United States Patent [19]

Georgiade et al.

[11] **3,927,664**

[45] **Dec. 23, 1975**

[54] **APPARATUS FOR USE IN THE CORRECTION OF MAXILLARY AND PREMAXILLARY CONDITIONS IN INFANTS**

[75] Inventors: **Nicholas G. Georgiade,** Durham; **Ralph A. Latham,** Chapel Hill, both of N.C.

[73] Assignee: **University of North Carolina,** Chapel Hill, N.C. ; by said Ralph A. Latham

[22] Filed: **Nov. 20, 1974**

[21] Appl. No.: **525,508**

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

[51] **Int. Cl.²** **A61F 5/00**

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

[56] **References Cited**

UNITED STATES PATENTS

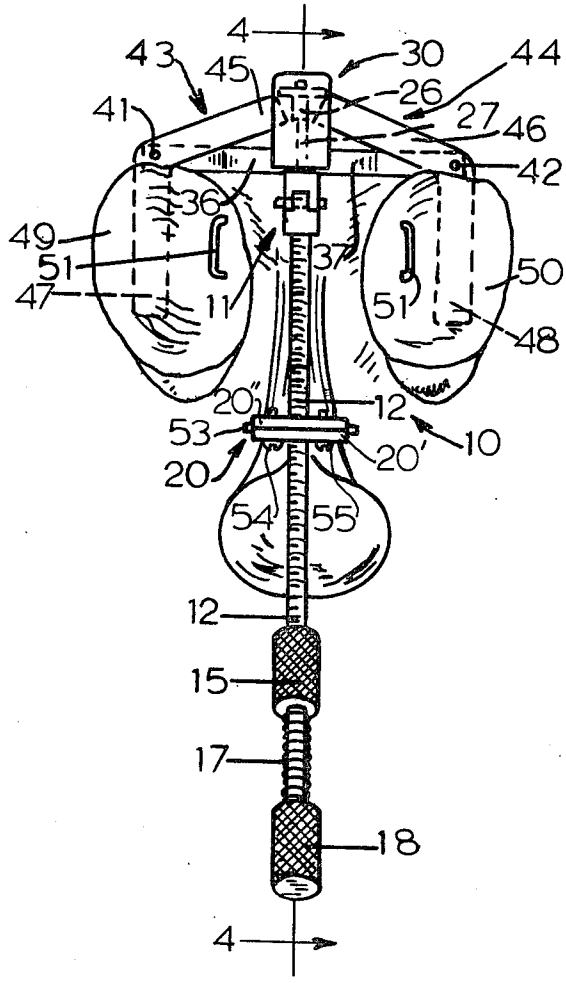
815,907	3/1906	Davis	128/17
2,587,245	2/1952	Terre	128/12
3,241,550	3/1966	Gelarie	128/12
3,454,001	7/1969	Stockfisch	128/76 R

Primary Examiner—Richard A. Gaudet
Assistant Examiner—J. Yasko
Attorney, Agent, or Firm—B. B. Olive

[57] **ABSTRACT**

An arch alignment appliance for use in the correction of the maxillary and premaxillary deformity in infants with bilateral cleft lip and palate is achieved through the application of an intra-oral maxillary expansion and premaxillary retraction device capable of extra-oral operation. A screw mechanism is provided for expansion of the maxillary segments and for retraction of the premaxillary segments. Mucosal tissue damage is avoided.

7 Claims, 7 Drawing Figures



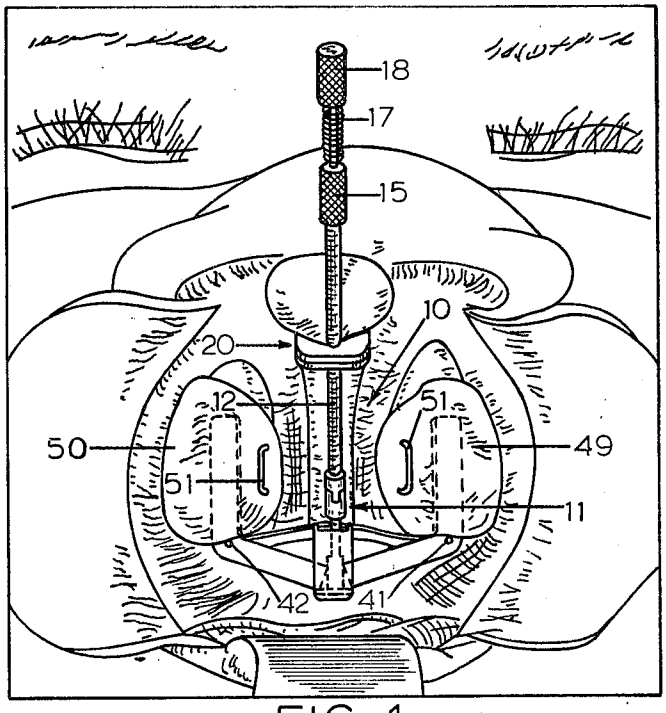


FIG. 1

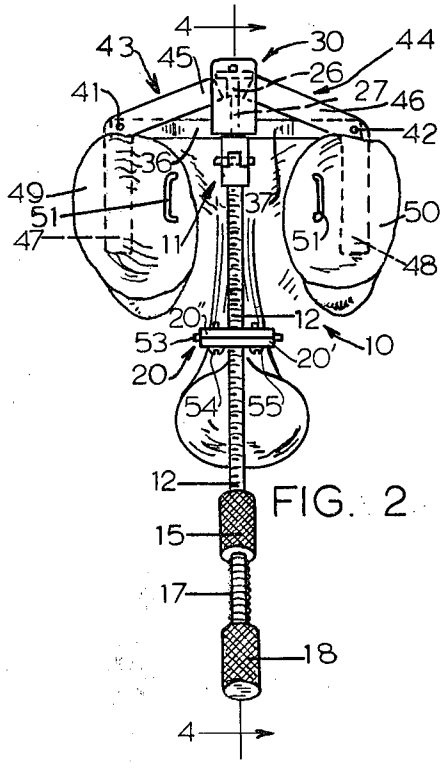


FIG. 2

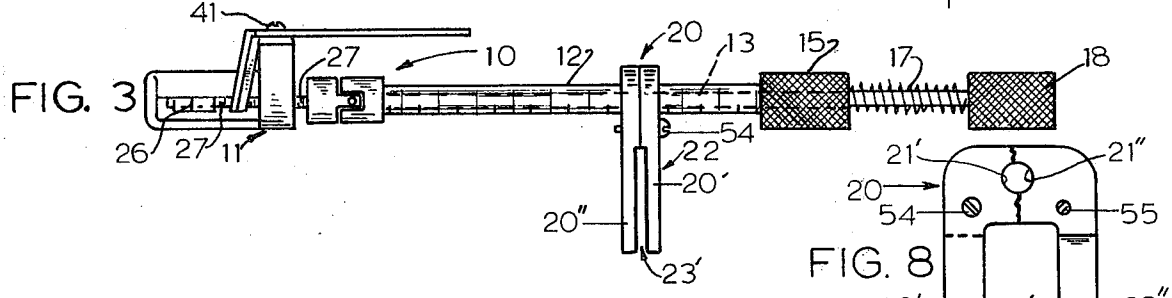


FIG. 3

FIG. 8

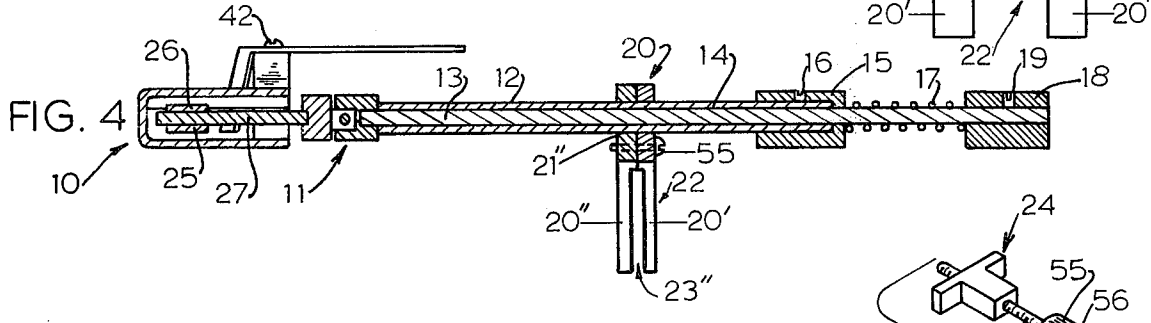


FIG. 4

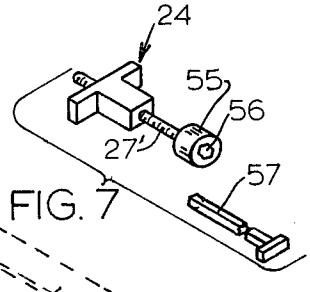


FIG. 7

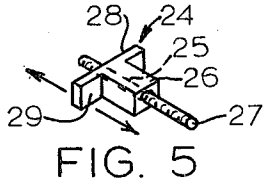


FIG. 5

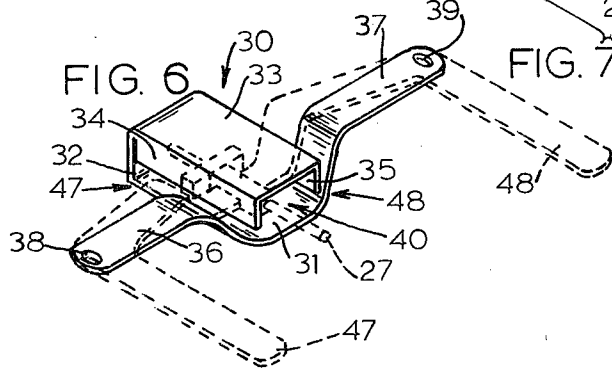


FIG. 6

APPARATUS FOR USE IN THE CORRECTION OF MAXILLARY AND PREMAXILLARY CONDITIONS IN INFANTS

CROSS-REFERENCE TO THE RELATED APPLICATION

This application relates to and constitutes an improvement over copending application Ser. No. 489,813 entitled "Apparatus For Use In Treatment Of The Bilateral Cleft Lip And Palate Condition In Infants" of which one of the co-inventors of the present application was sole inventor.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to an apparatus for use in the treatment of congenital bilateral cleft lip and palate conditions in infants and particularly to intra-oral devices which are extra-orally activated.

2. Description of the Prior Art

The prior art related to the present invention has been fully discussed in the referred to copending applications, Ser. No. 489,813 and to which reference may be made. For immediate reference to this invention much of such discussion will be repeated here.

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 reduction 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 premaxillary segment lingually with resultant malposition of the permanent incisor teeth in others. Decreased growth of the premaxillary segment has also been a consideration following wedge resection of a portion of the vomer. The surgical "lip adhesion" technique, described for gradual retro-positioning of the premaxilla, necessitates one or two additional operative procedures prior to the actual lip repair and is unreliable.

A method, which introduces an intra-oral approach was introduced by one of the co-inventors hereof, Dr. Nicholas G. Georgiade of Duke University Medical Center, Durham, North Carolina, 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 Krichner 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 interior wire is 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 posistion just under the soft palate cleft. The Kirschner wire is then drilled 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 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 retropositioning 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 represent the best means for obtaining the most rapid movement when considered in terms of the collagen adjustment mechanism involved. A method and apparatus which accomplishes the desired movement in a series of steps, employing intermittent force is thus much to be desired.

The apparatus described in copending application Ser. No. 489,813 has accomplished the desired expansion and retraction operations in a series of steps. Thus, the apparatus of the copending application has made a substantial advance in the art. However, use of the prior apparatus has indicated the need for improvements directed to simplifying the construction, reducing irration to the mucosal tissues and improving the utility of the expansion portion of the apparatus as an independent device. Thus, the present invention has these improvements in mind as a general objective and further seeks to provide for the satisfactory management of not only the premaxillary segment but the

maxillary aleveolar arch as a whole.

SUMMARY OF THE INVENTION

The apparatus of this invention, like that of the co-pending application, 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 intra-orally positioned 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 universal joint receives the shafts. The universal joint drives another threaded shaft which mounts a theaded block. The block slides in a housing. A pair of pivotal arm members pivot on arm extensions of the housing and are positioned by movement of the block which in turn is driven by the universal joint. These arm members, when the apparatus is in service, are secured, as with the apparatus of the copending application, to the maxilla segment through a pair of plates made integral with the lateral palatal segments of the maxillae by appropriate staple pine. 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 controll shaft. The mentioned universal joint, block and housing arrangement reduces irritation of the mucosal tissue and provides a somewhat simpler construction as compared to the apparatus of the co-pending application.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the present invention apparatus for use in maxillary arch alignment with the apparatus being shown as it is installed in the mouth cavity for use.

FIG. **2** is a plan view of the apparatus of FIG. **1.**

FIG. **3** is a side elevation view of the apparatus of the present invention.

FIG. **4** is a sectional view taken along line **44** of FIG. **2.**

FIG. **5** is a perspective view of the screw block which is used in the present invention to activate the arm members shown in dashed lines.

FIG. **6** is a perspective view of a housing member which receives the screw block and which also mounts the arm members.

FIG. **7** is a perspective view of the screw block equipped with a cap for turning with a mating wrench.

FIG. **8** is a fragmentary elevation view of the saddle arrangement.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The improved intra-oral maxillary arch alignment apparatus of the present invention, generally designated by numeral **10,** is illustrated as being adapted for extra-oral activation.

A universal joint assembly **11** is integrally secured to one end of a shaft member **13** which itself is mounted within an externally threaded hollow shaft **12** in a manner enabling shafts **12** and **13** to each be rotated independent of the other, shaft **12** to be free to slide outwardly on shaft **13** and shaft **13** to extend, at its free end, beyond the end of shaft **12.** Shaft **12** has integrally secured to its extra-oral, free end a knurled knob portion **15** which as shown in FIG. **4** is secured to shaft **12** be means of a set screw **16.** A second knurled knob **18** is secured to the end of shaft **13** by set screw **19.** A relatively easily compressed coil spring **17** mounts and is compressed between knobs **15** and **18** on that portion of shaft **13** which extends beyond knob **15.** Spring **17** thus pushes against knob **15** and in turn forces shaft **12** to slide inwardly on shaft **13** and against the face of universal joint **11.** Spring **17** should preferably be at least slightly compressed when knobs **15** and **18** have their maximum spacing and should be compressible when knob **15** is turned to decrease such spacing.

Prior to placing knobs **15** and **18** and spring **17** on their respective shafts, a saddle arrangement **20** is placed on shaft **12.** Saddle arrangement **20** is composed of two U-shaped plates **20'**, **20''** secured together by screws **54, 55.** Plate **20'** has a non-threaded hole **21'** which slides freely on shaft **12.** Plate **20''** has a threaded hole **21''** which mates hole **21'** and receives threaded shaft **12.** Thus, when plates **20'**, **20''** are secured together to form saddle **20** and plate **20''** is threadably mounted on shaft **12,** saddle **20,** if prevented from rotating, can be caused to move back and forth along shaft **12** by turning knurled knob **15.** A U-shaped yoke portion **22** of saddle arrangement **20** is adapted to be pinned to the premaxillary bone segment by a pin **53** passing through the segment and through slots **23'**, **23''** of yoke portion **22** of saddle arrangement **20.** Pin **53** is positioned within slots **23'**, **23''** by loosening screws **54, 55** and sliding plate **20'** as required after which screws **54, 55** are tightened so that pin **53** becomes clamped between plates **20'**, **20''**. Such pinning by pin **53** thus fixes saddle **20** against rotation and provides a fixed point to hold the premaxillary segment as it is being retracted and it can be seen that the provision of knob **15** on shaft **12** at its end opposite universal joint assembly **11** enables extra-oral rotation of shaft **12** to be translated into linear movement of the saddle arrangement **20** relative to shaft **12.**

A T-shaped block **24,** see FIG. **5,** has a threaded passage **25** which extends completely through central body portion **26** of the block **24,** Passage **25** receives a relatively short threaded shaft **27.** One end of shaft **27** is integrally secured to the end of universal joint **11** which is opposite the end of universal joint **11** that is integrally secured to shaft **13.** Rotation of shaft **13** thus acts to rotate universal joint **11** which rotates shaft **27** and causes block **24** to move in or out depending on the direction of rotation.

As best seen in FIG. **6,** a housing member **30** is formed of sheet metal, or the like, and has a base **31,** back **32,** top **33,** and downwardly extending side members **34, 35.** A pair of integrally formed arms **36, 37**

extend outwardly from base **31** and reside in a common plate parallel to and above base **31**. Arms **36, 37** have respective apertures **38, 39**. Base **31**, back **32**, top **33**, and sides **34** and **35**, extending down a predetermined distance as extensions of top **33**, form a cavity **40** which is sufficiently large to house and slidably receive the previously mentioned T-shaped block **24**. A pair of crank arms **43, 44** mount respective pins **41, 42** which rotate in the respective apertures **38, 39** thereby enabling arms **43, 44** to pivot on the arms **36, 37**. The outer ends **47, 48** of arms **43, 44** operate in a common plane parallel to and above base **31** of housing **30**. The inner ends **45, 46** of arms **43, 44** occupy a lower common plane above and near base **31** and extend into housing **30** through slots **47, 48** as best seen in FIG. **6**.

T-shaped block **24** is placed into housing **30** so that back **28** of block **24** is substantially adjacent to back **32** of housing **30**. At this point, arms **43, 44** are rotated on pins **41, 42** until their respective inner ends **45, 46** are extending into cavity **40** and rest against front **29** of block **24**. As later explained, the outer ends **47, 48** of arms **43, 44** are adapted to receive, e.g., by molding thereto, a pair of plastic plates **49, 50** which are secured to the maxillary segments and are molded to conform to the segments.

The description will next refer to the insertion and operation of the intra-oral maxillary arch alignment apparatus **10** which is the subject of the invention. In preparation of insertion, an impression is taken of the maxillary and premaxillary segments. A pair of plastic plates **49, 50** are molded from the impression so that plates **49, 50** fit as near perfectly as possible over the maxillary segments. In the molding process, each plate **49, 50** is preferably molded around a respective offset outer end portion **47, 48** of arms **43, 44** so that each respective arm end and associated plate effectively become an integral unit. In order to mold the retaining staples **51** into plates **49, 50**, the apparatus is placed so that the pivot points established by pins **41, 42** are over the maxillary tuberosities with the segment arms **43, 44** in the fully closed position. The position of the retaining **51** is marked on the palatal area and holes are then drilled into the plastic to accept the staples **51** which in one embodiment have been made of 0.030 inch high tension stainless steel wire. The points of the staples are oriented laterally and somewhat anteriorly so that expansion and retraction forces will be withstood. Prior to insertion, the appliance is sterilized and with staples **51** partly inserted into plates **49, 50**, the apparatus is positioned in the mouth. Tongue and cheek retractors are employed as needed during insertion of the invention apparatus **10**. When apparatus **10** is in proper position so that plates **49, 50** mate with the proper maxillary bone area, staples **51** are driven level with plates **49, 50** so that the apparatus becomes attached to the maxillary bone.

Next, saddle arrangement **20** has to be positioned in the desired spot along the posterior premaxillary stem. Correct location of premaxillary pin **53** is probably the most exacting procedure. The location is first determined on a lateral dental radiograph of the septopremaxillary segment and should preferably be in the basal premaxillary bone just posterior to the dental crypts and well anterior to the premaxillo-vomeral suture. Measurements from the labial mucosal outline and from the inferior mucosal outline to the marked position on the radiograph serve to establish the correct point for insertion of pin **53** in the patient. Premaxillary pin **53** is obtained, for example, from an 0.035 inch Kirschner wire and after being drilled through the premaxillary bone, pin **63** is cut to the width of yoke **22**. The coaxial shaft arrangement and the saddle arrangement are placed in the patient's mouth at the time of the original insertion of the expansion component so that the T-shaped block **24** fits properly into housing **30**. Yoke portion **22** is then engaged onto pin **53** by loosening screws **54, 55** and allowing slots **23', 23''** to slide down over pin **53**. Once in place, screws **54, 55** are tightened thereby holding pin **53** between plates **20', 20''** in slots **23', 23''** by being clamped.

Now, by rotating knob **18**, the maxilla bones may be gradually expanded as desired. Once knob **18** is rotated, shaft **13** and integral universal joint assembly **11** are rotated. Universal joint **11** adapts the apparatus to a deviated septopremaxillary segments, and allows freedom of movement to the premaxillary segment as it responds to tractional force. For expanding the maxillary segments, rotation of universal joint assembly **11** causes shaft **27** to rotate and effectively moves T-shaped block **24** back away from the interior of the mouth. As block **24** moves outward on shaft **27**, arm ends **45, 46** tend to be moved outward away from back plate **32**. Since plates **49, 50** are molded integral with arm ends **45, 46** and since plates **49, 50** are attached to the maxillary bone by staples **51**, the outward movement of arm ends **45, 46** effectively expands the maxillary bone segments. For example, a time schedule may be established for precise, measurable and controllable incremental changes in the expansion. The coil spring **17** which mounts between knobs **15** and **18** is compressed as the space between the knobs decreases. Thus, spring **17** effectively provides a visual gauge and may be used to register, when in operation, the retraction force so that the load placed upon the premaxillary bones may be maintained with safe limits.

In a specific apparatus embodying the present invention, one turn of knob **18** has been effective to expand the maxillary bone segments **1** mm. In the same embodiment, each rotation of knob **15** acts to retract saddle arrangement **20** and consequently to retract the premaxillary bone segment 0.5 mm. Thus, with the use of the present invention apparatus, there is achieved an improved apparatus for rapid, closely controlled, alignment of the cleft segments which can be immediately followed through with a gingivoperiosteoplasty at the same time as lip repair. Thus, bone can be expected to grow into the cleft, unifying the upper jaw and stabilizing the alignment of the maxillary arch. Such conditions are favorable for subsequent growth to follow a normal pattern. In this way, it is hoped to avoid crossbite malocclusion and to render long term use of intra-oral retention appliances unnecessary.

In summary, it can be seen that while the present invention apparatus operates basically like the apparatus of the prior invention, a number of improvements are evident. In particular, the universal joint-block-housing arrangement eliminates exposing mucosal tissue to the ends of rotating shafts as sometimes occurred with the prior apparatus. The universal joint also provides a much desired flexibility for meeting the numerous kinds of cavity conditions encountered in infants. As previously mentioned, the expansion apparatus of the present invention can be used independent of the retraction apparatus. Where retraction is of no particular interest, block **24** may be driven as illustrated in FIG. **7**. Thus, shaft **27** of FIG. **5** may be modified as

represented by shaft 27' in FIG. 7 to include a recessed cap 55 with a recess 56, e.g., hexagonal such that shaft 27' may be turned with a mating tool 57. This concept of using the expansion apparatus independently can be further visualized by noticing that the expansion structure of FIG. 6 when equipped with the intraoral drive structure of FIG. 7 represents such an independent expansion device. Parents can be taught to make the necessary adjustments with the FIG. 7 arrangement. Thus, treatment of the infant can proceed out of the hospital and at a substantial reduction of cost of the patient.

What is claimed is:

1. 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 corresponding laterally displaced maxillary bone and opposite inner end portions adapted to extend intra-orally from such securement;

b. a pair of plate means molded to conform and to be secured to said bone, said plate means being secured to respective said arm member outer end portions thereby adapting such outer end portions to be secured to said bone;

c. housing means adapted to be intra-orally placed and formed by connected walls and positioned between and rearwardly of said plate means, said housing providing integral outwardly extending portions for making pivotal connections with medial portions of said arm members enabling said arm members to be pivoted thereon, said housing walls being formed to receive the respective said arm member inner end portions within said housing and to allow corresponding reciprocal movements therein;

d. screw block positioning means adapted to be intra-orally placed and slidably mounted and confined within said housing such that said positioning means is isolated from any surrounding mucosal tissue during use thereof, said positioning means being between and having surfaces loosely 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 an extra-oral direction to effect corresponding outward pivotal movements of said arm member outer end portions; and

e. drive means including a drive shaft having one inner 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 outer 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 an appropriate direction and with respective said arm member outer end portions secured to said bone through said plate means, the lateral spacing of said bone may be increased to effect appropriate correction thereof.

2. An apparatus as claimed in claim 1 including a securing member adapted to be intra-orally mounted and having an end portion adapted to be fixedly secured to the premaxillary segment and an internally threaded body portion formed integral therewith an auxiliary externally threaded hollow shaft having one inner end adapted to be intra-orally placed and being rotatably mounted on and rotatably independent of said drive shaft, the opposite outer operating end of said auxiliary shaft adapted to be extra-orally placed and adapted for finger engagement thereof with the central portion of said auxiliary shaft being 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 outer operating end of said auxiliary drive shaft.

3. An apparatus as claimed in claim 2 including a coil spring mounted between the respective outer ends of said drive and auxiliary shafts and being compressible according to the amount by which said auxiliary shaft is turned and the distance between said outer ends is decreased as a visual gauge of the amount of said correction.

4. An apparatus as claimed in claim 1 wherein said drive shaft outer end is formed as a removable drive shaft member adapted to be detachably secured to the inner end of said drive shaft when needed for turning the inner end of said drive shaft.

5. An apparatus as claimed in claim 1 wherein said outer and inner drive shaft ends are connected through a universal joint.

6. An apparatus as claimed in claim 2 wherein said outer and inner drive shaft ends are connected through a universal joint.

7. An apparatus as claimed in claim 6 wherein for purposes of being fixedly secured, said securing member end portion is adapted to receive and to be clamped to a pin passing through said premaxillary segment.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,927,664 Dated December 23, 1975

Inventor(s) Nicholas G. Georgiade; Ralph A. Latham

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

Immediately following the title the following paragraph was omitted in the patent:

--The invention described herein was made in the course of work privately funded and also partially supported under a grant or award from the Department of Health, Education and Welfare. The United States Government is granted a non-exclusive, royalty free license to make, use and sell for governmental purposes under any patent issuing herefrom.--

Col. 1, line 24, "cations" should be --cation--.

Col. 1, line 52, "Krichner" should be --Kirschner--.

Col. 2, line 13, "posistion" should be --position--.

Col. 2, line 31, --end-- should be inserted after "each".

Col. 3, line 25, "pine" should be --pins--.

Col. 3, line 41, "controll" should be --control--.

Col. 5, line 2, "plate" should be --plane--.

Col. 5, line 42, --staples-- should appear after "ing" and before "51".

Col. 6, line 17, "segments" should be --segment--.

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,927,664 Dated December 23, 1975

Inventor(s) Nicholas G. Georgiade; Ralph A. Latham

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

Col. 7, line 11, the second appearance of the word "of" should be --to--.

Col. 8, line 15, a comma should be inserted after "therewith".

Signed and Sealed this

eighth Day of June 1976

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks