

AN ORTHOPEDIC DEVICE FOR MIDFACIAL BONE STRUCTURE

ADVANCEMENT

TECHNICAL FIELD OF THE DEVICE & METHOD

[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 surgery can advance the upper and lower 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 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 mid-face, or other bony structures of the cranium, that applies a ubiquitous 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

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 patients, this allows for periodic testing of the airway patency, as the mid-face that is being advanced, giving the practitioner the knowledge of when to stop advancement.

[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-borne or bone-anchored appliance. The dentofacial orthopedic 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 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 that can be retracted or advanced by turning a nut. The adjustable center screw is the anterior portion of the orthodontic bracket, which is “Y” shaped, with the two ends of the “Y” connected inside the mouth in multiple manners, two of which are described herein: In one manner, a tooth-borne connection is made to either a removal oral appliance that is worn on the teeth of the upper jaw or orthodontic brackets 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 a bone-anchored manner, 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 at the anterior end of the brace, the adjustable center screw 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] A slot is fitted to the anterior portion of the brace via a hinge. The slot is provided to host the adjustable center screw that can be angulated to suite the desired direction of motion of maxillary or bony structure advancement. The adjustable center screw is fitted in the slot in 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 can be changed according to the achieved target of advancement, desired angle of displacement, and the expected course of the advancement.

[16] The orthodontic “Y” bracket is configured to be angulated such that at any angle of advancement, the center of rotation is at 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 a hinge joint on the “Y” bracket, located outside of the mouth. This hinge can be locked into place at the desired angle, without impacting the placement of the “Y” bracket relative to the user’s mouth and lip seal.

[17] The front half 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] 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 brace that attaches onto the skull is anchored with screws that implant into the skull. These screws are made of titanium or another biocompatible material. These screws have an abutment that is screwed onto the head of the screw, 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 that can be adjusted in any direction and tightened against the abutment. This plate 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] In OSA patients, there may exist a need to maintain the patency of the airway during sleep while wearing the orthopedic appliance, 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 teeth of the lower jaw 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] 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] 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, 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] 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] 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] 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 show a perspective, top, side, front and back view, respectively, of the generic structure of a dentofacial orthopedic device (100) anchored to skull, with a rotating joint (115), attached to an orthodontic “Y” bracket (114) that is anchored at its posterior ends (110) to bony structures on the anterior side of the user’s skull, intra-orally, or extra-orally through punctures. The “Y” bracket may be reinforced with a bracket (106), and its tail end (114) is shown to pass through a rotatable slot (116). At the outside end of the slot (116), there is a bolt (108) on the end of the “Y” bracket (114) that can be turned to advance the “Y” bracket against the brace (102), pulling the “Y” bracket in the anterior, or desired direction, in accordance with preferred embodiment of the present disclosure.

[27] Fig. 1A-5 to 1A-9 show a perspective, top, side, front and back view, respectively of the 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.

[28] Fig. 2A-0 to 2A-4 show a perspective, front, back, side and top views, respectively of an assembly consisting of a cranial anchorage screw (200), designed to screw into the user’s skull. The screw is attached to an abutment (203) upon which a rotatable plate (202) is attached, that rests within a pocket formed by the assembly of two plates (201). This assembly (201) is affixed to the brace (100), in accordance with the preferred embodiment of the present disclosure.

[29] Fig. 2B-0 to 2B-4 show a side view, another side view, a top view, and cross section view, respectively, of the anchorage screws configured to be anchored into the skull (200), attached to an abutment (203) via an internal screw (205). A second internal screw (206) attaches a rotatable plate (202) to the abutment (203). The plate (202) is tightened with another screw (204) in accordance with the preferred embodiment of the present disclosure.

[30] Fig. 2B-7 to 2B-10 show a front, side, back and perspective view, respectively, of two plates that form a pocket (201), such plates that are 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.

[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 (300) that is configured to be implanted into the user’s maxilla, or appropriate bony structure, to serve as an anchor point for the “Y” bracket (114). The ball (301) may rotate freely at its top end, and it is attached rigidly to the “Y” bracket at its bottom end.

[33] Fig. 3C-0 to 3C-2 show a side and top view, respectively, of a tooth-borne option to anchor the maxilla to the brace (102). This option consists of a removable mouthpiece (303) that is worn on the teeth of the upper jaw, and is connected at a rotational joint (304) to rigid rods (305) that are configured to connect to the “Y” bracket outside the user’s mouth.

[34] Fig. 4A-0 to 4A-4 show an perspective, top, front, back and side view, respectively of a rotating slot (116) that the tail end of the orthodontic “Y” bracket (114) can screw into, in accordance with the preferred embodiment of the present disclosure. The rotating slot has an opening (117) for the tail end of the orthodontic “Y” bracket to insert into, grooves (118) for the brace (102) to fit into, screw openings (119) to tighten the rotating slot onto the brace (102), and two openings for screws to adjust the angle of the slot (120).

[35] Fig. 5A to 5C show three side views and one back view, respectively, of cushions (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 a protective helmet (602) that is configured to be worn by the user, above the brace (102).

[37] Fig. 7A-0 to 7A-4 show an embodiment of the brace (102) that 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] Fig. 7B-0 to 7B-4 show 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 concomitant mouthpiece 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 (803). A second rod (804) is connected to the “Y” bracket and may pass freely through the sleeve (803). This second rod (804) has a screw thread 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.

DETAILED DESCRIPTION

[40] 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. 1A-0 shows structure of a bone anchored orthopedic device (100), referred as to the device hereinafter, according to the preferred embodiment of the present device and method. The device (100) mainly includes a brace (102) anchored to the skull of a user through at least one anchorage screw. 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 (102) is contoured to the shape of the skull, which wraps around the front of the skull and terminates full circle in front of the mouth. The brace (102) can be separated into components by rotational joints on either side (115) that allow those components of the brace to be positioned at various angles. 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 to one embodiment, at least one anchorage screw (200), shown in Fig. 2A-0, is designed to be screwed to user’s the skull to anchor the brace (102)

to the skull. The screw (200) is paired with an abutment (203) via an internal screw (205) shown in Fig. 2B-3. The abutment can protrude from the user's skull, allowing the skin to heal around it, forming a seal. The screw (200) and abutment (203) may also be coated in an anti-bacterial or anti-infective material. The abutment is connected to a rotatable plate (202) that is held in place by a second internal screw (206), which is tightened at its head (204).

[43] The anchorage screw (200) 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 as possible to perpendicular to the desired direction of force application at the entry point of the screw.

[44] The rotatable plate (202) rests within a metal bracket that is an assembly of two metal plates (201), that form a pocket, as shown in Fig. 2A-1 for the plate (202) to rest into.

[45] The plate (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) penetration.

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

[47] In accordance with one feature of the preferred embodiment, an orthodontic "Y" bracket (114) shown in Fig. 1A-0 and 3A-0 is attached at its posterior ends (110) to both the left and right side of a user's maxilla, or appropriate bony structure, inside the mouth on the split end of the bracket at freely rotating ball and socket joints (301 & 302), shown in Fig. 3B-0, implanted into both the left and right side of the maxilla by way of a screw (300), or other appropriate bony structure within the face that allows the position of the "Y" bracket to be optimized in relation to the mouth of the user such that the user may maintain a closed mouth while wearing the appliance.

[48] The orthodontic “Y” bracket may also be attached in a tooth-borne method as shown in Fig. 3C-0 to 3C-1, via a removable rigid or flexible mouthpiece or orthodontic bracket (303) that is designed to fit on the 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 (303) bears rotational joints (304) that are connected to rods (305), which then connect to the orthodontic “Y” bracket.

[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 the user’s mouth can be independently rotated in multiple directions at a lockable hinged joint (113) located outside of the mouth as shown in Fig. 1A-0, including the up and down direction, by unlocking the hinge and rotating the front half of the brace 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 the “Y” bracket 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), or rotational joints.

[51] The slot (116) has a center of rotation that is designed to match the combined centers of rotation of the brace’s rotational joints (115), and the angle of the “Y” bracket, as determined by the angle of the hinge (113).

[52] The “Y” bracket 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

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

[53] The appliance further consists of a concomitant mouthpiece (801), as shown in Fig. 8-1 to 8-3, that is designed to be temporarily worn onto the teeth of the lower jaw, such mouthpiece (801) that is attached to the middle of the “Y” bracket with a straight metal rod (802) that may be rigidly connected to a sleeve (803), which may be spring loaded (807), whereby a second rod (804) connected to the “Y” bracket may slide freely through the sleeve (803), whereby this second rod may have a screw thread pattern on it (805), and a bolt (806) at the end of it that protrudes through the sleeve, whereby the bolt can be turned to advance the sleeve (803) in the anterior direction, which will advance the rod (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 brace (102) may be split into left and right halves (702) as shown in Fig. 7A-0, 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 metal brace.

[55] The half side of the brace 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 halves.

[56] A cushion (502) is configured to be placed between the brace (102) and the skin of the user, as seen in Fig. 5A, so as to divert the weight of the user’s skull from the brace 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 and 5C show the cushion (502) inserted beneath the brace (102) from side view and rear view

respectively. The cushion (502) can be made up of flexible and shock absorbing material.

[57] A protective helmet (602) as shown in Figs. 6A to 6C, may be configured to be worn above the brace that is configured to be anchored to the user's skull, for safety purposes. Figure 6A shows the helmet (602) fitted on the device (100) when the user is wearing it. Figure 6B shows the device (100), when not worn by the user, with the helmet (602). Figure 6C shows a helmet frame.

[58] According to the preferred embodiment, due to rotation of the adjustable center screw (108), the orthodontic bracket (114) is displaced which results in generation of displacement force. The displacement force is transmitted to the anchorage screws 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 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] The rotation of the adjustable center screw (108) 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 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] 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] 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] 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.

TITLE OF THE INVENTION:

ORTHOPEDIC DEVICE FOR MIDFACIAL BONE STRUCTURE ADVANCEMENT**CLAIMS**

1. A dentofacial orthopedic device that comprises:

- a. a rigid or semi-rigid brace, configured to be anchored to patient's skull through implanted screws, that wraps around the front of the skull, whereby the front portion of the brace can rotate up or down, or in multiple directions at once, at 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, 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 1b, 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 1a, 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 jaw requires to keep their airway open during sleep.

2. The brace as claimed in claim 1a, wherein a portion of the brace is designed to be in front of the user's mouth.
3. The brace as claimed in claim 1a, 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 1a, 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 1a, 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 1a, 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 1b 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 1b, 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 1a and the hinge of the orthodontic "Y" bracket as claimed in claim 1e.
9. The adjustable slots as claimed in claim 1b, 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 1b, 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 socket 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 1d, 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 1d, 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 1e, such hinge that is capable of rotating in multiple directions in synchronous motion with the joints of both the brace as claimed in claim 1a, and the rotating slot as claimed in claim 1b.
17. The hinge, as claimed in claim 1e 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 1f 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 1f 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 anti-bacterial 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 1a, 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. The dentofacial orthopedic device as claimed in claim 1, wherein a removably wearable helmet can be worn over the dentofacial orthopedic device to ensure protection from accidental damages.