ORTHOPEDIC DEVICE FOR MIDFACIAL BONE STRUCTURE

ADVANCEMENT

~~ADVANCEMENT~~

TECHNICAL FIELD OF THE DEVICE & METHOD

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[1] Embodiments of the present method and device described herein in general relates to an orthopedic device, particularly useful for advancing midface and maxillomandibular structures. More particularly, the present method and device relates to a dentofacial orthopedic device configured to be anchored to a skull and midface. The device is capable of exerting expansive extra-oral force antero-posteriorly across cranial structures and sutures in order to advance mid-face and maxillomandibular structures.

BACKGROUND OF THE DEVICE & METHOD

[2] Underdevelopment of the mid-face, maxilla, which is often paired with a downwardly rotated and posteriorly positioned mandible, affects both adults and children. It can be caused by improper development of facial and oral muscles, weak nasal breathing patterns, weak tongue musculature and posture, a soft diet during infancy, untreated impedances to nasal breathing such as tongue ties, enlarged adenoids and tonsils, a diet that causes inflammation of the airways, and prior orthodontic treatment that was aimed at limiting growth of the skull using appliances such as headgears, or aimed at reducing the size of the oral cavity. In the case of adults, this type of underdevelopment can result in postural and temporomandibular problems, recessed chins, flattened skull bases, vertically grown faces, and not to mention the psychological side-effects of such craniofacial deformities, and worse, obstructive sleep apnea (OSA), in which the patient's airway is too small to withstand normal tongue and soft tissue collapse during sleep, causing the airway to cut off at night, resulting in disturbed sleep and in some cases a drop of oxygen levels.

[3]-___A significant number of children world-wide endure cranio-facial birth defects. Mid-face deficiencies are often treated surgically, whereby an antero-posteriorly deficient maxilla, or other part of the cranium, is osteotomized and advanced.

[4]-___In the treatment of OSA and underdeveloped jaws, patients often undergo double jaw surgery, in which both the upper and lower jaw are resected and moved forward, then fastened into place with screws and plates. Known in the art are the risks of relapse, and injury to neurovascular structures.

[5]-___Another drawback of current surgical approaches may be that for people with OSA, surgical resection followed by advancement of the maxilla does not allow for multiple discrete advancements of the maxilla to optimize patency. In some surgical cases, the maximum surgical advancement in one attempt may not be enough to cure the OSA, due to limits of stretching soft tissues at once.

[6]-___While double ~~jaw~~jaw surgery can advance the upper and lower ~~jaw~~jaw, it may not fully solve problems related to underdevelopment of the cranium. More specifically, there are patients with underdevelopment of the entire mid-face. Such patients may not only exhibit posteriorly positioned maxillae, but also underdeveloped eye sockets, incorrectly positioned sphenoid bones, compressed sinus cavities, retruded cranial foramina with reduced opening size, and possible unusual pressure on nerves from compressed bones.

[7]-___The current surgical solution of cutting and segmenting individual bony segments to advance them forward may not address the above mentioned-_____and-___other-__effects-of _____generalized-__mid-face-_____and-___cranial underdevelopment.

[8]-___Prior art with patent application numbers 20170312053, 20060029899 and 20050244769 describe maxillary and mid-face advancement appliances. These appliances rely on heavy elastics to deliver the pulling force against the maxilla, such elastics which may not be able to apply enough force in discrete intervals to separate cranial sutures in adults. As well, these appliances rely on applying counter-pressure on other structures on the anterior side of the skull to pull against the maxilla, such as the forehead and the chin, and these structures may be adversely affected from such pressure. Therefore, there exists a need for a maxillary and

mid-face advancement appliance that does not rely on elastics, nor on putting counter forces on anterior structures of the skull and face.

OVERVIEW OF THE INVENTION

[9]-___To address the limitations of existing techniques, there is a need for a ~~midfacial~~mid-facial advancement method that allows for multiple discrete advancement steps that puts minimal stretching loads on soft tissues at once to reduce the risk of relapse and increase the advancement distance potential of the maxilla and ~~midface~~mid-face, or other bony structures of the cranium, that applies a ubiquitous ~~anteroposterior~~antero-posterior force across the entire cranium in order to decompress internal structures that were previously compressed, that does not require surgical detachment and reattachment of bony structures, hence reducing the risk of neurovascular injuries, that does not rely on elastics to deliver force, and that does not require the use of counter-force against other structures that are at the anterior region of the skull.

[10]-__The proposed device and method addresses the above problems by applying a controlled and general expansive force between the back of the head and the maxilla without the use of bony cuts and segmentations, such force that will extend through other cranial bone and neurovascular openings that may also be underdeveloped. This approach may address the above-_mentioned issues of underdeveloped eye sockets, incorrectly positioned sphenoid bones, compressed sinus cavities, retruded cranial foramina with reduced opening size along with reduced cranial blood flow and unusual pressure on nerves, including others. It may also allow the mandible to upwards through the use of the proposed device.
_advance and rotate upwards in response to maxilla that has been rotated upwards through the use of the proposed device.

[11]-__The proposed device applies discrete and gradual displacement forces at regular intervals across cranial sutures, expanding them and stretching the soft tissues over a gradual period, potentially increasing the physiologically tolerable advancement distance. For OSA

[12] The device also allows for the lower jaw to be mechanically advanced during sleep, to prevent airway collapse in OSA patients while they wear the appliance.

[13] Various embodiments of the present subject matter are applicable for various applications. One embodiment of the present subject matter is configured to be used as a dentofacial orthopedic device.

[14] Embodiments of the present device and method described herein in general relates to a dentofacial orthopedic device, particularly useful for advancing midfacial bony structures. More particularly, the present device and method relates to a bone anchored dentofacial orthopedic device with one end anchored to the skull and other end anchored to the mid-face, either by a tooth-~~bome~~borne or bone-anchored appliance. The dentofacial ~~orthopedic~~orthopaedic device, referred as to the device hereinafter is capable of exerting expansive extra-oral force antero-posteriorly across the anchored points on the skulls and the mid-face. The device is useful in particular, but not limited to, advancing mid-face and cranial maxillomandibular structures.

[15] According to one feature of the present embodiment, a ~~rigid~~ brace, which may be configured to have some flexibility, made of metal or another rigid or semi-rigid material, is screwed to the rear section of the skull – to the occipital region, or another appropriate region of the skull through at least one anchorage screw, with or without subcutaneous plates. The location of the anchorage is optimized for skull thickness and force alignment.

[16] The ~~rigid~~ brace is contoured to the shape of the skull, which wraps around the front of the skull, forming a ring-shaped loop around the skull that terminates full circle in front of the mouth. At the mouth-end of the brace, there is a slot for an adjustable center screw/first bracket member that can be retracted or advanced by turning a nut/adjuster. The adjustable center screw/first bracket member is the anterior portion of the orthodontic bracket, which is "Y" shaped in one embodiment, with the two ends of the "Y" connected inside the mouth in multiple manners with a fastener, two of which are described herein~~:~~. In one manner, a tooth-borne connection is made ~~to~~ either with a ~~removal~~removable oral appliance type of fastener that is worn on the teeth of the upper jaw or an orthodontic brackets type of fastener installed onto

maxillary molars, connected to the "Y" bracket with rotational joints. In a second manner, there is no removable oral appliance, and the "Y" bracket is connected ~~in~~to a bone-anchored ~~manner,~~ball and socket system type of fasteners which are implanted into the bony structure intra orally into the maxilla, the zygoma, or into another appropriate bony structure~~, such connection to be made with ball and socket joints that are implanted into the bony structure.~~. Therefore, by turning the ~~nut~~adjuster at the anterior end of the brace, the adjustable center screw or the first bracket member which forms part of the orthodontic ~~"Y"~~ bracket can be advanced and will pull forward against the bony structures that need to be advanced or relocated. Turning the nut creates displacement forces that will be translated to the back of the skull where the brace is attached by the aforementioned screws and plates.

~~[15]~~

[17] A slot/receiving member is fitted to the anterior portion of the brace via a ~~hinge~~clamp. The ~~slot~~receiving member is provided to host the ~~adjustable center screw~~proximal end of the first bracket member that can be angulated to suite the desired direction of motion of maxillary or bony structure advancement. The ~~adjustable center screw~~proximal end of the first bracket member is fitted in the ~~slot in~~receiving member of the clamp at a predetermined position. The position can be determined based on the midfacial bone structure, geometry of the midfacial bone, and amount of displacement force required. During a course of midfacial advancement, the ~~screw~~ position of the proximal end of the first bracket member can be changed according to the achieved target of advancement, desired angle of displacement, and the expected course of the advancement.

~~[16]~~

[18] The orthodontic ~~" Y"~~ bracket is configured to be angulated at a plurality of angular positions such that at any angle of advancement, the center of rotation ~~is at~~remains outside the opening of the patient's mouth. This configuration ensures that the mouth can be sealed at any given angle of advancement. This is achieved ~~with~~by a hinge joint ~~on~~of the ~~"Y"~~ bracket~~, located~~ that connects the first bracket member and the second bracket member outside of the mouth. This hinge ~~and~~joint can be locked into place at the desired angle, without impacting the placement of the ~~"Y"~~second bracket member of the bracket relative to the user's mouth and lip seal.

~~[17]~~

[19] The front half/segment of the brace, which is configured to be situated in front of the user's mouth, is hinged with rotational joints on either side, such that when the angle of the

orthodontic ~~"Y"~~ bracket is adjusted, the front half of the brace can be adjusted up, down, and side to side with it, so that all parts may move in unison.

~~[18]~~

[20] The materials of the brace can be titanium or any biocompatible rigid material. The orthodontic bracket too is made of similar materials such as titanium or any biocompatible rigid material.

~~[19] The~~

[21] The rear segment of the brace that attaches onto the skull is anchored with ~~screws~~cranial anchorage assemblies having screw ends that implant into the skull. These screws are made of titanium or another biocompatible material. ~~These screws have~~Each of the cranial anchorage assemblies has an abutment that is screwed onto the head of the screw end, and this abutment is configured to protrude from the skull, at a penetration point where the user's skin is intended to heal and form a seal. These screws may be coated with an anti-bacterial or anti~~-~~ infective coating. The length of the abutment can be adjusted to match the thickness of the user's skin layer. At the far end of the abutment outside of the skull, when installed, is a circular plate shaped free end that can be adjusted in any direction and tightened against the abutment. This ~~plate~~free end serves as an attachment point for the brace that wraps around the user's skull, and it is designed to be adjusted to match the angle at which the brace attaches onto the user's skull, such that the surface of the skull can be tangential to the attachment point of the brace, by making the plate serve as a proxy surface between the attachment point of the brace and the user's skull, to prevent pressure from being exerted from the brace onto the user's skin.

~~[20]~~

[22] In OSA patients, there may exist a need to maintain the patency of the airway during sleep while wearing the orthopedic appliance type of fastener, by keeping the lower jaw in an advanced position, which prevents the tongue from encroaching onto the airway when the muscles of the throat and tongue relax during sleep. One part of the appliance consists of a removable rigid mouthpiece that is designed to be worn on the bony structure (teeth of the lower jaw, for example) and connected via a rod to the orthodontic ~~"Y"~~ bracket. This rod is connected to a sleeve that a screw-threaded portion of the orthodontic ~~"Y"~~ bracket can slide into which protrudes from the sleeve. At the protruding end of this portion of the ~~"Y"~~ bracket, there is a bolt that can be turned to advance the rod against the orthodontic ~~"Y~~ bracket, through the sleeve, by a set distance that is matched by the amount of forward displacement that the lower

jaw needs to maintain patency of the airway during sleep. Between the bolt and the sleeve there may be a compression spring designed to increase the comfort of the user.

~~[21]~~

[23] The device may be designed by a person or an artificially intelligent software program. The device requires a planning stage, which would normally be undertaken by an oral surgeon, such stage which involves cephalometric and CT-Scan analysis, which takes into account the current position of the bones of the skull, and the desired position of those bones as determined by the patient and the practitioner. The path of movement and displacement of the mid-face is determined, and accordingly the device is designed to follow that path. Over the course of the treatment period, the angular or linear displacement of the device is achieved that results in movement of the bony structure per the results of the planning stage. Optimizing the placement of anchorage screws at the back of the skull and intraorally can be done using computer assisted surgery.

~~[22]~~

[24] When the user is sleeping on their side, there may exist a need to prevent the weight of the user's skull from applying a rotational force against the anchorage screws of the brace. A form fitted ~~cushion~~cushioning pad, or a set of them, is designed to be placed between the brace and the user's skin, such cushion that will protrude from the surface of the brace, such that when the user is sleeping on their side, the weight of their face bypasses the brace as the face rests against the cushion, which rests directly onto the sleeping surface, such as a mattress or a pillow, thus diverting the weight of the skull away from the brace, and thus the anchorage screws that attach it to the user's skull.

~~[23]~~

[25] As an alternative to the use of supportive cushions during sleep, the brace can be designed in another version that consists of half a brace that wraps around either the left or right side of the skull, whichever side is not in contact with the sleeping surface, and this brace may be worn during sleep. As a result, the side of the user's face that does not have the brace around it can rest directly and freely onto the sleeping surface without any weight of the user's skull against the implanted screws that are designed to attach the brace the to skull.

~~[24]~~

[26] The expansive extra-oral force that results from separating the cranial anchorage points of both the ~~"Y"~~ bracket and the brace may separate cranial sutures, eventually pushing the midface forward, and upward if desired, allowing both the maxilla and mandible to advance.

BRIEF DESCRIPTION OF THE DRAWINGS

~~[25]~~

[27] A better understanding of embodiments of the present disclosure (including alternatives and/or variations thereof) may be obtained with reference to the detailed description of the embodiments along with the following drawings, in which:

~~[26] Fig. 1A-0 to 1A-4~~

[28] Figs. 1A, 1B, 1C and 2A, 2B show a perspective, top, side, front and back view, respectively, of the generic structure of a dentofacial orthopedic device (100) anchored to skull~~,~~ (107), with a rotating joint (115), attached to an orthodontic ~~"Y"~~ bracket (114) that is anchored at ~~it's posterior~~its inner ends (~~110~~135) to bony structures on the anterior side of the user's skull, intra-orally, or extra-orally through punctures. ~~The "Y"~~ Reference to Figs. 1A-1C, 2A-2B, 3A-3C, 8A-8C and 11A-11E the bracket (114) may be reinforced with a reinforcement bracket (106), and the proximal end (123) of its tail end ~~(114)~~/first bracket member (122) is shown to pass through a rotatable ~~slot (116).~~receiving member (117). At the outside end of the ~~slot (116~~receiving member (117), there is a bolt ~~(108~~/adjuster (127) on the proximal end (123) of the ~~"Y"~~first bracket member (122) of the bracket (114) that can be turned to advance the ~~"Y"~~ bracket (114) against the brace (102), pulling the ~~"Y"~~ bracket (114) in the anterior, or desired direction, in accordance with preferred embodiment of the present disclosure.

~~[27]~~

[29] FIGs. 2C and 2D illustrate anchoring of the inner ends (135) of the dual-arm and single-arm second bracket member (131) respectively of the intra-oral version of the bracket (114) ~~Fig. 1 A- 5~~ to ~~1 A-9~~a bony structure (166) of the anterior portion of skull (160) with ball and socket type of fasteners (900).

[30] Figs. 3A, 3B, 3C and 4A and 4B show a perspective, top, side, front and back view, respectively of the full-brace, full-bracket type dentofacial orthopedic device (100), in accordance with the preferred embodiment of the present disclosure, in an embodiment wherein it is not anchored to a user's skull. FIG. 3D illustrates a perspective view of a half-brace (102), full- bracket (114) type of the device (100). FIG. 3E illustrates a perspective view of a half-brace (102), half-bracket (114) type of the device (100).

~~[28] Fig. 2A-0 to 2A-4~~

[31] Figs. 5A, 5B, 5C, 5D and 5E show a perspective, front, back, side and top views, respectively of ~~an assembly consisting of~~ a cranial anchorage ~~screw~~assembly (200), designed to screw into the user's skull. The cranial screw is attached to an abutment (203) upon which a rotatable plate/free end (202) is attached, that rests within a pocket formed by the plate assembly (204) of two plates ~~(201).~~. This plate assembly (~~201~~204) is affixed to the brace (~~100~~102), in accordance with the preferred embodiment of the present disclosure.

[32]~~[29]~~ Fig. ~~2B-0 to 2B-4~~6A, 6B, 6C, 6D, 6E and 6F show a side view, another side view, a top view, and cross section view~~, respectively,~~ of the cranial anchorage ~~screws~~ assembly (200), a side view of the free end (202) and a top view of the free end (202) respectively. The screw end (201) is configured to be anchored into the skull (~~200),~~107) and attached to an abutment (203) via an internal screw (205). A second internal screw (206) attaches ~~a~~the rotatable plate/free end (202) to the abutment (203). The plate/free end (202) is tightened with another screw ~~(204~~/head (208) in accordance with the preferred embodiment of the present disclosure.

~~[30] Fig. 2B-7 to 2B-10~~

[33] Figs. 7A, 7B, 7C and 7D show a front, side, back and perspective view, respectively, of ~~two plates~~the plate assembly (204) that form a pocket (~~201), such plates that are~~701) adapted to receive the free end (202). The plate assembly (204) is also configured to be affixed to the brace (102), in accordance with the preferred embodiment of the present disclosure.

~~[31] Fig. 3A-0 to 3A-3 show a perspective, top and side view, respectively, of an orthodontic "Y" bracket, with the "Y" ends configured to be anchored to the maxillary bone structure on both the left and right side, or another appropriate bony structure, via ball and socket joints (302) that are configured to be implanted into the bony structure, and the tail end of the "Y" bracket (114) configured to be hinged at a joint (113), and slotted through a rotating slot (116) at the anterior end of the "Y" bracket in accordance with the preferred embodiment of the present disclosure.~~

[34] Fig. 8A illustrates a perspective view of the bracket (114) with the clamp (116). Figs. 8B and 8C show a top and side view, respectively, of an orthodontic bracket (114) without the clamp (116). The inner ends (135) of the second bracket member (131) of the bracket (114) are configured to be anchored to the maxillary bone structure on both the left and right side, or another appropriate bony structure of the anterior portion of skull (160), via fasteners which can be ball and socket joints (900) configured to be implanted into the anterior portion of skull or via orthodontic appliance (1000) or (1900) configured to be removably affixed to the bony structure (teeth, for example) of the anterior portion of the skull. The tail end or the distal end (124) of the first bracket member (122) of the bracket (114) is configured to be hinged at a joint

(113), and slotted through a rotating slot/receiving member (117) at the anterior end of the bracket (114) in accordance with the preferred embodiment of the present disclosure. FIGs. 8D and 8E illustrate another embodiment of the bracket (114) having a single-arm anterior member (132) of the second bracket member (131) with and without the clamp (116) respectively. FIGs. 1D and 1E illustrate this single-arm version of the bracket (114) in use with the brace (102). FIGs. 8F and 8G illustrate front view and top view respectively of yet another embodiment of the bracket (114). In this embodiment also the proximal end (123) is adjustably secured by an adjuster (127) to a receiving member (117) of the clamp (116). The clamp body (128) enables selective mounting to any section of a mounting portion of the brace (102). The adjuster (127) can be positioned over the proximal end (123) on either side of the receiving member (117). The first bracket member (122) is rotatable about the receiving member (117) for a selective locking of the first bracket member (122) at a plurality of angular positions relative to the second bracket member (131) with the hinge joint (113). FIG. 8H shows the first bracket member (122) and the second bracket member (131) locked at an angular position different from that shown in FIG. 8F with the help of the hinge joint (113). In another embodiment, as shown in FIGs. 26A-26D and 27A-27D, the second bracket member (131) further comprises one or more couplers (2602) disposed between the tail end (133) and the anterior member (132). The one or more couplers (2602) are configured to enable selective locking engagement of the anterior member (132) in adjustable relation to the tail end (133). For example, the anterior member (132) can be adjusted or twisted/turned and locked by engaging screws (2604) at different positions with respect to the tail end (133) as per requirement. In some embodiments, as shown in FIGs. 26A-26B, the anterior member (132) may further comprise a bridging element (2606) which rigidly couples both the brackets (114) over the anterior portion (160) of the skull (107).

[35] Figs. 9A, 9B, 9C and 9D

~~[32] Fig. 3B-0 to 3B-3~~ show two side views, a cross section and a perspective view, respectively, of a ball and socket joint system (~~302) designed with a screw~~

900) type of fastener configured to flexibly and rotatably couple the inner end(s) (135) of the bracket (114) with an anterior portion of the skull e.g. with a bony structure (166) inside the mouth (164) of the user as shown in FIGs. 2C-2D. The ball and socket system (900) comprises a fastener end (300) that is configured to be implanted into the user's maxilla, or appropriate

bony structure, and a socket (301) configured to rotatably receive the inner end (135) to serve as an anchor point for the ~~"Y"~~ bracket (114). The ball

~~(301~~ type inner end (135) may rotate freely at its top end, and it is attached rigidly to the ~~"Y"~~ bracket (114) at its bottom end.

~~[33] Fig. 3C-0 to 3C-2~~

[36] Figs. 10A and 10B show a side and top view, respectively, of a tooth-~~born option~~ borne type of fastener to anchor the brace (102) to the maxilla~~ to the brace (102).~~ /bony structure. This option consists of a removable mouthpiece/orthodontic bracket (303) that is worn on the teeth of the upper jaw, and is connected at a rotational joint (304) to ~~rigid rods~~linkages (305) that are configured to connect to the ~~"Y"~~ bracket (114) outside the user's mouth.

[37]~~[34] Fig. 4A-0 to 4A-4~~ Figs. 11A, 11B, 11C, 11D and 11E show ~~an~~a perspective, top, front, back and side ~~view~~views, respectively of a ~~rotating slot~~clamp (116) that the tail end/first bracket member (122) of the~~ orthodontic "Y"~~ bracket (114) can screw into, in accordance with the preferred embodiment of the present disclosure. The rotating ~~slot~~ receiving member (117) has an opening (~~117~~141) for the ~~tail~~proximal end (123) of the ~~orthodontic "Y"~~first bracket member (122) to insert into, grooves (118) for the brace (102) to fit into, screw openings (119) to tighten the ~~rotating slot~~clamp body (128) onto the brace (102), and two openings (120) for screws to adjust the angle of the ~~slot (120~~receiving member (117).

~~[35] Fig. 5 A to 5C show three~~

[38] Figs. 12A, 12B and 13A illustrate side views and ~~one~~13B show a back view~~, respectively,~~ of ~~cushions~~the device (100) with cushioning pads (502) that are configured to be inserted between the brace (102) and the user's skin, such that the cushions protrude from the external surface of the brace (102), configured such that when the user is sleeping on their side, the weight of their face is distributed across the cushions (502), which then distribute the weight onto the sleeping surface, such as a pillow or a mattress, allowing the user to sleep on their side without putting any pressure on the brace (102), thus reducing counter forces from the brace onto the skull at the location of the implants (200), and also potentially dampening unwanted external forces.

~~[36] Fig. 6A to 6B show~~

[39] Figs. 14A illustrates a perspective view of a protective helmet (602) ~~that is configured to be~~ worn ~~by~~over the ~~user, above the brace (102).~~device (100).

[37] Fig. 7A-0 to 7A-4 show an14B shows another embodiment of the protective helmet (602). Fig. brace (102) that14C illustrates a perspective view of the protective helmet (602).

[40] Figs. 15A shows a perspective view of a half-brace type embodiment (1500) of the device (100) worn over the skull (107) wherein the front brace segment of the brace (702) extends only partially over the anterior region of the skull of the user and the rear brace segment of it extends partially over the rear section of the skull (107). Figs. 15B, 15C, 16A and 16B illustrate a top view, a side view, a front view and a rear view of the embodiment (1500) with the skull (107). In this embodiment, brace (702) is modified in such a way that it can be worn on the left or right side of the user's face, for use when the user is sleeping. It is called the "sleeping brace" (702)."). This alternative embodiment (702) consists of structural reinforcements (703) that give the sleeping brace (702) the same stiffness properties as the initial brace (102), allowing the user to sleep on their side without putting any pressure on the brace (702), thus eliminating counter forces from the brace onto the skull at the location of the implants (200).

[38] (107) at the location of the implants (200). FIGs. 15D and 15E illustrate the half-brace type of the embodiment (1500) with half-bracket type bracket (114) which has a single-arm anterior member (132) of the second bracket member (131).

[41] Fig. 7B-0 to 7B-4 show17A, 17B, 17C, 18A and 18B show a perspective view, top view, side view, front view and rear view respectively of the sleeping brace (702) as a full assembly in combination with the orthodontic "Y" bracket (114 & 113).

[39] Fig. 8-1 to 8-3 show a

[42] Figs. 19A, 19B and 19C show two side views and a top view of a concomitant mouthpiece/orthodontic appliance (1900) which is a type of fastener that is configured to be worn on the lower jaw (801) during sleep. It is connected to a rod (802) that is rigidly connected to a sleeve (803801). A second rod (804) is connected to the "Y" bracket (114) and may pass freely through the sleeve (803). This second rod (804) has a screw thread (805) on it (805). A bolt (806) rests upon the screw thread (805) and can be turned to advance the mouthpiece (801) in the anterior direction, thus advancing the mandible anteriorly to open the user's airway during sleep. _A compression spring (807) may be inserted between the bolt (806) and the sleeve (803), for user comfort.

[43] FIGs. 20A and 20B illustrate a perspective view and a top view of another embodiment of the device (100) having a bracket (114) configured to access the anterior portion (160) of the skull (107) extra-orally through the skin of the user, if required. FIGs. 20C and 20D are the perspective view and top view of that embodiment of the device (100) respectively which has a second bracket member (131) with a single arm anterior member (132) dimensioned to access the anterior portion (160) of the skull (107) extra- orally;

[44] FIGs. 21A, 21B and 21C show a perspective view, a top view and a front view respectively of the half-brace type embodiment (1500) of the device (100) having an extra-oral type of anterior member (132) dimensioned to fit at least partially over the anterior portion (160) of the skull;

[45] FIGs. 21D, 21E and 21F show a perspective view, a top view and a front view respectively of the half-brace type embodiment (1500) of the device (100) having a single-arm extra-oral type of anterior member (132) dimensioned to fit at least partially over the anterior portion (160) of the skull;

[46] FIG. 22A illustrates anchoring of the inner ends (135) of the double arm second bracket member (131) of the extra-oral version of the bracket
(114) to a bony structure (166) of the anterior portion of skull (160) with ball and socket type of fasteners (900);

[47] FIG. 22B illustrates anchoring of the inner ends (135) of the single arm second bracket member (131) of the extra-oral version of the bracket
(114) to a bony structure (166) of the anterior portion of skull (160) with ball and socket type of fastener (900);

[48] FIGs. 23A and 23B illustrate the brace (102) comprising only the full- rear brace segment (105) with cranial anchorage assemblies (200) in perspective and top views;

[49] FIGs. 23C and 23D illustrate the brace (102) comprising a half-rear brace segment (105) with cranial anchorage assemblies (200) in perspective and top views;

[50] FIG. 23E illustrates a top view of the device (100) comprising two extra-oral brackets (114) coupled to a full-rear brace segment (105) of FIGs. 23A-23B by clamps (116);

[51] FIG. 23F illustrates a top view of the device (100) comprising a one- arm extra-oral bracket (114) coupled to a half-rear brace segment (105) of FIGs. 23C-23D by clamp (116);

[52] FIGs. 24A and 24C illustrate a bottom view of the device (100) having a full-rear brace segment (105) with two one-arm extra-oral brackets (114) in use;

[53] FIG. 24A illustrates a bottom view of the device (100) having a full- rear brace segment (105) with two one-arm extra-oral brackets (114) in use;

[54] FIG. 24B illustrates a side view of the device (100) having an extra- oral bracket (114) in use;

[55] FIG. 24C illustrates a bottom view of the device (100) having a half- rear brace segment (105) with a one-arm extra-oral bracket (114) in use;

[56] FIGs. 25A-25B illustrate a bottom view and a side view respectively of the device (100) having a full-rear brace segment (105) with extra-oral brackets (114) anchored to the upper teeth i.e. bony structure (166) of the anterior portion (160) with the help of orthodontic appliance (1000) type of fastener extra-orally;

[57] FIG. 26A illustrates the device (100) having a full-rear brace segment (105) coupled to two one-arm intra-oral brackets (114);

[58] FIG. 26B illustrates a bottom view of the device (100) having a full- rear brace segment (105) coupled to two one-arm intra-oral brackets (114) in use;

[59] FIG. 26C illustrates the device (100) having a half-rear brace segment (105) coupled to an one-arm intra-oral brackets (114);

[60] FIG. 26D illustrates a bottom view of the device (100) having a half- rear brace segment (105) coupled to an one-arm intra-oral brackets (114) anchored to the anterior portion (160) of a user;

[61] FIGs. 27A-27B illustrate a bottom view and a side view respectively of the device (100) having a full-rear brace segment (105) with intra-oral brackets (114) anchored to the lower teeth i.e. bony structure (166) of the anterior portion (160) with the help of concomitant mouthpiece (1900) type of fastener intra-orally; and

[62] FIGs. 27C-27D illustrate a bottom view and a side view respectively of the device (100) having a full-rear brace segment (105) with two one-arm intra-oral brackets (114) anchored to the upper teeth i.e. bony structure (166) of the anterior portion (160) with the help of orthodontic appliance (1000) type of fastener intra-orally.

DETAILED DESCRIPTION

~~[40]~~

[63] Embodiments and features of the present invention are described herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms.

~~[41] Fig~~

[64] Figs. 1A-~~0 shows~~ 1C, 2A-2B, 3A-3C and 4A-4B show the structure of a bone anchored orthopedic device (100), referred as to ~~the~~as device (100) hereinafter, according to ~~the~~a preferred embodiment of the present ~~device and method.~~invention. The dentofacial orthopedic device (100) ~~mainly includes~~comprises a brace (102) and one or more brackets (114) coupled to one or more mounting portions (129) of the brace with the help of one or more clamps (117). The brace (102) is anchored to the skull (107) of a user through at least one anchorage ~~screw.~~assembly (200). The brace (102) is a rigid or semi-rigid structure that adjustably holds other components of the device (100), described in subsequent description, at the desired place. The brace may comprise at least one front brace segment (104) and at least one rear brace segment (105) hingedly connected to the front brace segment (104) by a rotating joint (115). The front brace segment (104) and the rear brace segment (105) may extend to both sides of the skull (107) as shown in FIG. 3A or may extend to only one side of the skull (107) as shown in FIG. 3D and 3E. The bracket (114) may have different shapes and sizes depending upon the application type. FIG. 3D shows use of one-arm type of bracket (114) while FIG. 3E shows

dual-arm type of bracket (114). In some embodiments, the at least one front brace segment (104) is removable/detachable at the rotating joint (115). For example, the brace (102) may comprise only one or more rear brace segments (105) which extend to both the sides of the skull (107) as shown in FIG. 23A or to only one side of the skull (107) as shown in FIG. 23C. The brace (102) is contoured to the shape of the skull, which, if the front brace segment (104) is used, wraps around the front of the skull and terminates full circle in front of the mouth. In a preferred embodiment, the at least one rear brace segment (105) is so configured that, when it is anchored to the rear section (109) of the skull (107), the at least one front brace segment (104) extends at least partially over the anterior region (160) of the skull (over the face, for example) of the user and is rotatable about a first axis of rotation (139). The brace (102) can be separated into components by rotational joints (115) on either side ~~(115)~~ that allow those components of the brace to be positioned at various angles. The rotating joint (115) having straps (152) and (154) enables adjustment of the spacing between the front brace segment (104) and rear brace segment (105), as required. The brace (102) is subject to various physical and anatomical forces and limitations. The brace (102) can be designed by an artificially intelligent system and 3D printed, or designed and forged by hand.

~~[42] According~~

[65] Reference to Figs. 5A-5E, 6A-6F and 7A-7D, according to one embodiment, at least one anchorage ~~screw~~assembly (200~~), shown in Fig. 2A-0,~~) is designed to be screwed to user's the skull (107) to anchor the brace (102) to the skull. ~~The screw (200) is paired with~~ The anchorage assembly (200) includes a screw end (201) configured to be fastened to said any section of the skull (107) (for example, anchored to the rear section (109) as shown in FIG. 2B), an opposite free end (202) spaced apart by a selectable distance with an abutment (203) and a plate assembly (204) configured to rotatably couple the free end (202) to the rear brace segment (105). The screw end (201) is paired with the abutment (203) via an internal screw (205) as shown in Fig. ~~2B-3~~6E. The abutment (203) can protrude from the user's skull, allowing the skin to heal around it, forming a seal. The screw (~~200~~201) and abutment (203) may also be coated in an anti-bacterial or anti--infective material. The abutment (203) is connected to ~~a~~the rotatable plate/free end (202) that is held in place by a second internal screw (206), which is tightened at its head (~~204).~~208). Slots 207A and 207B enable the free end

~~[43]~~(202) to be adjustably mounted to the abutment (203) at a desired orientation. An abutment (203) of desired length can be used to get the required spacing between the screw end (201) and the free end (202).

[66] The anchorage screw ~~(200~~end (201) is screwed at a location that has been optimized for bone geometry, skull thickness and force alignment such that the plane of the screw-thread is as close is possible to perpendicular to the desired direction of force application at the entry point of the screw.

~~[44]~~

[67] The rotatable plate/free end (202) rotatably rests within a metal bracket~~that is an~~/pocket (701) defined by the plate assembly (204) comprising of two metal plates ~~(201), that form a pocket,~~ as shown in Fig. ~~2A-1 for the plate (202) to rest into.~~7C.

~~[45]~~ The plate assembly (204) is in turn mounted to the rear brace section (105) as illustrated in FIGs. 3A-3C and 4A- 4B.

[68] The free end (202) is the connection point between the user's skull and the brace (102), and it is adjustable such that it can be rotated and angulated to match the tangential angle of the skull at the point of screw ~~(200~~end's (201) penetration.

~~[46]~~

[69] The ~~plate~~free end (202) is configured to serve as a proxy surface between the brace (102) and the user's skin, such that the brace (102) never has to touch the user's skin, or exert any force against the skin, as the brace rests entirely upon the ~~plate~~free end (202).

~~[47]~~

[70] Reference to Figs. 1A-1C, 3A-3C and 8A-8C, the orthodontic bracket (114) comprises a first bracket member (122), a second bracket member (131) and a lockable hinge joint (113). The first bracket (122) has a proximal end (123) and an opposite distal end (124) and the second bracket member (131) comprises an anterior member (132) and a tail end (133). In accordance with one feature of the preferred embodiment, an ~~orthodontic "Y" bracket (114) shown in Fig. 1 A-0 and 3A-0~~inner end (135) of the anterior member (132) is adapted to be rotatably attached ~~at it's posterior ends (110) to both~~to an anterior portion of the skull (for example, to either or both of the left and right side of a user's maxilla, or appropriate bony structure, inside the mouth~~on~~) with the ~~split end~~help of ~~the bracket at freely rotating~~a fastener. The fastener, in one embodiment, is a ball and socket ~~joints (301 & 302), shown in Fig. 3B-0,~~ system (900) as shown in Figs. 9A-9D. The ball and socket system (900) type of the fastener comprises a fastener end (300) configured to be implanted into ~~both~~either of the left ~~and~~or right side of the maxilla ~~by way of a screw (300),~~ or other appropriate bony structure~~within the face~~, and a socket (301) configured to rotatably

receive the ball type inner end (135) that allows the position of the ~~"Y"~~ bracket (114) to be optimized in relation to the mouth of the user such that the user may maintain a closed mouth while wearing the appliance. FIG. 2C illustrates an exemplary way of anchoring the inner ends (135) of a pair of arms/double- arm/dual-arm second bracket member (131) of the intra-oral version of the bracket (114) to one of the anterior portions of skull (160) i.e. to a bony structure (166) intra-orally/ inside the mouth of a patient with ball and socket type of fasteners (900). FIG. 2D illustrates similar anchoring for a single-arm version of the second bracket member (131) intra-orally.

~~[48]~~

[71] The orthodontic ~~"Y"~~ bracket (114) may also be attached ~~in~~with a tooth-~~borne method as shown in Fig. 3C-0 to 3C-1, via~~ borne orthodontic appliance (1000) type of fastener as shown in Figs. 10A- 10B, 25A-25B and 27C-27D. In this type of fastener, an orthodontic appliance (1000) comprises a removable rigid or flexible mouthpiece or orthodontic bracket (303) that is designed to fit on the bony structure i.e. on the anterior portion of said skull (teeth of the upper jaw, ~~to be optimized in relation to the mouth of the user such that the user may maintain a closed mouth while wearing the appliance. The mouthpiece~~for example) and one or more linkages (305) configured to pivotally and/or adjustably connect the orthodontic bracket (303) ~~bears rotational~~to the inner end (135) of the anterior member (132). The dimensions and shapes of the orthodontic bracket (303) and the linkage (305) are optimized in relation to the mouth of the user such that the user may maintain a closed mouth while wearing the appliance. Rotational joints (304) ~~that are~~connect the linkage (305) to the orthodontic bracket (303) at one end, and the other end of the linkage (305) is rotatably connected to ~~rods (305~~the inner end (135) of the anterior member (132) of the orthodontic bracket (114) extra-orally i.e. with skin penetration as shown in FIGs. 25A-25B and intra- orally i.e. through the mouth cavity as shown in FIGs. 27C-27D. The orthodontic appliance (1000), attached to an extra-oral bracket (114), can also be anchored to the lower jaw/teeth line if needed.

[72] The clamp (116), as shown in FIGs. 1A-1E, 3A-3E and 23E-23F, enables mounting of the bracket (114) to a mounting portion (129) of the brace (102). Reference to FIGs. 1A-1C and 3A-3E, the first bracket member (122), at its proximal end (123), is attached to a mounting portion (129) of the front brace segment (104) by a clamp (116). More specifically, the proximal end (123) is adjustably secured by the adjuster (127) to the receiving member (117) of the clamp (116) and the clamp (116) is selectively mounted to any section of the mounting

portion (129) with the help of its clamp body (128). Reference to Figs. 8A-8C and 11A-11E, the opening (141) is configured to freely receive the proximal end (123) such that, when the adjuster (127) is actuated i.e. turned in either direction, the proximal end (123) having threads thereupon is pulled or pushed through the opening (141) producing a translational movement of the first bracket member (122). The distal end (124) connects the first bracket member (122) to the second bracket member (131) at its tail end (133) by the hinge joint (113). The hinge joint (113) is configured to enable rotation of the first bracket member (122) about a second axis of rotation (140) with selective locking of the first bracket member (122) at a plurality of angular positions relative to the second bracket member (131). So, turning of the adjuster (127) pulls the bracket (114) through the opening (141), which then ~~connect to the orthodontic "Y" bracket~~exerts a pulling force against the user's maxilla or other bony structure, using the brace (102) as a counter force due to it being anchored to the back of the user's skull, which may be considered as a fixed point.

~~[49] At the other end of the "Y" bracket where it is a rod outside the mouth (114), it is attached to the front of the brace (102) whereby it screws through a rotating slot fitted onto the brace (116), where it is bolted at the outside end of the slot (108) as shown in Fig. 1A-0, whereby the turning of that bolt pulls the rod through the slot, which then exerts a pulling force against the user's maxilla or other bony structure, using the brace as a counter force due to it being anchored to the back of the user's skull, which may be considered a fixed point.~~

~~[50] The rod (114) at the end of the "Y" bracket outside~~

[73] The first bracket member (122) at the end of the bracket (114) located outside the user's mouth can be independently rotated in multiple directions at ~~a~~the lockable hinged joint (113) located outside of the mouth as shown in ~~Fig~~Figs. 1A-~~0~~1C, including the up and down direction~~,~~ about the second axis of rotation (140), by unlocking the hinge and rotating the front half of the brace (104) i.e. rotating the front brace segment (104) at the brace's rotation joints (115)~~ as shown in Fig. 1A-0~~ to adjust the pulling angle of the maxilla and other facial bones without disrupting the inner portion ~~of~~i.e. the ~~"Y"~~second bracket member (131) of the bracket (114) and its position relative to the user's mouth that may have been previously determined by setting the angle of the ball and socket joints (~~302~~900) about its longitudinal axis 901 (shown in Fig. 9A and 9B), or rotational joints.

~~[51] The slot~~

[74] Reference to Figs. 1A-1C, the receiving member (117) of the clamp (116)~~-~~ has a center of rotation about a third axis of rotation (145) that is designed to match the combined centers

of rotation of the brace's rotational joints (115), and the angle of the ~~"Y"~~ bracket~~,~~ (114), as determined by the angle of the hinge (113).

~~[52]~~

[75] The ~~"Y"~~ bracket (114) may also be adjusted from left to right, and it may be split into two or more separate brackets, such that one side or part of a user's maxilla, or appropriate bony structure may be pulled independently from another part. ~~In the case of the "Y" bracket being split into parts, each part is designed to be~~In the case of more than one bracket (114) being used, each bracket (114) is designed to be independently connected to the front brace segment (104), through its own clamp (116), each held with its own adjuster (127) at the front of its receiving member (117). Whether the anterior member (132) of the second bracket member (131) has a pair of arms i.e. a dual-arm/double-arm version (in "Y" shape extending from the tail end (133) as shown in FIGs. 8A-8C, for example) or has only one arm (i.e. a single-arm version as shown in FIGs. 8D-8F, for example), in either case, the anterior member (132) is dimensioned to fit intra-orally i.e. to fit at least partially inside an anterior portion of the skull such as the mouth of the user in case of the intra-oral version of the bracket (114) as shown in FIGs. 1A-1D, 2A-2D or to fit extra-orally i.e. to fit at least partially over an anterior portion (160) of the skull and then penetrates the skin, through (2402) for example, of the user to access the point of anchorage as shown in FIGs. 20A- 20D, 21A-21E, 22A-22B and 24A-24C in case of the extra-oral version of the bracket (114).

~~independently connected to the brace, through its own rotating slot, with its own bolt at the front of its slot.~~

[76] FIGs. 22A-22B further illustrate how the anterior member(s) (132) of the dual-arm and single-arm versions of the extra-oral second bracket member (131) are configured for anchorage to an anterior skull portion (the bony structure of the maxilla, zygoma, or temporal bone, for example) with ball and socket type of fasteners (900) when the bracket (114) is mounted to the front brace segment (104) as shown in FIGs. 20A-20D. FIGs. 24A-24C illustrate anchoring of similar extra-oral bracket (114) to an anterior skull portion (160), such as to the bony structure (166) of upper jaw, when the bracket (114) is mounted directly to a mounting portion (129) to the full or half rear brace segment (105). The term "anterior portion/region (160)" is used herein to refer to any section of the frontal and mid sections of the skull including upper and lower teeth/jaws, zygomatic bones, sphenoid bone, frontal bone, parietal bone and temporal bone of the skull etc.

[77] FIG. 26B illustrates the rear segment brace (105) anchored to the skull

(107) and the dual brackets (114) anchored intra-orally to the anterior portion (160), such as to the bony structure (166) of upper jaw, with the help of ball and socket type fasteners (900). FIG. 26D illustrates similar anchoring for the device (100) having a half rear brace segment (105) with one intra-oral bracket (114).

[78] The

~~[53] The~~ appliance (100) further ~~consists of~~comprises a concomitant mouthpiece (~~801~~1900), as shown in ~~Fig. 8-1 to 8-3,~~Figs. 19A-19C, which is another form of fastener that is designed to be temporarily worn onto the ~~teeth of the lower jaw, such mouthpiece~~ bony structure i.e. over the anterior portion of said skull (teeth of the lower jaw, for example). The concomitant mouthpiece type fastener (1900) comprises an orthodontic bracket (801) configured to be removably fitted over the bony structure i.e. the anterior portion of said skull (teeth of the lower jaw in this example) and a linkage having an elongated first member (802) connected to the orthodontic bracket (801) ~~that is attached to the middle of the "Y" bracket with a straight metal rod (802) that may be rigidly connected to a~~ at one end, a sleeve (803~~), which may be spring loaded (807), whereby a second rod~~) disposed at the other end of the first elongated member (802) and a second elongated member (804) ~~connected to the "Y" bracket may slide freely through~~configured to be threadably received by the sleeve (803~~), whereby this second rod may have a screw thread pattern on it (805), and a~~). A compression spring (807) is mounted over the second elongated member (804) between the sleeve (803) and a bolt head (806) disposed at the orthodontic bracket (801) facing side of the second elongated member (804) in such a way that the second elongated member (804) is biased toward the orthodontic bracket (801). As showed in FIGs. 19A and 19B, and 27A and 27B, the distal end (808) of the second elongated member (804) is coupled to the inner end (135) of the anterior member (132) through the socket (1908).The bolt ~~(806) at the end of it that protrudes through the sleeve, whereby the bolt~~head (806) can be turned to advance the sleeve (803) in the anterior direction, which will advance the ~~rod~~first elongated member (802) connected to the mouthpiece (801) in the anterior direction, hence advancing the mouthpiece (801) in the anterior direction, with the purpose of anchoring the lower jaw in a forward position relative to both the brace (102) and the user's airway, to keep the user's airway open during sleep while they wear the entire appliance (100).

~~[54] The~~

[79] Figs. 15A-15C, 16A-16B, 17A-17C and 18A-18B illustrate an embodiment (1500) of the device (100) in which the brace (102) may be split into left and right halves ~~(702) as shown~~

~~in Fig. 7A-0,~~in such a way that the brace at the front extends only partially over the anterior region/portion of the skull of the user ~~may~~and it extends partially at the rear to be just sufficient for anchoring to the rear section (109) of the skull (107) of the user. This embodiment of the device (100) enables the user to wear one half of the appliance to sleep, allowing the user to sleep on the side of their skull upon which they are not wearing one half of the said ~~metal~~ brace.

~~[55]~~

[80] The half side of the brace (702) that is configured to be worn during sleep ~~(702)~~ may have removable structural reinforcements (703) that can be attached to it, allowing it to have the same stiffness and structural integrity as the brace that is not split up into two left and right halves.

~~[56] A cushion~~

[81] Reference to Figs. 12A-12B and 13A-13B, in another embodiment, the rear brace segment (105) and the cranial anchorage assembly (200), particularly the abutment (203), are adapted to provide a space between the rear brace segment (105) and the skull (107) of the user to accommodate one or more cushioning pads (502) ~~is~~which are configured to be placed between the brace (102) and the skin of the user~~, as seen in Fig. 5 A,~~ so as to divert the weight of the user's skull from the brace (102) onto the cushion during sleep, in the event the user does not wear the half brace that is designed for sleep, or during other motion that may require the use of diverting the weight of the user's skull, or weight of an impact, away from the brace (102), for comfort or safety purposes. Figs. ~~5B~~12A and ~~5C~~12B show the ~~cushion~~cushioning pad (502) inserted beneath the brace (102) from side view and rear view respectively. The ~~cushion~~cushioning pad (502) can be made up of flexible and shock absorbing material.

~~[57] A~~

[82] In some embodiments, the brace (102), the bracket (114) and the clamp (116) are configured to accommodate a protective helmet (602) ~~as shown in Figs. 6 A to 6C, may be configured to~~ to be worn ~~above~~at least over a portion of the brace ~~that is configured to be anchored to the user's skull,~~(102) for safety purposes~~.~~ as shown in Figs. 14A-14C Figure ~~6A~~14A shows the helmet (602) fitted on the device (100) when the user is wearing it. Figure ~~6B~~14B shows the device (100), when not worn by the user, with another embodiment of the the helmet (602). Figure ~~6C~~14C shows a helmet frame~~.~~ (602).

~~[58]~~

[83] According to the preferred embodiment, due to rotation of the adjustable center screw ~~(108~~i.e. actuation of the adjuster (127), the orthodontic bracket (114) is displaced with respect

to the brace (102) which results in generation of ~~displacement~~a first force~~. The displacement~~ (148), as shown in Fig. 1B, in a first direction on the bony structure to which the bracket (114) is anchored through the fastener. This results in generation of a second force (150) in a second direction opposite to the first direction which is transmitted to the cranial anchorage ~~screws~~assemblies (200) through the brace (102). Gradual application of displacement force, at regular interval, results into expansion of cranial sutures, and eventually, into separation of cranial sutures. Separation of cranial sutures ultimately pushes ~~maxilla~~the maxilla and/or other cranial structures desired to be advanced forward and upward with respect to the back of the skull, allowing the mandible to rotate forward and upward. Separation of cranial sutures may also result in widen opening of foramina. Wider opening of foramina may improve blood flow and neural signaling in the appropriate cardiovascular and neural pathways.

~~[59]~~

[84] The rotation of the ~~adjustable center screw (108~~first bracket member (122) and/or the adjuster (127) is highly subjective to degree of deformity of an individual. According to one aspect of the embodiment, a surgeon may keep the patient under regular observation to track the maxillary advancement. Close medical examination, for example Computed Tomography (CT) Scanning, can give clear insight of the current progress. Based on the scanning results, the surgeon can determine the required course of action. The surgeon may use computer assisted pre-operative planning tools to construe a required operative action plan. Calculated shear forces are applied on the set of cranial anchorage screws. The forces to be applied are calculated to be greater than internal retentive forces within the cranial sutures to be separated. For the calculations of determining the required shear forces, the computer operated ~~preoperative~~pre-operative planning tool may consider maxillary, or other cranial structural advancement achieved, desired advancement, internal retentive forces and within the cranial sutures and maximum shear forces that the anchorage screws can withstand. The action plan is construed for gradual separation of the cranial sutures and advancement of the maxillary structure, and other structures.

~~[60]~~

[85] The described embodiment is particularly advantageous as it does not require pre-operative surgical process of bone segmentation as required in distraction osteogenesis. The device (100) and its implementation require less surgical intervention. Strategic placements of the screws, gradual displacement force, and minimal surgical process may reduce risk of neurovascular loss. It may also pose reduced risk of relapse. Further, as the displacement forces

are applied extra-orally and antero--posteriorly to cranial foramina, gradual expansion of the opening of foramina may be observed. Expanded opening of foramina may result into increased blood flow to the brain, as well as improved neural signaling. The described embodiment exhibits gradual incremental forward movement of the midface and maxillary structure over time, it allows the patency of the patient's airway to be tested and determined as forward midface and maxillary movement progress.

~~[61]~~

[86] The device disclosed herein may be embodied in other specific forms without departing from their essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

~~[62]~~

[87] To the extent not already described, the different features and structures of the various embodiments can be used in combination, or in substitution with each other as desired. That one feature is not shown in all of the embodiments is not meant to be construed that it cannot be so shown, but is done for brevity of description. Thus, the various features of the different embodiments can be mixed and matched as desired to form new embodiments, whether or not the new embodiments are expressly described. All combinations or permutations of features described herein are covered by this disclosure.

What is claimed is:

~~1.~~

1. (New) A dentofacial orthopedic device ~~that comprises~~comprising:

a~~. a rigid or semi rigid~~ brace~~,~~ configured to be anchored to ~~patient's skull through implanted screws, that wraps around the front~~ a skull of ~~the skull, whereby the front portion of the brace can rotate up or down, or in multiple directions at once, at~~ a user with one or more ~~sets of rotational joints, each set of joints which may exist on either side of the brace;~~

~~b. one or more adjustable slots fastened to the front of the brace on rotating axis', such slots which may rotate in multiple directions,~~cranial anchorage assemblies; and ~~which are designed with a screw thread on the internal portion of the slot that can receive a rod with a matching screw thread pattern;~~

~~c. an orthodontic "Y" bracket having two or more ends anchored with ball and socket joints to bony structures including, but not limited to the maxilla and the zygoma at the front of the patient's skull intra-orally; the "Y" bracket may also be anchored extra-orally through punctures, or intra orally to a removal mouth piece or orthodontic bracket that fits rigidly on top of or around the teeth of the upper jaw, using rotating joints as the connection points to the "Y" bracket;~~

~~d. the "Y" bracket having one or more tails which are threaded with a screw pattern passing through the adjustable slots attached to the front of the brace as claimed in Claim lb, anchored to those adjustable slots with bolts, such that when the bolts are turned, the entire "Y" bracket advances forward, pulling forward the bony structures anchored to the ball and socket joints, using the brace as an anchor point, which is configured to be anchored to the user's skull, which is the final anchor point of the dentofacial orthopedic appliance; the ball and socket joints attached to the "Y" bracket are configured to have their rotational angles adjusted by rotating the joints on the brace as claimed in claim la, thus allowing the angle of the "Y" bracket to be modified to ensure that the user may close their mouth while wearing the entire appliance;~~

~~e. hinges at the tail ends of the "Y" bracket which may be designed to be located outside of the user's mouth, such that they may be adjusted in multiple directions and locked into place through a mechanical locking mechanism that may include a screw to be tightened at the location of the hinge, such that the "Y" bracket can be set into place at multiple angles and~~

directions by locking into place the angle at the hinge, thus allowing the appliance to apply displacement forces against the bony structures, whether linear, angular or rotational;

f. a concomitant dental mouthpiece that is designed to be temporarily worn on the user's teeth of the lower jaw, that can be made of a solid material such as acrylic, which may have a smooth upper surface so that it may slide freely against the teeth of the upper jaw; this mouthpiece may be connected to the "Y" bracket via a rod, or a number of rods; these rods may be attached to a second set of rods that are attached to the "Y" bracket through a sliding sleeve that may be spring loaded for user comfort, such sliding sleeve that allows both rods to pass through it, with one rod rigidly attached to that sleeve, and another rod moving freely through it; the rods that moves freely through it may have a screw thread pattern upon it, and as it passes through the connecting sleeve, there may be a bolt on that rod that can be turned to advance that rod through the sleeve, thus pulling the rigidly fixed rod, along with the mouthpiece in the anterior direction, by a set distance to be determined by measuring the minimum amount of anterior displacement that the user' s lower j aw requires to keep their airway open during sleep.

2. The brace as claimed in claim la, wherein a portion of the brace is designed to be in front of the user's mouth.

3. The brace as claimed in claim la, wherein the brace is designed to be anchored to the patient's skull, with or without subcutaneous plates.

4. The brace as claimed in claim la, wherein the brace is configured to be anchored at a predetermined location on the user's skull, which may be the occipital or another region of the skull, and wherein the location is determined based on skull thickness, bone geometry and degree of deformity pertaining to the patient's midface and maxillary structure.

5. The brace as claimed in claim la, wherein the brace is made of titanium, or aluminium, or another rigid or semi rigid material that is biocompatible and lightweight,

6. The brace as claimed in claim la, wherein it is divided into two or more sections, each section attached to the next through a rotating joint on either side of the brace, which may be adjusted to alter the angle of the brace relative to the user's face, and such joint which may be locked into place.

~~7. The adjustable slots fastened to the front of the brace, such slots as claimed in claim lb which may be made of titanium, or aluminium, or another rigid material that is biocompatible and lightweight,~~

~~8. The adjustable slots fastened to the front of the brace, such slots as claimed in claim lb, which may be able to rotate concurrently with any rod passing through them, such rod which may comprise a portion of the dentofacial orthopedic appliance, and which may have a center of rotation that is designed to match the combined centers of rotation of both the joints of the brace as claimed in claim la and the hinge of the orthodontic "Y" bracket as claimed in claim lc.~~

~~9. The adjustable slots as claimed in claim lb, wherein an adjustable center screw can be advanced through these slots, which may be rotated to allow for angular, rotational and linear displacement.~~

~~10. The adjustable slots as claimed in claim lb, wherein the position of the adjustable center screw in the slot may be determined by the desired angular and linear position of the brace that it is attached to.~~

~~11. The orthodontic "Y" bracket as claimed in claim 1c, wherein this bracket is configured in a "Y" formation or is split into two or more separate brackets that can act independently.~~

~~12. The orthodontic "Y" bracket as claimed in claim 1c, wherein this bracket is configured to be anchored to the left and right sides of bony structures on the user's skull, including but not limited to the maxilla and zygoma at ball and sockets joints that are rigidly fixed to the ends of the "Y" bracket and configured to be implanted into the user's bony structures such that the "Y" bracket may freely rotate at the ball and socket joint without exerting a rotational force at the site where the ball and socket joint is configured to be implanted.~~

~~13. The orthodontic "Y" bracket as claimed in claim 1c, wherein it may be configured to be connected to a removable mouthpiece or orthodontic bracket that is rigidly connected to the teeth of the upper jaw, such mouthpiece or bracket that is also connected to the ends of the "Y" bracket by a rod, or rods that are connected each to a rotating joint.~~

~~14. The ball and socket joints as claimed in claim 1c, which may be made of titanium or another rigid biocompatible material.~~

15. The tail ends of the "Y" bracket as claimed in claim Id, which may have a screw thread pattern on them, designed to be screwed through adjustable slots fastened to the front of the brace, and held in place with adjustable bolts that can be turned to advance or retract the "Y" bracket, using the brace as a counterforce.

16. In the middle of the "Y" bracket as claimed in claim Id, wherein there is a hinge located between the tail end of the "Y" bracket outside the user's mouth and the ends of the "Y" bracket attached inside the user's mouth, as claimed in claim le, such hinge that is capable of rotating in multiple directions in synchronous motion with the joints of both the brace as claimed in claim la, and the rotating slot as claimed in claim lb.

17. The hinge, as claimed in claim le that is designed to be locked into place with a screw that tightens a clasp around the said hinge, such that when a pulling force is applied to the "Y" bracket, the angle of the tail end of the "Y" bracket can be maintained, allowing the maxilla to be moved in an upwards manner, allowing the mandible to rotate up and forward, bringing the tongue out of the airway and advancing the user's chin.

18. A concomitant mouthpiece or orthodontic bracket, as claimed in claim If configured to fit around the teeth of the user's lower jaw, such mouthpiece that may be made of metal wire or acrylic, or another biocompatible material, which may have a smooth surface that is designed to allow the said dental brace to slide smoothly across the teeth of the upper jaw, while the user is wearing it.

19. The concomitant mouthpiece or orthodontic bracket, as claimed in claim If that is attached to the "Y" bracket as described in claim 1c, via two sets of rods, one set that is rigidly attached to the mouthpiece, and the other set that is rigidly attached to the "Y" bracket, wherein both sets of rods are connected to one another through a sliding sleeve, wherein one set of rods is rigidly connected to the sliding sleeve and the other set may slide freely through the sleeve, wherein the set of rods that slides freely through the sleeve has a screw thread pattern on it, wherein a bolt may be attached to the rod with the screw thread and advanced to pull or retract the other rod in an anterior or posterior direction.

20. The bolt and sliding sleeve as claimed in claim 19, wherein a compression spring may be placed between the bolt and the sliding sleeve.

21. The bolt as claimed in claim 19, which can be advanced anteriorly by a set distance which is designed to prevent the user's lower jaw and tongue from retracting posteriorly into the user's airway during sleep, such distance to be set by measuring the minimum amount of forward displacement that the user's lower jaw requires to keep their airway open during sleep.

22. The brace, as claimed in claim 1a, wherein the anchorage screws that screw into the skull have a removable abutment that protrudes from the soft tissue that covers the skull, that can be adjusted for the thickness of the soft tissue that covers the skull.

23. The anchorage screws as claimed in claim 22, wherein the abutment is fastened to the anchorage screw by an internal screw, which is fastened to a rotatable plate by a second internal screw, which is tightened in place by a backing screw.

24. The anchorage screws as claimed in claim 22, which may be coated with an anti bacterial or anti infective material.

25. The abutment as claimed in claim 23, which may be coated with an antibacterial or anti infective material.

26. The entire orthopedic appliance as claimed in claim 1, and it's parts thereof, which may be coated with an anti bacterial or anti infective material.

27. The rotatable plate, as claimed in claim 23, wherein there is a coupling joint attached to the plate that couples it, along with the abutment and cranial anchorage screw to the brace as described in claim 1a.

28. The rotatable plate, as claimed in claim 23, that can be rotated to be at a tangent to a screw that penetrates the skull.

29. The rotatable plate, as claimed in claim 23, that can serve as a proxy surface between a brace configured to be worn on the user's skull, and the user's skin, such that the brace does not exert pressure on the user's skin.

30. The brace, as claimed in claim 1a, that may be split into left and right halves, such that the user may wear one half of the appliance to sleep, allowing the user to sleep on the side of their skull upon which they are not wearing one half of the said brace.

~~**31.** The half side of the brace as claimed in claim 21, which may have removable structural reinforcements that can be attached to it, allowing it to have the same stiffness and structural integrity as a brace that is not split up into two halves.~~

~~**32.** The dentofacial orthopedic device as claimed in claim 1, wherein a cushion is configured to be placed between the face of the user and the brace as claimed in claim la, so as to divert the weight of the user's skull from the brace onto the cushion during sleep, or to divert undesired forces that may land upon the brace during other motion.~~

~~**33.**~~at least one bracket, said at least one bracket comprising:

a first bracket member having a proximal end and a distal end, said proximal end being adjustably secured by an adjuster to a receiving member of a clamp having a clamp body selectively mounted to any section of a mounting portion of said brace;and

a second bracket member having a tail end hingedly connected to said distal end of said first bracket member by a hinge joint, and an anterior member having an inner end configured to be rotatably anchored to an anterior portion of said skull of saiduser by at least one fastener, said first bracket member being rotatable about said receiving member for a selective locking of said first bracket member at a plurality of angular positions relative to said second bracket member with said hinge joint;

wherein an actuation of said adjuster at any of said plurality of angular positions of said first bracket member is configured to cause a displacement of said bracket with respect to said brace to exert a first force on said anterior portion of said skull through said at least one fastener in a first direction and a second force in a second direction opposite to said first force on said skull through said one or more cranial anchorage assemblies.

2. (New) The dentofacial orthopedic device of claim 1, wherein said brace comprises at least one front brace segment and at least one rear brace segment hingedly connected to said at least onefront brace segment by a rotating joint, said at least one front brace segment being configured to extend at least partially over said anterior portion of said skull when said at least one rear brace segment is anchored to said skull.

3. (New) The dentofacial orthopedic device of claim 2, wherein said mounting portion is disposed in said at least one front brace segment or in said at least one rear brace segment.

4. (New) The dentofacial orthopedic device of claim 1, wherein said second bracket member further comprises a coupler between said tail end and said anterior member, said coupler being configured to enable selective locking engagement of said anterior member in adjustable relation to said tail end.

5. (New) The dentofacial orthopedic device of claim 1, wherein said anterior member of said second bracket member is a single arm or a pair of arms dimensioned for said anchoring of said inner end to said anterior portion intra-orally or extra-orally.

6. (New) The dentofacial orthopedic device ~~as claimed in~~of claim 1, wherein ~~a removably wearable helmet can be worn over the~~ said at least one fastener is a ball and socket system comprising a fastener end configured to be implantable in said anterior portionof said skull and a socket configured to rotatably receive said inner end of said anterior member.

7. (New) The dentofacial orthopedic device ~~to ensure protection from accidental damages~~of claim 1, wherein said at least one fastener is an orthodontic appliance comprising an orthodontic bracket configured to be removably fitted over said anterior portion of said skull of said user and a linkage configured to pivotally and/oradjustably connect said orthodontic bracket to said inner end of said anterior member, said anterior portion of said skull being teeth or a dental arch of said patient.

8. (New) The dentofacial orthopedic device of claim 1, wherein each of said one or more cranial anchorage assemblies comprises a screw end configured to be fastened to said skull, an opposite free end spaced apart by a selectable distance with an abutment and a plate assembly configuredto rotatably couple said free end to said brace, said free end being configured to be adjustably mounted to said abutment at a desired orientation.

9. (New) A dentofacial orthopedic device comprising:

a brace having at least one front brace segment and at least one rear brace segment hingedly connected to said at least one front brace segment by a rotating joint, said at least one rear brace segment being configured to be anchored to a skull of a user with one or more cranial anchorage assemblies such that said at least one front brace segment extendsat least partially over an anterior region of said skull of said user; and

at least one bracket, said at least one bracket comprising;

a first bracket member having a proximal end and a distal end, said proximal end being adjustably secured by an adjuster to a receiving member of a clamp having a clamp body selectively mounted to any section of a mounting portion of said at least one front brace segment; and

a second bracket member having a tail end hingedly connected to said distal end ofsaid first bracket member by a hinge joint, and an anterior member having an inner end configured to be rotatably affixed to an anterior portion of said skull of said user by at least one fastener, said at least one front brace segment being rotatable about a first axis of rotation passing through said rotating joint relative to said at least onerear brace segment to enable a rotation of said first bracket member about a secondaxis of rotation for a selective locking of said first bracket member at a first plurality of angular positions relative to said second bracket member with said hinge joint;

wherein an actuation of said adjuster at any of said plurality of angular positions of said first bracket member is configured to cause a displacement of said bracket with respect to said brace to exert a first force on said anterior portion of said skull through said at least one fastener in a first direction and a second force in a second direction opposite to said first force on said skull through said one or more cranial anchorage assemblies.

10. (New) The dentofacial orthopedic device of claim 9, wherein said receiving member is configured to be swivelable relative to said clamp body about a third axis of rotation substantially parallel to said second axis of rotation for a selective locking of said receiving member at a second plurality of angular positions corresponding to said first plurality of angular positions of said first bracket member.

11. (New) The dentofacial orthopedic device of claim 9, wherein said anterior member of said second bracket member is a single arm or a pair of arms dimensioned for said anchoring of said inner end to said anterior portion intra-orally or extra-orally.

12. (New) The dentofacial orthopedic device of claim 9, wherein said at least one fastener is a ball and socket system comprising a fastener end configured to be implantable in said anterior portionof said skull and a socket configured to rotatably receive said inner end of said anterior member.

13. (New) The dentofacial orthopedic device of claim 9, wherein said at least one fastener is an orthodontic appliance comprising an orthodontic bracket configured to be removably fitted over said anterior portion of said skull of said user and a linkage configured to pivotally and/or adjustably connect said orthodontic bracket to said inner end of said anterior member, said anterior portion of said skull being teeth or a dental arch of said patient.

14. (New) The dentofacial orthopedic device of claim 9, wherein each of said one or more cranial anchorage assemblies comprises a screw end configured to be fastened to said skull, an opposite free end spaced apart by a selectable distance with an abutment and a plate assembly configuredto rotatably couple said free end to said at least one rear brace segment, said free end being configured to be adjustably mounted to said abutment at a desired orientation.

15. (New) A method for midfacial advancement, said method comprising:

anchoring a brace to a skull of a user with one or more cranial anchorage assemblies; mounting, selectively, a clamp body of a clamp to any section of a mounting portion ofsaid brace;

providing a bracket having a first bracket member and a second bracket member comprising an anterior member and a tail end, said first bracket member having a proximal end adjustably secured by an adjuster to a receiving member of said clamp and a distal end hingedly connected to said tail end of said second bracket member by a hinge joint such that said first bracket member is rotatable about said

receiving member for a selective locking of said first bracket member at a plurality of angular positions relative to said second bracket member with said hinge joint;

anchoring, rotatably, an inner end of said anterior member to an anterior portion of said skull by at least one fastener;

locking said first bracket member at a selected angular position of said plurality of angular positions relative to said second bracket member with said hinge joint;

actuating said adjuster at said selected angular position to cause a displacement of said bracket with respect to said brace to exert a first force on said anterior portion through saidat least one fastener in a first direction and a second force in a second direction opposite to said first force on said skull through said one or more cranial anchorage assemblies.

16. (New) The method of claim 15, wherein said brace comprises at least one front brace segmentand at least one rear brace segment hingedly connected to said at least one front brace segment by a rotating joint, said at least one front brace segment being configured to extend at least partially over said anterior portion of said skull when said at least one rear brace segment is anchored tosaid skull.

17. (New) The method of claim 15, wherein said mounting portion is disposed in said at least onefront brace segment or in said at least one rear brace segment.

18. (New) The method of claim 15, wherein said anterior member of said second bracket member is a single arm or a pair of arms dimensioned for said anchoring of said inner end to said anterior portion intra-orally or extra-orally.

19. (New) The method of claim 15, wherein said at least one fastener is a ball and socket system comprising a fastener end configured to be implantable in said anterior portion of said skull and a socket configured to rotatably receive said inner end of said anterior member.

20. (New) The method of claim 15, wherein said at least one fastener is an orthodontic appliance comprising an orthodontic bracket configured to be removably fitted over said

anterior portion of said skull of said user and a linkage configured to pivotally and/or adjustably connect said orthodontic bracket to said inner end of said anterior member, said anterior portion of said skull being teeth or a dental arch of said patient.

21. (New) The method of claim 15, wherein each of said one or more cranial anchorage assemblies comprises a screw end configured to be fastened to said skull, an opposite free end spaced apart by a selectable distance with an abutment and a plate assembly configured to rotatably couple said free end to said brace, said free end being configured to be adjustably mounted to said abutment at a desired orientation.

22. (New) The dentofacial orthopedic device of claim 1, wherein said second bracket member further comprises a coupler between said tail end and said anterior member, said coupler being configured to enable selective locking engagement of said anterior member in adjustable relation to said tail end.