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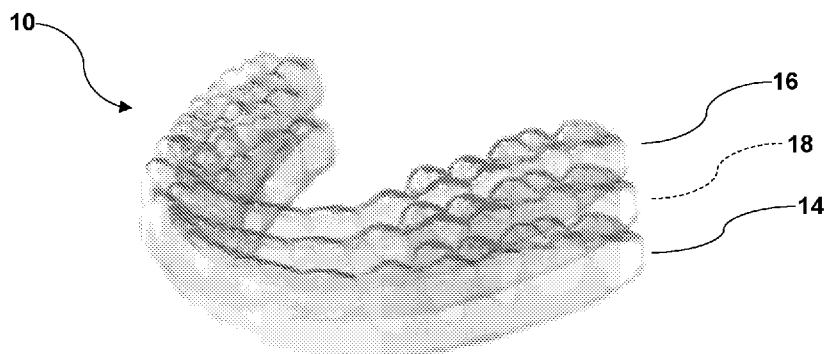


FIG. 2

(57) Abstract: An orthodontic appliance is constructed from shells shaped to receive teeth. The shells can be constructed from one or more polymer materials and stacked and also varyingly affixed to one another, which can include affixing only about the edge of each shell. The orthodontic appliance can be one of a series of similar appliances for incremental orthodontic modification of teeth.



ELASTIC ORTHODONTIC APPLIANCES, SYSTEMS, AND METHODS FOR USE**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims the benefit of U.S. Provisional Application No. 62/797,797, filed January 28, 2019, which is incorporated by reference herein.

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FIELD OF THE INVENTION

[0002] The subject matter of the present disclosure relates generally to the field of orthodontic devices. More particularly, the present disclosure relates to user removable orthodontic devices.

BACKGROUND

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[0003] An objective of orthodontics is to move a patient's teeth to positions where function and/or aesthetics are optimized. Traditionally, appliances such as braces are applied to a patient's teeth by a treating practitioner and the set of braces exerts continual force on the teeth and gradually urges them toward their intended positions. Over time and with a series of clinical visits and reactive adjustments to the braces by the practitioner, the appliances to

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[0004] More recently, alternatives to conventional orthodontic treatment with traditional affixed appliances (e.g., braces) have become available. For example, systems including a series of molded plastic aligners have become commercially available from Align Technology, Inc., San Jose, Calif., under the trade name Invisalign® System. The Invisalign® System is described in numerous patents and patent applications assigned to

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[0005] The Invisalign® System typically includes designing and fabricating multiple aligners to be worn by the patient before the aligners are administered to the patient and used to reposition the teeth (e.g., at the outset of treatment). Often, designing and planning a customized treatment for a patient makes use of computer-based 3-dimensional planning/design tools. The design of the aligners relies on computer modeling of the patient's teeth in a series of planned successive tooth arrangements, and the individual aligners are designed to be worn over the teeth, such that each aligner exerts force on the teeth and elastically repositions the teeth to each of the planned tooth arrangements.

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[0006] Arguably, such aligners are less noticeable than traditional braces because typically aligners are constructed from a transparent material, however, many believe that aligners are

easily noticeable due to the glossy sheen of the transparent material. Like traditional braces, aligners are required to be worn nearly constantly (20-22 hours a day), with breaks allowed for eating and cleaning teeth. Only small breaks are allowed because aligners do not have enough flexibility to account for teeth drifting out of alignment, which based on physical and material characteristics of the aligner. Increasing the working tolerance to account for higher drift requires increasing the working elasticity of an aligner, *i.e.*, the amount an aligner can stretch to mount to teeth without causing permanent deformation, but a highly elastic aligner typically will not provide enough force to move teeth required for orthodontic treatment. Issues like these contribute to failed results or require restart of treatments because patients fail to wear the aligners according to prescribed requirements.

SUMMARY OF THE INVENTION

[0007] Embodiments of the invention relate to orthodontic appliances, systems, and methods of use as summarized in the following paragraphs. Some embodiments relate to orthodontic appliances that maximize working elasticity.

[0008] Some embodiments relate to an orthodontic appliance that can have shells shaped to receive teeth. The shells can be stacked and substantially non-affixed to one another.

[0009] Some embodiments relate to an orthodontic appliance that can have shells shaped to receive teeth. The shells can be stacked and varyingly affixed to one another.

[0010] Some embodiments relate to an orthodontic appliance that can have a plurality of shells shaped to receive teeth being mechanically engaged provide stiffness for applying force to reposition teeth and substantially non-affixed to maximize working elasticity.

[0011] Some embodiments relate to an orthodontic appliance that can have a stack of mechanically engaged shells. The stack of mechanically engaged shells can have a stiffness substantially equivalent to a single shell of the same thickness as the stack. The stack of mechanically engaged shells can have the ability to at least partially mechanically disengage to increase working elasticity.

[0012] Some embodiments relate to an orthodontic appliance that can have a first shell having cavities shaped to receive teeth. The orthodontic appliance can include a second shell than can be shaped to receive the first shell. The second shell can be stacked over the first shell. Surfaces between the first shell are second shell can be mechanically engaged but significantly non-affixed to each other.

[0013] In some embodiments, the second shell and first shell can be affixed to one another at discrete attachment locations of the first and second shells

[0014] In some embodiments, the first shell can have a bottom first surface for directly engaging the teeth and a top first surface opposite the bottom first surface. The second shell
5 can have a bottom second surface for mechanically engaging the top first surface of the first shell and a top second surface opposite the bottom second surface. The top first surface and the bottom second surface are not significantly affixed to each other.

[0015] In some embodiments, the discrete attachment locations of fixation comprise less than 1-80 % of the combined surface areas of the top first surface and the bottom second
10 surface.

[0016] In some embodiments, the first shell has a first edge between top first and bottom first surfaces, and the second shell has a second edge between top second and bottom second surfaces, wherein the discrete attachment locations are located about the first and second edges.

15 **[0017]** In some embodiments, the shells can be made of the same material.

[0018] In some embodiments, a relatively highly elastic shell can be provided between said shells.

[0019] In some embodiments, the shells can include a first shell that can have cavities shaped to receive teeth, and at least one additional shell that can be shaped to receive the first
20 shell, wherein the at least one additional shell can be stacked over the first shell.

[0020] In some embodiments, the first shell and at least one additional shell can be affixed to one another at discrete attachment locations of the first and at least one additional shells.

[0021] In some embodiments, the first shell can have a bottom first surface for directly engaging the teeth and a top first surface opposite the bottom first surface. The at least one
25 additional shell can have a bottom second surface for mechanically engaging the top first surface of the first shell and a top second surface opposite the bottom second surface. The top first surface and the bottom second surface can be arranged to not be significantly affixed to each other.

[0022] In some embodiments, the first shell can have a first edge between top first and
30 bottom first surfaces, and the at least one additional shell can have a second edge between top

second and bottom second surfaces. The discrete attachment locations can be located about the first and second edges.

5 **[0023]** In some embodiments, the first shell can have a bottom first surface for directly engaging the teeth and a top first surface opposite the bottom first surface and a first edge defined therebetween. The at least one additional shell can have a bottom second surface for mechanically engaging the top first surface of the first shell and a top second surface opposite the bottom second surface and a second edge defined therebetween. Some or all of the first edge and the second edge can be arranged to not contact one another.

10 **[0024]** In some embodiments, the at least one additional shell can be a second shell, and the shells can include a third shell.

[0025] In some embodiments, the shells can only consist of the first, second, and third shells.

[0026] In some embodiments, the second edge can be affixed to the top or bottom first surface.

15 **[0027]** In some embodiments, the first edge can be affixed to the bottom or top second surface.

[0028] In some embodiments, the first edge and the second edge can be separated by 0.2-2.0 mm.

20 **[0029]** In some embodiments, the at least one additional shell can be a second shell, and the shells can include a third shell having a bottom second surface for mechanically engaging the top second surface of the second shell and a top third surface opposite the bottom third surface and a third edge defined therebetween. Some or all of the first edge, second edge, and third edge can be arranged to not contact one another.

25 **[0030]** In some embodiments, the first edge, second edge, and third edge are separated by 0.2-3.0 mm.

[0031] In some embodiments, all of the shells can be constructed from a same type of material.

[0032] In some embodiments, varying affixed can mean having attachment locations that can be less than 1-80 % of the combined surface areas of the shells.

[0033] In some embodiments, varyingly affixed can mean having attachment locations that can be less than 1-60 % of the combined surface areas of the shells.

[0034] In some embodiments, varyingly affixed can mean having attachment locations that can be less than 1-40 % of the combined surface areas of the shells.

5 **[0035]** In some embodiments, varyingly affixed can mean having attachment locations that can be less than 1-20 % of the combined surface areas of the shells.

[0036] Some embodiments relate to a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The system can include a plurality orthodontic appliances shaped to receive and reposition teeth. The plurality orthodontic appliances can
10 include at least one aspect of the orthodontic appliances described herein.

[0037] Some embodiments relate to a method for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. The method can include steps of incrementally using the system.

[0038] In some embodiments, the at least one orthodontic appliance of the system can be
15 used less than 12 hours a day.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] For a better understanding of at least certain embodiments, reference will be made to the following Detailed Description, which is to be read in conjunction with the accompanying drawings.

20 **[0040]** FIG. 1 is a perspective view of a jaw and an orthodontic appliance, according to some embodiments.

[0041] FIG. 2 is an exploded view of an orthodontic appliance, according to some embodiments.

[0042] FIG. 3A is a connection schematic for an orthodontic appliance, according to some
25 embodiments.

[0043] FIG. 3B is a detail view of a connection schematic for an orthodontic appliance, according to some embodiments.

[0044] FIG. 4 is a perspective view of a process for molding an orthodontic appliance, according to some embodiments.

[0045] The figures depict various embodiments of the present invention for purposes of illustration only, wherein the figures use like reference numerals to identify like elements. One skilled in the art will readily recognize from the following discussion that alternative embodiments of the structures and methods illustrated in the figures may be employed
5 without departing from the principles of the invention described herein.

DETAILED DESCRIPTION

[0046] Embodiments are disclosed that relate to orthodontic appliances constructed from multiple shells for the purpose of maximizing working elasticity, which is defined herein as the capability of an orthodontic appliance to elastically deform to attach to an initial location
10 of the teeth. This flexibility can allow an orthodontic appliance to obtain a greater range of initial tooth arranging (i.e., flexing) positions that differ from the appliance's target tooth arranging (i.e., resting) position. Possible benefits include greater break time (e.g., 8-12 hours) between required wear periods and greater latitude for patient non-adherence to required wear-times, and hence increased efficacy.

[0047] Before the present invention is described in greater detail, it is to be understood that
15 this invention is not limited to particular embodiments described, as such can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0048] Where a range of values is provided, it is understood that each intervening value, to
20 the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges can independently be included in the smaller ranges and are also encompassed within
25 the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[0049] Unless defined otherwise, all technical and scientific terms used herein have the same
30 meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

[0050] It is noted that, as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements or use of a “negative” limitation.

[0051] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which can be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order that is logically possible.

[0052] FIG. 1 provides an appropriate starting point in a detailed discussion of various embodiments of the present invention with respect to tooth repositioning appliances designed to apply repositioning forces to teeth. An orthodontic appliance 10 can be worn by a patient in order to achieve an incremental repositioning of individual teeth in the jaw 12. The orthodontic appliance 10 can include a shell having teeth-receiving cavities that receive and resiliently reposition the teeth. In some embodiments, a polymeric appliance can be formed from a sheet of suitable layers of polymeric material. An appliance can fit over all teeth present in an upper or lower jaw, or less than all of the teeth.

[0053] In some embodiments, only certain teeth received by an appliance will be repositioned by the appliance while other teeth can provide a base or anchor region for holding the appliance in place as it applies force against the tooth or teeth targeted for repositioning. In some cases, many or most, and even all, of the teeth will be repositioned at some point during treatment. Teeth that are moved can also serve as a base or anchor for holding the appliance as it is worn by the patient. Typically, no wires or other means will be provided for holding an appliance in place over the teeth. In some cases, however, it may be desirable or necessary to provide individual anchors on teeth with corresponding receptacles or apertures in the appliance so that the appliance can apply a selected force on the tooth.

Basic methods for determining an orthodontic treatment plan using a series of incremented appliances as well as instructions for molding orthodontic appliances, are described in U.S. Pat. Nos. 6,450,807, and 5,975,893, which are incorporated by reference herein, but only to an extent that those patents do not contradict the newer teachings disclosed herein.

[0054] An appliance can be designed and/or provided as part of a set of a plurality of appliances. In such an embodiment, each appliance may be configured so a tooth-receiving cavity has a geometry corresponding to an intermediate or final tooth arrangement intended for the appliance. The patient's teeth can be progressively repositioned from an initial tooth arrangement to a target tooth arrangement by placing a series of incremental position adjustment appliances over the patient's teeth. A target tooth arrangement can be a planned final tooth arrangement selected for the patient's teeth at the end of all planned orthodontic treatment. Alternatively, a target arrangement can be one of many intermediate arrangements for the patient's teeth during the course of orthodontic treatment. As such, it is understood that a target tooth arrangement can be any planned resulting arrangement for the patient's teeth that follows one or more incremental repositioning stages. Likewise, an initial tooth arrangement can be any initial arrangement for the patient's teeth that is followed by one or more incremental repositioning stages.

[0055] The orthodontic appliances can be generated all at the same stage or in sets or batches, e.g., at the beginning of a stage of the treatment, and the patient wears each appliance until the pressure of each appliance on the teeth can no longer be felt or has resulted in the maximum amount of expressed tooth movement for that given stage. A plurality of different appliances (e.g., set) can be designed and even fabricated prior to the patient wearing any appliance of the plurality. After wearing an appliance for an appropriate period of time, the patient replaces the current appliance with the next appliance in the series until no more appliances remain. The orthodontic appliances are generally not affixed to the teeth and the patient may place and replace the appliances at any time during the procedure (e.g., patient-removable appliances).

[0056] The final orthodontic appliance or several appliances in the series may have a geometry or geometries selected to overcorrect the tooth arrangement, i.e., have a geometry which would (if fully achieved) move individual teeth beyond the tooth arrangement which has been selected as the "final." Such over-correction may be desirable in order to offset potential relapse after the repositioning method has been terminated, i.e., to permit movement of individual teeth back toward their pre-corrected positions. Over-correction may also be beneficial to speed the rate of correction, i.e., by having an appliance with a geometry that is positioned beyond a desired intermediate or final position, the individual teeth will be shifted toward the position at a greater rate. In such cases, the use of an appliance can be terminated before the teeth reach the positions defined by the appliance.

[0057] FIG. 2 shows an exploded view of an example of the orthodontic appliance 10. The orthodontic appliance 10 can include a first shell 14 having a teeth engaging surface and an opposite upper surface. The orthodontic appliance 10 can also include a second shell 16 having a lower-shell engaging surface and an opposite upper surface that is exposed to the mouth. Optionally, one or more additional shells 18 can be located between the first shell 14 and the second shell 16. In some embodiments, the more shells that are used, the greater the working elasticity of the orthodontic appliance 10, assuming use of the same material for each shell.

[0058] While the orthodontic appliance 10 is shown in an exploded view for the purpose of better understanding, the shells of the orthodontic appliance 10 are intended to be mechanically engaged with one another in a stack. "Mechanically engaged" is defined herein as the substantially non-affixed or varyingly affixed engagement between one or more shells to approximate the strength of a single shell appliance of approximately the same thickness as the stacked shells. Mechanical engagement can be obtained by stacking the shells while having the lower-shell engaging surface of the second shell largely conforming to the upper surface of the first shell. In some embodiments, shells can be stacked loosely, i.e., without a compressive or an interference fit between shells or such that an upturned stack of shells self-disassembles, before being made substantially non-affixed or varyingly affixed. The shells are substantially non-affixed (or varyingly affixed) because a substantial amount of surface areas between the shells are not bonded or otherwise made inseparable through some process, with the remaining surfaces being affixed. In some embodiments, substantially non-affixed or varyingly affixed shells have less than 1-2 %, 1-5 %, 1-10 %, 1-20 %, 1-40 %, 1-60 %, or 1-80 % of the combined contacting surfaces of the shells affixed. The area of non-fixation can be limited according to the needs of the appliance, hence, in some embodiments, a majority the surface areas of the appliance are affixed, while the remaining part is non-affixed because only the latter requires high working elasticity.

[0059] In some embodiments, the lack of substantial fixation between shells provides greater working elasticity to the orthodontic appliance 10 because the teeth-engaging shell can flex more due to being thinner while the outer shells are allowed to flex in multiple directions away from the teeth-engaging shell. In some embodiments, this can result in partial mechanical disengagement between some of the engaging surfaces of the shells, however the disengagement is not enough to significantly impair flexural modulus of the device required for aligning the teeth to the target position.

[0060] FIG. 3A shows a schematic for affixing the shells of the orthodontic appliance 10 at discrete locations. Each encircled “X” represents a possible point of fixation between the shells. Alternatively, as shown by the dashed line, the edges of each shell can serve as a continuous or non-continuous area of fixation. Generally, the more fixation provided, the less working elasticity the orthodontic appliance 10 will have. Points of fixation can be determined based on the amount of working elasticity required, which teeth are being moved, and which teeth are serving as anchors. Alternatively, the shells can be uniformly and weakly bonded with a highly elastic material of low cohesive strength that allows for a large amount of stretching and/or shearing. Such embodiments are substantially non-affixed or varyingly affixed because the working flexibility of such an orthodontic appliance are maintained due to the properties of the weak bond.

[0061] In some embodiments, shells of the orthodontic appliance 10 can be non-identical such that surface areas of one shell is greater or less than another shell. Accordingly, in some embodiments, edges, which are defined by the top and bottom surfaces of each shell, of such shells can be separated by gaps (e.g. 0.20-3.0 mm), as depicted by FIG. 3B, which shows an example with three shells 14, 16, 18 and three edges 14a, 16a, 18a. In some embodiments, referring to the arrangement shown at FIG. 2, bottom-most shell 14 can have the greatest surface area, resulting in edge 14a being at the bottom most position, shown, with shells 18 and 16 respectively having smaller surfaces areas such that edge 16a is at the top-most position. In such embodiments, the shells 14, 16, 18 are stacked such that steps formed by edges 14a, 16a, 18a face outward, away from the teeth. In some embodiments, referring to the arrangement shown at FIG. 2, top-most shell 16 can have the greatest surface area, resulting in edge 16a being at the bottom most position, shown, with shells 18 and 14 respectively having smaller surfaces areas such that edge 14a is at the top-most position. In such embodiments, the shells 14, 16, 18 are stacked such that inward facing steps formed by edges 14a, 16a, 18a face inward, i.e., towards the teeth.

[0062] Providing one or more of such gaps can be used to tune flexural modulus of the orthodontic appliance 10 and also result in less tongue irritation to the patient that can occur due to material thickness where edges are bonded at the same location. To alleviate irritation, gaps can be placed in areas that face inwards towards the mouth, resulting in stepped edges (e.g., edges 14a, 16a, 18a) facing the tongue, or the tooth-engaging shell can have a smaller surface area than shells stacked thereon, resulting in interior, tooth-facing steps and a single shell edge (e.g., edge 16a) that can contact the tongue. In some embodiments, the bottom-

most, tooth-engaging shell, can have a greater or lesser total surface area than a second shell stacked thereon, which can result in at least a portion of the edge of the second shell being separated from the edge of the tooth-engaging shell. In some embodiments, only portions of the edges that face towards the mouth have such a gap, and in other embodiments, a uniform or non-uniform gap can exist between the entirety of edges. In some embodiments, the orthodontic appliance 10 can include shells, each having different surface areas.

[0063] The shells can have thicknesses ranging from 0.001 - 0.015 inches thick, and can be constructed from a polyester, a co-polyester, a polycarbonate, a thermoplastic polyurethane, a polypropylene, a polyethylene, a polypropylene and polyethylene copolymer, an acrylic, a cyclic block copolymer, a polyetheretherketone, a polyamide, a polyethylene terephthalate, a polybutylene terephthalate, a polyetherimide, a polyethersulfone, a polytrimethylene terephthalate or a combination thereof. In some embodiments, shells are coated with lubricous materials or provided with surface treatments to decrease friction between the shells. In some embodiments, interior portions of the shells are treated with hydrophobic coatings to prevent liquid intrusion into the shells. In some embodiments, shells of relatively more flexibility can be used in conjunction with stiffer shells. Flexible shells can be constructed from hydrogels, styrenic block copolymers (SBC), silicone rubbers, elastomeric alloys, thermoplastic elastomers (TPE), thermoplastic vulcanizate (TPV) elastomers, polyurethane elastomers, block copolymer elastomers, polyolefin blend elastomers, thermoplastic co-polyester elastomers, thermoplastic polyamide elastomers, or a combination thereof. Flexible shells may also provide the benefit of a gasket to prevent liquid intrusion between the shells.

[0064] FIG. 4 depicts an example of a basic process 30 for forming an orthodontic appliance. As shown, a material 32 can be formed into an orthodontic appliance 36. The material 32 can be of one layer to form a single shell or multiple non-affixed layers of material to form multiple shells at once. In this example process, the tooth positioning appliance 36 can be produced with the use of a physical tooth model, or mold, 34. The tooth positioning appliance 36 can be produced by heating the thermoformable material 32 and then vacuum or pressure forming the material over the teeth in the physical tooth model 34. The tooth positioning appliance 36 is a direct representation of the physical tooth model. In some embodiments, material 32 is dimensioned (e.g., 120mm and/or 125mm diameter circle) for ready processing on a commercially available forming device (e.g., Erkoform®, Erkoform-3dmotion®, Biostar®, Ministar S®, Drufomat Scan®, Drufosmart®, Essix®

SelectVac®). Guidelines for operating such forming devices can be found at Scheu Dental Technology, *Biostar Operating Manual*, DE/GB/FR/IT/ES/1.000/06/19 G REF PM 0113.01; Scheu Dental Technology, *Application booklet for the pressure moulding technique*, GB 2.000/07/19 G REF 0111.02; Erkodent, *Thermoforming*, S15-3106-48; Erkodent, *Erkoform 3D*, 61-8002-2; Erkodent, *Erkoform-3D+ Instructions*, BA-Erkoform-3d+-anl-EN-04-04-2019, which are incorporated by reference herein.

[0065] After formation, shells can be affixed to one another according to the desired working elasticity required for the patient. Methods of fixation include chemical bonding, localized melting, fasteners, and/or localized physical deformation to key the shells together. Before or after fixation takes place, excess material from the sheet can be trimmed to form a final tooth positioning appliance that can be used for orthodontic treatment of a patient. The edges of the shells can be sealed with a flexible material such as silicone to prevent liquid intrusion.

[0066] One or a series of physical tooth models, such as the model described above, may be used in the generation of elastic repositioning appliances for orthodontic treatment. Similar to the process above, each of the appliances can be generated by thermoforming a multilayer polymeric material over a mold of a desired tooth arrangement to form a dental appliance. The tooth positioning appliance of the desired tooth arrangement generally conforms to a patient's teeth but is slightly out of alignment with the initial tooth configuration. Placement of the elastic positioner over the teeth applies controlled forces in specific locations to gradually move the teeth into the desired configuration. Repetition of this process with successive appliances comprising new configurations eventually moves the teeth through a series of intermediate configurations to a final desired configuration.

[0067] Throughout the foregoing description, and for the purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the described techniques. It will be apparent, however, to one skilled in the art that these techniques can be practiced without some of these specific details. Although various embodiments that incorporate these teachings have been shown and described in detail, those skilled in the art could readily devise many other varied embodiments or mechanisms to incorporate these techniques. Also, embodiments can include various operations as set forth above, fewer operations, or more operations; or operations in an order. Accordingly, the scope and spirit of the invention should be judged in terms of the claims, which follow as well as the legal equivalents thereof.

CLAIMS

What is claimed is:

1. An orthodontic appliance comprising shells shaped to receive teeth, the shells being
5 stacked and being varyingly affixed to one another.
2. The orthodontic appliance of claim 1, wherein the shells comprise:
a first shell having cavities shaped to receive teeth,
at least one additional shell shaped to receive the first shell, wherein the at least one
10 additional shell is stacked over the first shell.
3. The orthodontic appliance of claim 2, wherein the first shell and at least one
additional shell are affixed to one another at discrete attachment locations of the first and at
least one additional shells.
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4. The orthodontic appliance of claim 2, wherein the first shell has a bottom first surface
for directly engaging the teeth and a top first surface opposite the bottom first surface,
wherein the at least one additional shell has a bottom second surface for mechanically
engaging the top first surface of the first shell and a top second surface opposite the bottom
20 second surface, wherein top first surface and the bottom second surface are not significantly
affixed to each other.
5. The orthodontic appliance of claim 4, wherein the first shell has a first edge between
top first and bottom first surfaces, and the at least one additional shell has a second edge
25 between top second and bottom second surfaces, wherein the discrete attachment locations
are located about the first and second edges.
6. The orthodontic appliance of claim 2, wherein the first shell has a bottom first surface
for directly engaging the teeth and a top first surface opposite the bottom first surface and a
30 first edge defined therebetween, wherein the at least one additional shell has a bottom second
surface for mechanically engaging the top first surface of the first shell and a top second
surface opposite the bottom second surface and a second edge defined therebetween, wherein
some or all of the first edge and the second edge do not contact one another.

7. The orthodontic appliance of claim 6, wherein the second edge is affixed to the top or bottom first surface.
- 5 8. The orthodontic appliance of claim 6, wherein the first edge is affixed to the bottom or top second surface.
9. The orthodontic appliance of claim 6, wherein the first edge and the second edge are separated by 0.2-2.0 mm.
- 10
10. The orthodontic appliance of claim 6, wherein the at least one additional shell is a second shell, and wherein the shells comprise a third shell having a bottom second surface for mechanically engaging the top second surface of the second shell and a top third surface opposite the bottom third surface and a third edge defined therebetween, wherein some or all
15 of the first edge, second edge, and third edge do not contact one another.
11. The orthodontic appliance of claim 10, wherein the first edge, second edge, and third edge are separated by 0.2-3.0 mm.
- 20 12. The orthodontic appliance of claim 1, wherein all of the shells are constructed from a same type of material.
13. The orthodontic appliance of claim 1, wherein varyingly affixed comprises having attachment locations that comprise less than 1-80 % of the combined surface areas of the
25 shells.
14. The orthodontic appliance of claim 13, wherein varyingly affixed comprises having attachment locations that comprise less than 1-60 % of the combined surface areas of the
30 shells.
15. The orthodontic appliance of claim 14, wherein varyingly affixed comprises having attachment locations that comprise less than 1-40 % of the combined surface areas of the shells.

16. The orthodontic appliance of claim 15, wherein varyingly affixed comprises having attachment locations that comprise less than 1-20 % of the combined surface areas of the shells.

5 17. The orthodontic appliance of claim 2, wherein the at least one additional shell is a second shell, and wherein the shells comprise a third shell.

18. The orthodontic appliance of claim 17, wherein the shells only consist of the first, second, and third shells.

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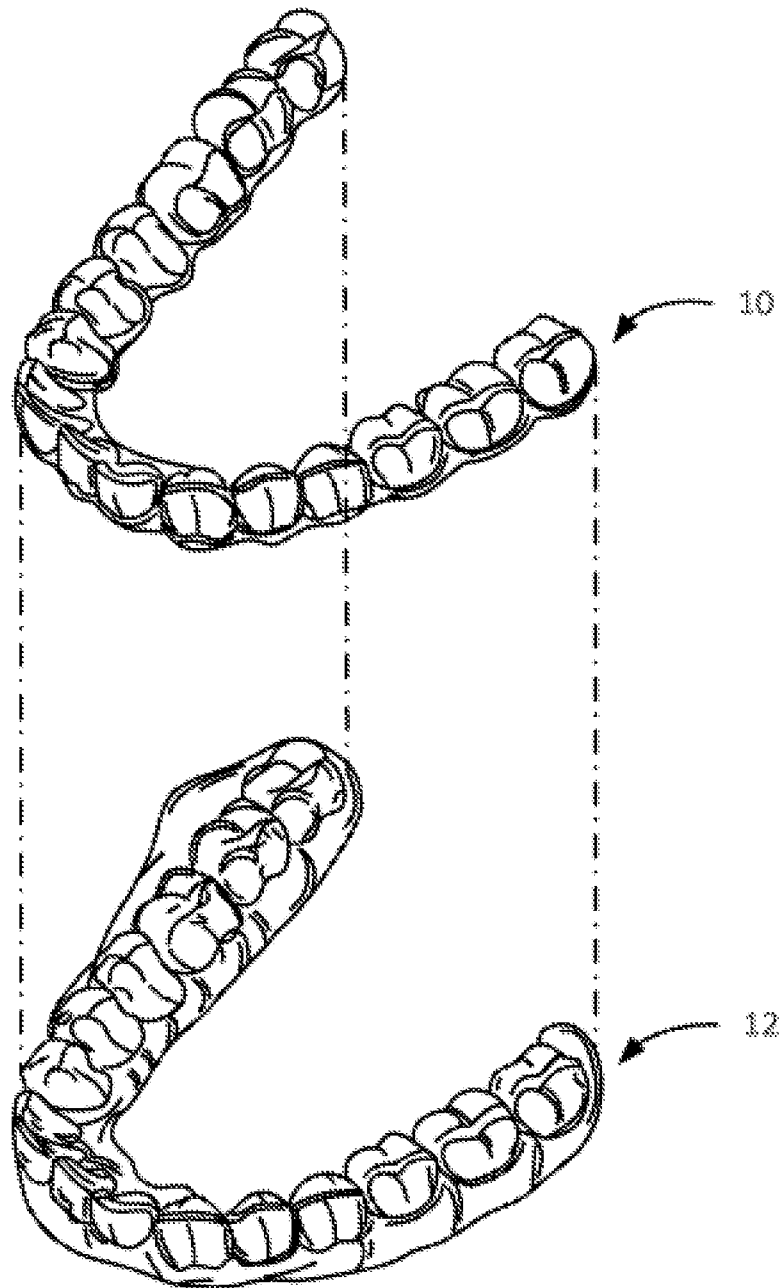


FIG. 1

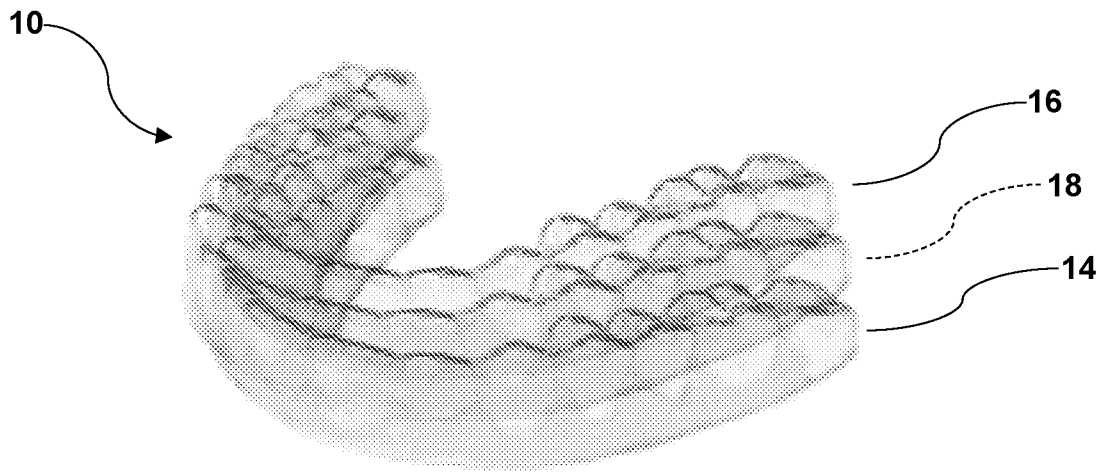


FIG. 2

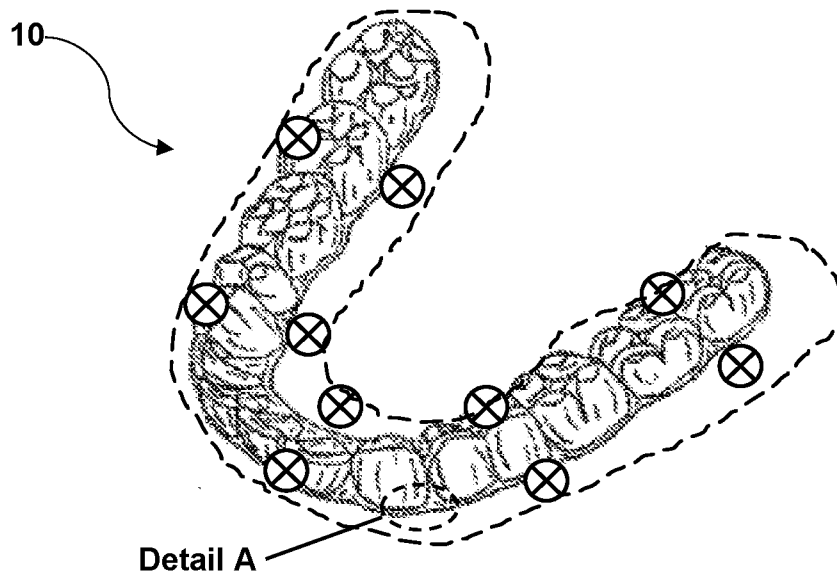


FIG. 3A

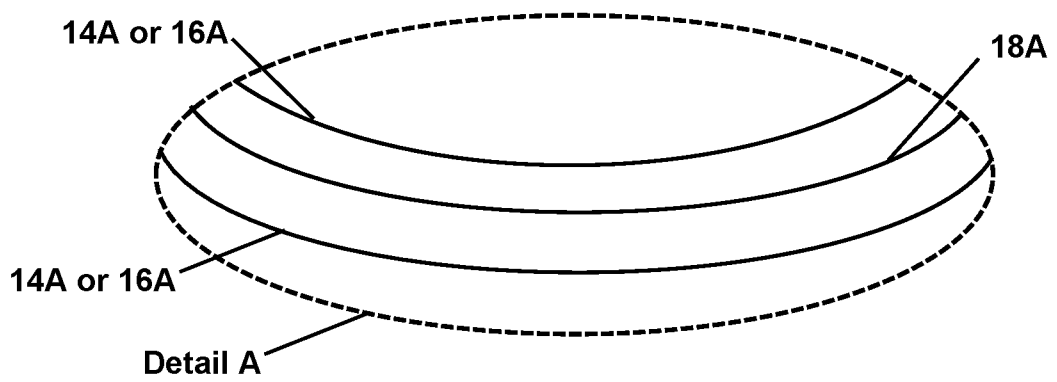


FIG. 3B

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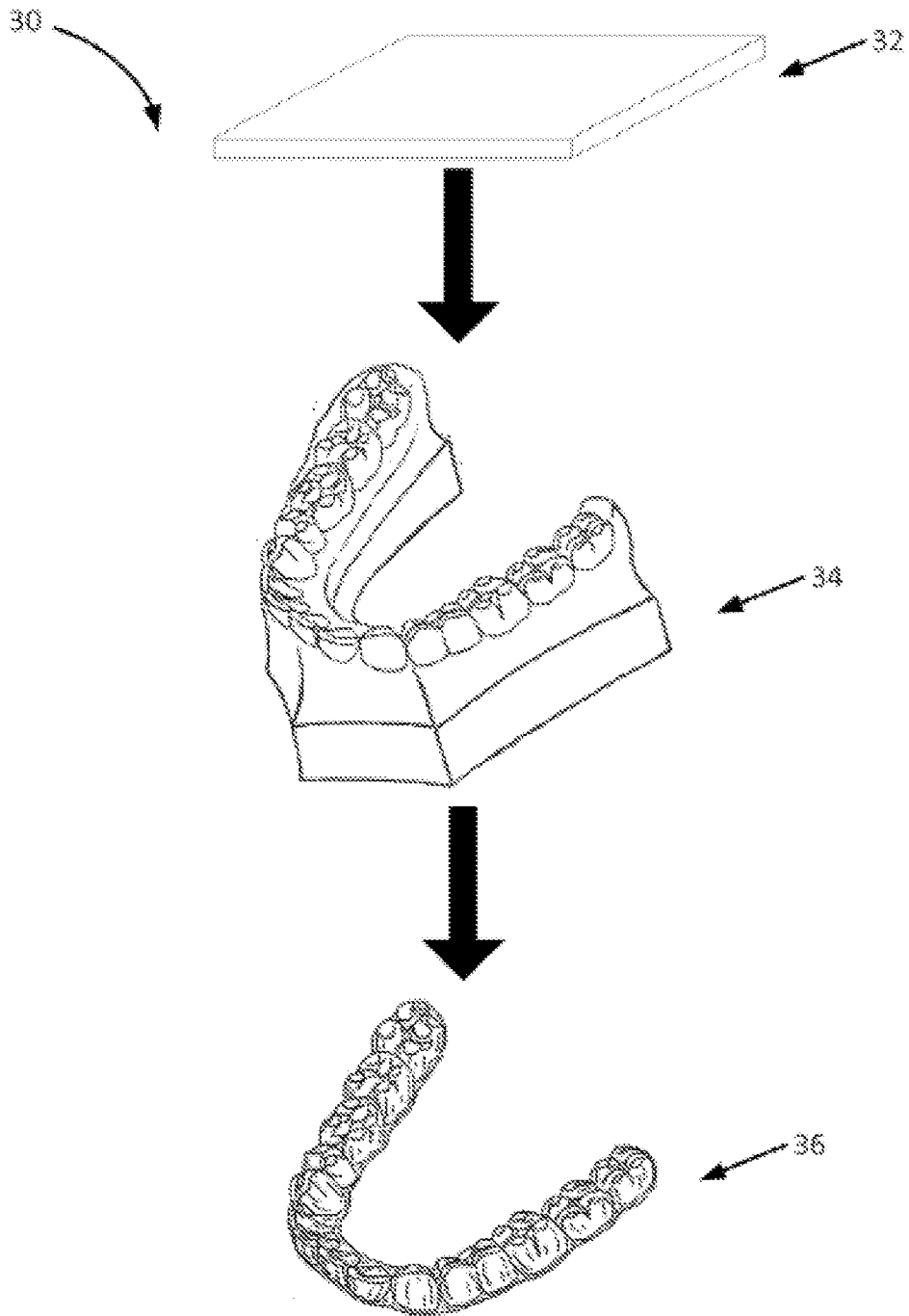


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No PCT/US2020/015490

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61C7/08
 ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 A61C

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/239018 A1 (KIM TAEWEON [KR]) 24 August 2017 (2017-08-24) paragraphs [0061] - [0066]; figures 9-12 -----	1,2,4, 12,17,18
X	US 2011/247214 A1 (HUGE SCOTT A [US]) 13 October 2011 (2011-10-13) paragraphs [0146] - [0154]; figures 23-25 -----	1,2,4,12
X	US 2010/129763 A1 (KUO ERIC [US]) 27 May 2010 (2010-05-27) paragraph [0036]; figure 5 -----	1-6, 12-16
A	US 2018/333226 A1 (TSAI EVAN YIFENG [US] ET AL) 22 November 2018 (2018-11-22) paragraphs [0064] - [0068] -----	1-7,10, 12,17,18

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

30 April 2020

Date of mailing of the international search report

13/05/2020

Name and mailing address of the ISA/
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/015490

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

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

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

2. Claims Nos.: 1-18(partially)
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

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

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 1-18(partially)

The wording "varyingly affixed" used in independent claim 1 has no well-recognized meaning and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT. It could refer to a choice in the relative position of one shell relative to the other, so that the way the shells are affixed can be varied. But it is not the case: the description of the present application gives a definition of this wording:

According to paragraph [0058], the wording "varyingly affixed" means that a substantial amount of surface areas between the shells are not bonded or otherwise made inseparable through some process, with the remaining surfaces being affixed.

The non-compliance with the substantive provisions is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search (PCT Guidelines, 9.19 and 9.24). The extent of the search was consequently limited in taking into account the definition given in paragraph [0058], as if it already had been introduced into independent claim 1.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/015490

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017239018	A1	24-08-2017	NONE

US 2011247214	A1	13-10-2011	NONE

US 2010129763	A1	27-05-2010	AU 2009316948 A1 07-07-2011
		EP 2355909 A2	17-08-2011
		US 2010129763 A1	27-05-2010
		US 2018036623 A1	08-02-2018
		WO 2010058255 A2	27-05-2010

US 2018333226	A1	22-11-2018	NONE
