

[54] APPARATUS FOR USE IN TREATMENT OF THE BILATERAL CLEFT LIP AND PALATE CONDITION IN INFANTS

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[57] ABSTRACT

[21] Appl. No.: 489,813

The correction of maxillary and premaxillary deformities in infants with bilateral cleft lip and palate is achieved through the application of an intra-oral device capable of extra-oral activation. A miniature gear mechanism is provided for expansion of the maxillary segments and screw means for retraction of the premaxillary segment. By positioning the premaxillary segment in its appropriate relationship to the lateral maxillary segments, satisfactory repair of the bilateral cleft lip is accomplished in one stage.

[52] U.S. Cl. 128/76 R; 128/17

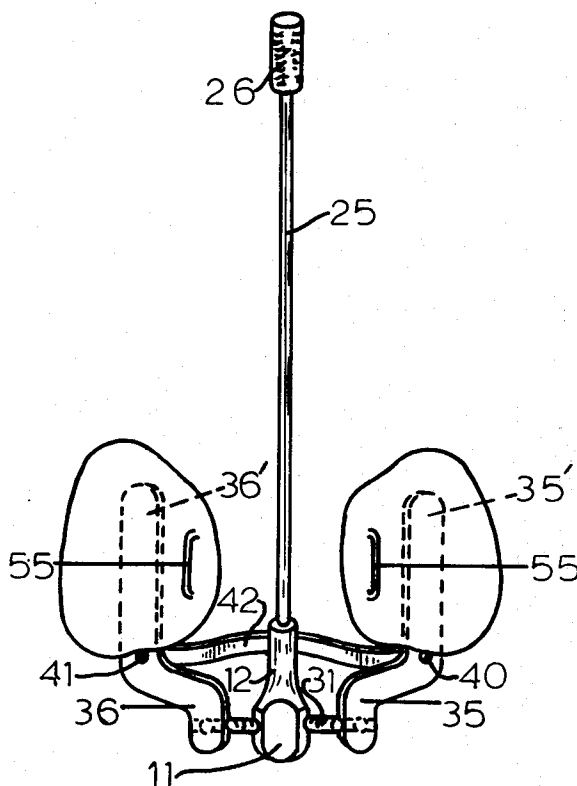
[51] Int. Cl. A61f 5/00

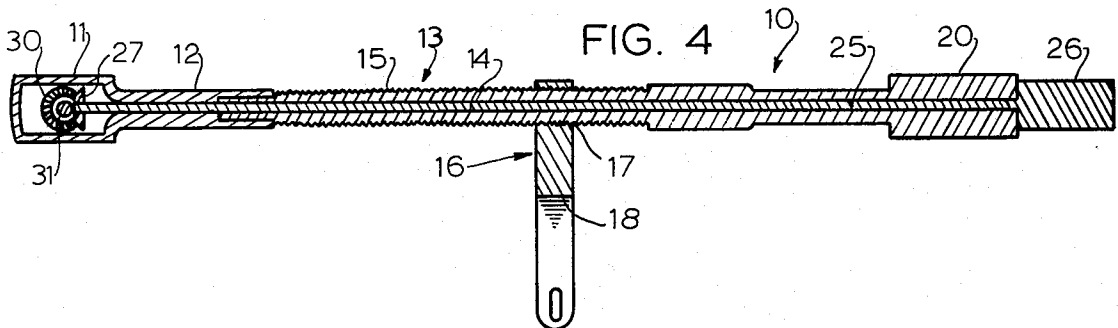
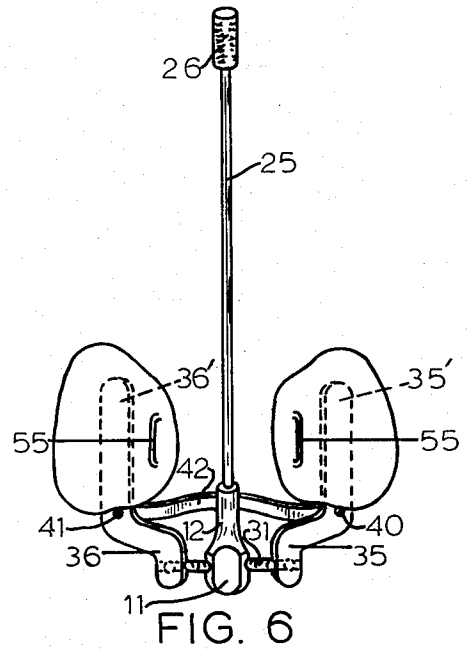
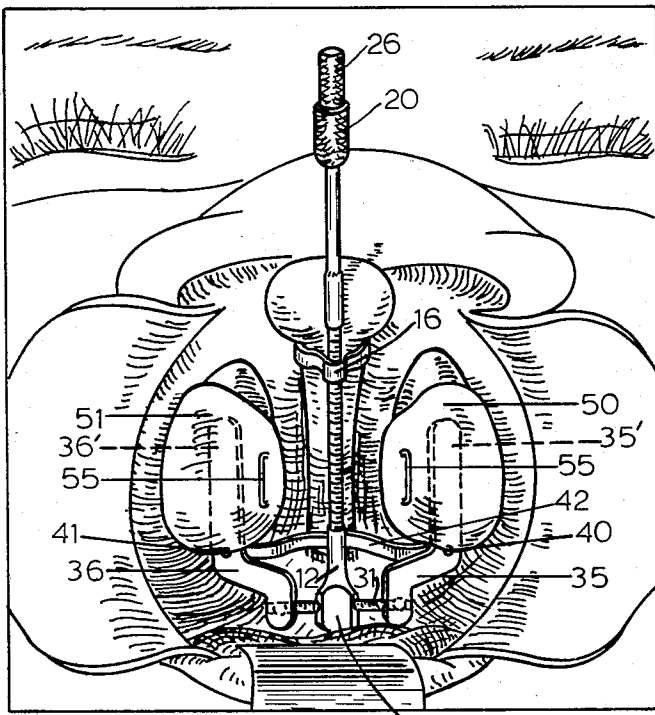
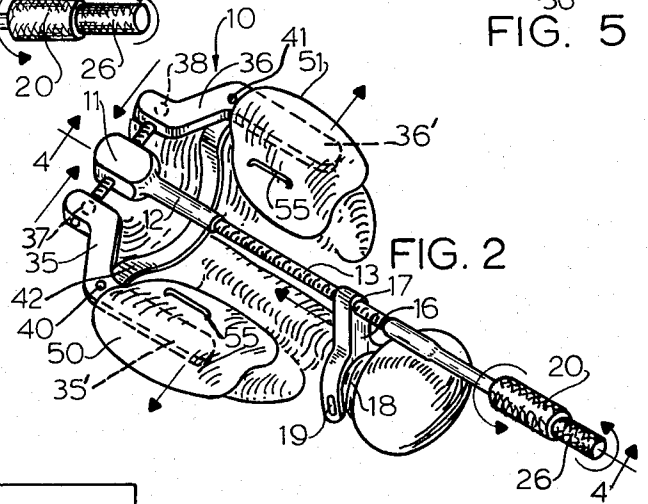
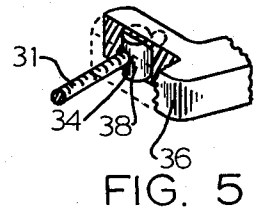
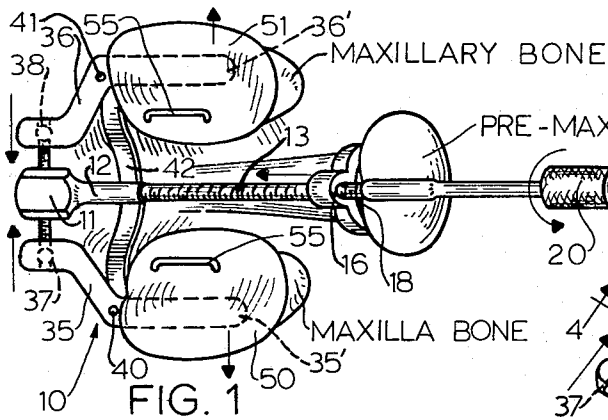
[58] Field of Search 128/76, 12, 17, 20, 345; 32/40, 2, 4

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18 Claims, 6 Drawing Figures





APPARATUS FOR USE IN TREATMENT OF THE BILATERAL CLEFT LIP AND PALATE CONDITION IN INFANTS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to a device for use in the treatment of bilateral cleft lip and palate condition in infants.

2. Description of the Prior Art

The markedly protruding premaxilla and its positioning in the maxillary arch in severe bilateral clefts has been a topic of varied discussions, publications and devices for many years. Heretofore, external traction has been cumbersome, difficult to maintain and, if applied with too much tension, has caused loss of the soft tissue elements of the philtrum.

Various surgical methods and devices for sectioning and repositioning the vomer are available; however, this has led to an unstable premaxillary segment in some patients and eventual "tilting" of the premaxilla lingually with resultant malposition of the permanent incisor teeth in others. Deceased growth of the premaxillary segment has also been a consideration following wedge resection of a portion of the vomer. The "lip adhesion" technique, described for gradual retro-positioning of the premaxilla, necessitates one or two additional operative procedures prior to the actual lip repair.

A method which introduces an intra-oral approach was introduced by Dr. Nicholas G. Georgiade of the Duke University Medical Center in 1968. This utilizes Kirschner pins which are inserted through the cheeks, under local anesthesia, in the posterior maxillary area distal to the tooth follicles. The excess Kirschner wire is then cut allowing sufficient wire to be present in each buccal sulcus so that the ends can be bent with thin nosed pliers in the shapes of hooks for rubber band fixation. If the patient has a complete palatal cleft associated with the premaxillary protrusion, rubber bands can be placed around the Kirschner wire half-way across the palatal cleft, facilitating their attachment to the anterior hooked wire. This anterior wire is carefully inserted with a hand drill through the buccal aspect of the premaxilla in the region of the naso-maxillary curve. Adequate lengths of wire are allowed to remain for hook formation at either end similar to that performed on the posterior maxillary wire. At this point, the rubber bands are applied and traction instituted, either directly posteriorly, or along the buccal aspect, depending on the cleft type. Twin oral pin fixation and traction appears to have advantages in attempting premaxillary retro-positioning. Pin fixation and traction can be instituted prior to surgery.

Another method of positioning the protruding premaxillary segment also utilizes intra-oral traction to pull the segment back into its proper relationship in the maxillary arch. Under local anesthesia, a Kirschner wire is inserted through one cheek just back of the maxilla. The wire is posterior to the location of any possible tooth follicles.

The patient's mouth is opened to facilitate insertion of the wire which is then advanced until the correct alignment is attained, as judged by its position just under the soft palate cleft. The Kirschner wire is then drill laterally on through the opposite maxillary-

pterygoid area until it is palpable in the opposite cheek. It is then cut as short as possible, so that soft tissues of both cheeks will cover the wire. A strip of Dacron is cut down the middle for half its length to create a Y-shaped sling. One limb of the Y is threaded across the anterior-superior surface of the premaxilla subcutaneously, under the prolabium as close to the bone as possible and superior to the point of the most forward position of the segment. The second limb of the Y is placed over the lower anterior (labial mucosal) aspect of the premaxilla and the two previously separated ends are now sutured together with nylon. This makes it one continuous single band again, creating a length of Dacron on either side of the premaxilla, to pull on a double sling over the bony segment. A standard rubber band is cut then at one end, threaded through each end of the Dacron sling, and brought around the posterior Kirschner wire. The rubber band is now re-united to exert sufficient traction on the anterior segment, as judged by the tension on the tied rubber band. The two cut ends of the rubber band are sutured together with silk, using two small mosquito clamps to grasp them and advance both of them until sufficient traction has been obtained. This traction can be adjusted at the time of the lip repair to compensate for the interval retro-positioning of the premaxillary segment.

Intra-oral rubber bands have now been used in many patients and have achieved what was expected of them, namely, a one-stage closure of the lip, and in some cases closure of the alveolar arch as well. However, rubber bands lose their elasticity when used in the mouth and their tension is reduced as retraction occurs. Ideally, they should be replaced every two days.

The continuous unremitting pull of rubber bands does not appear to be the best means for obtaining the most rapid movement when considered in terms of the collagen adjustment mechanism involved. A method or apparatus which would accomplish the desired movement in a series of steps, employing intermittent force would greatly advance work in this area.

SUMMARY OF THE INVENTION

The apparatus of this invention provides for incremental and intermittent retraction of the premaxilla and expansion of the maxilla, either independently or together. In the embodiment disclosed, a pair of control shafts, one within the other, extend outward the length of the oral cavity. Each control shaft has a knob which can be rotated extra-orally to impart the desired expansion or retraction reaction within the cavity. An intra-oral housing receives the shafts and one of the shafts further extends into the housing and mounts a bevel gear. Another bevel gear meshes with the first bevel gear and drives a threaded stub shaft. A pair of pivotal arm members pivot about a pair of pins which have threaded openings through which the ends of the stub shaft pass. These arm members, when the apparatus is in service, are secured to the maxilla segment through a pair of plates made integral with the lateral palatal segments of the maxillae by appropriate staple pins. A saddle or U-shaped premaxillary yoke rides, through a screw arrangement, back and forth on the outer control shaft. The U-shaped yoke is secured by pin means to the premaxillary segment. Rotation of the outer control shaft causes the U-shaped yoke to move in or out and effectively causes the premaxillary bony segment to be repositioned to a more normal position.

While being internally mounted within the patient's mouth, the apparatus is externally activated and if desired, either function, i.e., retraction or expansion, may be obtained independent of the other. When the retraction function is of primary interest, the inactive expansion members attached to the maxilla simply serve as an anchoring means and when expansion is of primary interest the mentioned yoke and outer control shaft act merely as a support for the inner control shaft.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the intra-oral expansion-retraction device of the invention in place.

FIG. 2 is a further perspective view of the apparatus of FIG. 1.

FIG. 3 is a perspective view of the intra-oral expansion-retraction device in place and showing tongue and cheek retractors in use.

FIG. 4 is an enlarged section view of the apparatus taken substantially along line 4—4 of FIG. 2.

FIG. 5 is a partial perspective view illustrating the threaded pin arrangement employed with each of the expansion arms.

FIG. 6 is a perspective view illustrating the expansion apparatus without the retraction apparatus.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The intra-oral apparatus of the invention, generally designated by numeral 10, is illustrated as being adapted for extra-oral activation. A gear housing 11 has an appended shaft housing 12. Shaft 13 has one end mounted for rotation in housing 11. Shaft 13 is hollow internally and provides a shaft passage 14 and an externally threaded portion 15. A saddle arrangement 16 has a threaded hole 17 which receives the threaded portion 15 of shaft 13. A U-shaped yoke 18 of saddle 16 is adapted to be pinned as at 19 to the premaxillary bony segment. The pinning at 19 thus provides a fixed point to hold the premaxillary segment. Shaft 13 is further provided at its outer end opposite gear housing 11 with a knurled knob 20 which may be used extra-orally to rotate shaft 13 and thereby cause gear housing 11 and its appendages to move relative to saddle 16 to effect retraction of the premaxillary segment. Knob 26 secures shaft 13 against axial movement.

A second shaft 25 has at its outer end a knurled knob 26 and is of a reduced diameter such that it may be mounted and rotatably received within passage 14 of shaft 13 and with its opposite end extending inside gear housing 11. Within gear housing 11, shaft 25 is suitably secured to drive a bevel gear 27. Thus, as shaft 25 is rotated by knob 26, bevel gear 27 may be rotated.

A second bevel gear 30 is secured to a cross shaft 31 and meshes with bevel gear 27. As gear 27 is driven by turning of knob 26, gear 30 is caused to rotate which also causes cross shaft 31 to rotate in gear housing 11.

A pair of laterally spaced, offset shaped arms 35, 36 have end portions 35', 36' which reside in a common plane and forward of housing 11. Opposite end portions 35'', 36'' reside in a common plane and mount pins 37, 38 with the axis thereof generally perpendicular thereto. Each of the pins 37, 38 is provided with a threaded hole 34 perpendicular to the pin axis. The outer threaded end portions of cross shaft 31 are received by the respective threaded holes in pins 37, 38. Thus, when gear 30 and cross shaft 31 are rotated in a

given direction, the arm ends 35', 36' move in or out in a corresponding direction. Pin connections 40, 41 are located intermediate the length of arms 35, 36 and provide means for attaching the ends of a leaf-shaped strip 42, which strip links arms 35, 36 together and allows the pin connections 40, 41 to serve as pivots. Thus, as arm ends 35', 36' move in and out as cross shaft 31 is rotated, the offset ends 35', 36' also move in and out corresponding amounts to the pivoting on strip 42.

The description will next refer to the insertion and operation of the intra-oral device 10 of the invention. In preparation of insertion, an impression is taken of the maxillary and premaxillary segments. A pair of plastic plates 50, 51 are molded from the impression so as to fit over the maxillary segments. In the molding process, each plate 50, 51 is preferably molded around a respective offset end portion 35', 36' of arms 35, 36 so that each respective arm end and associated plate effectively become an integral unit.

Tongue and cheek retractors are employed as needed during insertion of invention appliance 10. Once appliance 10 is in proper position so that plates 50, 51 mate with the proper maxillary bone area, plates 50, 51 are attached to the maxillary bone by staples 55. Next, saddle 16 is positioned as desired along the posterior premaxillary stem. Once so positioned, saddle 16 is pinned to the premaxillary bone as at 19.

As previously described, the prior art devices have not enabled either gradual, incremental, or precisely controlled expansion of the maxilla bones or retraction of the premaxillary bone segment, whether done independently or together on the same patient. However, from the foregoing description, it can be seen that all of these desirable objectives can be achieved with the device of the invention. Thus, by rotating knob 26, ends 35', 36' may be gradually spread and the maxilla bones may be gradually expanded as desired. For example, a time schedule may be established for precise, measurable and controllable incremental changes in expansion at precise times. Also, by gradually rotating knob 20, the relative distance between housing 11 and saddle 16 may be gradually shortened, thus allowing the premaxillary bone segment to be retracted in the same precise manner with measurable and controlled incremental changes in the retraction.

In a specific device embodying the invention, one turn of knob 26 has been effective to spread the maxillary bone segments 1 mm. In the same embodiment, each rotation of knob 20 has acted to retract saddle 16 and consequently to retract the premaxillary bone segment 1 mm.

From the foregoing, it will be apparent that by following a series of steps employing intermittent force and incremental movements through the coaxial screw and gear arrangement of this invention, an advantage is obtained over the previous constant, uncontrollable pull of rubber bands. Use of the invention device may thus result in rapid repositioning of a markedly protruding premaxilla into its proper arch position.

As illustrated in FIG. 6, the saddle 16 and shaft 13 may be eliminated and the device may be employed solely as a means for adjusting the lateral spacing of the maxillary bone segments. In the same sense, where the patient's needs are primarily directed to retraction of the premaxillary bone segment, the maxillary bone adjusting structure which includes plates 50, 51 and arms

35, 36 basically becomes an anchoring structure for anchoring the intra-oral end of shaft 13. Thus, the two functions of the device are easily used together or independently and in either event the coaxial shaft arrangement and extra-oral control knobs provide ease of use and preciseness in application.

The described coaxial shaft arrangement offers many advantages, both from the viewpoint of construction as well as operation. It is recognized, however, that the shaft could be otherwise arranged, e.g., in a side-by-side arrangement, and effect the purposes of the invention. What should also be recognized is that the described gear arrangement and leaf-shaped support arrangement (strip 42) effectively provide a positioning means for the arm members used to adjust the maxillary bone position and that other extra-orally and threaded shaft operated positioning means could be substituted for the specific arrangement described. Also to be recognized is the fact that when the primary interest is concerned with retraction of the premaxillary bone, the arm member positioning apparatus once located and appropriately secured, effectively serves as an intra-oral anchoring arrangement for the retraction apparatus.

Various materials lend themselves to the invention, with stainless steel, or the like, being a preferred material for all components except plates 50, 51. For these, moldable materials are readily available and well known.

What is claimed is:

1. A mouth cavity bone correction apparatus, comprising:

- a. a pair of elongated laterally spaced arm members adapted to be intra-orally placed and having outer end portions residing in a common plane and adapted for intra-oral securement to selected similarly laterally displaced maxillary bone and having opposite end portions adapted to be positioned more intra-orally within the cavity and unsecured to said bone;
- b. means for securing said arm member outer end portions to said bone;
- c. an auxiliary structure adapted for intra-oral placement in operative association with said arm members providing an intra-oral mount for the said unsecured opposite ends of said arm members and including movable positioning means responsive to a connected rotated drive shaft, said positioning means being engaged with said unsecured opposite end portions in a manner adapted when connected to an appropriate said drive shaft to laterally position said secured outer end portions of said arm members according to the direction and amount of turning of such shaft; and
- d. a drive shaft having one end adapted to be intra-orally placed and connected to drive said movable positioning means and an opposite end adapted to be intra-orally placed and adapted for finger engagement to turn said drive shaft to effect desired positioning of said arm members and thereby achieve corrective positioning of said bone.

2. An apparatus as claimed in claim 1 including an auxiliary externally threaded shaft having its axis mounted parallel to the axis of said drive shaft with one end adapted to be intra-orally placed and rotatably mounted on and secured against axial movement with respect to said structure and the opposite end adapted

to be mounted extra-orally and adapted for finger engagement turning thereof, a premaxillary bone securing member adapted to be intra-orally placed and having an end portion adapted to be pinned thereto and an internally threaded body portion formed integral therewith, a central portion of said auxiliary shaft being threadably mounted to turn in said body portion such that with said one end of the securing member pinned to said premaxillary bone and with said arm members secured to said maxillary bone, said premaxillary and maxillary bones may be moved relatively, bidirectionally, and incrementally for cleft lip and palate correction by corresponding extra-oral rotation of said operating end of said auxiliary drive shaft.

3. A mouth cavity maxillary bone correction apparatus, comprising:

- a. a pair of elongated laterally spaced arm members having outer end portions residing in a common plane and adapted for intra-oral placement and securement to selected similarly laterally displaced maxillary bone and opposite inner end portions adapted to extend intra-orally from such securement;
- b. means for securing said respective arm member outer end portions to said bone;
- c. mounting means adapted to be intra-orally placed and positioned between and having pivotal connections with medial portions of said arm members enabling said arm members to be pivoted thereon;
- d. positioning means adapted to be intra-orally placed and mounted between and engaged with said inner end portions of each of said arm members to control the positioning thereof, said positioning means having a shaft drive enabling said inner end portions to be moved in given directions dependent on the direction of rotation of the shaft driving said positioning means to effect corresponding movements of said arm member outer end portions; and
- e. a drive shaft having one end adapted to be intra-orally placed and connected to drive said positioning means by the turning of said drive shaft and having the other end thereof adapted to be extra-orally placed and adapted for finger engagement to effect rotation thereof whereby as said drive shaft is rotated in a given direction and with respective said arm member outer end portions secured to said bone, the lateral spacing of said bone may be changed to effect appropriate correction thereof.

4. An apparatus as claimed in claim 3 wherein said securing means comprises a pair of plate means secured to the respective arm member outer end portions and molded to fit and to be secured to the said bone.

5. An apparatus as claimed in claim 3 wherein said mounting means comprises a strip member extending between said medial portions and having its ends pivotally connected thereto.

6. An apparatus as claimed in claim 3 wherein said positioning means includes a gear box connected to be driven by said drive shaft and having a pair of driven threaded stub shafts extending therefrom, each said arm member inner end portion having a threaded securement to a respective said stub shaft enabling said arm member outer end portions to be adjusted by driving said gear box with said drive shaft and moving said inner end portions along said stub shafts.

7. An apparatus as claimed in claim 3 wherein said securing means comprises a pair of plate means secured to the respective arm member outer end portions and molded to fit and to be secured to said bone and said positioning means includes a gear box connected to be driven by said drive shaft and having a pair of driven threaded stub shafts extending therefrom, each said arm member inner end portion having a threaded securement to a respective said stub shaft enabling said arm member outer end portions to be adjusted by driving said gear box with said drive shaft and moving said inner end portions along said stub shafts.

8. An apparatus as claimed in claim 7 wherein said mounting means comprises a strip member extending between said medial portions and having its end pivotally connected thereto.

9. An apparatus as claimed in claim 3 including an intra-orally placed securing member having an end portion adapted to be pinned to the premaxillary segment and an internally threaded body portion formed integral therewith, an auxiliary externally threaded shaft having one end adapted to be intra-orally placed and rotatably mounted on and secured against axial movement with respect to said positioning means, the opposite end adapted to be extra-orally placed and adapted for finger engagement thereof and the central portion thereof threadably mounted in said securing member body portion such that with said one end of the securing member pinned to said segment and with said arm members secured to said bone, said segment and bone may be moved relatively, bi-directionally, and incrementally for cleft lip and palate correction by corresponding extra-oral rotation of said operating end of said auxiliary drive shaft.

10. An apparatus as claimed in claim 9 wherein said end portion of said securing member is yoke-shaped and is adapted to be pinned to opposite sides of said segment.

11. An apparatus as claimed in claim 9 wherein said positioning means includes a gear box connected to be driven by said drive shaft and having a pair of driven threaded stub shafts extending therefrom, each said arm member inner end portion having a threaded securement to a respective said stub shaft enabling said arm member outer end portions to be adjusted by driving said gear box with said drive shaft and moving said inner end portions along said stub shafts.

12. An apparatus as claimed in claim 9 wherein said drive shaft and said auxiliary shaft are arranged in a coaxial relation and the ends adapted to be intra-orally placed and are proximate one another.

13. An apparatus as claimed in claim 11 wherein said mounting means comprises a strip member extending between said medial portions and having its end pivotally connected thereto wherein said end portion of said securing member is yoke-shaped and is adapted to be pinned to opposite sides of said segment, and wherein said drive shaft and said auxiliary shaft are arranged in a coaxial relation and the ends are adapted to be intra-orally placed and are proximate one another.

14. A bilateral cleft lip and palate correction apparatus, comprising:

- a. a gear box adapted to be intra-orally placed and including drive and driven gear means mounted

therein;

- b. a first driven shaft adapted to be intra-orally placed and having threaded ends extending outwardly from opposite sides of and connected to be turned by said driven gear means;
- c. a pair of elongated laterally spaced arm members adapted to be intra-orally placed and having one set of ends residing in a common plane and adapted for intra-oral securement to selected laterally displaced maxillary bone and the other set of ends of the arms secured through threaded connections to respective threaded ends of said first shaft;
- d. a second drive shaft extending from said gear box and connected to said gear box drive gear means and being of sufficient length to enable extra-oral rotation of an extra-oral protruding operating end thereof whereby with said gear box, first shaft and arm members so placed and secured intra-orally, incremental corrective positioning of said maxillary bones is obtained by corresponding incremental rotation of said extra-oral protruding operating end of said second drive shaft;
- e. a third hollow externally threaded drive shaft having one driven end rotatably secured to said gear box and further secured against axial movement with respect thereto, an opposite operating end adapted to be intra-orally placed and proximate the extra-oral operating end of said first drive shaft, said second drive shaft being confined in said third shaft and arranged to rotate therein; and
- f. a premaxillary bone securing member adapted to be intra-orally placed and having an end portion adapted to be pinned thereto and an internally threaded body portion formed integral therewith, a central portion of said third shaft being threadably mounted to turn in said body portion such that with said one end of the securing member so pinned and with said arm members so secured, said premaxillary and maxillary bone may be moved relatively, bi-directionally, and incrementally for cleft lip and palate correction by corresponding extra-oral rotation of said operating end of said third drive shaft.

15. An apparatus as claimed in claim 14 wherein said correcting apparatus includes a pair of plate means secured to the respective said arm members and molded to fit and adapted to be secured to said maxillary bone.

16. An apparatus as claimed in claim 14 wherein said end portion of said premaxillary bone securing member is yoke-shaped and is adapted to be pinned to opposite sides of said premaxillary bone.

17. An apparatus as claimed in claim 16 wherein said correcting apparatus includes a pair of plate means secured to the respective said arm members and molded to fit and adapted to be secured to said maxillary bone.

18. An apparatus as claimed in claim 14 wherein said threaded connections include a pin member mounted in each such other end perpendicular to the axis of said first shaft, each pin member having a threaded aperture axially oriented perpendicular to the pin member axis and threadably engaged with said first shaft to make such connections.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,895,624 Dated July 22, 1975

Inventor(☒) Nicholas G. Georgiade

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 5, line 10, "shaft" should be --shafts--.

Column 5, line 58, "intra-orally" should be --extra-orally--.

Column 7, line 50, "intra-orally" should be --extra-orally--.

Column 7, line 59, "intra" should be --extra--.

Column 8, line 27, "intra-orally" should be --extra-orally--.

Signed and Sealed this

fourteenth Day of *October* 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks