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(54) Title: VARIATIONS OF DENTAL ALIGNERS

(57) Abstract: Dental appliances for producing corrective movement in a subject's teeth include dental aligners which may be worn on a subject's teeth, gingiva or other region of the oral cavity. Described herein are dental appliances that include features that enhance the performance and comfort of the appliance, including features for preventing damage or wear on the appliance. Described herein are fluid-permeable aligners, wrinkled aligners, modular aligners, aligners of varying thickness, aligners of varying stiffness, snap-on aligners, textured aligners, aligners having multiple layers, and lateral correction aligners. Methods of making and using such aligners are also described.

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VARIATIONS OF DENTAL ALIGNERS

Inventors: Huafeng Wen and Frank Zhenhuan Liu

TECHNICAL FIELD

[0001] This application generally relates to the field of dental care, and more particularly to the field of orthodontics.

CROSS-REFERENCES TO RELATED INVENTIONS

[0002] The present invention claims priority to US patent applications: U.S. Patent Application Serial No. 11/074,301, titled "Dental Aligner for Providing Accurate Dental Treatment" by Wen et. al.; U.S. Patent Application Serial No. 11/074,297, titled "Producing Wrinkled Dental Aligner for Dental Treatment" by Wen et al.; U.S. Patent Application Serial No. 11/074,300, titled "Fluid Permeable Dental Aligner" by Huafeng Wen; U.S. Patent Application Serial No. 11/107,584, titled "Dental Aligner Devices Having Snap-On Connectors" by Wen et al.; U.S. Patent Application Serial No. 11/074,298, titled "Disposable Dental Aligner" by Huafeng Wen; and U.S. Provisional Patent Application Serial No. 60/676,100, titled "Nonuniform Dental Aligner and Methods" by Huafeng Wen. Each of these applications is herein incorporated by reference in its entirety.

[0003] Refer also to commonly assigned U.S. Patent applications: U.S. Provisional Patent Application Serial No. 60/676,546, titled "Digitization of Dental Arch Model Components" by Huafeng Wen; U.S. Provisional Patent Application 60/673,970, titled "System for Digitizing and Registering a Subject's Upper and Lower Dental Arches" by Wen et. al.; and U.S. Patent Application 11/205,496, titled "System for Organizing Dental Aligners" by Huafeng Wen. Each of these applications is herein incorporated by reference in its entirety.

[0004] Refer also to U.S. Patent Application Serial No. 11/074,301, titled "Dental aligner for providing accurate dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,297, titled "Producing wrinkled dental aligner for dental treatment" by Liu et al, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,300,

titled "Fluid permeable dental aligner" by Huafeng Wen, filed 3/7/2005, U.S. Patent Application Serial No. 11/074,298, titled "Disposable dental aligner by Huafeng Wen, filed 3/7/2005, and U.S. Patent Application Serial No. 11/050,051, titled "Storage system for dental devices" by Huafeng Wen, filed 2/3/2005. Each of these applications is herein incorporated by reference in its entirety.

[0005] Refer also to U.S. Patent Application Serial No. 10/979,823, titled "Method and apparatus for manufacturing and constructing a physical dental arch model" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,497, titled "Method and apparatus for manufacturing and constructing a dental aligner" by Huafeng Wen, filed 11/2/2004, U.S. Patent Application Serial No. 10/979,504, titled "Producing an adjustable physical dental arch model" by Huafeng Wen, filed 11/2/2004, and U.S. Patent Application Serial No. 10/979,824, titled "Producing a base for physical dental arch model" by Huafeng Wen, filed 11/2/2004. Each of these applications is herein incorporated by reference in its entirety.

[0006] Refer also to U.S. Patent Application Serial No. 11/013,152, titled "A base for physical dental arch model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/012,924, titled "Accurately producing a base for physical dental arch model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,145, titled "Fabricating a base compatible with physical dental tooth models" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,156, titled "Producing non-interfering tooth models on a base" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,160, titled "System and methods for casting physical tooth model" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,159, titled "Producing a base for accurately receiving dental tooth models" by Huafeng Wen, filed 12/14/2004, U.S. Patent Application Serial No. 11/013,157, titled "Producing accurate base for dental arch model" by Huafeng Wen, filed 12/14/2004. Each of these applications is herein incorporated by reference in its entirety.

BACKGROUND

[0007] Orthodontics is the practice of manipulating a subject's teeth to provide better function and appearance. In general, brackets are bonded to a subject's teeth and coupled together with an arched wire. The combination of the brackets and wire provide a force on the teeth causing them to move. Once the teeth have moved to a desired location

and are held in a place for a certain period of time, the body adapts bone and tissue to maintain the teeth in the desired location. To further assist in retaining the teeth in the desired location, a subject may be fitted with a retainer.

[0008] To achieve tooth movement, orthodontists utilize their expertise to first determine a three-dimensional mental image of the subject's physical orthodontic structure and a three-dimensional mental image of a desired physical orthodontic structure for the subject, which may be assisted through the use of x-rays and/or models. Based on these mental images, the orthodontist further relies on his/her expertise to place the brackets and/or bands on the teeth and to manually bend (i.e., shape) wire, such that a force is asserted on the teeth to reposition the teeth into the desired physical orthodontic structure. As the teeth move towards the desired location, the orthodontist makes continual judgments as to the progress of the treatment, the next step in the treatment (e.g., new bend in the wire, reposition or replace brackets, is head gear required, etc.), and the success of the previous step.

[0009] In general, the orthodontist makes manual adjustments to the wire and/or replaces or repositions brackets based on his or her expert opinion. Unfortunately, in the oral environment, it is difficult for a human being to accurately develop a visual three-dimensional image of an orthodontic structure due to the limitations of human sight and the physical structure of a human mouth. In addition, it is difficult (if not impossible) to accurately estimate three-dimensional wire bends (with accuracy within a few degrees) and to manually apply such bends to a wire. Further, it is difficult (or impossible) to determine an ideal bracket location to achieve the desired orthodontic structure based on the mental images. It is also extremely difficult to manually place brackets in what is estimated to be the ideal location. Accordingly, orthodontic treatment is an iterative process requiring multiple wire changes, with the success and speed of the process being dependent on the orthodontist's motor skills and diagnostic expertise. As a result of multiple wire changes, cost and subject discomfort is increased. The quality of care may also vary greatly from orthodontist to orthodontist, as does the time to treat a subject.

[0010] The practice of orthodontic is very much an art, relying on the expert opinions and judgments of the orthodontist. In an effort to shift the practice of orthodontic from an art to a science, many innovations have been developed. For example, U.S. Pat. No. 5,518,397 issued to Andreiko, et. al. provides a method of forming an orthodontic brace. Such a method includes obtaining a model of the teeth of a patient's mouth and a

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prescription of desired positioning of such teeth. The contour of the teeth of the patient's mouth is determined, from the model. Calculations of the contour and the desired positioning of the patient's teeth are then made to determine the geometry (e.g., grooves or slots) to be provided. Custom brackets including a special geometry are then created for receiving an arch wire to form an orthodontic brace system. Such geometry is intended to provide for the disposition of the arched wire on the bracket in a progressive curvature in a horizontal plane and a substantially linear configuration in a vertical plane. The geometry of the brackets is altered, (e.g., by cutting grooves into the brackets at individual positions and angles and with particular depth) in accordance with such calculations of the bracket geometry. In such a system, the brackets are customized to provide three-dimensional movement of the teeth, once the wire, which has a two dimensional shape (i.e., linear shape in the vertical plane and curvature in the horizontal plane), is applied to the brackets.

[0011] Other innovations relating to bracket and bracket placements have also been described. For example, such patent innovations are disclosed in U.S. Pat. No. 5,618,716 entitled "Orthodontic Bracket and Ligature," which describes a method of ligating arch wires to brackets, U.S. Pat. No. 5,011,405 "Entitled Method for Determining Orthodontic Bracket Placement," U.S. Pat. No. 5,395,238 entitled "Method of Forming Orthodontic Brace," and U.S. Pat. No. 5,533,895 entitled "Orthodontic Appliance and Group Standardize Brackets therefore and methods of making, assembling and using appliance to straighten teeth".

[0012] Kuroda et al. (1996) Am. J. Orthodontics 110:365-369 describes a method for laser scanning a plaster dental cast to produce a digital image of the cast. See also U.S. Pat. No. 5,605,459. U.S. Pat. Nos. 5,533,895; 5,474,448; 5,454,717; 5,447,432; 5,431,562; 5,395,238; 5,368,478; and 5,139,419, assigned to Ormco Corporation, which describe methods for manipulating digital images of teeth for designing orthodontic appliances.

[0013] U.S. Pat. No. 5,011,405 describes a method for digitally imaging a tooth and determining optimum bracket positioning for orthodontic treatment. Laser scanning of a molded tooth to produce a three-dimensional model is described in U.S. Pat. No. 5,338,198. U.S. Pat. No. 5,452,219 describes a method for laser scanning a tooth model and milling a tooth mold. Digital computer manipulation of tooth contours is described in U.S. Pat. Nos. 5,607,305 and 5,587,912. Computerized digital imaging of the arch is described in U.S. Pat. Nos. 5,342,202 and 5,340,309.

[0014] Other patents of interest include U.S. Pat. Nos. 5,549,476; 5,382,164; 5,273,429; 4,936,862; 3,860,803; 3,660,900; 5,645,421; 5,055,039; 4,798,534; 4,856,991; 5,035,613; 5,059,118; 5,186,623; and 4,755,139.

[0015] Efficiency in treatment and maximum quality in results may depend on a realistic simulation of the treatment process. Plaster models of the upper and lower arch may be made, the model may be cut into single tooth models and these tooth models can be stuck into a wax bed, in a desired position, to create a "set-up." This approach allows modeling of a perfect occlusion without any guessing. The next step is to bond a bracket at every tooth model. This would tell the orthodontist the geometry of the wire to run through the bracket slots to receive exactly this result. Then the bracket position may be transferred to the original malocclusion model. To make sure that the brackets will be bonded at exactly this position at the real patient's teeth, small templates for every tooth would have to be fabricated that fit over the bracket and a relevant part of the tooth and allow for reliable placement of the bracket on the patient's teeth. To increase efficiency of the bonding process, another option would be to place each single bracket onto a model of the malocclusion and then fabricate one single transfer tray per arch that covers all brackets and relevant portions of every tooth. Using such a transfer tray guarantees a very quick and yet precise bonding using indirect bonding.

[0016] U.S. Pat. No. 5,431,562 to Andreiko et al. describes a computerized, appliance-driven approach to orthodontics. In this method, first certain shape information of teeth is acquired. A uniplanar target archform is calculated from the shape information. The shape of customized bracket slots, the bracket base, and the shape of the orthodontic archwire, are calculated in accordance with a mathematically-derived target archform. The goal of the Andreiko et al. method is to give more predictability, standardization, and certainty to orthodontics by replacing the human element in orthodontic appliance design with a deterministic, mathematical computation of a target archform and appliance design. Hence the '562 patent teaches away from an interactive, computer-based system in which the orthodontist remains fully involved in patient diagnosis, appliance design, and treatment planning and monitoring.

[0017] Align Technologies recently began offering transparent, removable aligning devices as a new treatment modality in orthodontics. In this system, an impression model of the dentition of the patient is obtained by the orthodontist and shipped to a remote appliance-manufacturing center, where it is scanned with a CT scanner. A computer model

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of the dentition in a target situation is generated at the appliance-manufacturing center and made available for viewing to the orthodontist over the Internet. The orthodontist indicates changes they wish to make to individual tooth positions. Later, another virtual model is provided over the Internet and the orthodontist reviews the revised model, and indicates any further changes. After several such iterations, the target situation is agreed upon. A series of removable aligning devices or shells are manufactured and delivered to the orthodontist. The shells, in theory, will move the patient's teeth to the desired or target position.

[0018] US Patent 6,699,037 by Align Technologies describes an improved methods and systems for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Repositioning is accomplished with a system comprising a series of appliances configured to receive the teeth in a cavity and incrementally reposition individual teeth in a series of at least three successive steps, usually including at least four successive steps, often including at least ten steps, sometimes including at least twenty-five steps, and occasionally including forty or more steps. Most often, the methods and systems will reposition teeth in from ten to twenty-five successive steps, although complex cases involving many of the patient's teeth may take forty or more steps. The successive use of a number of such appliances permits each appliance to be configured to move individual teeth in small increments, typically less than 2 mm, preferably less than 1 mm, and more preferably less than 0.5 mm. These limits refer to the maximum linear translation of any point on a tooth as a result of using a single appliance. The movements provided by successive appliances, of course, will usually not be the same for any particular tooth. Thus, one point on a tooth may be moved by a particular distance as a result of the use of one appliance and thereafter moved by a different distance and/or in a different direction by a later appliance.

[0019] The individual appliances will preferably comprise a polymeric shell having the teeth-receiving cavity formed therein, typically by molding as described below. Each individual appliance will be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the patient, some of the teeth will be misaligned relative to an undeformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and will apply

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sufficient resilient force against such misaligned teeth in order to reposition the teeth to the intermediate or end arrangement desired for that treatment step.

[0020] The fabrication of aligners by Align Technologies utilizes stereo lithography process as disclosed in US patents 6471,511 and 6,682,346. Several drawbacks exist however with the stereo lithography process. The materials used by stereo lithography process may be toxic and harmful to human health. Stereo lithography process builds the aligner layer by layer by layer, which may create room to hide germs and bacteria while it is worn by a patient. Furthermore, stereo lithography process used by Align Technology also requires a different aligner mold at each stage of the treatment, which produces a lot of waste and is environmental unfriendly. There is therefore a long felt need for practical, effective and efficient methods to produce a dental aligner.

[0021] Another challenge for orthodontic treatment using removable dental aligning devices is that dental aligners often deform or otherwise loose their shape with age, use and/or environment. For example, a dental aligner (e.g., a "shell") may be deformed by chewing, biting, and hot beverages during wearing by the patient. The deformation can affect the proper function of the removable dental aligning device, because the ability of the aligner to effectively move teeth may depend upon the contact that the aligner makes with the teeth.

[0022] Furthermore, dental aligners may become relaxed and open up after repeated usage by a patient, which causes a loss of corrective forces applied by the aligner to the patient's teeth. This results in insufficient or inaccurate teeth movement and costly corrective measures in the orthodontic treatment.

[0023] Another difficulty with the current removable dental aligning devices is that the narrow tolerance for the removable dental aligning devices to fit to the patient's teeth. The removable dental aligning devices have to be produced very close to the surface profiles of the patient's teeth. Mismatch between the removable dental aligning devices and patient's teeth often produce discomfort in wearing the removable dental aligning devices.

[0024] Existing aligner have not adequately addresses these problems. For example, U.S. Patent 4,793,803 by Martz discloses separate appliances insertable in and removable from the upper and lower jaws of the subject to correct minor malocclusions. Martz describes: (a) a fairly rigid portion which mates with or securely grips the tooth surface, (b) a rigid portion to provide the base and shape, and (c) an intermediate, flexible resilient portion interposed between (a) and (b) which biases the teeth into the desired

position. The rigidity of the rigid portion may vary depending on the condition of an individual case. In some instances the rigid portion need only be somewhat flexible, thereby performing the function of the intermediate portion as well.

[0025] US Patent 6,309,215 by Phan et al. describes systems and methods for removably attaching a dental positioning appliance to the teeth of a subject during orthodontic treatment. Such removable dental positioning appliances are often preferred over conventional braces for tooth repositioning due to comfort, appearance and ease of use. These appliances apply force to specific surfaces of the teeth to cause directed movement. However, the type of movement and amount of force applied is usually dependent on the surface characteristics and positions of connection to the teeth. The appliances or connection between the appliance and the teeth may not provide sufficient anchoring to impart a desired force on the teeth to be repositioned. Thus, such systems may require the use of one or more attachment devices that may be positioned on the teeth to provide the appropriate physical features. Appliances may attach to a subject's teeth by interactions with a pit or dimple on the dental aligning devices are often not secure enough, especially when large teeth movements are required. Furthermore, over a period of usage by a subject, an aligner can also become relaxed and open up. Dental aligning devices that attach to the subject's teeth by dimples may slip over the attachment, which can result in inaccurate teeth movement and costly corrective measures in the orthodontic treatment. However, specific design and location of these attachment devices may provide more effective repositioning forces, anchoring ability and appliance retention.

[0026] Another issue with most commercially available removable aligning devices (e.g., the devices manufactured by Align Technologies) is that the aligning devices do not allow oxygen to pass through them. A typical treatment takes about 18 to 24 months, and during this interval the cervical lines of the patient wearing such appliances typically remain covered for the major part of the day without letting air to pass through them. Oxygen cannot reach the cells of the cervical lines, and air trapped inside the aligning appliances cannot readily escape. Anaerobic bacteria such as Fusobacterium and Actinomyces often thrive in an oxygen-deprived environment and may produce volatile sulfur compounds (VSC) as byproducts, which can result in bad breath (halitosis) and hygiene problems in the patient's mouth.

[0027] In addition to the problems identified above, many aligners are also limited in their ability to effect corrections requiring lateral expansion of the palate. Most

presently available aligners move only the teeth, with only minimal impact on the motion of the palate. Further, traditional devices for expanding the palate are difficult to manufacture, and are incapable of correcting the entire upper dental arch. For example, US Patent application Serial Number 10/636,313 to McSurdy (herein incorporated by reference in its entirety) describes a palatal expansion device. Thus, it would be desirable to provide an economical, easily fabricated aligner capable of reforming the entire upper dental arch, including the palate.

[0028] The devices, systems, and methods described herein illustrate removable dental aligners having one or more features addressing at least some of the problems described above. In particular described herein are variations of dental aligners including dental aligners having through-holes through which connectors securable to a subject's teeth may pass and be secured, dental aligners including controllably deformable regions or textured surfaces (e.g., wrinkled aligners), non-uniform and/or multilayer dental aligners, and dental aligners which are fluid and/or gas permeable. Any or all of these features may be combined to form a dental aligner, as described more fully below.

SUMMARY OF THE INVENTION

[0029] Described herein are systems, methods and devices to correct or modify the position of a subject's teeth. Methods of manufacturing such apparatuses are also described. In particular dental appliances are described. Any of the variations of dental appliances, as well as methods of designing, fabricating, and using them are illustrated. Dental appliances may be any appropriate dental device, including dental aligners. The term dental aligner may also generally refer to any appropriate dental appliance.

[0030] Any of the features described (e.g., snap-on dental aligners, textured, fluid- and/or gas- permeable, wrinkled, modular, or varying thickness, stiffness or other properties) may be incorporated as part of a dental aligner, individually or in any reasonable combination. For purposes of descriptive convenience only, individual dental aligners are described or illustrated to emphasize only one or a few features. This arrangement is not intended to be limiting or to imply that the aligners, system, and methods of making or using these aligners are restricted to the examples shown or described.

[0031] Dental aligners may incorporate features that assist in securing the dental aligner to a subject's teeth, for helping the aligner maintain its conformation or resisting

wear and relaxation, and for improving the comfort and effectiveness of the aligner. For example, the dental aligner may be a "snap-on" dental aligner (which may be secured to connectors on a subject's teeth). The dental aligners may be fluid permeable. The dental aligners may be non-uniform and/or may be multi-layered dental aligners. The dental aligners may be textured or shaped to permit a predictable expansion or contraction of the dental aligner. For example, the dental aligner may be a wrinkled aligner.

[0032] Snap-on dental aligners may include one or more of the following.

[0033] Snap-on dental aligners may produce corrective movement in a subject's teeth, and may include a dental aligner (or shell) configured to be worn on a subject's teeth, and one or more through-holes passing through the device. The aligner device includes a shell portion having an outer surface and an inner surface, wherein at least a portion of the inner surface is configured to contact the subject's tooth. Thus, the thorough-holes extend from the outer surface to the inner surface of the shell portion of the dental device. The through-hole is configured to mate with a connector.

[0034] A system for producing corrective movement in a subject's teeth may includes a dental aligner device having one or more through-holes, configured to be worn on the subject's teeth, and one or more connectors that are configured to be fixed to the subject's teeth. The connectors are configured to engage with the through-holes when the dental aligner is worn on the subject's teeth.

[0035] A system for producing a snap-on dental aligner for dental treatment may include a guide to indicate the location where through-holes (corresponding to connectors on the subject) are to be formed on a dental aligner, and a positioner (a positioning device) to position a hole-maker with respect to the dental aligner based on the information provided by the guide. In some variations, the system also includes a hole-maker to produce through-holes in the dental aligner at the positions indicated by the guide to produce the snap-on dental aligner.

[0036] A method for moving a subject's teeth in a dental treatment may comprise fabricating a dental aligner to be worn on the subject's teeth, producing one or more through-holes in the dental aligner, fixing one or more connectors on the subject's teeth to engage the through-holes, and engaging the one or more connectors on the subject's teeth with the through-holes of the dental aligner to secure the dental aligner on the subject's teeth.

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[0037] Embodiments described herein may provide practical methods and systems for making dental aligners (e.g., snap-on dental aligners) and associated receiving connectors on the subject's teeth. The aligners can be attached onto the subject's teeth and assure the dental aligner to be in precise registration as designed throughout the period of wearing by the subject. The aligners may also overcome the aligner relaxation problem due to repeated uses, which is common in prior art dental aligners. The snap-on dental aligner therefore can ensure that the aligner produces the correct force to achieve a desirable movement in the subject's teeth, which improves the accuracy and effectiveness of the orthodontic treatment by the aligner.

[0038] One disclosed mechanisms in the dental aligners described include through-holes in the dental aligners and connectors fixed on a subject's teeth to receive the through-holes. The disclosed mechanisms allow the dental aligners to be effectively locked into intended positions during wearing by the subject. The registration and holding capability may thus be significantly enhanced.

[0039] The snap-on dental aligners may also lengthen the usage lifetime of an aligner by sustaining corrective forces for a longer period of time. As a result, the number of visits to the dentist office may be reduced. The material and manufacture costs of the aligners for an orthodontic treatment may be decreased. The need for corrective rework due to aligner deformation may also be significantly reduced, which may further reduce costs of the orthodontic treatment.

[0040] Snap-on dental aligners may allow a thinner dental aligner while still engaging that subject's teeth and providing sustainable forces to cause teeth movement. Thinner and lower profiled removable dental aligners are less intrusive to subject's mouth and often more comfortable for the subject to wear. Snap-on dental aligners may be applicable to class II bite corrections in dental treatment.

[0041] The properties of the snap-on aligners may also be simulated and optimized in the design process. The performance of the snap-on aligners can be optimized by varying parameters such as the number, the locations, and the density of the snap-on connectors, and the sizes and locations of the through-holes in the snap-on mechanisms, etc. The snap-on dental aligners can be manufactured by cost-effective processes such as vacuum forming, cutting by a cutter, etching by a laser beam or thermal applier, and CNC based manufacturing.

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[0042] Dental appliances may have properties that differ in various portions of the appliance. Properties that may differ in various regions of the appliance may include one or more of the following: color, texture, flexural strength, tensile modulus, flexural modulus, hardness, thermal conductivity, heat capacity, compression modulus, and toughness. Thus, regions of the appliance may differ from one another by one or more of the properties listed above. Examples of appliances having regions of different properties (as well method of designing, manufacturing and using such appliances) are described herein.

[0043] The difference in properties of the appliance (e.g., a dental aligner) may be introduced by incorporating two or more polymers into an appliance. The polymers may be the same type (e.g. thermoplastic or thermoset) or may be of different types. The polymers may be different chemical compositions (e.g. polyurethane and silicone polymer), or they may be the same chemical composition (e.g. acrylic polymer) that has been formed under different conditions to provide polymers of distinctive properties. The polymers may be homopolymers or copolymers in which the ratio of monomers in regions differs or is the same. The polymers may also be one or more polymer blends or alloys.

[0044] The appliances may be made by e.g. utilizing different polymer sheets in molds to provide an appliance in which layers of polymer in one or more regions or in the entire appliance differ from an adjacent layer or layers, or the appliances may be made by treating a polymer to different processing conditions during appliance manufacturing to provide a continuous polymeric construction across borders of the regions but in which properties differ from region to region across the appliance.

[0045] For example, a method for making a multi-layer dental aligner may comprise placing a first layer of a first aligner-making material over one or more physical tooth models, conforming the first layer of the first aligner-making material to the surfaces of the one or more physical tooth models, placing a second layer of a second aligner-making material over the first layer of the first aligner-making material, and conforming the second layer of the second aligner-making material to the surfaces of the first layer of the first aligner-making material over the one or more physical tooth models to produce the multi-layer dental aligner.

[0046] In some variations, a method for making a multi-layer dental aligner comprises heating a first layer of the first aligner-making material, holding the first layer of the first aligner-making material against one or more physical tooth models by vacuum

suction, cutting the first layer of the first aligner-making material along the gingival lines of the physical tooth models, heating a second layer of the second aligner-making material, holding the second layer of the second aligner-making material against the first layer of the first aligner-making material over the physical tooth models by vacuum suction, and cutting the second layer of the second aligner-making material along the gingival lines of the physical tooth models to produce the multi-layer dental aligner.

[0047] In some variations, a multi-layer dental aligner may comprise a first layer of a first aligner-making material and a second layer of a second aligner-making material, wherein at least one of the first layer and the second layer is formed by heating a layer of an aligner-making material and holding the layer of the aligner-making material against one or more physical tooth models.

[0048] Another method for making a non-uniform dental aligner comprises non-uniformly heating the sheet of aligner-making material, and holding the sheet of aligner-making material against one or more physical tooth models to produce the non-uniform dental aligner.

[0049] Additionally, a method for making a non-uniform dental aligner may comprise heating a first section of a sheet of aligner-making material at a first temperature for a first period of time, heating a second section of the sheet of aligner-making material at a second temperature for a second period of time, holding the sheet of aligner-making material against the one or more physical tooth models to produce the non-uniform dental aligner by vacuum suction; and cutting the sheet of aligner-making material along the gingival lines of the physical tooth models to produce the non-uniform dental aligner.

[0050] Dental appliances may also be fluid permeable. For example, a dental aligner may be fluid permeable while still supplying adequate strength and structure necessary to move the teeth in the desired manner. "Fluid permeable" may refer to permeability to both liquids (e.g., water, saliva, etc.) and/or gasses (e.g., oxygen). A dental appliance may be fluid permeable because it comprises a fluid permeable material, or because it has been permeabilized by the addition of pores, passages or holes of any appropriate size or shape.

[0051] For example, a shell-shaped dental aligner for producing predetermined movement in a patient's tooth may comprise a shell portion comprising a fluid-permeable material; an outer surface of the shell portion; and an inner surface of the shell portion, the inner surface to be in contact with the patient's tooth, wherein the fluid-permeable material

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can allow fluid to communicate between the patient's tooth and the vicinity of the outer surface.

[0052] A method for treating a patient's teeth may therefore comprising determining an initial configuration of the patient's teeth, determining a final configuration of the patient's teeth, designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps (each having a target configuration for the patient's teeth) and producing a dental aligner comprising a fluid-permeable material to move the patient's teeth to the target configuration associated with a treatment step. A system for treating a patient's teeth may comprising a computer configured to determine a target configuration for the patient's teeth and an apparatus configured to produce a dental aligner comprising a shell portion that comprises a fluid-permeable material, an outer surface, and an inner surface to be in contact with one of the patient's teeth. The fluid-permeable material can allow fluid to communicate between the one of the patient's teeth and the vicinity of the outer surface and the dental aligner is configured to move the patient's teeth to the target configuration.

[0053] Fluid permeable dental aligning devices may readily allow oxygen to pass through to the patient's teeth and cervical lines in the arch. Permitting an increased oxygen concentration under the dental aligning devices can overcome problems related to bacterial growth under the aligner device (which may be a problem for conventional aligner systems). Porous channels may also allow saliva to pass through the dental aligners. Saliva plays a critical role in controlling halitosis and bacterial growth. Saliva contains proteins, carbohydrates, and immunoglobulins that interfere with bacterial metabolism and bacterial adherence to oral surfaces. Saliva is also a solvent that can control mouth odor in the oral chemical environment. Thus, oral hygiene and odor associated with the mouth of a patient wearing a fluid permeable dental aligner may be improved, particularly in comparison with non-permeable or less-permeable appliances. Further, the ability to pass oxygen and saliva not only improves the patient's oral hygiene but may also allow the patient to clean the aligner less frequently, enhancing convenience. The less frequent removal (because of extended wearing) can also lengthen the usage lifetime and the effectiveness of the dental aligning devices.

[0054] The appliances described herein may also be disposable. Thus, a method for treating a patient's teeth with a disposable aligner may include using more than one

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appliance (e.g., 2, 3, 4, etc.) that are otherwise identical for each step of the treatment. For example, one method of treating a patients teeth using disposable aligners includes: determining an initial configuration of the patient's teeth, determining a final configuration of the patient's teeth, designing a movement path for at least one of the patient's teeth from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps, each having a target configuration for the patient's teeth, and producing two or more dental aligners of substantially identical shape for at least one of the treatment steps in accordance with the target configuration. Aligners having substantially identical shape are generally aligners that would produce the same movement of the teeth if either aligner were placed on an identical (e.g., initial) dental arch.

[0055] A method for treating a patient's teeth may also comprise: determining a target configuration for the patient's teeth, producing two dental aligners having substantially identical shape, and using the two dental aligners to move the patient's teeth to the target configuration.

[0056] Disposable aligner may be used for each step of the treatment process, or may be used for only some (e.g., steps requiring the same shaped aligner to be worn for an extended period) treatment steps. In some variations, a disposable aligner may be provided for pre-determined increments of time (e.g., for each day, each week, each month, etc.). Thus, a system for treating a patient's teeth may comprise: a computer configured to determine a target configuration for the patient's teeth; and an apparatus configured to produce two dental aligners configured to move the patient's teeth to the target configuration, wherein the two dental aligners have substantially identical shape.

[0057] Disposable aligners may provide convenient dental aligning devices for patients. The dental aligners. As used herein the term "disposable" aligners refers may refer to redundant dental aligners provided to the patient at each treatment step so that a "new" aligner having the same shape can be used during one or more of the treatment steps. Thus, if a dental aligner is lost or damaged, the patient does not have to request another aligner and wait for it to be made and sent to her. This may make treatment and storage of the aligners easier for the patient, as special care (to prevent damage, loss or wear) does not need to be taken. The disclosed disposable dental aligners are therefore more convenient for patients to use. The costs may also be reduced for re-ordering and remaking lost or damaged dental aligners.

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[0058] Disposable aligners may also provide more accurate and effective dental treatment for the patients. Conventional dental aligners often relax over the use of a period of time and lose their strength to exert intended forces on the patients' teeth, which results in ineffective and inaccurate movements for the dental treatment. When multiple dental aligners are provided at each treatment step, dental aligners can be disposed before they become relaxed. The accuracy and effectiveness of the dental treatment are therefore improved. As a result, the overall treatment time and cost can be reduced.

[0059] Furthermore, disposable aligners may also improves a patient's oral hygiene by allowing the patient to frequently replace the dental aligner worn by a short period of time by new dental aligner.

[0060] The dental appliances described herein may also be configured or fabricated so that they prevent deformation of the appliance. For example, a dental aligner may be configured to allow some flexion or expansion of the appliance in predetermined regions. For example, the appliance may include "wrinkles" over at least a region of their length. A wrinkled aligner typically has one or more surfaces (or regions) that are furrowed, ridged, or creased rather than normally smooth. For example, the wrinkles in the aligner surface may appear crumpled, folded, or curved. The wrinkles may allow the appliance to bend or expand to a greater degree than an otherwise unwrinkled aligner, thereby preventing material stresses that may damage the appliance.

[0061] A method for manufacturing wrinkled dental aligner for a patient's tooth may comprise: developing a digital dental aligner model specifying at least one wrinkled surface on a dental aligner, and producing a dental aligner having the wrinkled surface in accordance with digital dental aligner model.

[0062] In some variations, a method for manufacturing wrinkled dental aligner for a patient's arch, comprises: developing a digital dental arch model based the patient's arch, developing a digital dental aligner model based on the digital dental arch model, wherein the digital dental aligner model specifies one or more wrinkles on a surface, and producing a wrinkled dental aligner in accordance with the digital dental aligner model. A system for manufacturing a wrinkled dental aligner for a patient may comprise: a computer configured to store a digital dental aligner model specifying at least one wrinkled surface on the wrinkled dental aligner, and an apparatus configured to produce the wrinkled dental aligner in accordance with digital dental aligner model.

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[0063] Wrinkled appliances may provide advantages over non-wrinkled appliances. For example, a wrinkled aligner prevents the relaxation of the dental aligner after repeated uses, which is common in prior art systems. The wrinkled dental aligner therefore can ensure the aligner to produce the correct force to produce desirable movement in the patient's teeth, which improves the accuracy and effectiveness of the orthodontic treatment by the aligner. The reduction or elimination of the relaxation and force loss that are problems associated with conventional dental aligners may also lengthen the lifetime of the aligner. As a result, the number of visits to the dentist office is reduced. The material and manufacture costs of the aligners for an orthodontic treatment are decreased. Additionally, corrective rework due to aligner deformation may be significantly reduced, further reducing costs of the orthodontic treatment.

[0064] The properties of the wrinkled aligners can be simulated and optimized in the design process. The performance of the wrinkled aligners can be optimized by simulating and varying wrinkle parameters such as wrinkle depth, wrinkle location and orientation, and wrinkle density. The wrinkled dental aligner can be manufactured by cost-effective processes such as vacuum forming, cutting by a cutter, etching by a laser beam or thermal applier, or CNC based manufacturing.

[0065] Also described herein are aligners that are capable of lateral corrections, including expanding the upper palate. Such aligners may be referred to as "lateral correction aligners" and are for the upper dental arch. Lateral correction aligners typically include a shell region that covers the teeth and contacts at least a portion of the upper pallet. The aligner design encourages movement of the upper palate by modeling the target position of the upper palate and generating one or more incremental steps (as described herein with respect to movements of the teeth). This allows lateral corrections to be made on the teeth and upper pallet.

[0066] Typically, aligners configured for laterally correcting the teeth and/or remodeling the upper palate include a palate-spanning region. In order to provide later force on the teeth and pallet by the aligner, the palate-spanning region may include a support piece for maintaining and/or applying force against the palate and/or teeth. Support pieces may include any material having structural strength (e.g., metals, ceramics, etc.), but in particular, may comprise materials capable of applying force to remodel the upper dental arch. For example, the support piece may be a spring or other expandable member. The support piece may be included (e.g., sandwiched) within the palate region of the aligner.

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This may make the aligner more comfortable, and prevent damage to either the tongue or palate region.

[0067] The lateral correction aligners may be configured either to expand or contract the palate. Further lateral correction aligners may be formed by any of the methods described herein. For example, the lateral correction aligners may be formed using a model of the upper dental arch (e.g., by vacuum-forming one or more layers of material) or may be formed from a digital model (e.g., by CNC, lithography, etc.).

[0068] Thus, lateral correction dental aligners for remodeling a subject's upper dental arch (including the palate region) may include a shell having an outer surface and an inner surface, and a palate-spanning region, wherein the palate-spanning region is configured to contact the subject's upper palate and provide force to remodel the subject's upper arch. The shell region typically comprises a tooth contacting region configured to contact the teeth of the subject's upper arch. As described herein, the shell region typically contacts both sides of the subject's teeth (front and back). The shell region of the lateral correction aligner typically contacts all of the subject's teeth that are present (e.g., including the incisors, canines, bicuspids, molars). The palate-spanning region generally covers at least a portion of the subject's palate when the subject wears the aligner. For example, the palate-spanning region may correspond to a substantial portion of the subject's hard palate. The palate-spanning region may correspond to the front of the subject's hard palate (near the incisors) as well as the back of the subject's hard palate region (e.g., near the molars).

[0069] In some variations, the palate-spanning region further comprises a support piece configured to provide structural support to the palate-spanning region. The support piece may span the entire palate-spanning region, or it may be a portion of the palate-spanning region. The palate-spanning region may be made of a fluid-permeable material as described above, including materials that have been permeablized by adding passages through them (e.g., by laser perforation, etc.).

[0070] Also described herein is a method for reshaping a patient's dental palate, comprising: determining an initial configuration of the patient's teeth and upper palate region (e.g., by modeling or by direct measurement), determining a final configuration of the patient's teeth and upper palate region, designing a movement path for at least a portion of the upper palate region from the initial configuration to the final configuration, dividing the movement path into a plurality of successive treatment steps, and producing a plurality

of dental aligners including a palate-spanning region to remodel the upper palate region to the target configuration.

[0071] The details of one or more embodiments of these dental aligners are set forth in the accompanying drawing and in the description below. Other features, objects, and advantages of the invention will become apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0072] The accompanying drawings, which are incorporated in and form a part of this specification, illustrate embodiments of the invention and, together with the description, serve to explain the principles of the invention:

[0073] Figure 1A-1F show cross-sectional profiles of various through-holes as described herein.

[0074] Figure 2A-2E show cross-sectional profiles of various connectors as described herein.

[0075] Figure 3 illustrates an arrangement of fabricating a snap-on dental aligner.

[0076] Figure 4 illustrates a system diagram for fabricating a snap-on dental aligner.

[0077] Figure 5 is a flow chart for fabricating a set of connected dental aligners for a dental treatment in accordance with the present invention.

[0078] Figure 6 illustrates the side view of a conventional dental aligner newly worn on a subject's tooth.

[0079] Figure 7 shows the side view of a conventional dental aligner worn on a subject's tooth after a period of usage.

[0080] Figure 8 illustrates the top views of a conventional dental aligner when it is newly worn and after it is worn for a period of time.

[0081] Figure 9 illustrates a cross-sectional view of a snap-on dental aligner.

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[0082] Figure 10 is a flow chart for providing orthodontic treatment using a removable multi-layer dental aligner.

[0083] Figure 11 illustrates a tooth model having registration features.

[0084] Figure 12 is a top view of a dental base comprising a plurality of sockets for receiving pins affixed on the physical tooth models.

[0085] Figure 13 illustrates the fabrication of the first layer of a multi-layer dental aligner.

[0086] Figure 14 illustrates the fabrication of the second layer of a multi-layer dental aligner.

[0087] Figure 15 is a top view of a multi-layer dental aligner.

[0088] Figure 16 is a view of another aligner.

[0089] Figure 17 is a cross-sectional view of a multi-layer or non-uniform dental aligner worn on a patient's tooth.

[0090] Figure 18 illustrates an orthodontic process for using a dental aligner comprising a fluid-permeable material.

[0091] Figure 19a illustrates the side view of a new conventional dental aligner worn a patient's tooth.

[0092] Figure 19b shows the side view of a conventional dental aligner worn after a period of usage.

[0093] Figure 20 illustrates the top views of a conventional dental aligner when it is newly worn and after it is worn for a period of time.

[0094] Figure 21 illustrates a process for producing a disposable dental aligner.

[0095] Figure 22 is a flow chart for producing a physical aligner in accordance with the present invention.

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[0096] Figure 23 illustrates the smoothening of the digital aligner model in preparation for a CNC based manufacturing of physical aligner in accordance with the present invention.

[0097] Figure 24 illustrates the segmentation of digital aligner model into segmented components suitable for CNC based manufacturing in accordance with the present invention.

[0098] Figures 25a-25d illustrate the segmentation of an inter-proximal region by removing a space around the inter-proximal region and replacing it by a wedge.

[0099] Figures 26a-26d illustrates aligner components comprising features that allow them to assemble to form an aligner.

[00100] Figure 27 illustrates an aligner assembled from a plurality of aligner components each comprising features that assist the assembling.

[00101] Figure 28 illustrates an arrangement of the wrinkles on aligners.

[00102] Figure 29 illustrates the fabrication of a wrinkled aligner from a sheet of aligner material.

[00103] Figure 30 illustrates the process of designing and fabrication of the wrinkled dental aligners.

[00104] Figure 31a shows a cross-section of one variation of a lateral correction aligner on a dental arch. The same dental aligner is shown in Figure 31b without the dental arch.

[00105] Figure 32a shows a perspective view of one variation of a lateral correction aligner as described herein on a dental arch. Figure 32b shows another perspective view of a lateral correction aligner.

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[00106] Figure 33a shows a cross section of one variation of a lateral dental aligner. Figure 33b shows an expanded view of a region of the lateral dental aligner shown in Figure 33a.

DESCRIPTION OF INVENTION

[00107] Dental appliances are described herein. In general, dental appliances (e.g., dental aligners) are devices which may be worn on a subject's teeth, gingiva or other region of the oral cavity. Dental appliances are typically used to treat malocclusion. Dental appliances may include features which enhance the performance of the appliance. The dental appliances described herein may include features for preventing damage or wear on the appliance (e.g., fluid-permeability, wrinkled structure, modular construction, and varying thickness, stiffness, etc.). The dental appliance may also include features for enhancing the fit of the appliance, (e.g., snap-on features, through-holes, textured surfaces, etc.).

[00108] The following description is presented to enable any person of ordinary skill in the art to make and use the invention. Descriptions of specific materials, techniques, and applications are provided only as examples. Various modifications to the examples described herein will be readily apparent to those of ordinary skill in the art, and the general principles defined herein may be applied to other examples and applications without departing from the spirit and scope of the invention. Thus, the present invention is not intended to be limited to the examples described and shown, but is to be accorded a scope consistent with the appended claims.

[00109] As used herein, the term "dental aligner" refers to a dental device or appliance for rendering corrective teeth movement or for correcting malocclusion. An orthodontic treatment usually includes plurality of treatment steps. One or more dental aligners can be worn on the subject's teeth at each treatment step. The orthodontist first determines the initial configurations of the subject's teeth and decides target final configurations for the subject's teeth at the end of the treatment. One or more dental aligners can then be produced so that a subject wearing the dental aligners will gradually have his or her teeth repositioned by the dental aligner "pushing" (or pulling) against the teeth, or gums (gingiva).

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[00110] As used herein a "subject" may be any subject who may benefit from the use of a snap-on aligner, including orthodontic patients.

[00111] Individual dental aligner appliances generally cover some (or all) of a subject's teeth and may extend to the gums (or other regions of the oral cavity, including the roof of the mouth). In some variations, a dental aligner may comprise a polymeric shell having a teeth-receiving cavity formed therein. The dental aligner may be formed by molding. Each individual appliance may be configured so that its tooth-receiving cavity has a geometry corresponding to an intermediate or end tooth arrangement intended for that appliance. That is, when an appliance is first worn by the subject, certain of the teeth will be misaligned relative to an un-deformed geometry of the appliance cavity. The appliance, however, is sufficiently resilient to accommodate or conform to the misaligned teeth, and may apply sufficient resilient force against such misaligned teeth to reposition the teeth to the intermediate or end arrangement desired for that treatment step. Examples of dental aligners, as well as additional description, may be found in the figures described below, as well as in the incorporated references.

[00112] The portion of the dental aligner covering the teeth may be referred to as the shell region of the dental aligner. The shell region typically has an inner (e.g., teeth-contacting) surface and an outer surface (opposite to the inner surface). The dental aligner may also be considered to have a tip region (e.g., near the crown of the teeth on which the aligner is worn) and a bottom portion, which may sit near the gums (or gingival) when the aligner is worn on the teeth. Side regions may be identified between the tip region and the bottom region (e.g., and inner side region facing the tongue, and an outer side region facing the lips).

[00113] The dental aligners described herein may further include any or all of the features described below (e.g., snap-on dental aligners, textured, fluid- and/or gas-permeable, wrinkled, modular, or varying thickness, stiffness or other properties) which may be incorporated as part of a dental aligner, individually or in any reasonable combination. For purposes of descriptive convenience only, individual dental aligners are described or illustrated to in the sections that follow to individually emphasize features or aspects of the dental aligners described herein. This arrangement is not intended to be limiting or to imply that the aligners, system, and methods of making or using these aligners are restricted to the examples shown or described.

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[00114] Dental aligners may incorporate features that assist in securing the dental aligner to a subject's teeth, including connectors and through-holes and textured contact surfaces.

Manufacturing a Dental Aligner

[00115] Dental aligners may be fabricated from a digital or actual (e.g., physical) model of a subject's dental arch. The subject's current dental arch is modified to represent a target dental arch (or a series of target dental arches) my incrementally moving the teeth from their current position towards the intended position. Typically, a dental aligner is made by forming an aligner to fit the model of the dental arch that is incrementally different from the current dental arch. Thus, the dental aligner provides force to help correct malocclusions of teeth. In forming the aligner from the model of the dental arch (either digital or actual), it may be beneficial to smooth the model of the teeth, so that the aligner accurately conforms to the dental arch, but does not include surfaces corresponding to sharp edges or spaces which may interfere with the comfort and effectiveness of the aligner.

[00116] Figure 22 illustrates one variation of a process of producing a dental aligner as described herein. First, a three dimensional (3D) digital dental arch model is acquired from a patient's arch in step 4110. The digital dental arch model can be obtained by 3D scanning of a cast produced from the patient's arch. The digital model includes a mesh of points in three dimensions that define the surfaces of an entire or a large portion of an upper or lower arch. Details of obtaining a digital model of an arch are disclosed in above referenced US Patent Application titled "Producing a base for a physical dental arch model" by Huafeng Wen, filed 12/14/2004, the content of which is incorporated herein by reference.

[00117] Next, in step 4120, the digital dental arch model is smoothened by computer processing using computer software. One or more criteria for the degree of smoothness can also be provided by a user. Undesirable features such as sharp edges, gaps, and divots are removed from the digital dental arch model. When a physical model alone is used, the edges may be manually smoothed, and gaps may be filled in (e.g., using wax, etc.).

[00118] The degree of smoothness that is required may depend upon the specific dental application. For example, plastic aligners cannot reach into the gaps between the teeth, and therefore these gaps may be filled in when forming the aligner. In addition, it is also undesirable to have aligner to have fine features inside the gaps because that could

potentially create resistance to desired tooth movement in an orthodontics treatment procedure.

[00119] The criteria for the degree of smoothness can also be determined by the type of tools used to manufacture the aligner components, as described below. For example, Computer Numerical Control (CNC) based manufacturing refers to the automated and computer controlled machining. A CNC machine typically provides automatic, precise, and consistent motion control. All forms of CNC equipment have two or more directions of motion, called axes. These axes can be precisely and automatically positioned along their lengths of travel. The two most common axis types are linear (driven along a straight path) and rotary (driven along a circular path). Instead of causing motion by manually turning cranks and hand wheels as is required on conventional machine tools, CNC machines allow motions to be actuated by servomotors under control of the CNC, and guided by the part program. Generally speaking, the motion type (rapid, linear, and circular), the axes to move, the amount of motion and the motion rate (feed rate) are programmable with almost all CNC machine tools. In the present invention, in addition to CNC based milling, the CNC based manufacturing is also compatible with other computer numerical controlled manufacturing processes such as stereolithography, laser machining, molding as well as other types of CNC based machining.

[00120] For manufacturing a physical dental arch model, however, the drill bit in CNC based milling is usually too big to reach into the gaps and holes in a dental arch model. CNC milling is usually around one axis, which makes it difficult to machine the complex shapes within the gaps between teeth. CNC based milling also has limitations in accuracy and repeatability between different stages of milling.

[00121] Several techniques may be used to remove the gaps in the digital dental arch model to produce a smoothened digital dental arch model. These techniques include:

[00122] (1.) Boolean union with primitive 3D objects. Graphics Constructive Solid Geometry primitives or self developed predefined geometries can be inserted into the gaps in the digital dental arch model and then combine with the original 3D digital mesh.

[00123] (2.) Extrusion. The surfaces near the gaps are extruded to fill the gaps in the original 3D digital mesh.

[00124] (3.) Geometry modification by moving vertices. Sharp gaps can be closed by specifying the desired boundaries and modifying the mesh to the desired boundaries in the problem regions.

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[00125] (4.) Subdivision of surfaces and movement. Similar to Technique 3, the dental arch surfaces are subdivided in the regions of surface modification for greater smoothness and continuity.

[00126] (5.) Convex hull creation of sub parts to be used as filling objects in the gaps. The gap regions are first located and the points defining edges of the sharp gaps are identified. A convex hull is computed based on these points. The convex hull is joined with the original mesh to fill the gaps using Boolean union.

[00127] (6.) Using parametric surfaces to model fill objects that will be used fit in the gaps.

[00128] Figure 23 illustrates the smoothening effects of the gap filling by comparing the surfaces 4210 of before gap fillings and the surfaces 4220 after the gap fillings.

[00129] A simulation can be conducted using the smoothened the digital dental arch model as input to check and verify the smoothness of the digital dental arch model. The simulation can be run using simulator software in response to the smoothness criteria required by the manufacturing process such as CNC based milling or the dental applications. Refinement ad smoothening iterations may be called for if the smoothness criteria are not completely satisfied.

[00130] Once the dental arch model is smoothed, an aligner model may be developed based on the smoothed dental arch model (e.g., a digital arch model). For example a smoothed digital arch model may be used to develop a digital aligner model, as shown in Fig. 22, Step 4130. The digital aligner model typically comprises an inner surface and an outer surface. Since the inner surface(s) of the aligner will be in contact with the outer surface of the patient's teeth (and sometimes gingiva), the inner surfaces of the digital aligner model may approximately follow the contours of the outer surface of the digital dental arch model, so that the dental aligner will fit (e.g., snap) onto the arch. Moreover, the inner and outer surfaces of digital aligner may be designed to various shapes and thickness that may apply the desired forces in order to achieve the movement of the teeth in accordance with a treatment plan.

[00131] In the method outlined in Figure 22, the digital aligner is next divided into smaller components that may be easily manufactured (e.g., by CNC techniques) and reassembled to form a final aligner. In Step 4140, the digital aligner model is segmented into digital aligner components suitable for CNC manufacturing. A typical aligner in the digital aligner model includes an upper or lower aligner respectively for the upper and

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lower arch or a portion of an arch comprising a plurality of teeth. An aligner 4300 is shown in Figure 24. The aligner components 4310, 4320 can correspond to a portion or region of a dental arch model (e.g., a portion of a tooth, a whole individual tooth, or sometimes a segment of arch including several teeth).

[00132] The criteria for the size, location, and the number of aligner components are based on both orthodontic needs and manufacturing requirements. The orthodontic criteria require the tracking of how the original locations of the aligner components and which components can be moved together as a group, which aligner components must be moved independently, and which teeth cannot be moved.

[00133] The manufacturing requirements relate mainly to the manufacturability of the digital aligner components, which usually supersedes the orthodontic criteria. For example, a single tooth can be divided into multiple components to make its model manufacturable. The segmented digital components can be evaluated by a simulation software to verify their manufacturability by a specific manufacture process such as CNC based milling, which may suggest refinement in the size, location, and numbers of the segmentation. The simulation can also include an evaluation and estimation of the physical strength after the assembly, as described below, to determine if the assembled aligner components are strong enough to withstand the physical forces in a pressure forming process.

[00134] In one variation, a digital aligner model can be smoothened during the segmentation. Different segmented digital components may receive different types or degree of smoothening so that the smoothening is tailored to the segments and manufacturing requirements.

[00135] By the method described in Figure 22, an aligner model can be segmented to small, manufacturable aligner components that can be manufactured by automated, precise numerical manufacturing techniques. The manufacturability of the digital components may be simulated, verified and refined if necessary prior to manufacturing. As a result, complex aligner shapes that cannot be made can now be practically manufactured. Waste and cycle times are reduced in the process from design, testing, pilot, to production.

[00136] After designing the segmented aligner and manufacturing the segments, the segments may be assembled to form a complete aligner. For example, in step 4150, one or more features are added to the aligner components to assist the assembling of the aligner components to form an aligner. These features may include a pin, a registration slot, a

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notch, a protrusion, a hole, an interlocking mechanism, a socket, a jig, and a pluggable or an attachable feature. The adjacent manufactured aligner components may include matching male (e.g. mushroom, push pins) and female features (e.g. hole, notches etc.) for attachment. The male and female features can be fabricated for example by casting mold that include female and male matching features in the mold, each responsible for making respective male and female features. The adjacent aligner components can be attached together by simply pushing male feature into the female feature, for example, by pressing a pushpin into a receiving hole. In some variations, the segments may be secured together by an additional step (e.g., by an adhesive, sintering, etc.)

[00137] Special care may be applied to the inter-proximal regions when segmenting the arch into digital components. For example, the inter-proximal regions may involve complexity and details so that CNC based manufacturing techniques (such as cutting or milling) can result in losing details. As shown in Figures 25a and 25b, an inter-proximal region 4440 may be removed between a tooth model 4410 and a tooth model 4420 along the lines 4430. This can be achieved by data processing over the digital dental arch model. A thin gap 4450 may be formed between tooth model 4410 and tooth model 4420. A wedge 4460, shown in Figure 25c, can then be made using CNC based manufacturing technique similar to other manufacturable digital components. The wedge 4470 can be inserted into the gap 4450 to complete the digital tooth arch model. The wedge making and insertion can take into account of the movement of the tooth models 4410, 4420 during the orthodontic treatment. As shown Figure 25d, the wedge 4480 may be made to be slightly sheared. The wedge 4490 inserted between the tooth models 4410, 4420 can therefore induce a relative movement between the tooth models 4410, 4420. In general the relative movement can include translational and directional adjustment in different degrees of freedoms. The resulted tooth arch model can then be used to made dental aligners.

[00138] Figures 26a, 26b, 26c and 26d illustrate examples of the features 4515, 4525, 4535, 4545 in the aligner components 4510, 4520, 4530, 4540 that may allow the aligner components 4510, 4520, 4530, 4540 to be attached to each other to form a whole or part of a physical aligner. Figure 26a shows a feature 4515 having a cubic base for an aligner component 4510. Figure 26b shows a feature 4525 having a star-shaped base for an aligner component 4520. The star-shaped base defines unique orientation when aligner component 4520 is assembled with another aligner component. Figures 26c and 26d show features 4535 and 4545 respectively comprising two and three pins in the aligner

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components 4530 and 4540. The two pins ensure uniquely defined orientation when aligner component 4530 is assembled with another aligner component. Similarly, the three pins in feature 4545 ensure unique configuration when aligner component 4540 is assembled with another aligner component.

[00139] The aligner components 4310, 4320 are manufactured in Step 4160 using CNC based manufacturing techniques. The segmented digital aligner components are provided to as CNC objects input to a CNC machine. The aligner components 4310, 4320 are manufactured individually. In the disclosed methods and systems, the precision and yield of the CNC based manufacturing are high because manufacturability has been considered and verified as part of the designs of the aligner components. Common materials for the aligner components include polymers, urethane, epoxy, plastics, plaster, stone, clay, acrylic, metals, wood, paper, ceramics, and porcelain. A mechanism may be required to hold the components in place during the milling process.

[00140] As described in more detail below, the digital dental aligner model can include wrinkle features to be produced on the aligner components and finally formed on the surfaces of the physical dental aligner. The wrinkle features can be pre-designed and simulated to reduce the relaxation of the aligner after repeated use. The wrinkled aligner or aligner components can be fabricated in accordance with the digital dental aligner model.

[00141] The physical aligner model 4600 is assembled in Step 4170 by assembling the aligner components. Figure 27 illustrates one example of how aligner components 4610, 4520, 4530 can be assembled to form a whole or a portion of a physical aligner model 4600. The different aligner components 4610, 4620, 4630 can be attached or plugged into each other at joining features 650 that can be pins, registration slot, a notch, etc.

[00142] The physical aligners can be used in different dental applications such as dental crown, dental bridge, dental retainer, mouth guard and teeth whitening. For aligner fabrication, for example, each stage of the teeth treatment may correspond to a unique physical aligner model. Aligners can be fabricated based on the digital dental arch model as the teeth movement progresses during the treatment. At each stage of the treatment, the desirable teeth positions for the next stage are calculated. A physical aligner model is fabricated using the process described above for modifying teeth positions in Step 4180.

[00143] The methods and system for forming an aligner described herein may allow variable shape and thickness in the aligner designs as compared to other systems.

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Moreover, the disclosed methods and system provides a wider range of aligner material selections. Analyses over aligner shape can be conducted done to ensure the optimal shape of aligner to be produced to achieve the desired movements at each stage of the orthodontic treatment. In addition, aligners having optimized shapes can achieve certain movements that the prior art cannot achieve. Thus, aligners can be made thinner and more cosmetic, allowing more comfort in wearing. The manufacturing process may be easier and more consistent.

[00144] Aligner components can also be labeled with unique identification marks, and be assembled and detached in predetermined sequences. The assembling and detachment can also be readily automated (for example by a robotic arm under the control of a computer) in accordance with the predetermined sequences.

[00145] The aligner components may also be assembled by pressure forming. The aligner components may be hollow, and have outer surfaces that match the digital aligner components to allow proper union of the aligner components. The aligner components may also be pre-fabricated to interlock (e.g., similar to LEGO™ blocks). The surfaces of the aligner components may include standard registration and attaching features for them to join together. The interlocking aligner components could also be assembled automatically by robotic arms under computer control. The aligner components can be separated and repaired after the assembly. The attaching features between aligner components allow the components to be detached in a sequence. Broken components could be removed, repaired or replaced, followed by re-assembling.

Snap-on Dental Aligners

[00146] In general, Snap-on dental aligners comprise one or more through-holes (or passages) through a wall of the dental aligner so that the dental aligner may be secured to the teeth of a user. For convenience, the snap-on dental aligners described herein may be referred to as aligners (or dental aligners).

[00147] Generally, the snap-on dental aligners described herein also comprise one or more through-holes for a connector to pass through, to secure the aligner to a subject's teeth, to help maintain the shape of the aligner, or to direct force against a subject's teeth. Various types of through-holes and connectors may be used. In addition to serving as attachment sites, through-holes may also allow the gums to "breath" by providing passages in the aligner though which gases and fluids can be exchanged.

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Through-holes

[00148] Any appropriate dental aligner may be used as a snap-on dental aligner, having one or more through-holes for mating with one or more connectors. Furthermore, the through-hole may be any appropriate through-hole that is adequate to secure the aligner to a subject's teeth, or to help maintain the shape of the aligner, or to direct forces to realign a subject's teeth. Through-holes may form passages extending the thickness of a dental aligner (e.g., from the inner surface of the dental aligner to the outer surface of the dental aligner). Through-holes may be engaged by a connector. A through-hole may also be referred to as a "window" or a passage. Thus, the through-hole forms a window or passage through the aligner, potentially providing access to the teeth and gingiva.

[00149] Any number of through-holes may be formed in an individual aligner. One or more through-holes may be used. In some variations, only one through-hole is used. In some variations, one through-hole is used per tooth covered by the aligner. The number of through-holes may be chosen or selected based on individual subject criterion (e.g., based on the force to be applied to move the teeth, the shape of the subject's teeth, and/or the arrangement of the subject's teeth). An orthodontist or other health profession may select the number of holes to be formed on an individual aligner. The number of holes may also depend upon the material used to form the aligner. More through-holes may be formed when the material is more likely to deform with use or age. In some variations, more than one through-hole may be formed for individual teeth covered by the aligner. For example, a pair of symmetrically-located through-holes may be formed on the aligner.

[00150] The number of through-holes may correspond to the number of connectors. Generally, for each connector to be attached to a subject's tooth, there is a corresponding through-hole on the subject-specific aligner. However, an aligner may have more through-holes than connectors. Thus, there may be redundant through-holes, in the event that a connector becomes disengaged, removed, or never used.

[00151] In general, through-holes may be located anywhere on the aligner. For example, through-holes may be located on the bottom region (on either or both sides of a tooth), or may be located on the sides of the aligner, or may be located on the tip region of the aligner. The location may be chosen so that the aligner applies a desired force to the subject's teeth. Thus, through-holes may be more closely located together when the aligner is more likely to slide or become dislodged because of the forces between the teeth and the

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aligner. Similarly, it may be beneficial to have through-holes near the ends of an aligner to aid in securing the aligner to the teeth.

[00152] Thorough-holes may be of any configuration to effectively engage connectors attached to the teeth. Thus, through-holes may have a diameter that is complementary to the shape and size of the connectors to which the aligner with mate. In some variations, the through-holes are sized differently from the connectors for ease of use. For example, all, or a portion, of a through-hole may be larger in diameter than the diameter of a connector so that the connector can easily engage the through-hole. The through-hole may have a constant diameter, or a variable diameter. In one variation, the through-hole may have a wide opening that tapers in to a smaller diameter as it passes from the inner surface to the outer surface of the aligner. In one variation, the through-hole has a larger diameter within the middle of the passage or at the outer portion of the passage. A thorough-hole may also have a smaller diameter than a connector. In some variations, when the connector engages a through-hole having a smaller diameter, the through-hole may expand, and help hold the connector engaged.

[00153] The through-hole may have any appropriate profile. For example, the cross-sectional profile (transecting between the inner and outer surfaces of the device), may be round, polygonal (e.g., triangular, square, asymmetric, etc.). In one variation, the through-hole is a slit cut through the aligner which remains closed until a connector is inserted. The longitudinal profile of the through-hole may also be any appropriate shape. For example, the longitudinal profile may conform to the longitudinal shape of the connector. Thus, if the connector has a knobbed region, the longitudinal profile may include a cavity into which the knob may fit.

[00154] The through-hole may also be formed so as to secure the connector. Thus, the through-hole may be (or may have a region that is) slightly smaller than the profile of the connector. In some variations, the through-hole has a longitudinal profile that is jagged, or edged. For example, the through-hole may have an accordion-type profile. Such edges may mate with edges on the connector. The through-hole may have directional surfaces, such as edges which point in a direction (e.g., from the inner surface to the outer surface) so that a connector may easily engage a through-hole, but less easily withdraw. In one variation, the through-hole includes a rim having a narrower diameter than a region of the connector. Thus, when the connector must "snap" past the rim within the through-hole, and may be locked into position.

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