IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ORTHOACCEL TECHNOLOGIES, INC. *and* BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS,

Plaintiffs,

v.

PROPEL ORTHODONTICS, LLC,

Defendant.

Civil Action No. 1:16-cv-10641

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs OrthoAccel Technologies, Inc. ("OATI") and the Board of Trustees of the University of Illinois (the "Trustees") (OATI and the Trustees, collectively, "Plaintiffs") file this First Amended Complaint against Defendant Propel Orthodontics, LLC ("Propel") bringing an action for the infringement of U.S. Patent No. 6,648,639 (the "'639 patent," attached hereto as Exhibit 1), owned by the Trustees and exclusively licensed to OATI. In support of their claims of patent infringement, Plaintiffs allege as follows:

I. PARTIES

1. OATI is a Delaware corporation having its principal place of business at 6575 West Loop South, Suite 200, Bellaire, Texas, 77401.

2. The Trustees is a body corporate and politic of the State of Illinois, pursuant to the University of Illinois Act, 110 ILCS § 305, et seq., having places of business in Chicago and Urbana, Illinois.

3. Propel is a Delaware limited liability company. Upon information and belief, Propel maintains its principal place of business at 233 S. Highland Avenue, Ossining, New York,

10562. Propel may be served at 1900 East Golf Road Suite 950, Schaumburg, Illinois, 60173, which is the address of its registered agent for service of process in Illinois.

II. JURISDICTION AND VENUE

4. Subject matter jurisdiction over this cause of action for patent infringement in this case is proper under 28 U.S.C. §§ 1331 and 1338(a) because the cause of action raises a federal question under the patent laws of the United States, Title 35 of the United States Code.

5. The Trustees are the assignee and owner of legal title to the ’639 patent. OATI is the exclusive licensee of the ’639 patent. Plaintiffs therefore possess all rights under the ’639 patent and have standing to sue for infringement of the ’639 patent.

6. This Court has personal jurisdiction over Propel. Propel is registered to do business in Illinois. Part of that business includes sales and marketing of Propel’s VPro5 product directed at orthodontists in the Northern District of Illinois, including in the Chicago metropolitan area.

7. On information and belief, Propel has directed marketing and sales efforts for the VPro5 in this district and has an established presence in this district for the purpose of sales and marketing. On information and belief, Propel has sold the VPro5 product in this district and has instructed orthodontists in this district on the use of the VPro5, including by providing oral and written instructions. On information and belief, Propel has also provided such orthodontists with instructions to be given to patients in this district. On information and belief, orthodontists are providing the VPro5 product and instructions to patients, who are using the VPro5 product with clear aligners as instructed. Propel has therefore engaged in the alleged infringing acts in this district.

8. For example, one family of orthodontic practices advertises their use of the VPro5 product to treat patients in Antioch, Grayslake, and Gurnee, Illinois. (Exhibit 2.) In another

example, an orthodontic practice with offices in Lake Forest and Round Lake Beach, Illinois lists the VPro5 among its "Top five products used." (Exhibit 3.)

9. In addition, the Trustees have a place of business in this district.

10. Venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

III. FACTUAL BACKGROUND

A. The Origin of the '639 Patent

11. The '639 patent, entitled *Device and Method for Treatment of Malocclusion Utilizing Cyclical Forces*, issued on November 18, 2003. Dr. Jeremy Mao is the sole inventor of the '639 patent.

12. Prior to the invention of the '639 patent, the field of orthodontics relied on relatively static forces to treat malocclusions and other conditions. Dr. Mao discovered that cyclical forces could be used in combination with other orthodontic techniques to treat malocclusions. Dr. Mao applied for and received patents relating to this discovery, including the '639 patent.

13. At the time Dr. Mao conducted this research, he was a professor at the University of Illinois at Chicago. Dr. Mao assigned his invention to the Trustees.

B. OATI Has Built a Successful Enterprise on the Foundation of the '639 Patent

14. Subsequently, the founders of OATI approached the representatives of the Trustees about receiving an exclusive license to the patents Dr. Mao received on his invention, including the '639 patent. They founded OATI on the belief that Dr. Mao's invention, once it was developed into a commercial product, had the potential to revolutionize orthodontic treatment by accelerating the treatment process for millions of patients.

15. OATI started in 2007 as a company with just three employees and a handful of technical advisors, including Dr. Mao. The company's first product (below), which it marketed under the mark AcceleDent®, was the commercial embodiment of Dr. Mao's invention.

16. As shown in the picture, the AcceleDent® device includes a bite plate connected to a central hub for the electronic and electrical components. A patient uses the AcceleDent® device by biting the bite plate and activating the device, which produces cyclical forces in the hub that are transmitted through the bite plate.

17. OATI first launched the AcceleDent® device outside the United States in late 2009, while product launch in the United States was delayed until 2012, after OATI received FDA approval to market the product on November 5, 2011. OATI has achieved great commercial success with the AcceleDent® device. For example, when it is launched in a new country, sales of the AcceleDent® device rapidly grow in the period immediately following launch.

18. OATI launched the successor to the AcceleDent® device, the AcceleDent® Aura™ device (below), in 2013.

The AcceleDent® Aura™ device is now sold in 36 countries around the world.

19. OATI, which started as a company of 3 employees less than a decade ago, now employs over 100 people. This growth is entirely due to the sales of the AcceleDent® device and its successor, which are the only products currently marketed by OATI.

20. In addition, the AcceleDent® device received numerous awards and commendations, including the Michael E. DeBakey Award in 2007 and design excellence awards from Appliance Design magazine in 2010, in the Medical, Laboratory, & Test Equipment category, and from Medical Device and Diagnostic Industry in 2011, in the Dental Instruments, Equipment, and Supplies category.

21. To date, OATI has sold over 80,000 units of the AcceleDent® device and its successor products in the United States alone, for which the Trustees receive royalties.

C. Propel Unlawfully Copied The AcceleDent® Device and Infringed the '693 Patent

22. On information and belief, Propel obtained one or more of OATI's AcceleDent® devices in order to copy the design. The resulting product, Propel's VPro5, infringes at least claim 1 of the '693 patent. Propel's VPro5 is shown below:

23. The VPro5 comprises a white plastic hub that houses electrical and electronic components. The hub contains a microprocessor that, on information and belief, produces a cyclical force. The hub also contains a motor, and when the processor sends a signal, the motor is powered by a rechargeable battery that is also contained in the hub. The motor includes an eccentric weight that exerts a force in a cyclical manner when the motor is powered.

24. The VPro5 also includes a bite plate that is designed to connect to the hub. In accordance with Propel's patient instructions for the VPro5 (*see* Exhibit 4), a patient bites down on the bite plate while wearing clear aligners. The clear aligners exert a force on the patient's teeth.

25. According to Propel's patient instructions, the patient then pushes a button, which, on information and belief, signals the microprocessor to activate the motor. The cyclical forces generated in the hub are then transmitted through the bite plate.

26. On information and belief, Propel provides with the VPro5 instructions for its customers, such as the ones in Exhibit 4, to orthodontists for distribution to patients. On information and belief, Propel sells and offers to sell the VPro5 to orthodontists whose patients use the VPro5 in a manner consistent with the instructions.

27. On information and belief, Propel had OATI's AcceleDent® device and substantially copied it to arrive at the design of the VPro5, intending for the VPro5 to be used in essentially the same manner by patients as the AcceleDent® device. Propel did this despite the fact that the AcceleDent® device (and its successor) have always been marked with the '693 patent. Thus, on information and belief, Propel was aware of or willfully blind to the existence of the '693 patent. And, on information and belief, Propel either knowingly copied a product whose use is covered by the '693 patent or was willfully blind to the risk of infringing the '693 patent. At a minimum, Propel is now aware of the '693 patent as of the filing of this Complaint and its infringement of the '693 patent by virtue of the allegations herein.

IV. COUNT I – INFRINGEMENT OF THE '693 PATENT

28. Plaintiffs re-allege and incorporate by reference the allegations of Paragraphs 1 through 27 above as though fully set forth herein.

29. Propel's sale, manufacture, use, and/or offer for sale of the VPro5 directly and/or indirectly infringes at least claim 1 of the '693 patent literally and/or under the doctrine of equivalents.

30. Patients using the VPro5 while wearing clear aligners, consistent with Propel's instructions, directly infringe at least claim 1 of the '693 patent. Propel induces this use at least by selling and offering for sale the VPro5, by providing instructions directly or indirectly to patients, by providing instructions and demonstrations to orthodontists, and by generating and distributing marketing materials to orthodontists touting the benefits of patients using the VPro5 while wearing clear aligners. Propel's acts also constitute contributory infringement because the VPro5 is not a staple article of commerce and does not have substantial uses other than as described in Propel's instructions.

31. On information and belief, Propel has known or been willfully blind to the existence of the '693 patent since before it began selling the VPro5. Moreover, because Propel designed the VPro5 by copying a marked product, Propel knew or was willfully blind to the fact that the use of the VPro5 would infringe the '693 patent and intentionally induced such use. Furthermore, Propel knows of the '693 patent due to the filing of this complaint.

32. Based on the foregoing facts, Propel's infringement of the '693 patent was and is willful.

33. Propel's infringement has harmed and will continue to harm Plaintiffs unless it is enjoined by this Court. For example, OATI has lost sales to Propel and the Trustees have lost revenues from the royalties earned on OATI's sales. In addition, OATI has lost market share to Propel and goodwill for its brand as a result of Propel's infringement.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. A judgment declaring that Propel has infringed and is infringing at least claim 1 of the ’693 patent;

2. A judgment awarding Plaintiffs compensatory damages resulting from Propel’s infringement of the ’693 patent in the form of lost profits and in no event less than a reasonable royalty, together with interest and costs;

3. A judgment awarding Plaintiffs treble damages and pre-judgment interest under 35 U.S.C. § 284 as a result of Propel’s willful and deliberate infringement of the ’693 patent;

4. A judgment declaring that this case is exceptional and awarding Plaintiffs their expenses, costs, and attorneys’ fees in accordance with 35 U.S.C. §§ 284 and/or 285 and/or Rule 54(d) of the Federal Rules of Civil Procedure;

5. A grant of preliminary and permanent injunctions enjoining Propel from further acts of infringement of the ’693 patent; and

6. Such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demands a trial by jury.

Dated: November 22, 2016

By: /s/ Melissa A. Anyetei

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Counsel for OrthoAccel Technologies, Inc. and the Board of Trustees of the University of Illinois

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on November 22, 2016, a true and correct copy of the foregoing **FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL** is being served upon Propel Orthodontics, LLC via hand delivery on its registered agent for service at 1900 East Golf Road Suite 950, Schaumburg, Illinois, 60173.

By: /s/ Melissa A. Anyetei

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Counsel for OrthoAccel Technologies, Inc. and the Board of Trustees of the University of Illinois

EXHIBIT 1

US006648639B2

(12) **United States Patent**
Mao

(10) **Patent No.: US 6,648,639 B2**
(45) **Date of Patent: Nov. 18, 2003**

(54) **DEVICE AND METHOD FOR TREATMENT OF MALOCCLUSION UTILIZING CYCLICAL FORCES**

(75) Inventor: **Jeremy Jian Mao**, Chicago, IL (US)

(73) Assignee: **The Board of Trustees of the University of Illinois**, Chicago, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/957,770**

(22) Filed: **Sep. 21, 2001**

(65) **Prior Publication Data**

US 2002/0072029 A1 Jun. 13, 2002

Related U.S. Application Data

(60) Provisional application No. 60/234,530, filed on Sep. 22, 2000.

(51) **Int. Cl.**[7] **A61C 7/00**
(52) **U.S. Cl.** **433/18**
(58) **Field of Search** 433/24, 18, 7, 433/5, 20

(56) **References Cited**

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Storey et al., (1952) *Aust. J. Dent.*, 56:11–18.
Pygh et al., (1982) In Berkivitz et al. (Eds) *The Periodontal Ligament in Health and Disease,* Pergamon Press, Oxford, England, pp. 269–290.
Jager et al., (1993) *Histochemistry*, 100:161–166.
Ashizawa et al., (1998) *Arch Oral Biol.*, 43(6):473–484.
Gu et al., (1999 *Angle Orthod.* 69(6):515–522.
Melsen (1999) *Angle Orthod.*, 69(2):151–158.
Terai et al., (1999) *J. Bone Miner. Res.*, 14(6):839–849.
Tsay et al., (1999) *Am. J. Orthod. Dentofacial Orthop.*, 155(3):323–330.
Verna (1999) *Bone*, 24(4):371–379.
van Leeuwen et al., (1999) *Eur. J. Oral Sci.*, 107(6):468–474.

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Primary Examiner—Kevin Shaver
Assistant Examiner—Melba Bumgarner
(74) *Attorney, Agent, or Firm*—Welsh & Katz, Ltd.

(57) **ABSTRACT**

Methods of treating malocclusion and inducing osteogenesis as well as an apparatus for treating malocclusion are described. The methods and apparatus utilize cyclic forces as compared to static forces to achieve their results.

14 Claims, 2 Drawing Sheets

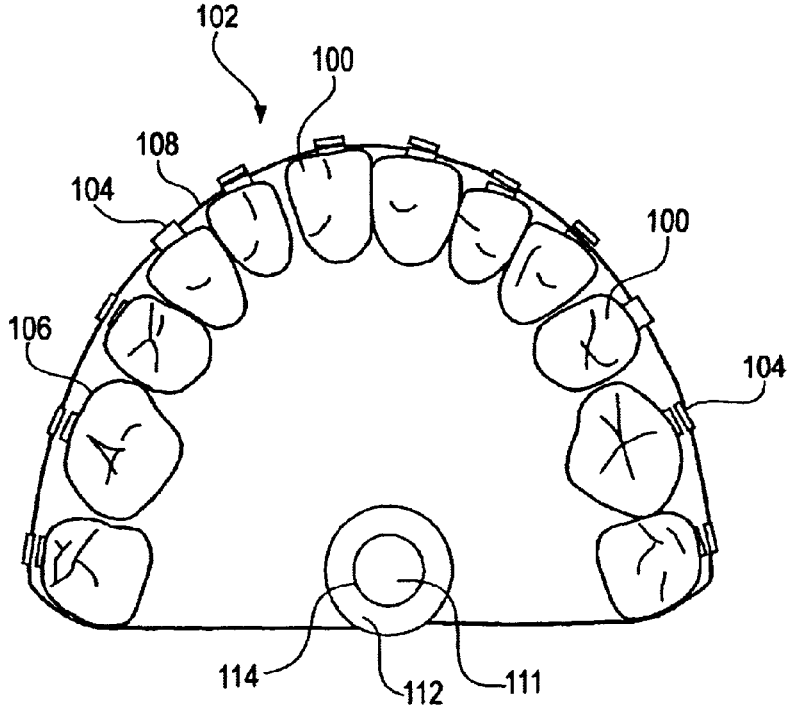

FIG. 1

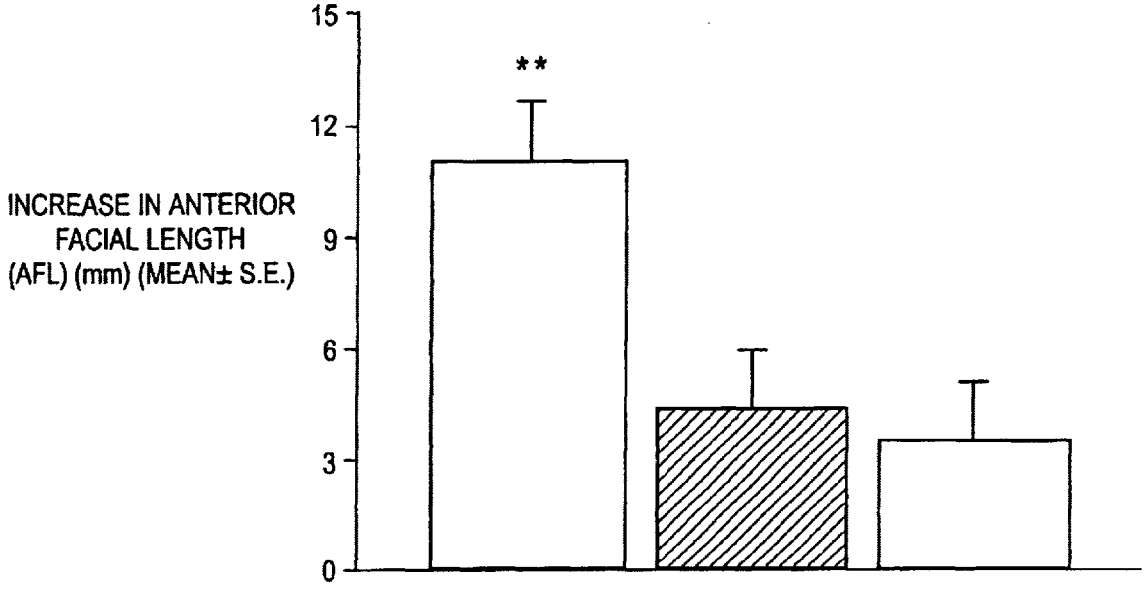
INCREASE IN ANTERIOR FACIAL LENGTH (AFL) (mm) (MEAN± S.E.)
15
12
9
6
3
0
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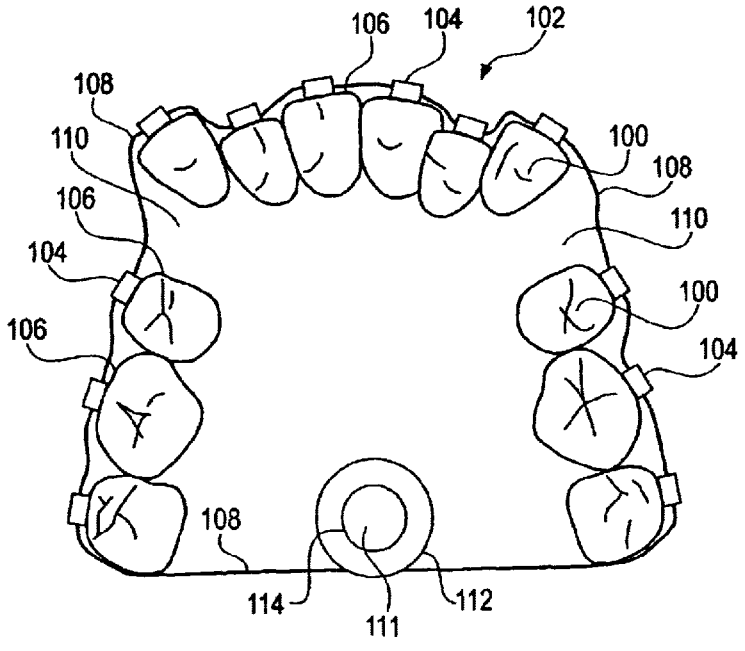
FIG. 2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112

FIG. 3

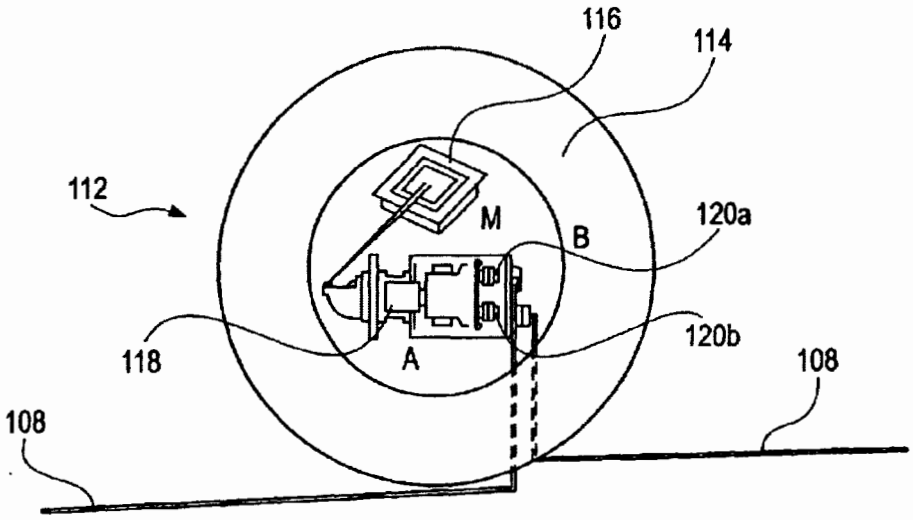
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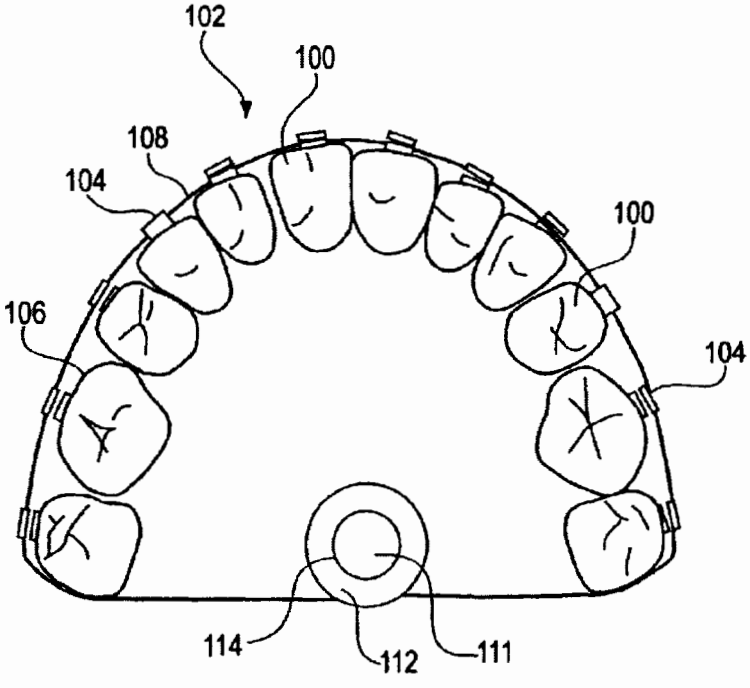
FIG. 4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DEVICE AND METHOD FOR TREATMENT OF MALOCCLUSION UTILIZING CYCLICAL FORCES

BACKGROUND OF THE INVENTION

Orthodontics involves purposefully moving teeth towards a certain predefined pattern so that the tooth row has an esthetically pleasing look. The condition of crowded or crooked teeth is called malocclusion. Although ancient attempts to correct malocclusion date back to 1000 BC, modern orthodontics began slightly more than a century ago [Proffit et al., (1993) *Mosby Year Book*: St. Louis. pp. 266–288].

In late 1800s, Edward Angle placed metal bands on the teeth and used continuous wires that fit into the slots of the bands. Elastics were used to apply forces with a result of aligning the teeth along the "track" of the wire. The forces applied by Angle were static and continuous, meaning that once the forces have been generated by elastics, the forces are continuously present unless and until they decayed to nil.

Since Angle's practice, orthodontists have used static forces to induce orthodontic tooth movement. Contemporary orthodontic treatment takes an average of two years to complete in one patient, involving multiple visits and repeated activations; i.e., reasserting the force on the teeth. No one has attempted to determine whether cyclic forces; i.e., forces with rapidly varying magnitude over time, induce more rapid tooth movement than the presently used continuous forces.

Orthodontics involves the use of mechanical forces to move teeth within the jaw bone and therefore, relies on force-induced bone remodeling. A force is a physical quantity and has several essential properties such as the magnitude, direction, point of application and frequency. All these properties of orthodontic forces have been subjects of scientific research and considered in clinical practice of orthodontics with the exception of force frequency. Exclusive use of continuously applied static forces in orthodontics and the resulting lack of consideration of force frequency contradict the overall scientific consensus-based evidence obtained from orthopedic studies of long bones that cyclic forces induce more effective bone remodeling than static forces of matching magnitude.

The main advantage of the current orthodontic technology of using continuously applied static forces to move the teeth towards predetermined positions to achieve esthetically pleasing look is its predictable, albeit slow, outcome, inducing controlled tooth movement towards predetermined position when treatment is carried out by a competent orthodontist. The principal shortcoming of the current technology is its requirement of excessively long treatment duration: approximately two years on average. The essential reason for this excessively long treatment duration is due to a lack of efficiency resulting from the present use of continuously applied static forces.

More specifically, except as described hereinafter, only continuously applied static forces have been studied and/or used in previous studies and clinical practice in orthodontics. First, about 36 percent of the US population receive orthodontic treatments [Brunelle et al., (1996) *J. Dent. Res.,* 75(Spec Iss):706–713]. Continuously applied static forces are used on a daily basis for orthodontic tooth movement in these patients. Second, in addition to day-to-day practice of application of continuously applied static forces in clinical orthodontics, orthodontic tooth movement has been simulated in animal models with elastics and coil springs [Reitan (1951) *Acta Odont. Scand. Suppl.,* 6:1–240; Storey et al., (1952) *Aust. J. Dent.,* 56:11–18; Pygh et al., (1982) In Berkivitz et al. (Eds) *The Periodontal Ligament in Health and Disease*, Pergamon Press, Oxford, England, pp. 269–290; Jager et al., (1993) *Histochemistry,* 100:161–166; Ashizawa et al., (1998) *Arch Oral Biol.,* 43(6):473–484; Gu et al., (1999 *Angle Orthod.* 69(6):515–522; Melsen (1999) *Angle Orthod.,* 69(2):151–158; Terai et al., (1999) *J. Bone Miner. Res.,* 14(6): 839–849; Tsay et al., (1999) *Am. J. Orthod. Dentofacial Orthop.,* 115(3):323–330; and Verna (1999) Bone, 24(4):371–379]. Without exception, continuously applied static forces have been used in all these studies.

Although there have been previous attempts to use "intermittent forces", the nature of the intermittent forces were static forces applied intermittently over time, for instance, two hours on and two hours off [Reitan (1951) *Acta Odont. Scand. Suppl.,* 6:1–240; van Leeuwen et al., (1999) *Eur. J. Oral Sci.,* 107(6):468–474] instead of the hereinafter described cyclic forces that rapidly change magnitude over short time, e.g. several cycles per second. The current technology of continuous, constant and static forces, such as those used in orthodontics, lacks either frequency modulation or change in force magnitude over time.

In addition to a lack of consideration of force frequency in both research studies and clinical practice of orthodontics as described above, both the threshold force and the duration of force application, which are two additional essential properties of a force, are not clearly understood in the field of orthodontics. First, a minimum of 6 hours has been thought to be the threshold below which orthodontic tooth movement does not occur [Proffit et al., (1993) *Mosby Year Book*: St. Louis. pp. 266–288]. However, this projected minimum threshold of 6 hours per day by Proffit et al. is largely theoretical, as stated in the caption of FIGS. 9–12 on page 275 of that work.

Although empirical clinical experience appears to support the notion that orthodontic forces must be applied beyond certain daily duration in order to induce tooth movement, the precise minimum daily duration is unclear. What appears of more significance than daily minimum duration is the overall duration of orthodontic treatment in association with current technology. The use of cyclic forces in orthodontic tooth movement described hereinafter can significantly shorten the present average two-year duration of orthodontic tooth movement.

Although there are more data on the threshold force magnitude required for tooth movement, the precise threshold is yet to be determined. In general a few hundred grams of force have been implicated to be the threshold for tooth movement. However, there remain projections as "theoretically, there is no doubt that light continuous forces produce the most efficient tooth movement" [Proffit et al., (1993) *Mosby Year Book*: St. Louis. pp. 266–288]. Although it has been shown that proliferation of periodontal ligament cells is greater in response to continuous forces than to intermittent forces of the same magnitude [Reitan (1951) *Acta Odont. Scand. Suppl.,* 6:1–240], the previously investigated intermittent forces were static forces applied intermittently over time [Reitan (1951) *Acta Odont. Scand. Suppl.,* 6:1–240; van Leeuwen et al., (1999) *Eur. J. Oral Sci.,* 107(6):468–474] instead of the presently proposed cyclic forces that rapidly change magnitude within time units of seconds.

Contemporary orthodontists not only use braces to align the teeth, they also use orthopedic appliances such as

headgear and facemask to change the shape of facial bones so that the overall facial shape is esthetically pleasant. The present technology (described hereinafter), in addition to providing a mechanism for rapidly aligning the teeth, also provides pathways by which the shape of facial bones can be rapidly changed, although the precise characteristics of the forces responsible for the two approaches are different. The present invention that is described hereinafter provides for the remodeling of craniofacial bones and treatment of malocclusion through the use of cyclic force application to the region to be remodeled.

BRIEF SUMMARY OF THE INVENTION

In accordance with the present invention, cyclic forces are used to expedite the remodeling of craniofacial bones to correct dentofacial deformities and expedite the remodeling of alveolar bone to treat malocclusion. One aspect of the invention contemplates a method for inducing a predetermined amount of osteogenesis in the craniofacial bones of a mammal in need thereof. That method comprises the steps of (a) applying cyclic forces to a craniofacial suture region of the mammal in which osteogenesis is desired with a peak magnitude of up to about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and frequencies of up to about 40 Hz, and preferably about 0.1 to about 8 Hz, for a predetermined period of time. That application is (b) repeated a plurality of times until a predetermined amount of osteogenesis is obtained.

Another aspect of the invention contemplates a method for realigning one or more of the teeth of a mammal in need thereof. That method comprises the steps of (a) applying cyclic forces to at least one tooth of the mammal in which tooth realignment is desired with a peak magnitude of about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz, in a direction of the desired realignment for a predetermined period of time. That application is (b) repeated a plurality of times until a predetermined amount of tooth realignment is obtained.

A particular apparatus for treating malocclusion is another contemplated aspect of this invention. This apparatus comprises a band and bracket of generally inelastic material that are affixable to one or more teeth. The band has first and second ends that are joined at a centralized hub. A power source connected to an actuator assembly is provided to generate cyclic mechanical forces with a peak magnitude of up to about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz in a direction of the desired realignment desired at the centralized hub and thereby to the band. The power source and actuator are controlled by a microprocessor that can direct the duration of the application of the force as well as the repeated application of the cyclic mechanical force.

A method for treating malocclusion to realign teeth in a mammal in need thereof is another contemplated aspect of this invention. This method comprises the steps of providing a band of generally inelastic material that is affixed to one or more teeth of the mammal to be treated. The ends of the band are joined at a centralized hub. A power source connected to an actuator assembly is used to apply cyclic mechanical forces with a peak magnitude of up to about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz, in a direction of the desired realignment desired at the centralized hub and thereby to the band, the cyclic forces being applied for a predetermined time period. The power source and actuator are controlled by a microprocessor that can direct the duration of the force application and the repeated application of the cyclic mechanical force. The cyclic mechanical forces are applied a plurality of times until the teeth are realigned and malocclusion is treated.

The present invention has several benefits and advantages. One benefit of the invention is its use to substantially markedly shorten the duration of orthodontic treatment as compared to the current technology.

An advantage of the invention is that craniofacial bone restructuring can be accomplished more rapidly than has been possible using previously known techniques.

Another benefit of the invention is an apparatus that can realign maloccluded teeth.

Still further benefits and advantages will be apparent to the skilled worker from the disclosure that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings forming a portion of this disclosure,

FIG. **1** shows bar graphs in which the increase in anterior facial length (AFL) of treated rabbits using a cyclic force application process of the present invention (left), a static force (center) or a sham control (right), and in which error bar tops are shown and double stars above the left graph indicate a statistically significant difference between those values and the values for each of the other two graphs. There is statistically greater amount of bone remodeling upon application of cyclic forces than both the sham control and static force.

FIG. **2** is a diagrammatic view of an orthodontic device utilizing a device of the present invention in place in a human mouth having a malocclusion.

FIG. **3** is a diagrammatic representation of a device of the present invention.

FIG. **4** is a diagrammatic view of the mouth and device of FIG. **2** after treatment with the device of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Static forces have been used for more than a century to modulate osteogenesis of cranial sutures in not only laboratory research but also clinical practice. Cyclic forces are shown here to stimulate more effective sutural osteogenesis than static forces. Similarly, static forces have been orthodontically used for a much longer period of history the realignment of patients' teeth for treating malocclusion. Cyclic forces are similarly used here to achieve a desired orthodontic effect in a reduced period of time.

In accordance with the present invention, cyclic forces are used to expedite the remodeling of teeth and craniofacial bones in living mammal. Thus, this invention concerns the remodeling of a mammal's face by osteogenesis of the craniofacial bones or by realigning one or more of the mammal's teeth. Exemplary mammals are humans, apes, monkeys, rabbits, mice, rats and other laboratory animals as well as companion animals such as cats and dogs, and livestock such as pigs, goats, horses, cattle, sheep and the like.

More specifically, one aspect of the invention contemplates a method for inducing a predetermined amount of osteogenesis in the craniofacial bones of a mammal in need thereof. That method comprises the steps of (a) applying

cyclical forces to a craniofacial suture of the mammal in which osteogenesis is desired with a peak magnitude of up to about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 8 Hz for a predetermined period of time. That application is (b) repeated a plurality of times until a predetermined amount of osteogenesis is obtained.

Another aspect of the invention contemplates a method for realigning one or more of the teeth of a mammal in need thereof. That method comprises the steps of (a) applying cyclical forces to at least one tooth of the mammal in which tooth realignment is desired with a peak magnitude of up to about 10 Newtons, and preferably about 0.1 to about 5 Newtons, and a frequency of up to about 40 Hz, and preferably about 0.1 to about 2 Hz, in a direction of the desired realignment for a predetermined period of time. That application is (b) repeated a plurality of times until a predetermined amount of tooth realignment is obtained.

A cyclical force or force that is applied cyclically is a force that progresses from a first value to a second value and then back toward if not to the first value. That force can also return to a third value that is less than that of the first value and then return to or through the first value.

In an idealized situation, where the initial force is taken as zero at time zero, a cyclical force can resemble a sine wave over a given time period, which time period is referred to as the wave length. Thus, continuing with the idealized example, the first force value is zero, the second value is one, the force returns to zero and then to minus one and back to zero again before returning to one in the next cycle. There is no net force vector for each cycle of force application in this idealized example. This type of cyclical force is similar to a wiggle, and is particularly useful for inducing osteogenesis in craniofacial sutures.

In another type of cyclical force, there is a net directional vector to the force. Here, in a typical idealized situation, the first force at time zero can again be zero and the second force value can be one, but the third force value on average is greater than minus one so that there is an average net positive force vector for each cycle of force application. Preferably, the force value returns from the second value to about the first value in each cycle. Continuing the analogy from above to the sine wave, the type of force having a net vector can be analogized to a rectified or fully rectified wave that is formed on converting alternating current to direct current.

Continuing the wave form analogy further the peak magnitude of the force applied or the amplitude is up to about 10 Newtons (N), preferably up to about 5 N, and is more preferably up to about 2 Newtons. These amplitudes apply to either type of cyclical force. Minimal peak magnitude values are about 0.1 N.

The cycle time at which the application of force is repeated is the wavelength. The reciprocal of the wavelength measured in seconds is the frequency or cycles per second and is in units of Hertz (Hz). Illustrative cyclical forces are applied at about 0.1 to about 40 Hz, preferably at about 0.1 to about 8 Hz, more preferably at about 0.1 to about 2 Hz, more preferable still 0.2 to about 1.5 Hz, and most preferably at about 0.2 to about 1 Hz, although forces of higher frequency can further accelerate bone remodeling.

The cyclical force is applied for a predetermined time period. That time period is typically shorter where higher frequencies are used and longer where lower frequencies are used. A typical time period (duration for the application of the cyclic force) for the before-discussed frequencies is about one minute to about 30 minutes, and more preferably for about 5 minutes to about 20 minutes. Thus, the force is applied repeatedly. The time between repeated force applications can be minutes to days. Typically, the force is applied one or more times in each 24-hour time period (per day), and that application is repeated. When applied a plurality of times per day, the force is applied periodically such as every hour or every three hours, or the like.

These cyclical applications of force are continued until the desired or predetermined amount of osteogenesis or reduction of malocclusion (tooth realignment) is achieved. This time period is typically several months to up to about two years, depending on the degree of treatment required.

Although the present invention is susceptible of embodiment in various forms, there is shown in the drawings a number of presently preferred embodiments that are discussed in greater detail hereafter. It should be understood that the present disclosure is to be considered as an exemplification of the present invention, and is not intended to limit the invention to the specific embodiments illustrated.

Referring now to FIG. **2**, tooth **100**, in a jaw having malocclusion, are shown having an intraoral orthodontic appliance **102** thereon. As is typical in such appliances, FIG. **2** shows that each tooth **100** has been fitted with a bracket **104**, which is typically cemented to the outer surface **106** of each tooth, and a generally inelastic band **108**, all made in a manner and of materials well known in the art. Band **108** is attached, through slots defined in each bracket **104** (as known in the art) to the brackets **104** and tightened. It is known that the band, of device of the prior art, generally is tightened at regularly scheduled orthodontist appointments throughout, typically, a six-month to two-year period. It will be seen, as the description proceeds, that the device of the present invention presents a means and method of continuously tightening a variation of such appliances throughout the treatment period.

As will be seen in FIG. **2**, some of the teeth are separated by spaces **110**, which may result from natural missing teeth, thumb or finger sucking or through dental extraction purposefully made to provide space for the movement of the teeth **100** to a pleasing position in the jaw. It will be understood by persons having skill in the art, that any of a plurality of orthodontic devices can be used, in manners well known in the art, in association with the device of the present invention, without departing from the novel scope of the present invention. It will also be understood that the present device can be used on fewer that all of the teeth in a jaw, such that corrective movement will be effected on only those teeth. The use of the devices illustrated herein is merely for illustrative purposes and is not meant as a limitation to the present invention.

As a departure from typical orthodontic devices of the prior art, and as shown in FIG. **2** and FIG. **4**, the generally inelastic band **108** of the device of the present invention is formed as a continuous band, in that the ends of the band are joined at a centralized hub **111**. As known to persons having skill in the art, typically, in prior art orthodontic devices the band is fixed to a tooth at each side of the jaw, and is therefore not continuous. It will also be known by persons having skill in the art that such devices are typically used simultaneously on the teeth of the upper and lower jaws. It will be understood by persons having skill in the art that the present invention can also be used simultaneously on the upper and lower jaws.

FIGS. **3** and **4** further show a diagrammatic drawing of a cyclical-force assembly **112** located at the centralized hub

111 of the present invention. Referring now to FIG. **3**, a more detailed diagrammatic view of the cyclical-force assembly **112** is shown. The outer container of the device **114** can be of any, sealed, moisture resistant type well known in the art, such that the items housed therein can be protected from the ambient conditions found in the mouth. Further, the housing can be of the type that provides means to maintain the items, housed therein, cool and at a necessary temperature range of operating conditions. Such housings, typically for any number of implantable electronic and chemical devices such as pacemaker, implantable defibrillators, insulin pumps and others, are well known in the art.

Within the outer container **114** of the cyclical-force assembly **112** of the present invention are housed a microprocessor **116**, an actuator **118**, two drive shafts **120***a*, **120***b* and a power source, typically a watch-battery type-cell (not shown). It is to be understood that a microprocessor and actuator of the type necessary for the operation of the present invention are well known in the art. Although these items, and watch battery-type cells, are shown and described, it is to be understood that any one or all of these items can be replaced with other elements without departing from the novel scope of the present invention. A motor and gears useful herein for a contemplated devise can be obtained from MicroMo Electronics, Inc., Clearwater Fla., USA.

In the operation of the cyclical-force assembly **112**, microprocessor **116** is preprogrammed with a predetermined cycle and amplitude of forces to be applied by actuator **118** onto, cyclically, band **108** through drive shaft **120***a* and drive shaft **120***b*. As can be seen in FIG. **3**, drive shafts **120***a*, **120***b* are attached, in a manner well known in the art, to the ends of band **108**. It will be understood by persons having skill in the art that the connection of actuator **118** to band **108** can be made in any manner that allows the cyclical force of actuator drive shafts **120***a* and **120***b* to apply forces both in a pushing and pulling manner, as needed, to provide the necessary tension, and thus tooth realignment forces, to band **108**. Such items as pulleys, rings, gears, angles and other devices can be used to permit the forces from actuator **118** to be effectively applied to band **108** without departing from the novel scope of the present invention.

The cyclical forces are applied to band **108** and thereby to the misaligned teeth causing, over a predetermined period, the correct alignment of the teeth, as shown in FIG. **4**. It will be seen in FIG. **4**, that, after a predetermined period of application of the cyclical forces of the present invention, the spaces **110** have been eliminated by the movement of the remaining teeth **100** into a more natural alignment. The desired alignment is further shown in the more graceful arc of band **108** about the outer surfaces **106** of the teeth **100**.

The devise illustrated in FIGS. **2–4** is adapted for use intraorally and can be referred to as intelligent microprocesor-controlled braces (IMB). An extraoral devise can be similarly be prepared for reshaping cranial bones by inducing osteogenesis as cranial sutures.

Illustrative Procedures

A total of twenty-four New Zealand White rabbits 6 weeks of age were used in these studies. Of those rabbits, 11 were used for acute studies and 13 were used for chronic studies.

The maxillae of different rabbits received exogenously supplied static forces with peak magnitude of 2 Newtons and a frequency of 0 Hz, as well as cyclic forces also at 2 Newtons but with frequencies of 0.2 and 1 Hz. The induced peak bone strain over the premaxillomaxillary suture did not differ significantly between the static forces (506 μstrain 182; mean S.D.), 0.2-Hz cyclic forces (436 μstrain.191) and 1-Hz cyclic forces (461 μstrain 229).

However, cyclic forces at 0.2 Hz delivered to the maxilla for 20 minutes per day over 12 days (240 cyclic per day) induced significantly more cranial growth ($p<0.01$), sutural separation and proliferation of osteoblast-like cells, in comparison with both sham controls and static forces of matching peak magnitude and duration. More significantly cyclic forces at 1 Hz delivered to the maxilla for 20 minutes per day over 12 days (1,200 cycles per day) induced more cranial growth ($p<0.01$), sutural separation and proliferation of osteoblast-like cells.

Thus, cyclic forces, although eliciting the same level of bone strain as static force of matching peak magnitude in craniofacial bones, induced significantly more osteogenesis and facial growth. These data demonstrate, for the first time, that extremely short dosages of cyclic forces induce more effective sutural osteogenesis than static forces, providing the basis for studying a wide range of cyclic forces with varying frequencies and daily dosages and their potential therapeutic use to modulate craniofacial osteogenesis.

Cyclic forces of 5 Newtons (N) and 0.2 Hz were applied to the maxillary incisors in the rabbit in vivo 20 minutes per day over 12 days (240 cycles per day). Static forces of matching peak magnitude and duration were applied in age- and sex-matched rabbits with additional rabbits as sham-operated controls.

On Day 1 and Day 13 of force delivery, standardized cephalometric X-ray films were taken, computer scanned and superimposed on preimplanted (immovable) markers to measure the overall and fractional facial lengths in the sagittal plane. Upon completion of force delivery, strain gages were implanted on the zygomatic arch to quantify bone strain in response to the cyclic forces, followed by harvesting the rabbit cranium: half for conventional histology and the other half for atomic force microscopy and computer-assisted histomorphometry.

The results of this study showed that the anterior facial length (AFL) of the rabbits loaded with cyclic forces (0.25 Hz and 5 N) in the sagittal plane was longer than the AFL in both sham-operated controls and those loaded with static forces of matching peak magnitude and duration. These quantifications were obtained by measuring the linear distance from the inion to the prosthion, which are defined as the most dorsal and ventral borders of the cranium in the sagittal plane respectively.

FIG. **1** illustrates that cyclic forces were more effective than static forces in causing bone growth and craniofacial remodeling. There was significantly more bone growth and therefore remodeling in the rabbit crania loaded with cyclic forces than static forces. The average anterior facial length (AFL) of the rabbits loaded with the cyclic forces was significantly longer ($p<0.01$) than the AFL in both sham-operated controls (right side bar) and those loaded with static forces (center bar) of matching peak magnitude and daily duration as revealed by Kruskal-Wallis test. No significant differences were found in the AFL between sham-operated controls and those loaded with static forces, suggesting that static forces were not effective in inducing craniofacial remodeling in the 12-day duration of the preliminary study.

The same trends were observed for the ratio of gain in the AFL over the gain of the posterior facial length; i.e., significant increase in the ratio of the AFL over the posterior facial length ($p<0.01$; Kruskal-Wallis test) and no significant

differences between sham-operated controls and those loaded with static forces, indicating significantly more gain in the AFL than the gain in the posterior facial length in association with cyclic forces. The AFL was measured as the linear distance from the prosthion to the MOP (mesial to P1: first premolar), whereas the posterior facial length was measured as the linear distance from the MOP to the inion.

Histological evidence indicated wider separation of the premaxillomaxillary suture, frontonasal suture and maxillopalatine suture associated with cyclic loading. In contrast, sutures associated with control and static loads were less separated. New bone formation fronts were present in some of the sutures associated with cyclic loading upon high power examination. The sutural separation and osteogenesis appear to account for the greater gain in the anterior facial length shown in FIG. **1**, above. The presence of marked sutural separation and craniofacial lengthening associated with in vivo cyclic forces at 5 Newtons, 0.2 Hz for 20 minutes per day over 12 days indicated the effectiveness of the treatment.

The zygomatic bone and squamosal bone across the zygomatiosquamosal suture were found to respond differently to anteriorly (ventrally) directed cyclic forces of 0.25 Hz and 5 Newtons peak-to-peak with two strain gages (ED-DY-062DW-350) (Measurements Group, Raleigh, N.C.) implanted above and below the zygomaticosquamosal suture in vivo. Whereas the squamosal bone experienced tensile strain, the zygomatic bone experienced compressive strain. In addition, the peak strain values are different: +100 microstrain (positive value denoted to tensile strain) for the squamosal bone and −300 microstrain (negative value denoted to compressive strain) for the zygomatic bone. These differential strain magnitude and contrasting strain patterns suggest probable activation of sutural osteoblasts via one of the several models of coupling between biomechanical stimuli and osteogenesis initiation such as fluid movement and direct coupling across the cell membrane, both of which appear more effectively accomplished by cyclic forces than static forces.

Additional in vivo bone strain recordings demonstrated that cyclic forces induced dynamic bone strain; i.e., both tensile and compressive, over the zygomaticosquamosal suture, whereas static forces of matching magnitude induced no dynamic change in bone strain. These recordings were obtained with a strain gage (ED-DY-062DW-350; Measurements Group) implanted "over" the zygomaticosquamosal suture with the longitudinal axis of the gage parallel to the course of the suture and with half of the gage on the squamosal bone and the other half on the zygomatic bone.

Although the peak cyclic and static bone strain was similar at approximately −140 to −150 microstrain, the effects of cyclic and static bone strains on the cortical bone surface are likely very different. Cyclic forces likely have induced dynamic strain in both the cortical bone surface and the suture with consequent activation of osteogenic cells for initiation of osteogenesis. This strain-induced osteogenesis, apparently never reported before in craniofacial bones, is consistent with a generally accepted view in long bones that cyclic strain per se or the fluid movement in bone induced by cyclic strain, instead of static strain, are the effective stimuli for osteogenesis.

Each of the patents, applications and articles cited herein is incorporated by reference. The use of the article "a" or "an" is intended to include one or more.

From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the invention. It is to be understood that no limitation with respect to the specific embodiment illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

What is claimed:

1. A malocclusion treatment apparatus for realigning teeth, comprising:

a band of generally inelastic material having a first end and a second end;

a hub;

a power source within the hub, means for producing cyclical forces within the hub, and an actuator within the hub such that when the actuator is powered, realignment cyclical forces controlled by the means for producing cyclical force can be applied to the band.

2. The malocclusion treatment apparatus of claim **1** wherein the band is adapted to be attached to at least one tooth.

3. The malocclusion treatment apparatus of claim **1** wherein the band is a adapted to be attached to a plurality of teeth.

4. The malocclusion treatment apparatus of claim **3** wherein the hub is centralized in relation to the position of the teeth.

5. The malocclusion treat of claim **1** wherein the means for producing cyclical forces is a microprocessor for controlling the actuator and the application of forces on the band.

6. The malocclusion treatment apparatus of claim **1** wherein the actuator, when powered, produces cyclical forces having a peak magnitude of about 10 Newtons and a frequency of about 0.1 Hz to about 40 Hz.

7. The malocclusion treatment apparatus of claim **1** including a pair of drive shafts, each drive shaft being, in mechanical communication with the actuator and each drive shaft being, in mechanical communication with the band.

8. A malocclusion treatment apparatus for realigning teeth, comprising:

a band of generally inelastic material having a first end and a second end, the band being adapted to be attached to a plurality of teeth;

a generally centralized hub, having a power source, a microprocessor and an actuator there within;

at least one drive shaft in mechanical communication with the actuator and in mechanical communication with the band such that when the actuator is powered cyclical realignment forces controlled by the microprocessor can be applied to the band.

9. The malocclusion treatment apparatus of claim **8** wherein the actuator, when powered, produces cyclical forces having a peak magnitude of about 5 Newtons and a frequency of about 0.1 Hz to about 5 Hz.

10. A method of treating malocclusion to realign teeth comprising the steps of:

providing a band of generally inelastic material affixed to one or more teeth, the band comprising a first end and a second end;

joining the first end and the second end of the band at a generally centralized hub;

providing a power source and an actuator assembly comprising an actuator;

applying cyclical mechanical forces with the actuator, in a direction of realignment desired, at the centralized hub and thereby to the band, for a predetermined period of time a plurality of times each day.

11. The method of treating malocclusion to realign teeth of claim **10** including the step of providing a microprocessor to control the actuator and power source.

12. The method of treating malocclusion to realign teeth of claim **1** including the step of providing a program within said microprocessor to cause said actuator to apply cyclical forces with a peak magnitude of about 2 Newtons and a frequency of between about 0.1 Hz and 2 Hz in a direction of the desired realignment for a predetermined period of time.

13. The method of treating malocclusion to realign teeth of claim **12** wherein said cyclical forces are repeatedly applied over a period of months.

14. The method according to claim **12** wherein said cyclical forces are applied at a frequency of about 0.2 to about 1.5 Hz.

* * * * *

EXHIBIT 2

Propel Vpro5 Accelerated Treatment

Dr. Sellke and Dr. Reily use Propel's Vpro5 Aura in conjunction with Invisalign® and braces treatments to accelerate the movement of your teeth. Please give us a call today to learn more about Propel's Vpro5 in Antioch, Grayslake, Gurnee, Illinois, and to schedule your appointment with one of our friendly orthodontists.

If you would like to reduce your treatment time with braces, Propel's Vpro5 might be just what you need. Vpro5 is a state-of-the-art device you can use to significantly reduce your treatment period and gain your beautiful, straight smile in less time.

The Vpro5 is a hands-free, easy-to-use device that you use for only 5 minutes every day to shorten your treatment time. Vpro5 gently vibrates the teeth and surrounding bone, allowing the teeth to move more freely, designed to accelerate the bone remodeling process. This works in conjunction with your braces or other kinds of orthodontic treatment to move your teeth in less time. **In fact, Vpro5 delivers four major clinical benefits:**

- Reduces orthodontic discomfort
- Accelerates tooth movement with braces or aligner treatment, reducing time in treatment
- Aligner treatment: properly seated aligners results in faster treatment
- Stimulates bone generation and remodeling: increasing bone density faster for a more stable result

We may recommend Vpro5 for patients who would like to reduce their orthodontic treatment time. This is perfect for patients who would like to straighten their teeth quickly for a special event, such as a wedding or graduation. To learn more about Propel's Vpro5 and to discover whether it's right for you, we welcome you to contact our office today. We are happy to answer your questions.

(https://goo.gl/maps/6PEn6nhBZzT2) (tel:847-223-2876)

See What Our
PATIENTS SAY ABOUT US

Meet Our
DOCTORS

Experience Our
OFFICE

Explore

Home
Meet Us
For New Patients
Treatments
About Orthodontics
Contact

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Blog

EXHIBIT 3

PRACTICE PROFILES

Combining Specialties

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By Alison Werner | Photography by Alan Klehr

There is one question that every orthodontist wants the answer to: What practice model will ensure career long success?

Unfortunately, there is as yet no crystal ball with the answer. Instead, orthodontists like Illinois-based Derek Bock, DMD, MS, must experiment and find their own answer to this question—and, along the way, accept the advice of those who might know better.

When Bock met his wife Anokhi Bock, DMD, MSD, at Tufts University School of Dental Medicine, they had both intended to go into orthodontics; but Anokhi soon changed paths and pursued a specialty in pediatric dentistry. Little did Bock realize, her decision would profoundly shape his future orthodontic practice.

When it came time to do their residencies, Anokhi persuaded Bock to return to the Midwest where she grew up—she to take up a residency at Riley Children's Hospital through the Indiana University School of Dentistry and he at the University of Illinois at Chicago. While there may have been promises to eventually return to Bock's native Massachusetts, the couple opted to stay in the Midwest following their residencies.

Today, they have a joint pediatric dentistry/orthodontic practice in Lake Forest, Ill. There had been no plan to go into practice together—well, at least Bock didn't think there was. "It was her plan," Bock says with a laugh, "but I didn't really understand that straight out." Anokhi's residency program included a strong orthodontics component. And it was she who saw the benefits of a combination pedo/ortho practice.

"She saw it as this is what you *should* be doing for the patient," Bock says. "She saw a need for early treatment and a synergistic approach to orthodontics and pediatric dentistry early on. She had worked at a very busy pediatric practice and saw a lot of orthodontic cases that were missed early on. She wanted to do that business model because she saw it was the best for the patient."

Bock, however, was hesitant to be in a practice that focused so much on early treatment. "At Illinois, I got very limited early treatment training. Most residency programs don't teach a lot of early treatment. And I came out and said, 'I'm not going to do that. We're going to wait for the teeth to come in like we are trained.'" But Anokhi persisted on the merits of a pedo/ortho combination. When Bock's buy-in to an existing orthodontic practice fell through, Anokhi finally convinced him to open their current pedo/ortho practice from scratch.

"We've been living this [pedo/ortho] model for quite a while now. That was not the original plan, but it should have been," Bock says.

Bock and his wife, Anokhi Bock, DMD, MSD, have been in practice together for 8 years.

Growing Pains

Bock is honest about the growing pains associated with a pedo/ortho model. When opening such a practice from scratch, the reality is the pediatric dentistry side will grow faster than the orthodontic side, he says. First off, a pediatric dental practice early on traditionally is filled with 3 to 7 year olds. Thus, the orthodontic partner is going to need to be patient. "Your ortho population isn't going to be there for quite some time," Bock points out.

Practice Profile

Practice name: Forest Orthodontics and Pediatric Dentistry

Location(s) and square footage: Lake Forest, Ill—3,900 sq ft; Round Lake Beach, Ill—2,400 sq ft

Number of chairs: Lake Forest—9 treatment chairs, 2 consult rooms; Round Lake Beach—8 treatment chairs, 2 consult rooms

Years in practice: 9

Education: DMD—Tufts University School of Dental Medicine; MS, Cert ortho—University of Illinois at Chicago

Average number of patients per day: 75 to 90

Days worked per month: 16 to 18

Top five products used: Damon Q (Ormco Corp), Invisalign (Align Technology Inc), Propel VPro5 (Propel Orthodontics), I-Cat (Imaging Sciences International), Dolphin Suite (Dolphin Imaging & Management Solutions)

And then there is the referral problem. "Ortho kind of suffers early on because your general dentist referrals don't want to send you anything," he says. "They're scared your pediatric side of the practice is going to take the 12-year-old hygiene patient, which is the easiest production in a general dentist practice. You have to accept the fact that you're not going to get a lot of outside referrals from other professionals."

While the fear among the general dental community has lessened over the years, Bock still doesn't rely on referrals for new orthodontic patients. Instead, the practice focuses on going direct to the consumer to bring new patients in.

"I really only have five general dentists that refer to me; but it's ok. It's harder to get those referrals in this day and age, and it's a lot more work than just doing word of mouth and whatever is in house from pedo," he says.

As a result, the practice allots about 70% of its marketing budget to the pediatric side, focusing on bringing in pediatric patients who will eventually funnel into the orthodontic side. Among the practice's marketing targets are preschools and community events that cater to children up to third/fourth grade.

"Your influx of new potential ortho patients through the pedo channel is more exponential. Pedo drives in twice as many new patients on a monthly basis than ortho does," Bock says.

Lessons Learned

Now with 8 years of experience with the pedo/ortho model under his belt, Bock firmly agrees with his wife's view that the model is better for the patient. "I think it's more comprehensive in treatment timing for a child," he says. "When they can come in at age 7, whether they need treatment or not (and most of them don't), they can be followed very closely on one system, in house, for years."

In addition, getting parents to accept their child's need for orthodontic treatment is a lot easier in this model, says Bock.

"[The parents and their children] have been here for years and they already trust the practice. There's no real hard selling in this business model. It's more about when they'll be ready for treatment."

So what are the downsides? "Noise. 100% noise," Bock jokes. Initially, he and his wife shared time, both working 3 days a week; but the noise of the pediatric practice called for a plan B. Today, the two only share 1 day a week in the office—a day that is dedicated to patients who overlap between the two sides of the practice. This allows the practice to do cleanings and adjustments at the same time, saving patients a visit.

And the other downside: Overcoming the idea that you're a pediatric orthodontist. "That is probably my biggest hurdle," Bock says. "Because our practice is called Forest Orthodontics and Pediatric Dentistry, in the consumer's mind, I'm a pediatric orthodontist no matter how many full mouth reconstruction cases I do or how many friends of parents I treat."

Bock also cautions that the prevalence of phase I and early treatment cases in the pedo/ortho model, if not done right, can be a financial drain on the practice. "You're seeing these kids for more appointments in two phases, for maybe only 25% to 30% more than your regular comprehensive treatment fee. So if you're not efficient and pragmatic, and you don't have the systems in place, it can be a cash drain until you figure it out," Bock says.

"My biggest word of wisdom for people out there that want to get into the pedo/ortho model: You have to be ok doing phase I and you have to do it efficiently."

Workplace Realities

Bock argues that starting a pedo/ortho combo practice from scratch together rather than joining an existing pediatric dentistry practice has its advantages. When Bock and his wife first opened their practice, Bock also joined an existing pediatric dentistry practice. He expected the large pediatric dentistry practice would have the patient base for an orthodontist to be instantly successful. He was wrong.

Bock contends that pediatric dentists can often have a mindset that makes it difficult to get those orthodontic patient referrals. "Pediatric dentists don't traditionally look at [their patients] for orthodontics. They look at them for oral hygiene and cavity prevention."

The Pragmatic Orthodontist

Derek Bock, DMD, MS, doesn't just rely on his own experience to make decisions about the future of his practice and treatment of patients. He also relies on the input of almost 1,700 other orthodontists throughout the country to inform his views about the path his practice should take and the

future of the profession as a whole.

Bock is the sole admin of his Facebook study group, The Pragmatic Orthodontist. The forum strives to help orthodontic residents and orthodontists at the beginning of their careers; however, its membership includes orthodontists at all career stages and ages. According to Bock, a self-described "tooth nerd at heart," the study group aims to be a welcoming environment for newer orthodontists to share and talk through clinical cases. As the group's description says, the goal is to provide advice that is based on learned experience rather than theory and to be another tool in an orthodontist's toolbox.

"I spend a good portion of my week, along with other contributors I've brought in, teaching younger practitioners what works and what doesn't work. We're sharing our trials and tribulations and putting it all out there," he says.

Now that the study group is 2 years old, Bock is in the process of taking it to the next level. This month, a Pragmatic Orthodontist website will launch. The website is designed to catalog the 2,400 threads on the Facebook page and give members search functionality. According to Bock, there are anywhere from 8 to 15 new subject threads per day on the study group's Facebook page. In addition, the website will offer on-demand learning.

To join the free study group, and have access to the new website portal, an orthodontist must submit an application and have their credentials verified.

Bock—whose wife, pediatric dentist Anokhi Bock, DMD, MSD, runs her own Facebook-based study

group, The Progressive Pediatric Dentist—contends that Facebook is a great platform that plenty of younger orthodontists embrace as a resource for learning and information sharing. "They were brought up on Facebook," Bock points out. However, many older orthodontists can be resistant to Facebook as a learning resource, which is unfortunate in his opinion. "There is an entirely different world out there that they are missing. There is so much data."

As Bock sees it, online study groups, like his Facebook group, are a more efficient way to learn from peers and a key to future learning. "It's like a phone conversation versus me flying out to meet you," he says. "It's just a lot more efficient." **OP**

So, what's an orthodontist to do in this situation? Bock says, pediatric dentists need to be coached to anticipate a patient's orthodontic needs.

Bock ended up leaving that pediatric dental practice, finding it easier and more profitable to work with his wife, with whom he was on the same page from the beginning.

As for actually working with pediatric dentists, well, Bock jokes that there are a lot more Care Bears and rainbows. "Pediatric dentists have to be able to relate to a 5-year-old kid and get [those children] to understand what they want them to do," he points out. "If you kind of peel back that personality, most pedos are just big kids. So that's the environment of your practice—and most orthodontists aren't big kids. They're more Type A, OCD. Sometimes that can be a friction in the pedo/ortho model. If you can't sit back, relax, and chill a little bit with a pediatric dentist, then it's hard to pull off. You have to figure out your personality when you want to start a group practice."

And that's if you can find a pediatric dentist with whom to partner. While the specialty is growing, there are only 7,163 pediatric dentists practicing in the United States as of 2015, according to the ADA Health Policy Institute's study, "Supply of Dentists in the US: 2001-2015." In addition, Bock contends that their salary requirements are higher than general dentists.

The Insurance Game

In April, the practice opened a satellite location with a specific agenda: to diversify the practice's revenue and patient streams. While the gross household income within 3 miles of the practice's main location in Lake Forest is $300,000, according to Bock, the new Round Lake Beach satellite office is in an area with a gross household income of $80,000. While still relatively high, the patient population is more dependent on insurance for orthodontic treatment.

As Bock sees it, insurance is going to be a major player in the years to come. Couple this with the fact that general and pediatric dentists are both doing more orthodontics, and fees are more likely to decrease, not increase over time. To get ahead of the curve, and to make sure his practice is in the game, the satellite office was opened to allow Bock and his wife to start capturing more of the insurance-based patient population.

In addition, Bock wanted to bring the same service associated with the Lake Forest brand to this community and make orthodontic treatment an easier prospect for this population. According to Bock, the satellite office possesses a higher-end, boutique style, with an

emphasis on high-quality customer service that isn't often seen in orthodontic practices in the area. In addition, by accepting insurance, the satellite office helps prospective patients overcome the sticker shock of orthodontic treatment. "People have benefits they want to use," Bock says. "[Our goal] is to make insurance more customer friendly and easier. We want to remove barriers to get them to commit to treatment. By being in network with their insurance, in their minds, it's easier."

As Bock sees it, the future lies in combo specialties like pedo/ortho and insurance-based practice models. "The pedo/ortho model is all about controlling the patient base—controlling your referrals. And the insurance model is about decreasing barriers and getting more people started in orthodontic treatment."

But the future of Bock's practice doesn't end with these models; he expects his practice to eventually transition to a multi-specialty model, adding general dental services. The goal is to create a family dental practice that captures the dental needs over the patient's lifetime. "We have an aging pedo population that needs to go somewhere," he says. Moreover, Bock can envision a time in which insurance will refuse to cover pediatric dentistry specialty fees, thus pushing families to seek treatment at family dental practices.

For Bock, the future of orthodontics is all about creativity and constant reinvention. "Just change your mindset from *you can't do that* to *people are doing it*. Go out there and fight a different way instead of being sucked into the negativity that's out there. We're still growing [as a profession] and we still have successful practices. As long as you figure out a way to get patients through your door, no matter what your fee is or what type of patient it is, everybody is successful." **OP**

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EXHIBIT 4

VPro5™

Fast in 5 Minutes

The VPro5 Approach

Simple, Easy, Fast

How often should I use it?

» Utilize the VPro5 for just 5 minutes a day.

» Continue use for the entirety of your orthodontic treatment, or as otherwise directed by your treating clinician.

How much pressure should I apply?

» Bite down gently on the mouthpiece. There is no need to bite down or clench any harder than as needed to support the device.

The VPro5 Comes With

» VPro5 Oscillator

» VPro5 Mouthpiece

» Charging Cable & Wall Adapter

"I love this device. It's easy to use and doesn't take a lot of my time."

-Patient, Dr. Gary Brigham

How To Guide

1. Connect the mouthpiece to the oscillator. Confirm that the device feels secure and stable.
2. Depress (apply firm pressure) the white on-switch on the oscillator to activate vibration function. A blue light will illuminate. Device will slowly ramp up to full vibration.
3. While wearing your aligners, bite down on the mouthpiece and begin vibration therapy.
4. The device will function for 5 minutes per use and will automatically shut-off after the duration of treatment.
5. LED Notification Light blinks green 3 times to indicate cycle is complete.
6. After use, clean and charge device as needed.

Your Guide to Light Notifications

Blue	• 5 minute cycle is in progress
Green	• 5 minute cycle is complete (3 blinks) • Device is fully charged
Red	• Switch is pressed by user before treatment is complete • When the 5 minute treatment is interrupted and not resumed within the 30 minute window • When the device is on/vibrating and user connects to USB (vibration will stop) • When the 5 minute treatment is interrupted and user connects to USB within the 30 • minute window.
Magenta	• Device is at low battery level
Amber	• Device is plugged into charger

Cleaning the VPro5

The mouthpiece should be cleaned after each treatment use. Detach the mouthpiece from the oscillator. Rinse the mouthpiece under water and let dry. Do not rinse or submerge the oscillator; however, it may be wiped with a moist towel.