

Development and evolution of distraction devices: Use of indigenous appliances for Distraction Osteogenesis- An overview

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ABSTRACT

An attempt has been made to review various devices as well as the outstanding studies done in the past for understanding the methodology of distraction for regeneration of bone. Lengthening of underdeveloped bones inclusive of the maxillofacial complex has been obtained by distraction osteogenesis by many authors. This could be achieved by the use of various extraoral or intraoral devices. Devices used for distraction osteogenesis must have a minimum of 2 important characteristics – they should be able to transfer distraction forces directly to the bone and secondly, should offer adequate rigidity for osseous consolidation to occur. With advanced technology and biomechanical engineering, preformed intraoral distraction devices are now available worldwide. The introduction of these intraoral bone-borne devices have eliminated the need for bulky, cumbersome extraoral distraction devices which had problems such as external scars, pin tract infections, nerve or tooth bud injuries and poor patient compliance. The design of completely internalized custom made appliance has opened new vistas in the field of Oral and Maxillofacial Surgery. Indigenous internal devices are also economical and locally available.

Keywords: Distraction devices, distraction osteogenesis, mandibular distraction, maxillary and midface distraction, bone transport, alveolar distraction

INTRODUCTION

“Distraction Osteogenesis” is one technique that has created ripples not only in the field of orthopaedics but also in the field of Oral and Maxillofacial Surgery. The technique has gone a long way in reducing the need for osteotomies and grafting in the treatment of dentofacial and craniofacial deformities.

The concept of Distraction Osteogenesis has been directly adopted from orthopaedic practice, where bulky extraoral appliances were used. However, the special anatomic features of the facial bones, tooth buds, curvature of the mandible, multiple bones in the midface and poor compliance in children, pose technical difficulties in placement of extraoral devices.

To overcome few of these difficulties smaller and submerged intraoral devices have been designed, when used judiciously they give excellent results.

An attempt has been made here to overview the evolution of various distraction devices used for the maxillofacial complex. At the same time, the applications of the locally manufactured, cost effective and equally efficient stainless steel internal distraction appliances have been presented.

Distraction Device Classification

Distraction devices used for craniofacial osteodistraction can generally be classified [Figure 1] into two basic types: external and internal devices

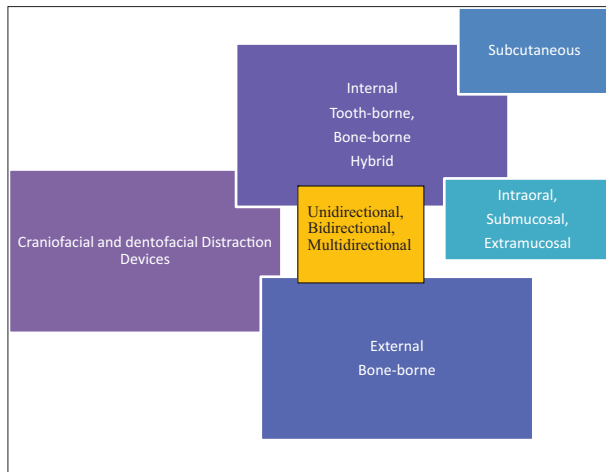


Figure 1: Classification of craniofacial and dentofacial devices

The external devices are attached to the bone by percutaneous pins connected externally to fixation clamps. The fixation clamps, in turn, are joined together by a distraction rod which when activated, effectively pushes the clamps and the attached bone segments apart, generating new bone in its path.

Depending on the direction of lengthening, devices have been classified as unidirectional, bidirectional, or multidirectional devices.^[1]

Internal devices are placed subcutaneously or within the oral cavity i.e. intraorally. They can be placed above i.e. extra mucosal or below i.e. sub mucosal or buried under the soft tissue. Devices attached to the bone are bone-borne; to the teeth are tooth-borne or attached to the teeth and bones are the hybrid type of distraction appliances.

EVOLUTION OF DISTRACTION DEVICES

Mandibular Distraction

Snyder and co-workers (1973) using an external distractor, primarily investigated the gradual distraction of mandible in canines. This was the first report demonstrating the application of Ilizarov's principles in the craniofacial skeleton.^[2] In 1989, McCarthy and colleagues were the first to clinically apply extraoral distraction osteogenesis on 4 boys with congenital anomalies such as hemifacial microsomia and Nager's syndrome.^[3,4] Guerrero in 1990, whilst using an intraoral tooth-borne hyrax-type device in patients with transverse deficiencies developed a midsymphyseal mandibular widening technique.^[5]

Though the application of osteodistraction to the human craniofacial skeleton demonstrated successful results, the first extraoral devices were capable of only unidirectional mandibular lengthening, either horizontal or vertical. Unidirectional mandibular lengthening provided complete correction of linear discrepancies only. However several deformities often involve the ramus, the corpus, and the angle of the mandible. Restoration of the mandible in such cases requires multidirectional devices.

Molina and Ortiz-Monasterio were the first to use bidirectional

osteodistraction in the mandible^[6] by creating two distraction sites via double-level corticotomies, this enabled them to lengthen both the parts of the mandible simultaneously.

In order to correct mandibular deformities in three- dimensions, independent lengthening of mandibular corpus and ramus must be combined with gradual angular adjustments.

As a result, several multidirectional distraction devices were developed, thereby allowing manipulation of bone segments in multiple planes of space. The ACE/Normed multidirectional Distractor was developed in cooperation with Bitter and Klein, the Multiguide Mandibular Distraction Device and the Multi Vector Mandibular Distractor were developed by McCarthy's group.^[7]

Despite the advantages of extraoral distraction devices the patients were apprehensive of wearing bulky external devices due to social inconvenience and the potential of permanent facial scars. These disadvantages and limitations were the primary driving force for the evolution of mandibular lengthening and widening for the development of intraoral devices.

The initial development of intraoral mandibular distraction devices progressed in two directions (1) miniaturization of external devices, (2) modification of available orthodontic devices. In 1994 McCarthy and coworkers developed a miniaturized bone-borne Uniguide Mandibular Distraction device suitable for intraoral placement, similar to his extraoral device. At the same time, Wangerin in Germany designed a similar device, the intraoral Titanium Mandibular Distractor which eliminated the tendency towards rotational movement.^[8]

The major advantages of the intraoral devices were the inconspicuous nature of the devices and absence of facial scars. However intraoral devices have design limitations primarily related to the limited size of the device and restricted access to the oral cavity. Due to these limitations, further development of intraoral devices took an alternative approach. They were (1) the design of specialized devices based on anatomic location or clinical application. (2) The development of a universal device adaptable to any situation in the craniofacial region. (3) The fabrication of a custom made, individually preprogrammed device.

Vasquez and Diner developed two types of intraoral bone-borne device for mandibular lengthening based on anatomic location of distraction, horizontal corpus or ascending ramus.^[9,10]

The Dynaform Intraoral Distractor developed by Guerrero and Bell is an example of distraction device that can be universally adapted based on the clinical application or anatomic location of the deformity.^[11]

Razdolsky developed a series of tooth-borne and hybrid ROD devices^[12,13] In addition he designed a special laboratory instrument to allow preprogrammed fabrication of the device along the predetermined axis of distraction based on preoperative records.

Similar to the development of the extraoral devices, recently developed intraoral devices have evolved from unidirectional to

bidirectional to multidirectional distraction. Walker developed a bidirectional buried mandibular distractor that allows mediolateral adjustments during bilateral sagittal mandibular distraction^[14,15] and Triaca and co-workers developed the Multi-Axis Intraoral Distractor, the only truly three-dimensional intraoral distractors available today.^[16]

Many other recent developmental advances include curvilinear, motorized, and hydraulic distraction devices. The curvilinear distractors allow sagittal distraction along the curvilinear path that closely mimics the natural growth pattern of the mandible. Motorized and hydraulic distractors with remote activation and monitoring allow precise directional control, as well as calibration of distraction forces. This simplifies the distraction activation procedure for patients and parents.

Maxillary and Midface Distraction

In 1993 Rachmiel and co-authors first demonstrated the possibility of maxillary distraction in their study; they performed midface gradual advancement on five sheep.^[17] In 1995, Block and associates demonstrated anterior maxillary advancement using tooth-borne distraction devices in dogs.^[18]

In 1996, Rachmiel and colleagues reported on multiple segmental distraction of the facial skeleton in three young adult sheep.^[19] The results of the study indicated that multiple segmental distractions may provide improved three-dimensional control correction of complex facial deformities.

Maxillary distraction has also been experimentally evaluated by Carls and colleagues as a potential treatment for velopharyngeal incompetence.^[20] They believed that distracting the hard palate toward the posterior pharyngeal wall would eliminate velopharyngeal incompetence, provided that the short soft palate had satisfactory muscle function.

One of the first clinical applications of midface distraction in humans was reported in 1995 by Polley and co-authors, which used an externally fixed cranial halo to distract the midface. The advantages of rigid external distraction (RED) are that it is a fairly simple technique to apply intra-operatively, it is easy to activate for patients and can be removed without the need for a second operative procedure at the completion of consolidation.^[21] Polley and Figueroa's group demonstrated that full correction of the midface deficiency, including both the skeletal and soft tissue deficiency, was possible with their technique.^[22,23]

Cohen developed the Modular Internal Distraction (MID) System in 1995.^[24,25]

In 1996, Chin and Toth reported on patients who underwent Le Fort III midface advancements with gradual distraction using internal devices with a protocol different from the traditional Ilizarov protocol.^[26,27] No latency period was observed; distraction was initiated intra-operatively and completed in the early postoperative period. With this protocol long-term stability was found to be good and the devices did not necessarily require removal.

Ortiz-Monasterio and Molina in 1999 introduced a technique for

simultaneous mandibular and maxillary distraction using only mandibular devices to simplify distraction in patients needing simultaneous maxilla-mandibular correction.^[28]

Bone transport

Bone transport is a distraction osteogenesis technique for treating long bone defects that result from trauma, oncologic resection, or congenital anomalies. The concept includes resection of a pathologic bone followed by gradual transport of an osteotomized healthy bone segment (transport disk) via a distraction device across the area of defect. As the transport bone segment is advanced new bone tissue is generated, gradually filling the defect. After the transport disk reaches the opposite host bone segment, the intervening fibrous tissue is removed followed by application of compression between the transport and host bone segments at the docking site.

In 1990, Constantino and co-workers demonstrated the feasibility of bone transport techniques for segmental mandibular regeneration using a canine model.^[29,30] Segmental mandibular defects (25 mm) were first created and then transported over a 25 day period and a regenerate bone was formed using bifocal and trifocal bone transport.

In 1995, Constantino and coworkers, successfully applied transport distraction to restore the continuity of a mandibular defect formed as a result of cancer resection following radiation therapy in a patient.^[31] Block in 1996 presented the results of four cases with bone transport using a Synthes lengthening device.^[32]

Since then, bone transport has been sporadically used to treat bone defects caused by trauma or bone resection. Distraction of bone segments in these cases allows mandibular reconstruction without bone grafting. Most importantly, mandibular distraction recreates the alveolar ridge with its attached mucosa.

Alveolar ridge distraction

An intriguing application of the bone transport technique is the augmentation of the maxillary and mandibular alveolar ridges. These deformities were managed by a variety of surgical techniques, such as autogenous onlay bone grafting, alloplastic augmentation, connective tissue grafting or guided tissue regeneration. Each of these modalities, however, had their limitations.^[33,34]

Alternatively, osteodistraction of the alveolar process provides superior reconstruction of these types of defects. Block and co-workers established the validity of distraction osteogenesis for alveolar ridge augmentation in canine mandible.^[35]

In 1996, Chin and Toth reported the first clinical application of vertical mandibular alveolar distraction osteogenesis.^[26] Following the clinical introduction of alveolar ridge distraction by Chin, the use of the technique, as well as the number of available devices, has increased tremendously. Similar to the intraoral device classification system, the alveolar ridge devices can be classified as [Figure 2] tooth-borne, bone-borne, and hybrid based on their fixation points. The bone-borne alveolar distraction devices, in turn, can be further classified based on their relationship to the bone, as either extra osseous or endosseous.

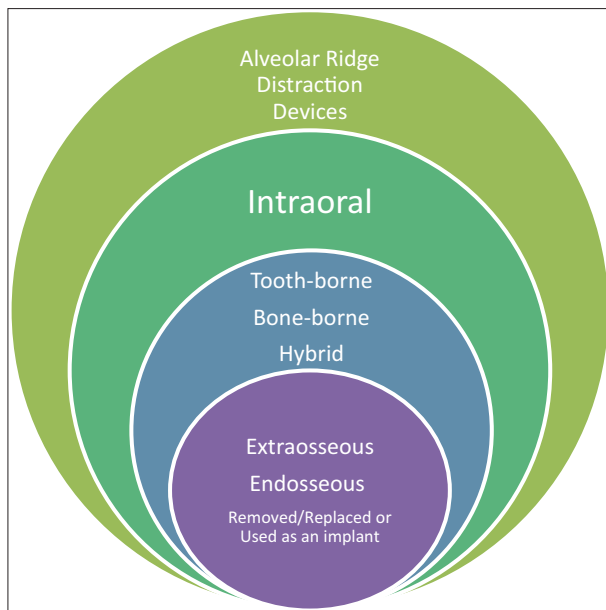


Figure 2: Classification of Alveolar distraction devices

Extraosseous alveolar distractors are placed on the lateral side of the alveolar bone and attached to the transport and host bone segments. Although extraosseous distractors can be applied for correction of local vertical defects and ankylosed teeth, soft tissue dehiscence or infection may arise due to stretching of the mucoperiosteal flap that covers the distractor.

An example of this type of distractor is the TRACK vertical distractor for alveolar ridge augmentation developed by Hidding, Lazar, and Zoller from Germany.^[36]

For the endosseous devices, the distraction rod is inserted into the transport and host bone segments. Some, such as the LEAD System, are removed and placed by a dentoalveolar implant whereas others such as the DIS-SIS distraction implant are left in place and used as the actual implant itself.

Periodontal ligament Distraction

Another interesting modification of the bone transport technique has been experimentally and clinically applied by Liou and Huang.^[37] This method is based on distraction of the periodontal ligament and is referred to as rapid canine retraction. Briefly, the technique involves premolar extraction followed by undermining of the interseptal bone distal to the canine to reduce bony resistance on the compression side. Next, the periodontal ligament is gradually stretched via distraction of the tooth-bearing segment and new bone is created mesial to the distally moving tooth. Importantly this is distinctly different from tooth movement into regenerate bone. The former involves movement of both a tooth and bone as new bone is generated, whereas the latter involves remodelling of bone as a tooth is moved into new bone.

Cranial Distraction

Distraction osteogenesis is a powerful tool for surgical reconstruction of complex deformities. Closure of posttraumatic

and postoperative skull defects is an important subject of debate. Primary cranioplasty of skull defects minimizes the development of brain scars at the site of injury and quickly restores brain function, thereby preventing complications of post-trephination and epilepsy. Also the layered closure of posttraumatic skull defects leads to a more physiologic activity of the brain. Earlier considering the low capability of regeneration of the cranial bone different plastic materials and bone substitutes were developed for closure of skull defects. However, artificial materials used currently for cranioplasty, can cause immune reaction in pediatric cases. Thus, cranial distraction osteogenesis can be a more valuable alternative.

The first experimental investigation on cranial osteodistraction was performed in 1957 by Polezhaev and colleagues.^[38,39] They demonstrated that a critical-size skull defect could be filled with regenerate bone by transporting an osteotomized bone segment across the defect. In multiple experimental studies, Ilizarov and colleagues and later several other authors, demonstrated that cranial bones respond to gradual stretching similar to the long bones and are characterized by formation of a typical distraction regenerate. A study was carried out on canines in which three cranial bone transport techniques were introduced along with detailed description of the different stages of cranial regenerate bone formation. Thus these experimental studies revealed that cranial bones respond to tensional stresses in a manner similar to long bones and are characterized by the formation of a typical distraction regenerate. Several distraction osteogenesis techniques have now been applied clinically for reconstruction of cranial deformities and cranial vault defects.

Various external and internal devices have been designed for use in cranial distraction in which cranial and midface distraction has been successfully conducted for correcting craniofacial deformities of various degrees like Crouzon's syndrome, Apert's syndrome, Pfeiffer's syndrome and midface abnormalities secondary to craniofacial anomalies. Simultaneous midface and forehead distraction using internal devices after Le Fort IV osteotomy has also been reported.^[1]

An external distraction device (Penning Dynamic Wrist fixator, Orthofix, Inc, Richardson, TX) was used following the conventional Le Fort III osteotomy. Using multiple internal devices, the midface and forehead can be distracted in different directions simultaneously.

Use of Indigenous appliances

In a developing and economically restrained country like ours, the choices of treatment are restricted. An expensive proprietary distractor is beyond the reach of the common man. Indigenously designed unidirectional stainless steel distraction appliances for horizontal mandibular lengthening [Figure 3], vertical ramus lengthening [Figure 4], maxillary and midface advancement [Figure 5], bone transport [Figure 6] and alveolar ridge augmentation [Figure 7] were used in our cases. An effort has been made to incorporate necessary features of the western distractors at an affordable price. All the distractors are made up of 316L stainless steel of density 4.2. Some are custom made to suit individual anatomic situations.

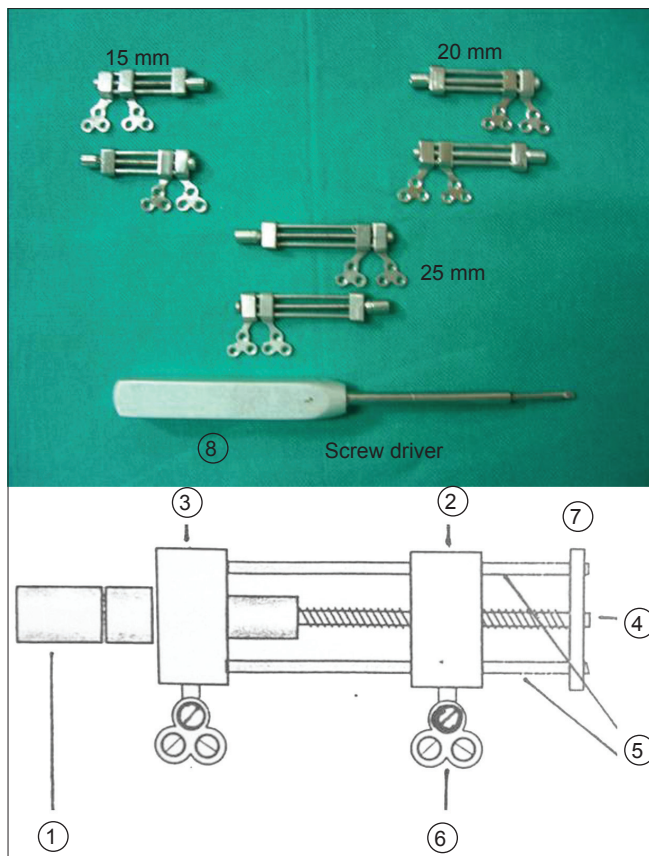


Figure 3: Intraoral custom-made distraction osteogenesis device for mandible. Components: The various components of distraction assembly suggestive of functions they carry out (1) Sleeve for the distraction screw (2) Fixed block comprising of three-hole stainless steel triangular bone plate fixed to the medial fragment with the help of three 2mm monocortical screws (3) Movable block also comprising of three hole stainless steel triangular bone plate fixed to the distal fragment which moves along the threaded rod with the fragment at the time of distraction (4) Threaded central rod each thread of the rod has the pitch of 0.5mm, therefore one turn of 360degrees brings about distraction of 0.5mm. The appliance is designed in such a way that a maximum of 25mm distraction is achieved (5) Two guiding supporting rods one above and one below the central threaded rod in parallelism with the central threaded rod (6) Three hole stainless steel triangular bone-plate used for fixation of distraction appliance (7) Stabilizing plate holding the threaded rod and the two guiding plates together at the posterior end of the assembly (8) A special custom made screw driver is manufactured to fit in the slot of the distraction screw

Right and left maxillary and mandibular distractors are separately available. They are light, non-bulky and miniaturized with intraoral distraction ports. They are also easy to handle and fixation is done with monocortical screws. A maximum of 25 mm distraction is possible. They are available in 4 sizes, 10 mm, 15 mm, 20 mm and 25 mm.

The indigenous transport devices used by us are of two types: bifocal and trifocal.

In bifocal bone transport, one transport disc is created and moved from the residual host bone segment through the defect towards the residual target bone segment (docking site).

In trifocal transport distraction, 2 transport discs are created from both residual bone segments and simultaneously moved centripetally towards each other so that they meet in the centre of the defect (docking site).

CONCLUSION

The application of distraction osteogenesis offers novel solutions for surgical-orthodontic management of developmental anomalies and defects of the craniofacial skeleton. Osteodistraction provides a means whereby bone may be modeled into different shapes to more adequately address the nature of skeletal deformities and asymmetries. Similar to distraction osteogenesis in the long bones, craniofacial osteodistraction evolved from skeletal traction, osteotomy techniques and external fixation methods. As demonstrated by the experimental studies, the underlying biologic mechanisms of craniofacial distraction are also comparable to that of long bones.

As clinicians begin applying this new technique, they will quickly realize that there is a learning curve associated with distraction osteogenesis. Although the technique has a great potential, it is not without inherent complications, most of which have already been encountered during the long history of limb lengthening and two decades of craniofacial osteodistraction. By learning from the orthopedic and initial craniofacial distraction experience, clinicians using osteodistraction to treat deformities of the head and neck can minimize the potential complications associated with distraction osteogenesis. This learning process has prompted us to modify various distraction devices for better results with fewer complications. This has led to an evolution of various distraction devices from bulky extraoral to miniaturized submerged intraoral devices. The costly imported distractors have also compelled us to explore the possibility of designing, manufacturing and then applying them clinically in various cases. The concept of bone transport and its further applications like alveolar ridge augmentation, periodontal ligament distraction and cranial distraction are still redefining themselves in helping to navigate to future advances in our field of Oral and Maxillofacial Surgery.

As we become more comfortable with mere application of exciting techniques, we will most certainly begin to find more novel uses for it, as well as different iterations of previous uses. The future development of craniofacial osteodistraction will almost certainly establish a more complete understanding of the biology of new bone formation under the influence of gradual distraction. Major trends will include:

1. A more detailed description of the effect of gradual bony distraction on the surrounding soft tissues,
2. Refinement of distraction protocols,
3. Modification of distraction techniques,
4. Further development of distraction devices, enhancement of regenerate maturation with pharmacologic agents, such as growth factors and cytokines, and
5. Development of new techniques to monitor distraction regenerate formation and remodelling.

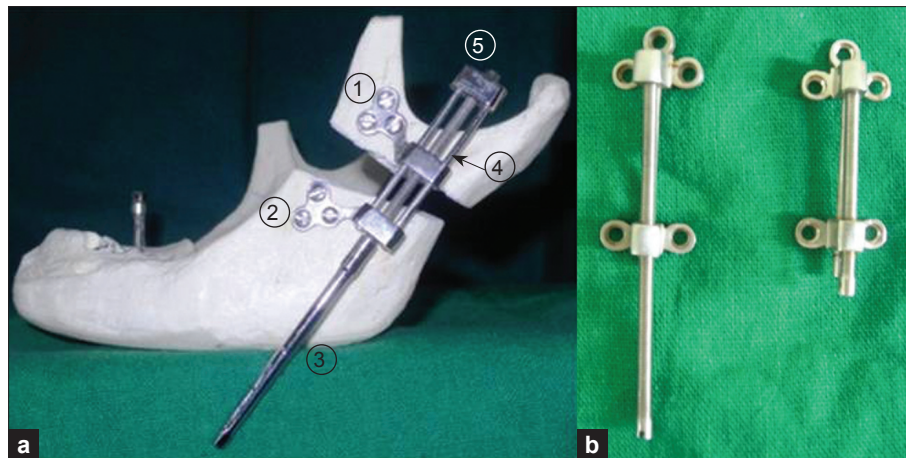


Figure 4: (a) Distractor for vertical ramus lengthening, (b) Modified Vertical Ramus Distractor. Components: (1) Fixed block with three hole bone plates (2) Movable block with three hole bone plates (3) Threaded central rod with extension for activation (4) Two guided supporting rods (5) Stabilizing plate holding the threaded rod and 2 guided supporting rods

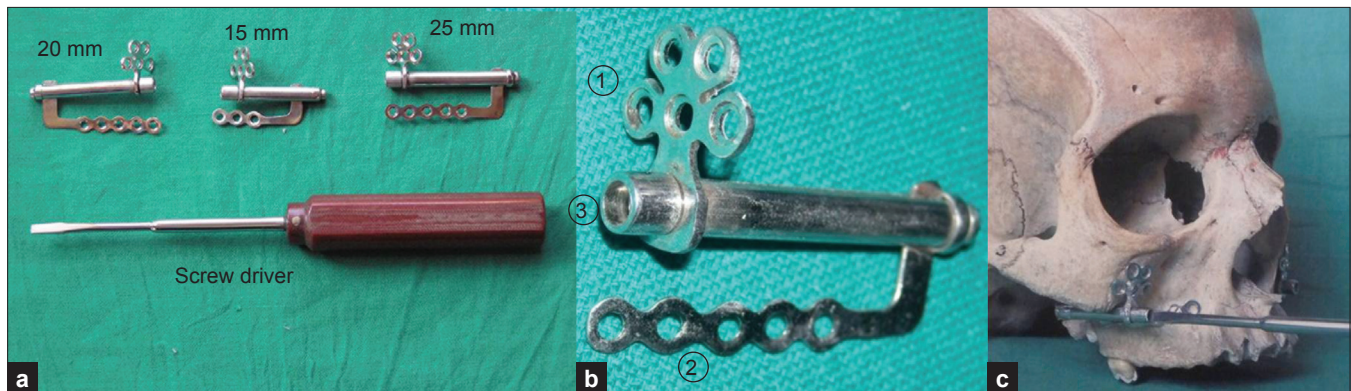


Figure 5: (a) Intraoral submerged maxillary distraction device, (b) Components: (1) Upper Bone Plate – hexagonal in shape and easily adaptable, is adapted to the malar bone/ buttress and fixed to the zygomatic buttress of maxilla above the osteotomy cut with stainless steel screws (8-10mm of 2mm diameter). (2) Lower Bone Plate – straight and also easily adaptable, is fixed to the alveolar process of maxilla 2 to 3 mm above the root apices of teeth below the osteotomy cut with stainless steel screws (8 to 10 mm in length 2 mm in diameter). (3) Activation Port- Consists of the activation screw present intraorally. It is to be activated daily 1 mm/day as per the requirement of the case. (c) Activation of device

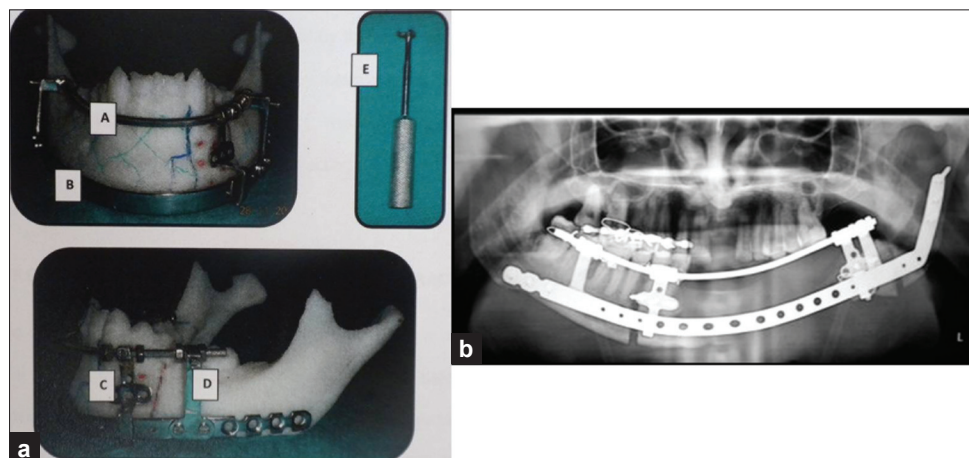


Figure 6: (a) Bifocal Transport distractor (b) OPG showing Trifocal Transport Distractor for mandibular defect, consisting of two transport discs created from both residual bone segments and simultaneously moved centripetally towards each other so that they meet in the centre of the defect (docking site). Components of transport distractor: (A) Intraoral curved threaded rod (B) Reconstruction plate (C) Transport segment plate (D) T- Plates (E) Activator



Figure 7: Indigenous extra osseous alveolar distractor. Components: (1) Fixed buccal plate (2) Movable buccal plate (3) Central rod (4) activator

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