient's alveolar ridge or jaw bone using bone graft material.

BACKGROUND OF THE INVENTION

[0003] According to a National Survey on Oral Health, conducted by the National Institute of Dental Research, approximately 42 percent of Americans over 65 years of age and four percent of those 35 to 64 are totally edentulous. Moreover, those over 65 years old who are not totally edentulous have nevertheless lost an average of 12 of their 28 teeth, and persons aged 55 to 64 have lost an average of 9 of their 28 teeth.

[0004] When an extracted or otherwise missing tooth is not immediately grafted or replaced with an implant, atrophy of the jaw bone occurs over time. Consequently, individuals who have been partially edentulous for an extended period of time are left with an atrophic alveolar ridge that can not securely support a denture. Furthermore, the edentulous individual faces deteriorated aesthetics and a compromised ability to chew leaving the quality of the individual's oral life in an unfortunate state.

[0005] **FIGS. 1 through 3** illustrate the deteriorating effect of tooth extraction on the alveolar ridge. **FIG. 1** illustrates a tooth of a patient, comprised of a crown **10** and root **20** seated in the alveolar bone or jaw bone **30**. The buccal and lingual portions of the alveolar bone are surrounded by a layer of tissue known as the gingiva or gum **40**. The crown **10** and root **20** are supported by the elevated portion of the alveolar ridge or jaw bone **30** and gingiva **40** which, in the ideal case, hold all of the teeth in place such that a level gum line **50** and crown line **60** are maintained. When such a tooth or series of teeth become infected, damaged or otherwise hygienically dangerous, such that the extraction of the crown **10** and root **20** are required, the root is removed from the alveolar bone **30** by separating the surface of the root **20** from the periodontal membrane **70**.

[0006] **FIG. 2** represents the portion of the jaw bone shortly after extraction of the crown **10** and root **20**. As is shown, the periodontal membrane clots such that bleeding ceases and a socket **90** remains in the alveolar bone **40** in the shape of the extracted root **20**.

[0007] The buccal and lingual portions of the alveolar bone **30** are composed of soft trabecular bone which has the unique characteristic of being capable of absorbing the shocks caused by the movement of teeth during speech, eating, etc. The removal of a tooth and the resulting absence of frequent bone pressure stimuli in the area, causes the alveolar bone **30** to shrink in that area, with the subsequent loss of 40 to 60 percent of the alveolar ridge's former height measured at the gum line **50**. **FIG. 3** shows an endulous extraction site with loss of buccal and lingual portions of the alveolar bone **30**, two years after the extraction of the tooth represented in **FIG. 1**. After initial 40-60% loss, the alveolar bone **30** continues to atrophy at a bone loss rate of one-half to one percent per year.

[0008] Bone replacement graft material has been used to immediately fill a socket **90** at an extraction site after a root **20** extraction, in order to promote bone growth and therefore avoid this atrophy. Bone growth is promoted via the bone graft material's intermixing with the patient's own marrow blood at the extraction site **90**. While methods of applying bone graft materials to a newly extracted root site are known, a method for applying bone graft materials to an area of jaw bone which has already atrophied is not known and would have obvious benefits.

[0009] Because an application of synthetic bone replacement materials during a ridge augmentation procedure would not be preceded by a root extraction, such a method must allow the bone graft material to come into contact with the alveolar bone marrow such that the synthetic bone graft material and the alveolar bone can fuse together to create dense lamina bone in the area where augmentation is desired. Furthermore, a method of shaping the alveolar ridge following the implantation of bone graft material in the augmentation area is required to properly maintain the shape of the implanted bone graft material consistent with the overall desired shape of the reconstructed alveolar ridge.

SUMMARY OF THE INVENTION

[0010] It is an object of the present invention to provide a method and apparatus for performing ridge augmentation on an atrophied jaw bone using synthetic or other bone replacement materials. It is a further object of the invention to provide a method and apparatus for constructing a provisional denture-stent to be used in the augmentation process either with or without implant insertion. Because the disclosed procedure involves surgery, it is also an object to provide post-operative instructions and recommended clinical follow-up procedures.

[0011] According to an aspect of the invention, a method for performing ridge augmentation on an atrophied alveolar ridge of the jaw bone of a patient utilizing synthetic bone alloplast comprises the steps of (1) constructing a denture-stent with a fitted hollow space on the underside of the stent conforming to the desired height, width and extent of ridge augmentation, (2) reflecting gingiva tissue covering the alveolar ridge at the site to be augmented, (3) inserting synthetic bone or other graft material into reflected gingiva tissue of the alveolar ridge and onto the bleeding cortical plate of the jaw bone in the area where ridge augmentation is desired, (4) suturing the reflected gingiva tissue, (5) placing the preconstructed stent over the area of the alveolar ridge containing the synthetic bone graft material immediately after the area has been sutured and (6) fixing the stent denture to the jaw bone when necessary.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Other objects and features of the present invention will be described hereinafter in detail by way of certain preferred embodiments with reference to the accompanying drawings, in which:

[0013] **FIG. 1** is a cross-sectional view of a tooth crown and root prior to extraction from the alveolar ridge;

[0014] **FIG. 2** is cross sectional view of the alveolar ridge following the extraction of the root illustrated in **FIG. 1**;

[0015] **FIG. 3** is a cross-sectional view an atrophied alveolar ridge two years following the root extraction illustrated in **FIG. 2**;

[0016] **FIG. 4***a* is a cross-sectional view of an atrophied alveolar ridge and an area of desired augmentation;

[0017] **FIG. 4***b* is a cross-sectional view of a stone or plaster model of the atrophied alveolar ridge of **FIG. 4***a;*

[0018] **FIG. 4***c* is a cross-sectional view of a final master model of the atrophied alveolar ridge of **FIG. 4***a;*

[0019] **FIG. 4***d* is a cross-sectional view of a denture-stent formed over the final master model of **FIG. 4***c;*

[0020] **FIG. 4***e* is a perspective view of the denture-stent of **FIG. 4***d* after final try-in.

[0021] **FIG. 5** is a cross-sectional view of the alveolar ridge following a full-thickness incision in the surrounding gingiva;

[0022] **FIG. 6** is a cross-sectional view of the alveolar ridge where the cortical plate of the alveolar ridge has been punched to create bleeding marrow points;

[0023] **FIG. 7** is a cross-sectional view of blood from the punched bleeding points of **FIG. 6** being drawn into a syringe filled with bone graft material;

[0024] **FIG. 8** is a cross-sectional view of blood wetted bone graft material being applied to the bleeding cortical plate of the alveolar ridge;

[0025] **FIG. 9** is a cross-sectional view of the alveolar ridge after the gingiva has been sutured and the secured dental stent has been placed over the alveolar ridge;

[0026] **FIG. 10** is a cross-sectional view of the alveolar ridge **18** months after the marrow-wetted bone graft material is added to the alveolar ridge promoting new bone foundation and increased height and width of the alveolar ridge; and

[0027] **FIG. 11** is a cross-sectional view of the augmented alveolar ridge into which has been inserted an implant used to support an artificial tooth (e.g., dental implant).

DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0028] The method of augmenting an atrophied alveolar ridge with synthetic bone material is optimally described as a three phase method (Phases I, II and III). Phase I comprises the construction of a provisional denture-stent.

[0029] In Phase I, a dental surgeon (or any other individual qualified to construct a denture-stent, e.g., a dental technician) constructs a provisional denture-stent with a "hollow" space on the underside of the stent to accommodate what will become the newly augmented ridge area. The patient's existing denture is never to be used as the Phase I denture-stent. The dental surgeon constructs either a partial denture-stent or a full denture-stent depending on the extent of the augmentation. When only a part of the alveolar ridge is to be augmented, the dental surgeon makes a partial denture-stent. When the entire, or a substantial portion, of the alveolar ridge is to be augmented, the dental surgeon constructs a full denture-stent. Where the term "denture-stent" is used in the following detailed description, the reference includes both fall and partial denture-stents.

[0030] Turning to **FIGS. 4***a* through **4***e,* a method for constructing a denture-stent for use in the present invention is illustrated. With reference to **FIG. 4***a,* a portion **28** of the patient's alveolar ridge of the lower jaw bone **30** is shown facing outward from the lingual portion of the jaw bone. As is shown, the alveolar ridge **30** is atrophied such that augmentation is desired in an area (represented by **100**) between the alveolar ridge and the desired gum line **50**.

[0031] The dental surgeon commences the construction of the denture-stent in the manner known in the art. Turning to **FIG. 4***b,* the dental surgeon constructs a stone or plaster model **120** of the atrophic alveolar ridge shown in **FIG. 4***a.*

[0032] Model **120** is constructed using methods known in the art. With continued reference to **FIG. 4***b,* the dental surgeon places wax on model **120** in the area representing the portion of the alveolar ridge **30** to be augmented (**100**). The resulting shape of the underside of the wax represents a wax impression **130** of the area of the alveolar ridge **30** to be augmented.

[0033] Turning to **FIG. 4***c,* the dental surgeon uses the wax impression **130** formed in **FIG. 4***b* to create a plaster impression **140** having the same shape as the wax impression **130** of **FIG. 4***b.* The dental surgeon uses the plaster impression **140** to create a final master model **150** of the ridge to be augmented using methods known in the art.

[0034] Turning to **FIG. 4***d,* the dental surgeon constructs the denture-stent **110** over the master model **150** of **FIG. 4***c.* As is shown, the hollow underside **155** of the denture-stent conforms to the shape of the plaster impression **140** of **FIG. 4***c.* Further, the dental surgeon adds prosthetic teeth **160** to the top of the denture-stent **110**. The denture-stent **110**, at this point, is constructed of a wax and acrylic mixture.

[0035] **FIG. 4***e* represents the final denture-stent **110** prior to surgery and ridge augmentation and after final try-in of the denture-stent of **FIG. 4***d.* As is known in the art, the final denture-stent **110** is constructed of hard acrylic or plastic. The hollow underside **155** of the final denture-stent has a shape that conforms to the shape of the desired ridge augmentation. **30** thereby filling the hollow-space **100** with a bone replacement graft. As will be explained fully below, the denture-stent **110** is placed after the surgery is completed.

[0036] Turning to **FIG. 5**, the first step of the Phase II surgical procedure, as performed on the mandible (lower jaw bone), is illustrated. The ridge of either the maxilla (upper jaw bone) or the mandible can be augmented using this procedure. For purposes of orientation in **FIG. 5**, the alveolar ridge of the mandible is shown positioned between the patient's tongue **170** and the patient's lip **180**.

[0037] Where the mandible is to be augmented, as shown in **FIG. 5**, the dental surgeon makes a crestal full-thickness incision **140** in the gingiva tissue **150** at the location along the alveolar ridge where augmentation is desired. Upon reflecting the gingiva tissue **150**, the cortical plate **160** of the atrophied alveolar or trabecular bone **120** is exposed. If the maxilla is to be augmented, a lingual split-thickness incision

reflecting to a full-thickness incision at the crest of the ridge going in a buccal direction is made. Again, the cortical plate **160** will be exposed.

[**0038**] The bone graft material is now added to the exposed alveolar ridge. Although any bone graft material, such as autogenous bone or synthetics, alone or mixed with autogenous bone (e.g., Bioglass® or Bio Oss®), may be utilized as the bone graft material, prepackaged synthetic bone HTR® manufactured by Bioplant®, Inc. is preferably used in Phase II of the ridge augmentation procedure. HTR® is a calcified microporous co-polymer synthetic bone alloplast which promotes bone growth by acting as a scaffold which supports the creation of dense lamina bone. Further, HTR®-24, which comprises granular particles of a larger size (750 microns in diameter), is preferably utilized. HTR-24® is prepackaged in Bioplant® 0.25 Gram straight syringes, Item #01-81002, which are available from the manufacturer. The granular form of HTR®-alloplast which promotes bone growth by acting as a scaffold which supports the creation of dense lamina bone. Further, HTR®-24, which comprises granular particles of a larger size (750 microns in diameter), is preferably utilized. HTR-24® is prepackaged in Bioplant® 0.25 Gram straight syringes, Item #01-81002, which are available from the manufacturer. The granular form of HTR®-24 must be wetted (i.e., hydrated) in order to change the consistency of HTR® to a more useable and formable paste-like substance that will not migrate when placed on bleeding bone. The dental surgeon may additionally mix the graft material with the patient's own bone (e.g., from the hip bone) in order to promote faster and more effective growth of bone in the alveolar ridge. U.S. patent application Ser. No. 08/831,941 describing the syringe tip and a method for using the same is hereby incorporated in its entirety by reference.

[**0039**] Although the HTR® can be wetted with liquid antibiotic, liquid bone-inducer protein (e.g., BMPs), or sterile saline solution, blood from the patient's alveolar marrow is preferably used to wet the HTR®. Accordingly, as shown in **FIG. 6**, the dental surgeon uses a round surgical bur to punch holes **200** into the exposed cortical plate **160** of the alveolar ridge **120**. The holes **200** are spaced approximately 2-4 mm apart. The use of the bur to create holes promotes marrow bleeding **210** via the small bleeding points **200** of alveolar marrow which brings to the area the precurser ("Pluri potential") cells that will form new bone.

[**0040**] As shown in **FIG. 7**, the dental surgeon draws the bleeding marrow **210** into the syringe **260** containing granular HTR® through the syringe filter tip **280**. The granular HTR® is, thereby, wetted by the blood to form a blood wetted mixture with HTR®**270**. The filter **280** in the tip is sized to allow the necessary bone forming cells into the syringe **260** to mix with the graft material. Excess blood can be expelled from the syringe once a sufficient quantity of blood is mixed with the HTR®. The blood wetted HTR®**270** is permitted to congeal for three to four minutes, at the conclusion of which time the blood wetted HTR® mixture **270** will have a viscous, paste-like consistency which can more easily be formed on the alveolar ridge **120** and not migrate off the ridge **120**.

[**0041**] As shown in **FIG. 8**, the dental surgeon thereafter removes the filter tip **280** of the syringe **260** and expels the wetted HTR®**270** onto the exposed and bleeding cortical plate **160**. The dental surgeon expels an amount of wetted HTR®**270** sufficient to provide the required augmentation of the atrophied area of jaw bone. Because the HTR® granules are wetted, they will stay in place without migration and can be molded to generally conform with the desired width, height and shape of the alveolar ridge consistent with the gum line **50**. Furthermore, by placing the wetted HTR®**270** on that portion of the cortical plate **160** where the marrow holes **200** have been punched, the wetted HTR®**270** and the alveolar marrow **280** will more readily interact to form dense lamina bone.

[**0042**] **FIG. 9** illustrates the suture and denture-stent placement operations. Once a satisfactory amount of wetted HTR®**270** has been added to properly augment the ridge **120**, the dental surgeon folds the reflected gingiva tissue **150** back over the alveolar ridge formed by the newly added wetted HTR®**270**. The dental surgeon makes a primary closure **300**, preferably using 3-0 silk sutures and horizontal mattress suturing. It is possible that a vertical release incision or split-thickness incision may be required in order to provide coverage of the wetted HTR®**270** and to properly heal the gingiva tissue **150**.

[**0043**] In order for the newly augmented ridge to form properly, the dental surgeon immediately places the Phase I denture-stent **110** over the new ridge as shown in **FIG. 9**. If the newly augmented alveolar ridge does not sufficiently fill the hollowed space of the denture-stent, the dental surgeon relines the denture-stent **110** with a soft-line material **157**. Alternately, if the newly augmented area of alveolar ridge impinges upon the hollow underside of the denture-stent, the dental surgeon relieves (removes) a portion of the denture-stent **110** adjacent to the hollow area using a large round bur on the under side soft line of the denture-stent **110**.

[**0044**] The denture-stent **110** will hold the newly augmented ridge in shape while the alveolar bone **120** fuses with the wetted HTR®**270** to form dense lamina bone. After inserting the denture-stent **110** onto the newly augmented area of the alveolar ridge, the dental surgeon checks the fit and bite of the denture-stent. A vestibular extension **305** may be needed at this point as well as a possible frenectomy to eliminate interfering muscle attachments. Once the dental surgeon is satisfied with the present fit of the denture-stent **110**, he secures the denture-stent **110** to the patient's alveolar ridge preferably using a palatal screw **310**. Alternately, circumferential wiring can be used on the mandible. The screw **310** insures that the denture-stent remains in place, as it is important that the denture-stent not be removed for 7 to 10 days following the Phase II surgery in order to promote initial healing.

[**0045**] The present method advantageously allows the patient to immediately function with the Phase I denture-stent. The edentulous individual, who may have been unable to support a full or partial denture before the Phase II surgery, aesthetically benefits at once since the patient leaves the dental surgeon's office with a prosthesis and aesthetic tooth or teeth which are properly aligned with the gum line **50** and crown line **60**. The patient never goes without teeth. Additionally, the pain and discomfort normally associated with dental surgery is minimized in that the stent acts to hold the HTR mixture in place and to prevent any remnant bleeding or trauma to the area which might occur following suturing without the denture-stent in place.

[0046] Phase III of the ridge augmentation method comprises follow-up procedures. The dental surgeon instructs the patient to avoid eating solid foods for approximately 7 to 10 days. The dental surgeon also prescribes systemic antibiotics and analgesics for about 10 days. In about two days after the Phase II surgery, the dental surgeon sees the patient and inspects the patient's bite in order to be sure that the dental stent is properly mounted on the patient's alveolar ridge. Approximately 7 to 10 days following Phase II surgery, the dental surgeon removes the denture-stent **110** and cleans the surgical area using, e.g., a Peridex rinse. The denture-stent **110** is then again placed onto the patient's alveolar ridge, now as a functioning full or partial denture.

[0047] In approximately two to three months after the Phase II ridge augmentation surgery, the dental surgeon sees the patient again and inspects the effected alveolar ridge area and denturestent **110** fitting. The dental surgeon may redo the soft-line **157** of the underside **155** of the denturestent **110** if necessary to maintain the denture-stent's proper fit on the patient's alveolar ridge. Around six months after surgery, the dental surgeon fits the patient for a new full or partial denture in the normal manner, i.e., the dental surgeon will make a normal denture without a hollow on the underside fitting the newly restored jaw bone.

[0048] **FIG. 10** illustrates the augmented alveolar ridge at about **18** months after the Phase II surgery. Both the height **400** and the width **410** of the alveolar ridge increased as a result of the dense lamina bone **420** which forms over the original bony ridge **430** during the 18 month interval. At this point, the patient may continue to function normally with a full or partial denture or, as shown in **FIG. 11**, the patient may be considered for implant therapy whereby an implant screw **500** may be inserted into the patients' newly augmented alveolar ridge in the normal manner to support a prosthetic crown **510**.

[0049] While the present invention has been particularly shown and described with reference to preferred embodiment thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. A denture-stent for placement over an alveolar ridge to be reconstructed into a desired shape by placing bone graft material under gingival tissue on the alveolar ridge, the denture-stent having a surface conforming to the desired shape of the alveolar ridge to be reconstructed and being adapted to maintain said bone graft material in the desired shape while the alveolar ridge and the bone graft material fuses.

2. The denture stent of claim 1, wherein the denture stent is comprised of a material selected from the group consisting of hard acrylic and plastic.

3. The denture stent of claim 1 further comprising a soft-line material lining the surface on the surface to fill space between the surface and the gingival tissue.

4. A denture stent for an atrophied area of a jawbone made by a method comprising the steps of:

a) constructing a model of said atrophied area of said jawbone;

b) placing wax on an atrophied area of said model corresponding to the atrophied area of said jawbone;

c) constructing a plaster impression model of said wax;

d) constructing a final master model of said denture-stent having an underside area with a shape conforming to said plaster impression model;

e) performing try-in of the final master model on the atrophied area of said jawbone; and

f) constructing a final denture-stent from said final master model.

5. The denture stent of claim 4 wherein said model of said atrophied area of said jawbone is constructed of a material selected from the group consisting of stone and plaster.

6. The denture stent of claim 4 wherein said final master model is constructed of a wax and acrylic mixture.

7. The denture stent of claim 4 wherein said final denture-stent is constructed of a material selected from the group consisting of hard acrylic and plastic.

8. The denture stent of claim 4 wherein the method includes the additional step of adding prosthetic teeth to said final master model.

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