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(54) **Title**: IMPROVED VIBRATING DENTAL DEVICES

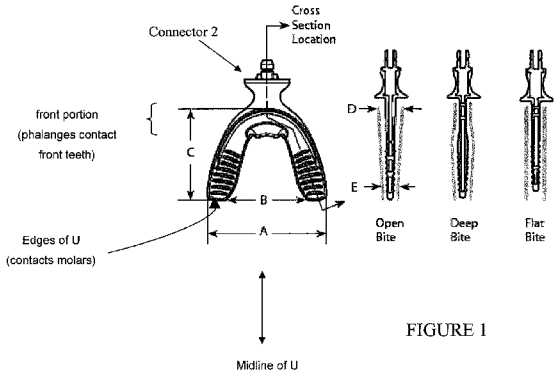

FIGURE 1

(57) **Abstract**: A variety of improvements to the vibrating devices for dental remodeling are provided, including improved bite plate designs that accomodate common patient bite structure, a connector for a bite plate, a sizing tray for same, as well as better motors providing improved performance characteristics for an extraoral vibrator, and a completely intraoral vibrating dental plate with very thin cross section.

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IMPROVED VIBRATING DENTAL DEVICES

PRIOR RELATED APPLICATIONS

This application claims priority to Continuation-in-Part Application No. 12/615,049, filed November 9, 2009, which is incorporated herein in its entirety.

FEDERALLY SPONSORED RESEARCH STATEMENT

Not applicable.

REFERENCE TO MICROFICHE APPENDIX

Not applicable.

FIELD OF THE INVENTION

The invention relates to vibrating dental devices for correcting malocclusion.

BACKGROUND OF THE INVENTION

Orthodontics is a dental specialty that treats malocclusion through the movement of teeth as well as control and modification of facial growth. This process is usually accomplished by using a continuous mechanical force to induce bone remodeling, thereby enabling the teeth to move to a better position. In this approach, orthodontic appliances provide a continuous static force to the teeth via an archwire connected to brackets affixed to each tooth or via a removable appliance such as an aligner, or some similar accessory, that fits over the dentition. As the teeth slowly move due to the force, the force is dissipated. The archwires are adjusted to add additional force and to continue the desired tooth movement. Although effective, this widely accepted approach takes about twenty four months on average to achieve success.

Dental researchers have long postulated that a pulsating force might also be used to move teeth more rapidly and to ease the discomfort of traditional orthodontics.

Mao was probably the first to prove that the use of cyclic forces could improve dental straightening in rabbits (see US6684639, US6832912, US7029276). Certain dynamic loading patterns (cycling force with rest periods) were shown to greatly increase bone formation compared to basic dynamic loading. Inserting rest periods is now known to be especially efficacious as it allows mechanosensitivity to be restored to the bone tissue. A point of diminishing returns is reached within each loading session. Therefore, intermittently loading cyclic force can increase the rate of bone formation significantly.

US4244688, US4348177, and US4382780 describe devices used to vibrate the teeth during orthodontic treatment, although each uses a different means of applying a vibration. The US4244688 patent employs a cumbersome external power source to power one to four small motors, whereas US4348177 uses pulsating fluids moved with the chewing motion of the jaw, and US4382780 uses a radio and speaker to set up a vibration. These devices are mounted on a bulky headgear that surrounds the head and are connected directly to the teeth by its intraoral portions. The devices are cumbersome, difficult to construct, expensive and are very difficult to use, thus reducing patient compliance.

US5030098 by Branford describes a hand-held device that simulates chewing in order to treat periodontal disease by increasing blood flow to the gums. The mouthpiece has a perforated malleable plate such that biting of the mouthpiece results in the plate adapting to the user's bite which, of course, varies with each user. The external vibrator imparts motion to the mouthpiece and thus the user's teeth. The device, however, uses an external power source and vibrator. Further, the dental plate is brass, and is very unpleasant to bite on, thus necessitating a second exterior coating and further complicating manufacture and cost.

US5967784 by Powers describes a similar device to that described by Branford. It too is a hand-held tooth vibrator that is simple and has an exterior motor housing connected to a vibrating interdental mouthpiece portion for gripping between the teeth of the patient. The exterior housing contains a battery and a switch for selectively operating a motor with an off-center weight attached to the motor rotating shaft for creating a high frequency vibration that vibrates the entire device. The mouthpiece is disposable, making the system affordable and more convenient to use. The patent teaches using the device to alleviate pain by inserting the interdental mouthpiece between the teeth and clenching and releasing the teeth over the mouthpiece, in an attempt to engage as many teeth as possible in the transmitted vibrations. The vibration is believed to alleviate discomfort by increasing blood flow.

The devices of Branford and Powers seem superficially similar to those of the invention herein. However, there is no recognition in either patent that the vibratory device can be used for alveolar bone remodeling or more rapid tooth movement. Furthermore, the shape of the dental plate in each case is a very flat U- or Y-shaped member that is largely ineffective for remodeling dentoalveolar bone. Additionally, the vibration is not optimized in frequency and amplitude for remodeling. Finally, neither device is entirely intraoral, and the extraoral component may cause drooling and inhibit patient compliance. The extraoral component may also lead to inhibition about use of the device in certain settings. All of these shortcomings reduce the effectiveness of these devices for craniofacial remodeling uses.

US6632088 describes a bracket with powered actuator mounted thereto to provide vibration, but this device is cumbersome, and thus may affect patient comfort and ultimately patient acceptance of the device. Further, the device locks to the bracket and archwire, and vibration of the tooth through the bracket is less than optimal, causing wear to the tooth enamel and causing discomfort.

WO2007116654 describes another intraoral vibrating mouthpiece, but the mouthpiece is complex, designed to fit over the teeth and will be expensive to manufacture. Further, to the extent that this device vibrates the brackets, it suffers from the same disadvantages above.

SUMMARY OF THE INVENTION

The invention generally relates to improved devices for dental remodeling through the application of cyclic forces. There are four main embodiments herein described as well as several variations thereon: 1) a variety of bite plate designs to accommodate common patient morphologies; 2) an improved extraoral vibrator with improved performance characteristics; 3) a bite plate connector; and 4) a completely intraoral bite plate.

In a first embodiment, the invention is an improved bite plate design that accommodates the various bite configurations that a patient may have. Thus, a wedge-shaped bite plate sloping with increased vertical dimension from anterior to posterior is provided for patients with a deep-bite malocclusion; a wedge-shaped bite plate sloping with increased vertical dimension from posterior to anterior is provided for patients with an open-bite; and a flat bite plate is provided for patients with malocclusion that does not involve an open-bite or deep-bite (see also FIG. 1).

In a second embodiment, the improved extraoral vibrator has a more stable vibrator with improved performance characteristics of decreased sound and low variability frequency and force. In particular, the improved vibrator has a noise level less than 55 dB when measured at 6 inches, a frequency at 20-40 Hz, with a variance of only 2 Hz, and a force of 0.1-0.5 Newtons, with a variance of ±0.05 N.

In preferred embodiments, vibrating dental devices have the capability of recording device usage and reporting same to the dental professional. Preferably these communications are wireless, e.g., via Bluetooth®, but can also be wired, and the communication can occur in the dental professional's office or via the internet. In another embodiment, the dental professional (and possibly patient) has the ability to modulate frequency, force, and which vibrators are used, as needed for patients with sensitivity to a high frequency X force combinations, and who need to vibrate certain teeth and omit others. Designing circuitry and programming for achieving these goals is well within the art, and is further described in US2008227046.

In other embodiments, the bite plate contains a chip with a short sound recording, such as is found in greeting cards and toys. The recording can be activated with, e.g., a depressible switch, and can be pre-recorded to indicate e.g., plate size, or can be recorded by the dental professional with e.g., a short message for the patient. Alternatively, plate size can be included on a chip within the plate which then can be read with a scanner, e.g., as is done with RFID scanners.

In other embodiments, the external housing of any dental device is customizable by printing thereon particular colors and/or designs, as specified by each customer. Alternatively, a reasonable range of colors and text or logo printing options may be available from which the customer can choose.

In other embodiments, the each device is printed with a unique serial number and/or bar codes to allow for device tracking.

In a third embodiment, an improved connector is provided for connecting the bite plate to an extraoral vibrator, wherein the connector is asymmetric and thus prevents the user from inserting the plate upside down. The connector comprises a flare at the midline of the bite plate with depressions therein so that the matching protrusions on the vibrator fit thereinto. The depressions are offset from the central axis of the connector, thus the

connector cannot be accidentally inserted upside down. The flare has a cylindrical shaft protruding therefrom for insertion into an appropriately shaped receptacle on the vibrator. The shaft has matching pins or protrusions on each side of the shaft, at the end near the bite plate, and there are corresponding depressions in the receptacle on the vibrator. This particular connector is a snap fit connector, configured so that only manual force is needed to insert and remove the bite plate. The snap fit in this instance is accomplished with a groove on the cylindrical shaft into which a circular spring in the vibrator will fit into. The application of a small amount of force stretches the spring slightly, allowing the device to be removed.

In a fourth major embodiment, the invention generally relates to a completely intraoral vibrating dental plate, wherein the entire device is contained in a thin, roughly planar, dentition shaped plate, and is hermetically sealed. All intraoral bite plate embodiments may be combined with the improved bite plate designs shown and discussed in FIG. 1. In its simplest embodiment, one or more vibrators are mounted on a bite plate and hermetically sealed. The device is then wirelessly activated with an external power source, such as that described in US2009058361 and all programming components are also external.

In another embodiment of the intraoral device, a battery is also placed on the bite plate, together with on/off switches on the plate, which can be, for example, activated by biting the plate.

For patient comfort, the smallest means of providing vibration are employed on the intraoral device. A large number of very small vibrating motors are available, as shown in the table below, but piezoelectric motors may be preferred due to the small size, and off-set weighted motors may be preferred due to low cost and availability. Particularly preferred are the substantially planar motors where the vibration is substantially parallel to the substrate (e.g, US5554971, US5780958, US2009224616, US2008129130, US2007103016, WO0178217, each incorporated by reference).

Company	Catalog	Size	Specifications
ELLIPTEC AG™	NA See US6870304	10 X 3 X 2 mm	3-6 volts piezoelectric motor
SURPLUS TRADERS™	MF820	8 X 4 mm (0.315 X 0.1575 inches)	1.5 to 4.5VDC weighted shaft
SURPLUS TRADERS™	MF918	0.45 X 0.16 inches	1VDC to 5VDC 18 ohms Weighted shaft
MOTOROLA™	G13566	0.44 x 0.18 inches	1VDC to 9VDC 10 ohms

Company	Catalog	Size	Specifications
			Weighted shaft
SURPLUS TRADERS™	MF835	0.45 x 0.24 inches	1.3Vdc 100mA Weighted shaft
MATSUSHITA™	V0296A	0.24 inch diameter	1.5VDC Weighted shaft
SURPLUS TRADERS™	ME235	0.24 x 0.5 inches	1.5 to 3 VDC 62 mA weighted shaft
PRECISION MICRODRIVES™	304-002	4m X 8 mm	2.3 VDC to 3.6VDC 100-120 mA 11000 rpm Weighted shaft
PRECISION MICRODRIVES™	308-100	3.4X8	2.—3.3 V, 120 mA 12000 rpm 8mm Shaftless Vibration Motor

In addition to electromagnetic motors and piezoelectric motors, other motor types can be used including mechanical actuators, ultrasonic motors and the like. Vibrations may be oscillating, random, directional, circular, and the like. Vibrators are well within the skill of the art, and several are described in the patent literature (and commercially available as seen above). For example, US2007299372, US2007255188, US2007208284, US2007179414, US2007161931, US2007161461, US2006287620, each incorporated by reference, describes various vibrator motors.

Batteries may drive the vibrational source for some intraoral embodiments. Small coin batteries, alkaline or lithium, are preferred due to their small size, but hydrogen batteries may also be preferred due to their power and power density, particularly as size and cost decrease with further technological development.

For certain embodiments, a battery that can be wirelessly recharged is preferred for longer product life (e.g., US2009051312, US7511454), but in other embodiments a low cost device is manufactured that is intended to be disposable. It is known in the art to select an appropriate power source/motor combination to provide an orthodontic vibrator that vibrates within the frequency and power suitable for orthodontic remodeling.

Any off the shelf on/off switch can be used. Particularly preferred for the intraoral device is an on/off switch with depressible activator (push button or rocker).

Generally speaking, the vibrator(s), and optional battery, on/off switch and circuitry are placed directly on the bite plate and hermetically sealed with no extraoral protrusions,

thus allowing the most compact bite plate, preventing drooling and maximizing patient compliance. In preferred embodiments, the core may contain depressions therein for fitting various components thereinto, thus maintaining the generally planar surface of the bite plate and maintaining a thin cross section.

The bite plate (whether for the intraoral embodiment or not) should have an average thickness of less than 10 mm and preferably is less than 7, 5, 4 or 3 mm. The various components (if any) can be placed anywhere on the bite plate, but preferably the switch is positioned near the molars, where good contact with teeth is easily made, and the vibrators are balanced on each side of the plate.

One or more vibrators can be placed on the plate, e.g., one on each side, or one for each of three tridents or four quadrants, as shown in FIG. 5. Where more than one vibrator is used, the vibrators should be synchronized when in use, so that the vibrations do not cancel each other out. In the alternative, the various portions of the bite plate can be separated with a thin divider portion of elastomeric material that serves to dampen the vibration and prevent its transfer to another portion of the bite plate. Either embodiment can be provided with control circuitry to either synchronize the motors, or to use the motors individually, thus vibrating only certain teeth.

The dental plate itself generally contains a stiff core, such as metal or rigid plastic onto which are placed the vibrator, and optional on/off switch, battery and the circuitry, as needed to run the device. Other stiff core materials can also be employed including ceramic, polymers and resins. However, aluminum and steel are preferred as easy to work with, inexpensive and having some flex, although certain plastic materials, such as polycarbonate, may be preferred as inexpensive and easily molded to fit components.

The dental plate can then be covered with a liquid-tight, elastic polymeric material to protect the user's teeth from the metal, to isolate any electrical components, and to provide a biocompatible and pleasant mouth feel. This is important for an intraoral embodiment, but the coating is optional on an extraoral device. Coatings, such as silicone rubber, polyethylene (PE), high density PE (HDPE), polycarbonate, polyurethane, polypropylene (PP), polyvinylchloride (PVC), polymethyl methacrylate, polyvinylidene fluoride, polyesters, acrylics, vinyl, nylon, rubber, latex, Teflon, or similar material, and combinations thereof may be used.

Preferably, the coating will not have an objectionable taste and will be FDA approved, such as silicone rubber, polypropylene, HDPE, and the like. In another embodiment the bite plate coating and other parts of the appliance that contact oral tissues have a selection of flavorings for additional comfort in use of the appliance. In yet another embodiment, the device is coated with a polymer that can be reshaped for custom fit, such as boil and bite polymers, or polymers that can be activated, cured and/or set with the addition of light and/or chemicals.

Depending on which teeth or regions of dentition that need to be treated, different dental plate shapes are possible. However, generally, the dental plate is flat to allow contact of the occlusal surfaces of all teeth when the dentition has reached a final level plane and U-shaped. Alternatively, the dental plate may cover only a portion of the dentition, thus being restricted to fewer teeth in use and differential tooth movement as a planned treatment approach. The dental plate can also have one or more vertical edges or phalanges (perpendicular to the midline when positioned inside the mouth), said edges being positioned to contact the facial and lingual surfaces of the teeth and possibly even apically beyond the gum line, thus providing increased circulation to the gums. In preferred embodiments, the dental plate has a U-shaped bite plate, and is slightly tapered to be thinner in the back of the mouth to accommodate the hinged nature of the teeth. In other preferred embodiments a series of bite plates such as described in FIG. 1 are provided.

A series of bite plates for sizing a patients bite are also provided. For example, the six bite plates of FIG. 1 can be packaged into a sizing kit for dental use. The sizes can be labeled thereon, or the plates can be color coded or otherwise distinguished with visible markings. Alternatively, as described above a chip containing size information can be read by scanner, or a sound recording can be activated to indicate size information. The sizing tray can contain any number of different sizes including 2, 3, 4, 6, 8, 10 and higher. Preferably, the sizing tray is shaped to display the bite plates in a horizontal configuration (U-shape showing) and allow any fluids, as used during the sterilization or disinfection process, to drain from the surface of the bite plate.

The devices can be used alone, or in combination with other orthodontic devices. In some embodiments, the appliance can be used to speed boney remodeling in orthodontic uses with traditional orthodontic fixed appliances or aligner based treatments or any other

appliance used for tooth movement. In other embodiments the appliance can be used to enhance boney remodeling in periodontal and oral surgical uses.

The device of the invention can be used in a variety of oral and maxillofacial applications including malocclusion, trauma repair, temporomandibular joint and muscle disorders (TMJDs), Lefort and other skeletal facial fractures, craniofacial anomalies such as boney clefts, bone defects, dentofacial deformities, dental implants, periodontal bone grafts as well as tooth, muscle, nerve, tendon, ligament, bone, and connective tissue repair.

Thus, the invention also includes a method for movement of one or more teeth by applying differential vibration to selected areas of a bite plate at frequencies between 1 to 1000 Hz (preferably 10-100 Hz and most preferred 20-40 Hz) and a force of 0.01-2 Newtons (or 0.1-0.5 or 0.2 Newtons) for a period of 1-60 minutes, preferably about 1-30 or 1-10 minutes or 20 minutes. This is followed by a period of recovery, ranging from 2-24 hours, preferably from 4-12 hours, and the cycle is repeated until one or more teeth are successfully moved. More particularly, the orthodontic appliance of the invention has a vibrational source capable of providing a vibratory force at a frequency of between 20 to 40 Hz or 30 Hz and a force of 0.2 Newtons. Excess force is generally unpleasant to the patient, especially force coupled with high frequency, and in preferred embodiments these parameters are adjustable.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1. Improved bite plate designs accommodating deep, flat and open bites.

FIG. 2 are perspective shadings of the bite plate with connector for attachment to extraoral vibrator. Shown is the inner core and clear polymeric overcoat, in this prototype Versaflax CL2250. Also, shown is a the inner core without the coating.

FIG. 3 is a line drawing of the bite plate and connector, showing a flare, a shaft, pins and depression, groove and the spring that fits into the groove.

FIG. 4 shows sizing details of the connector of FIG. 3.

FIG. 5 shows an intraoral bite plate in several views. One view is a perspective view of the core with battery, on/off switch and vibrators, where the hermetically sealed coating is omitted for clarity. Also shown is a side view with clear coating. Also shown is a top view of an embodiment showing polymeric dividers between various portions of the bite plate to

dampen the vibration between the segments (vibrator and other components omitted for clarity).

FIG. 6 provides basic dental nomenclature and is for reference purposes only.

DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The following examples are illustrative only and not intended to limit the invention.

EXAMPLE 1

The improved mouthpieces or bite plates are available in two sizes (small and large) based primarily on the anatomical dimensions of the patient's dental arches. Each size is available in three profiles based primarily on the type of malocclusion (open bite, deep bite and normal flat plane occlusion).

In the bite plates shown in Fig. 1, the phalanges that contact the lingual and buccal (inside and front) surface of the teeth are omitted for clarity, but such phalanges or edges are preferred since these edges allow greater contact with the teeth for improved comfort and improved transmission of the cyclic forces. Also shown in FIG. 1 (but not labeled) are optional ridges on the surface of the bite plate.

The sizes and profiles have been developed based on a statistical analysis of a sample population and are intended to allow for a maximum contact of teeth with the bite plate in a high percentage of patients and case types. The dimensions given in Table 1 are based on a minimum thickness E of 3.0-3.1 mm for the bite plate and based on using 6 sizes to fit most members of an average patient population. Obviously the final dimensions will change if the minimum thickness is changed (e.g., in an intraoral embodiment the thickness may increase to accommodate mechanical and/or electrical components), and customized bite plates may be required for outliers.

Generally speaking, the bite plate is U shaped, and can optionally have a connector at the midline to provide for secure attachment to an extraoral component. E represents the minimum thickness of the bite plate and ranges from 1-10 mm and preferably 2-5 mm or about 3 mm as in Table 1.

The thickness E increases from the ends of the U (where the molars would be when in use) towards the midline D (where the front teeth would be when in use) for use in patients having an open bite, and ranges from E to D= E + 0.5-10 or more preferably 1-3 mm.

In the bite plate for the patient having a flat bite, the thickness E does not vary substantially from the molars to the anterior teeth.

For the patient having a deep bite, the bite plate is generally thicker at the molars (ends) than at the front (midline) (not shown) by 0.5-10 mm. Alternatively, the deep bite plate may have two portions of different thickness with the thicker portion being at or near the ends and the thinner portion at or near the front, but not vary within each portion (not shown). In one preferred embodiment, the thickness E increases 0.5-10 mm (or 1-3 mm) from the ends towards the middle, but then narrows and again is roughly flat at the front to accommodate the 4-6 anterior teeth.

The exterior width (perpendicular to the midline) of the U-shaped bite plate ranges from 62-70 mm and the length (along the midline) ranges from 51-53 mm. More particularly, the U shaped plate also has an interior width B between the ends of the U and an exterior width A that includes the width of the bite plate ends. Further, the bite plate has a length C from the ends to the base of the U. In the small bite plate, the interior width B is 30-32 mm and preferably 31.8-31.9 mm, and the exterior width A is 61-63 mm, preferably 62.6-62.7 mm. The length C ranges from 51-53 mm, preferably 52.1.-52.4 mm. In the larger bite plate, B is 36-39 or about 37.7, A is 68-70 or 69.9-70, and C is 51-52 or 51.5-51.9.

Table 1: Optimal bite plate dimensions

all sizes in mm	Small			Large		
	Open Bite	Deep Bite	Flat Bite	Open Bite	Deep Bite	Flat Bite
A	62.6	62.6	62.7	69.9	69.9	70.0
B	31.9	31.9	31.8	37.8	37.8v	37.8
C	52.1	52.4	52.1	51.9	51.9	51.5
D	5.3	3.5	4.4	5.3	3.5	4.3
E	3.1	3.1	3.1	3.1	3.1	3.0

In general, the bite plate should be the smallest size possible for patient comfort without impinging on the cheeks, tongue and/or interfering with orthodontic appliances. During the course of orthodontic care the patient may require additional bite plates due to

wear, change in occlusion (particularly as the treatment plan corrects maligned dentition), or continued craniofacial growth. Therefore, the fit should be reevaluated at adjustment visits, particularly if the patient complains of poor fit or discomfort.

The bite plates can be sterilized using chemical or autoclaving methods as follows: 1) using full strength Centra Cidex 7 at room temperature for 10 hours; 2) Steam Sterilization with pre-vacuum: 3-4 minutes at 270°F to 274°F (132°C to 134°C) and 28-30 psi (193 – 207 kpa); 3) Steam Sterilization with gravity displacement: 20 – 30 minutes at 250°F (121°C) and 15 -17 psi (104 – 117 kpa). Alternatively, only the sizing plates may be manufactured so as to withstand sterilization, and the customer bite plates can be of different materials.

EXAMPLE 2

In a second embodiment, an improved extraoral vibrator has a more stable vibrator with improved performance characteristics of decreased sound and low variability frequency and force. In particular, the improved vibrator has a noise level less than 55 dB when measured at 6 inches, and preferably less than 50, 45, 40, or 35 dB. The improved vibrator provides a frequency at 20-40 Hz, preferably 30 Hz with a variance of only 2 Hz, and preferably 1 or 0.75 Hz. This is particularly important where the patient may move around during use, whereby lower quality vibrators may vary substantially with motion and/or orientation and thus provides an inconsistency that may be less efficacious, and may make FDA clearance of such a device more difficult. Further, the improved vibrator provides force at 0.1-0.5 Newtons, and preferably at 0.20 Newtons (20 grams) with a variance of ±0.05 N, and preferably less than ±0.03 N.

Consistency of frequency and force is achieved herein via a feedback loop whereby motor speed is monitored and software adjusts the motor as needed. More particularly, the motor contains an integrated encoder that provides multiple high and low signal outputs per every motor revolution. The software counts the time between every encoder event and compares this to the desired target (e.g., 30 Hz). Based on this comparison, the software then adjusts the pulse width modulation that is driving the motor to increase or decrease speed as appropriate to maintain the desired speed. Accurate controlling of speed also controls the force.

A DC 6V Motor having off-set weight and 8 line integrated encoder is known to provide these characteristics, but other vibrators may also provide these performance characteristics, and can be easily tested for same. Preferably the battery is a chargeable 100 mAh Li battery. Preferably, the motor is the Series 1506 DC Motor, by Micromo Electronics, Inc. (Part No. 1506N006SRIE2-8), and the battery is a 100 mAh Li-PO battery by Harding Energy (Part no. BAN-E601421).

Another improvement on the extraoral vibrating device is the provision of a charging stand that serves to dock the vibrator and charge it at the same time. The charging station also has a display and software so that the user can see the usage data. Thus, a dental profession (or parent) can determine whether the patient is using the device as intended. In one embodiment, the display shows the number of uses per week (for example 6/7 = 86%), the number of uses per month (25/30 = 83%)) and the total number of uses (145 uses).

EXAMPLE 3

The bite plate of FIG. 2 shows the substantially U shaped bite plate 1 with clear overcoat 3 covering a stiff inner core 5 (shown as solid). Also shown is the lingual phalange or edge 7 for contacting the lingual surfaces of the teeth, in this instance only the front or anterior teeth (see labial area of FIG. 6), and facial phalange 9 for contacting the facial surfaces of the teeth, as well as connector 2. The phalanges provide additional force transferring contacts with the teeth, but also aid in maintaining the correct position of the bite plate during use. Without the phalanges, the bite plate will vibrate away from the optimal position during use.

FIG. 3 shows the details of the bite plate of FIG. 2, and FIG. 4 includes sizing details of a preferred embodiment of the connector. In a basic configuration the connector 21 is a snap fit connector having a cylindrical shaft 23 that fits into a socket or receptacle on the vibrator. The shaft is of diameter 6-7 mm and preferably 6.35 mm (+0.03, -0.10). Further the shaft length is 5-15 mm, and preferably about 8-12 or 10.25 mm. In a preferred embodiment, the shaft is beveled at the end that fits into the socket to allow for easy insertion (not shown). A groove 25 in the shaft provides the snap fit, wherein a protrusion in the socket snap fits into the groove. The groove is of width >1.4 mm, and depth $\geq$ 0.4 mm, and preferably is of width 1.65 mm and depth at least 0.4 mm, and preferably 0.425 mm (diameter at the groove is 5.5 mm). The groove is positioned approximately midway (35-

65%) along the groove, in this instance 4 mm from the bite plate end of the shaft. However, this distance from either end of the shaft can be modified somewhat, depending on the length of the shaft, and yet the connector will still fit into the same socket.

In this case, we designed a circular coil to spring fit into the groove, as shown, but any appropriately placed protrusions in the socket will suffice, including a protrusion that completely encompasses the circumference of the socket, or two or more small protrusions along the circumference of the socket and in alignment with said groove (not shown). It is known in the art to vary the stiffness of the spring to provide the appropriate degree of tension so that the bite plate is not inadvertently dislodged, yet is easily removed by the patient or dental professional.

Other features of the connector are shown, including pins on either side of the connector, and a flare between the shaft and the bite plate which has two depressions off center from the axis of the shaft in order to prevent the bite plate from being inserted in the incorrect orientation. However, each of these features is exemplary and can be varied widely. For example, the protrusions (pins) and depressions can be varied in number, placement and size, and the flare is optional or can be differently shaped. Preferably, the flare is shaped for easy handling with the thumb and fore finger and thus has the dumbbell shape as shown.

EXAMPLE 4

The intraoral device 111 of FIG. 5 illustrates the core 11 having a battery 31, on/off switch 51, and two vibrators 71. The same device is shown in side view with the clear polymeric coating 91 to form the complete intraoral vibrating dental plate. The minimum intraoral device has an intraoral motor, and is activatable wirelessly (not shown). Thus, the battery and switch can be omitted. However, battery and various controllers can also be provided directly in the device as shown. Further, circuitry can be added to allow this device to store usage information and communication wirelessly with an external controller (not shown).

Another view shows an embodiment wherein segments of the inner core 11 (here shown three) are separated by portions of a polymeric material that serves to dampen vibration from one segment to the other, allowing the dental professional to vibrate 2, 3, 4, 5 or 6 segments of the device individually, thus customizing treatment for each patient. In this

instance, the polymeric overcoat that seals the device is sufficiently soft and elastomeric to also provide the dampening function and thus the same material meets both needs. In other embodiments, two or more different materials are used.

In those embodiments where an external controller is provided for the intraoral bite plate, the controller or processor can provide one or more of the following functions: 1) wirelessly power and activate the vibrators; 2) differentially activate multiple vibrators; 3) synchronize multiple vibrators to have the same frequency and timing; 4) differentially control multiple vibrators to provide different forces; 5) wirelessly charge an internal battery; 6) wirelessly download and display usage information (or transmit such information to an external display); and 7) wirelessly identify the size of the plate. Preferably, the controller has a display and is programmed to provide the dental professional with a variety of usage options via a menu and/or data entry fields, but these functions can also be provided with yet another processor (e.g, a laptop computer) having increased display space and computing power, and the initial processor merely serves as a dedicated interface between the two.

EXAMPLE 5

A pilot clinical study was performed by Chung How Kau, BDS, PhD with an extraoral vibrator and bite plate, as described herein. The study was conducted with 17 subjects, 14 of whom completed the study. Subjects with a Class I malocclusion and at least 6 mm of lower anterior crowding were provided with the device and instructed to use it for 20 minutes daily for six months during orthodontic treatment. Other selection criteria for the study included estimated level of compliance with use of the device in accordance with the instructions and good oral hygiene. Several subjects also required extractions and space closure.

Although compliance varied from patient to patient, patients reported using the device about 80% of the time, while the device microcomputer documented an average of 67% usage. No adverse events were reported during the study, and most patients watched television, listened to music, or played video games while using the device. The most common word used to describe device use was "easy."

A cone beam device (GALILEOS,™ by SIRONA™) was utilized to accurately measure tooth roots and to estimate any resulting root resorption, with imaging in all three

planes (sagittal, axial and coronal views). The study was designed to determine if any root resorption greater than 0.5 mm occurred or if there were alterations in root lengths, and no significant losses were found.

The study also measured distances between teeth using a digital caliper. The overall distance in millimeters between the front five teeth, both upper and lower, was calculated during the alignment phase. The gap between teeth due to extractions was measured directly. The overall movement rate during the study was 0.526 mm per week, which is higher than average movement without the device.

We conclude that the device increases the rate of orthodontic tooth movement and can be used with either fixed orthodontic appliances or clear aligners, offering flexibility. This is useful given the mix of orthodontic therapies available and particularly since some patients have combination therapy utilizing both fixed orthodontic appliances and clear aligner therapy. Short-term daily use for 20 minutes provides an advantage for patients.

The following references are expressly incorporated in their entirety:

- US2006287620
- US2007103016
- US2007161461
- US2007161931
- US2007179414
- US2007208284
- US2007255188
- US2007299372
- US2008129130
- US2008227046
- US2009051312
- US2009058361
- US2009224616
- US4244688
- US4348177
- US4382780
- US5030098
- US5554971
- US5780958
- US5967784
- US6632088
- US6684639
- US6832912
- US6870304
- US7029276

- WO200178217
- WO2007116654

What is claimed is:

1. A bite plate for a vibrating dental device for correcting malocclusion, the bite plate being substantially U shaped and having two ends that can contact one or more molar teeth, a front end that can contact one or more anterior teeth, a midline bisecting the U, a width A perpendicular to the midline, a length C parallel to the midline, and a thickness E, wherein said thickness E is 2-10 mm, wherein the bite plate is one of three configurations:

a) thickness E does not substantially vary from said ends to said midline;

b) thickness E increases from E at said ends to E plus 0.5-10 mm at said midline;

c) thickness E increases from E at said midline to E plus 0.5-10 mm towards said ends, or thickness E increases from E at said midline to E plus 0.5-10 mm between said midline and said end and then narrows to E at said end;

wherein each configuration can optionally be in more than one size.

2. The bite plate of claim 1, further comprising one or more raised edges on said bite plate to contact a lingual surface of one or more teeth or a facial surface of one or more teeth or both.

3. The bite plate of claim 1, further comprising a connector at said midline and facing away from said ends that is shaped to operably couple said bite plate to an extraoral vibrating device.

4. The bite plate of claim 3, wherein said connector comprises a cylindrical shaft of diameter 6-7 mm and length 8-12 mm and having a groove approximately midway (35-65%) along the shaft length, wherein said groove circumnavigates the shaft and is of width >1.4 mm and depth > 0.4 mm.

5. The bite plate of claim 1, comprising a stiff inner core and a biocompatible polymeric coating.

6. The bite plate of claim 5, wherein the stiff inner core is aluminum or steel or polycarbonate.

7. The bite plate of claim 5, wherein the biocompatible polymeric coating is a polyurethane, silicone, polyethylene, high density polyethylene, polycarbonate, polypropylene,

polyvinylchloride, polymethyl methacrylate, polyvinylidene fluoride, polyesters, acrylics, vinyl, nylon, rubber, latex, Teflon, and copolymers thereof.

8. The bite plate of claim 5, wherein the biocompatible polymeric coating is a polyurethane polymer or silicone polymer or copolymers thereof.

9. The bite plate of claim 5, wherein the biocompatible polymeric coating is custom shapeable to fit a patient.

10. The bite plate of claim 1 wherein the width A of the U-shaped bite plate ranges from 62-70 mm and the length C ranges from 51-53 mm.

11. An vibrating dental device comprising a detachable bite plate, and an extraoral vibrator operatively coupled to said detachable bite plate and an optional power source operably coupled to said vibrator, each of said vibrator and optional power source contained within a housing, wherein said vibrator provides less than 55dB of noise when in use and measured 6 inches from said device, and provides a frequency of 20-40 Hz with a variance of less than 2 Hz, and a force of 0.1-0.5 Newtons with a variance of less than 0.05 Newtons.

12. The vibrating dental device of claim 11, wherein said vibrator comprises a 3-6V DC off set weighted motor with 8 line integrated encoder to provide vibration.

13. The vibrating dental device of claim 11, wherein said power source comprises a 100-200 mA, rechargeable lithium battery.

14. The vibrating dental device of claim 11, wherein the frequency is 30 Hz +/- 0.75 Hz, and the force is 0.2 Newtons +/- 0.03 Newtons.

15. A connector for connecting a bite plate to an extraoral vibrator, comprising a connector protruding from a bite plate shaped to contact one or more teeth, wherein said connector comprises a cylindrical shaft of diameter 6-7 mm and length 8-12 mm and having a groove approximately midway (35-65%) along the shaft length, wherein said groove circumnavigates the shaft and is of width >1.4 mm and depth > 0.4 mm.

16. The connector of claim 15, wherein said shaft is beveled at an insertion end that fits into a

socket of a vibrator.

17. An intraoral vibrating dental plate, comprising:

a) a bite plate shaped to contact one or more teeth and comprising a core of material sufficiently rigid to transmit vibration,

b) at least one vibrator operatively mounted onto said core, and optionally a battery and on/off switch for operating said vibrator operatively mounted onto said core,

c) said core, and optional vibrator, battery and on/off switch for operating said vibrator being coated with a hermetically sealed biocompatible polymer.

18. The intraoral vibrating dental plate of claim 17, wherein said biocompatible polymer is a medical grade polymer.

19. The intraoral vibrating dental plate of claim 18, wherein the medical grade polymer is selected from the group consisting of polyurethane or silicone polymers and copolymers thereof.

20. The intraoral vibrating dental plate of claim 17, wherein the core is plastic or aluminum or steel and has one or more depressions therein shaped for receiving one or more of the vibrator and battery and on/off switch.

21. The intraoral vibrating dental plate of claim 17, wherein the vibrator is activated wirelessly from an extraoral controller.

22. The intraoral vibrating dental plate of claim 17, wherein the vibrator is a piezoelectric vibrator or an off-set weight vibrator or a disc shaped shaftless vibration motor.

23. The intraoral vibrating dental plate of claim 17, wherein said battery is a lithium battery or an alkaline battery or a hydrogen battery or a wirelessly chargeable battery.

24. The intraoral vibrating dental plate of claim 17, further comprising a bar code or unique serial number on said coating of bite plate.

25. The intraoral vibrating dental plate of claim 17, wherein said polymeric coating is clear and further comprising a bar code or unique serial number on said inner core of said bite plate.

26. The intraoral vibrating dental plate of claim 17, further comprising an activatable sound recording on said inner core.

27. The intraoral vibrating dental plate of claim 17, further comprising an identification chip on said inner core.

28. A vibrating dental device comprising a detachable bite plate, and an extraoral vibrator and controller contained within a housing and operably coupled to the detachable bite plate, and further comprising one or more of i) a custom colored housing, ii) a unique serial number on the exterior of the housing or inside the housing, iii) a bar code on the exterior of said housing, iv) a sound recording on said bite plate, v) an identification chip inside said housing or on said bite plate, or vi) a compatible charging station for charging the vibrator and for displaying usage information.

29. A bite plate sizing tray comprising, at least two bite plates of differing sizes and a container for holding the bite plates.

30. The bite plate sizing tray of claim 29, wherein there are 6 bite plates of differing sizes as claimed in claim 1 and wherein the container holds the bite plates in a horizontal configuration.

31. The bite plate sizing tray of claim 29, where each bite plate has a scannable chip or activatable sound recording therein or thereon identifying the size of said bite plate.

FIGURE 1

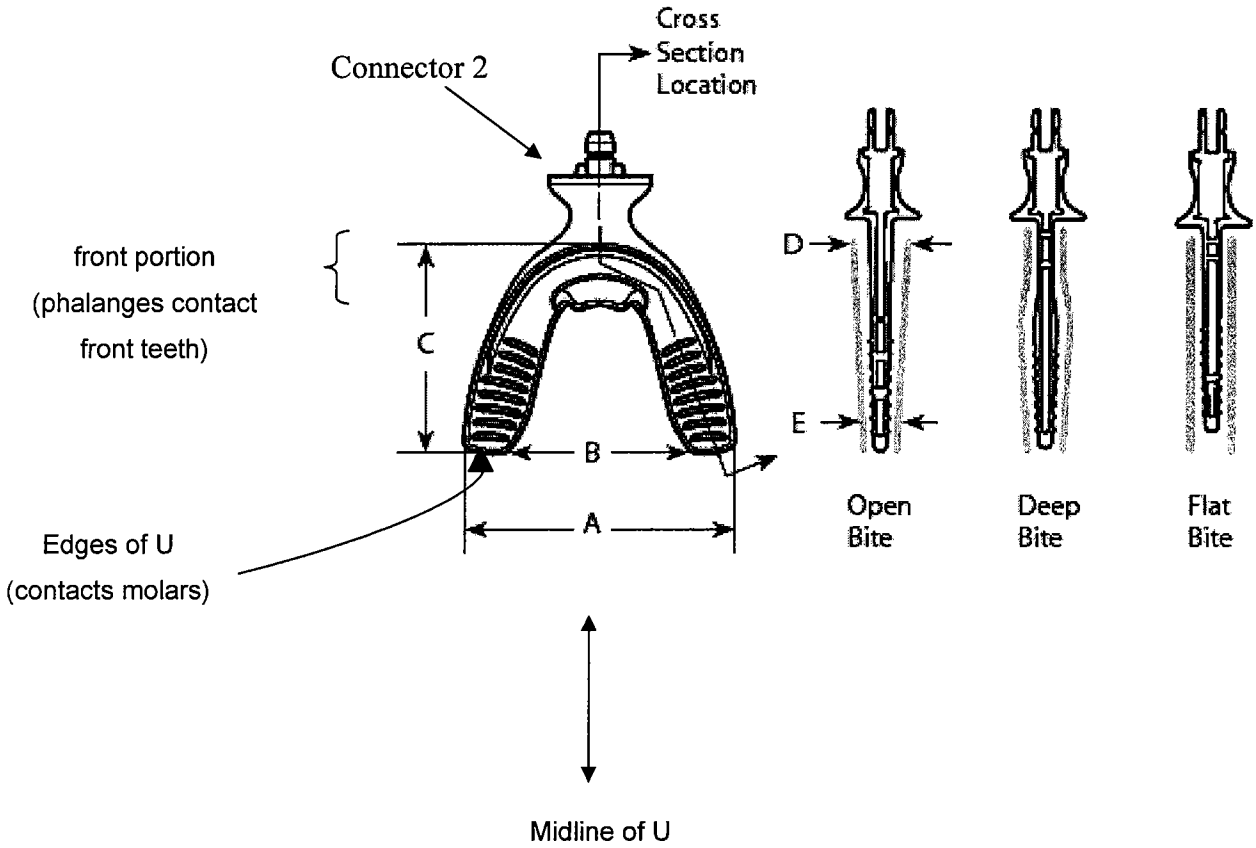

Cross
Section
Location
Connector 2
front portion
(phalanges contact
front teeth)
C
B
A
Edges of U
(contacts molars)
Midline of U
D
E
Open
Bite
Deep
Bite
Flat
Bite

FIGURE 2

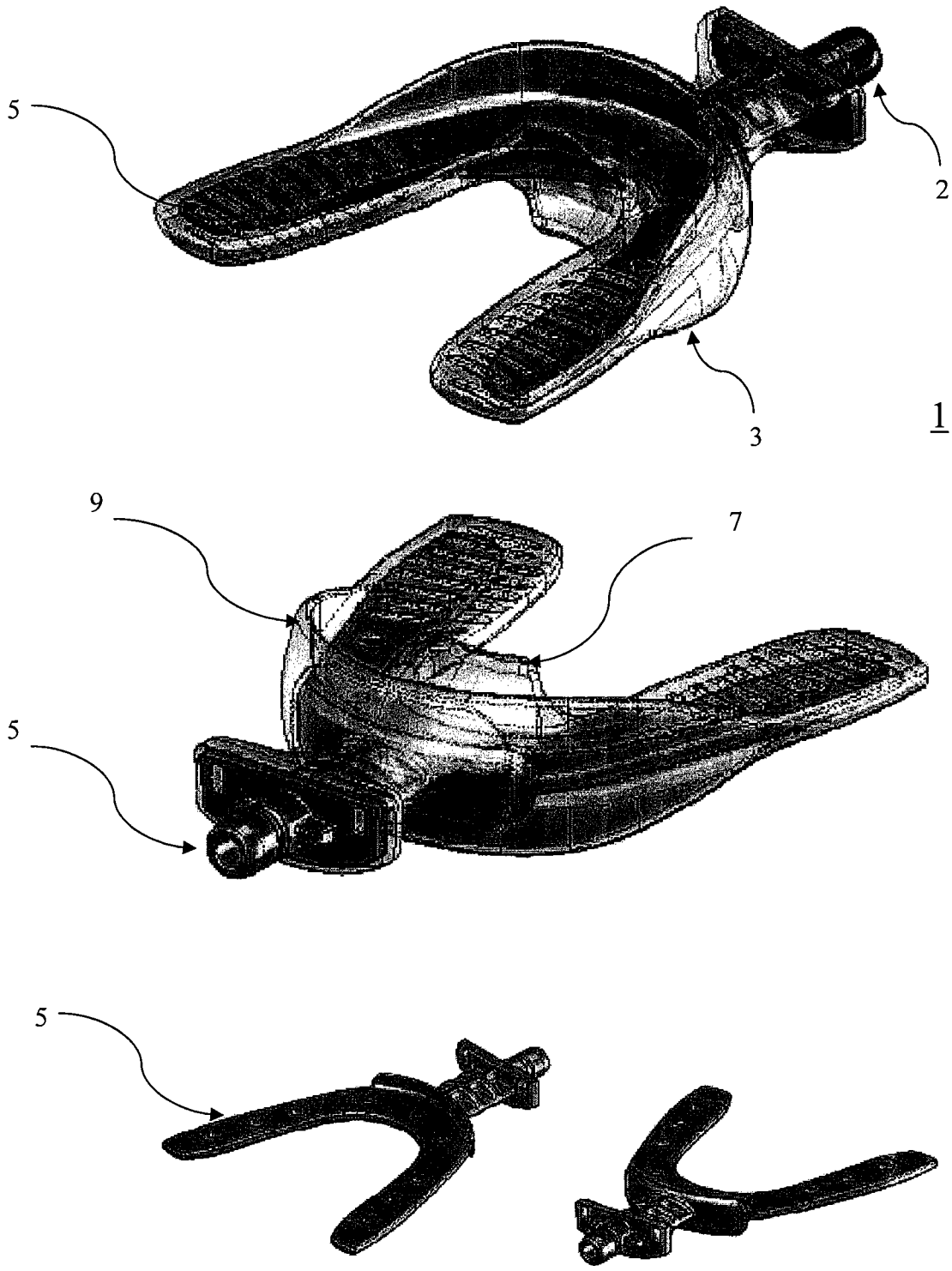


FIGURE 3

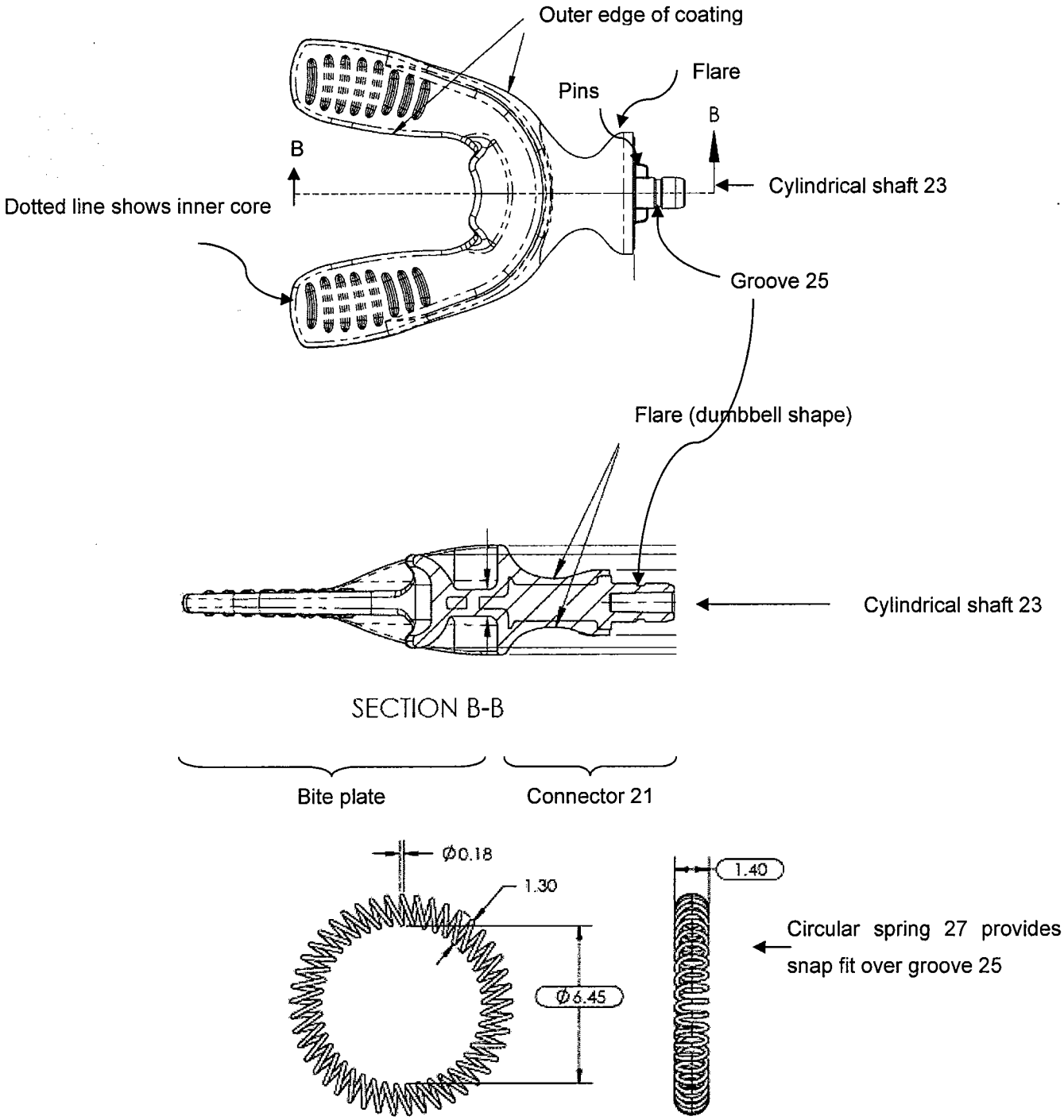
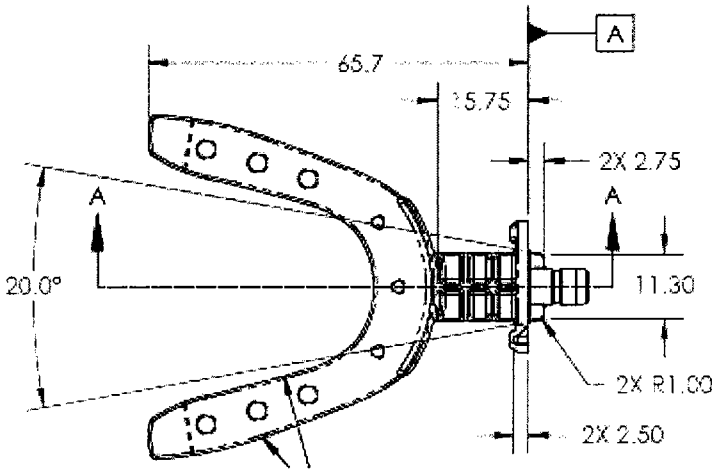

Outer edge of coating
Pins
Flare
B
B
Dotted line shows inner core
Cylindrical shaft 23
Groove 25
Flare (dumbbell shape)
Cylindrical shaft 23
SECTION B-B
Bite plate
Connector 21
Ø0.18
1.30
Ø6.45
1.40
Circular spring 27 provides snap fit over groove 25

FIGURE 4


A
65.7
15.75
2X 2.75
A
A
20.0°
11.30
2X R1.00
2X 2.50

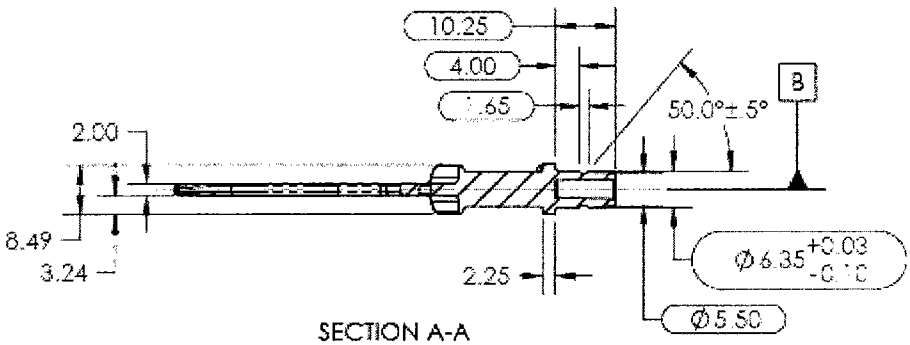

10.25
4.00
1.65
50.0°±.5°
B
2.00
8.49
3.24
2.25
Ø6.35 +0.03 -0.10
Ø5.50
SECTION A-A

FIGURE 5

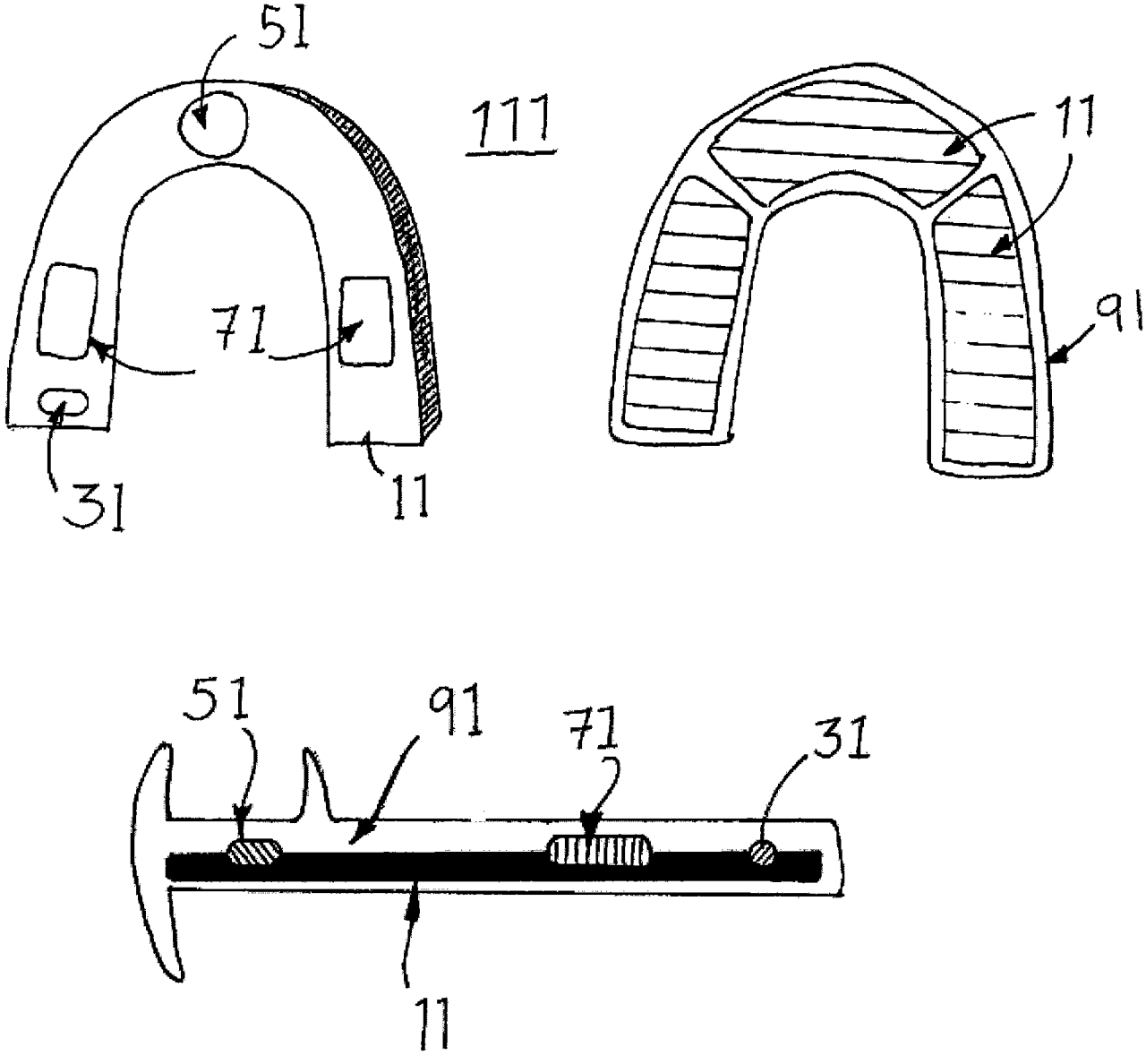
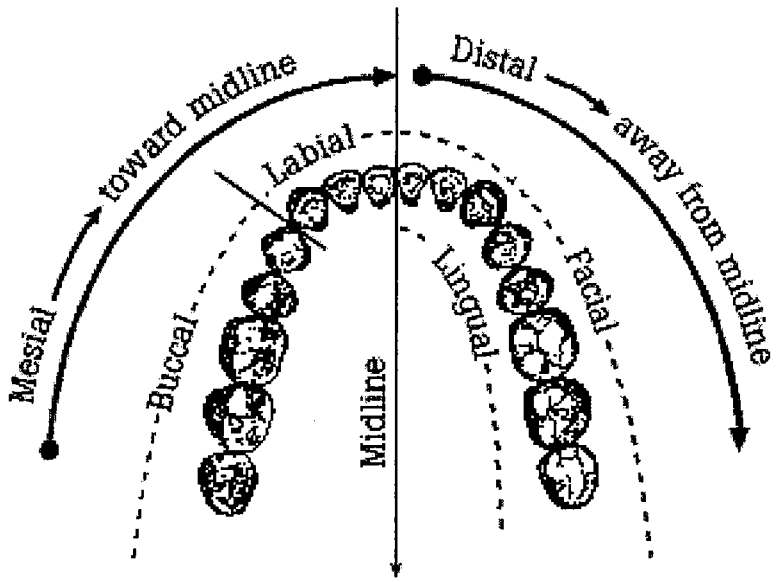
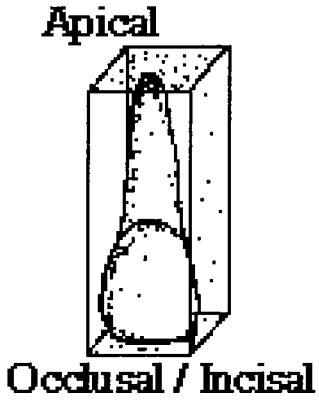


FIGURE 6


Mesial
toward midline
Distal
away from midline
Labial
Buccal
Lingual
Facial
Midline


Apical
Occlusal / Incisal

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/034303

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61C 7/06 (2010.01)
USPC - 433/5
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61C 7/06; A61H 23/00 (2010.01)
USPC - 433/5, 6, 18, 24; 601/46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase and Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	WO 2009/123965 A1 (RUBIN et al) 08 October 2009 (08.10.2009) entire document	1-3, 5-10 ---------- 4, 11-16, 19, 21-23
X -- Y	US 2009/0061379 A1 (YAMAMOTO et al) 05 March 2009 (05.03.2009) entire document	17-18, 20 ---------- 19, 21-27
X -- Y	US 2008/0032248 A1 (KUO) 07 February 2008 (07.02.2008) entire document	29, 31 ------- 24-28
Y	US 6,899,715 B1 (BEATY) 31 May 2005 (31.05.2005) entire document	4, 12, 15, 16
Y	US 5,967,784 A (POWERS) 19 October 1999 (19.10.1999) entire document	11-14, 28
Y	US 7,173,362 B2 (MAGNUSSEN et al) 06 February 2007 (06.02.2007) entire document	11-14

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 July 2010	15 JUL 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/034303

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 30
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.