

Resorbable bone distraction: current status and future directions

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The pioneering work of Dr. Ilizarov defined the theory and practice of clinical bone distraction [1,2]. He laid the foundation for the future application of the principles of bone distraction to craniofacial surgery. In 1992, McCarthy et al began applying the principles of long bone distraction used in orthopedics to the craniofacial skeleton [3–5]. He and his colleagues were able to demonstrate experimentally and clinically that distraction osteogenesis of membranous-derived bone was feasible, defining the scientific basis for craniofacial distraction and guiding early clinical applications. Distraction of the craniofacial skeleton offers many advantages over conventional advancement techniques, including gradual stretching of skin, muscle, and nerves, which minimizes the opposition to bone distraction and decreases the tendency for bony relapse of the advanced bony segments. Important neurovascular structures are slowly elongated, preserving continuity and function. In addition, distraction osteogenesis eliminates the need for bone grafting the osteotomy gaps, saving time and decreasing morbidity. Once the potential of this powerful new technique for “stretching bone” was fully realized, a frenzy of clinical and experimental work was unleashed. The early devices were adaptations of orthopedic instrumentation, used mostly in surgery of the hand, and had to be applied exter-

nally. Although these early external devices showed the feasibility of mandibular bone distraction, they had several drawbacks in clinical practice. The external pins that connected the devices to the underlying bone often became loosened, required constant pin site care, and were cumbersome for the patient. In addition, as the distraction proceeded, the pins tended to tract through the skin, leaving unacceptable scars. Multidirectional external devices gave a greater degree of directional control but had the many of the same disadvantages as uniplanar models [6]. These early devices were not applicable to maxillary distraction because of the early design constraints.

Chin, Toth, and several other authors [7–9] reported on various designs for internal distraction devices that could be used both for the mandible and the maxilla. Molina et al [10] further refined a system for internal maxillary and mandibular distraction. Polley and Figueroa [11] in 1997 reported on an ingenious external distraction system based on a cranial halo device coupled to an orthodontic appliance, which allowed precise midface distraction. Their system also allows for changing of the distraction vectors on an ongoing basis. The distraction process required skilled orthodontic monitoring for optimal results. Unfortunately, though technically appealing, this external system is somewhat cumbersome and may severely limit the patient's activities while applied. All of the internal metal-based distraction systems and most of the external systems require a second operation for removal of the device after the consolidation. Fibrous and bony ingrowth into the distraction mechanism, screws, and plates can make removal of the devices

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difficult. Additional morbidity and expense are also associated with the second operative procedure.

Resorbable materials

Over the last 8 years, there has been increasing acceptance of the absorbable hardware in craniofacial surgery [12,13]. The stimulus for the development and use of resorbable hardware has been multifactorial. Metallic plates and screws can migrate through the skull and become lodged intracranially (Fig. 1). There is potential for interference with normal growth when metallic implants cross suture lines or interfere with growth centers. In addition, metallic implants may not become fully osseointegrated and have to be removed at a later date because of pain, infection, or extrusion. Metallic implants may also become palpable and visible even years after application. Eppley et al [14,15] have investigated the physical characteristics and biologic interactions of resorbable materials in a series of animal models. The basic mechanism of resorption is that of hydrolysis, fragmentation, and phagocytosis of the hydrolyzed microparticles. The time it takes for this process to take place is a function of the composition and mass of the resorbable material. The more polyglycolic acid (PGA) contained in the plate the greater the mechanical strength. Poly L-lactic acid (PLLA) contributes to plate durability. Currently, plate materials are available that can begin to dissolve within 6 weeks and will be completely resorbed within 12 months. Other plate materials having a greater percentage of PLLA can take years to completely resorb. The authors have observed that the longer-lasting materials may fragment into fairly large particles, which can cause local irritation and

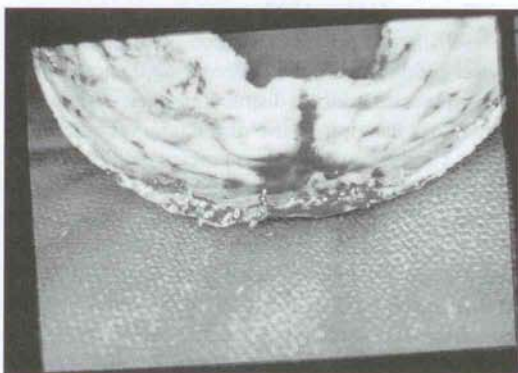


Fig. 1. Operative view of frontal bone flap demonstrating migration of hardware through inner table of frontal bone. Original frontal bone advancement 5 years before this photo.

extrusion. Note that all of these materials lose significant mechanical strength long before they lose volume. The authors have had extensive experience using the LactoSorb system (Lorenz/Biomet, Inc., Indianapolis, Indiana), which resorbs comparatively rapidly. This type of material is ideal for use in children and adolescents because it will not restrict growth along the suture lines or interfere with normal function. Furthermore, LactoSorb tends to fragment in small soft particles rather than large particles that can extrude and cause focal granulomas. The authors have observed that materials that have a long resorption curve can actually cause focal osteitis with underlying bone resorption and remain palpable or visible for years.

Cohen et al [16] recently reported on a prototype partially resorbable distraction system using long-lasting material. This system requires a second stage for removal of the metallic expansion device and placement of an interim resorbable stabilization bar. Based on the authors' experience with resorbable plating systems and conventional bone distraction, they began work on a fully resorbable, single stage, bone distraction system approximately 5 years ago. Design ideas from many metallic distraction devices, dental expansion appliances, and resorbable technology to create a new class of distraction devices were incorporated. The initial report in 2002 detailed their experiences with mandibular, maxillary, and orbitocranial expansion in 21 patients [17]. A subsequent report on specific applications in Pierre Robin Sequence was also produced [18]. The authors' experience with 50 patients ranging in age from 5 days to 17 years helped refine the designs of the various resorbable one-stage bone distraction devices and develop surgical techniques to facilitate the device applications and decrease operative time and morbidity.

Resorbable bone distraction devices

The entire family of one-stage resorbable devices has several common mechanical features. These include proximal and distal distraction plates and a connecting steel drive screw. In addition, each steel drive screw can be coupled to a distractor cable of varying length, depending on the application (Fig. 2). The proximal and distal anchoring plates can be easily and precisely bent to the shape of the underlying bone by thermal contouring in a water bath or with a thermal contouring pen (Fig. 3). All the devices can be used with standard 1.5- to 2.0-mm diameter resorbable screws, depending on the underlying bone density and mass. There are two sizes of devices; one used

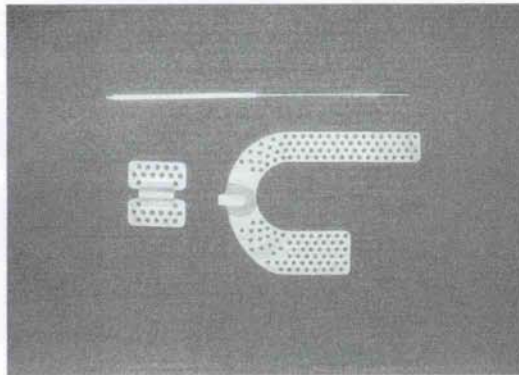


Fig. 2. Midface orbital frontal device (MOF) demonstrating rectangular resorbable proximal anchoring plate, resorbable distal U-shaped plate, and drive screw with attached drive cable. (Courtesy of W. Lorenz Surgical, Jacksonville, FL).

for different types of distraction in adolescents and children and another used in the pediatric and infant devices. Within each size class, the components are completely interchangeable. This allows changing of base plates, distal drive plates, and drive screws as anatomic needs dictate. There are several models of devices in each size class their characteristics, and clinical applications are presented.

Midface orbital frontal device (MOF)

The midface orbital frontal device (MOF) is designed to allow distraction of the midface, orbits, and frontal bone for Monobloc advancement (Fig. 4). Shortening of the superior limb allows for Lefort III level distraction. The device can be modified by

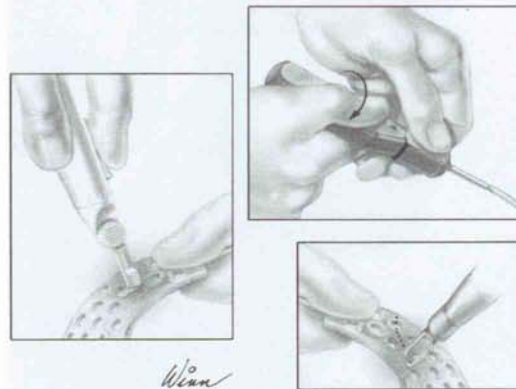


Fig. 3. Artists drawing of (from left to right): Thermal contouring pen used to bend resorbable plate. Turning distraction cable. Cutting excess plate material with thermal cautery.

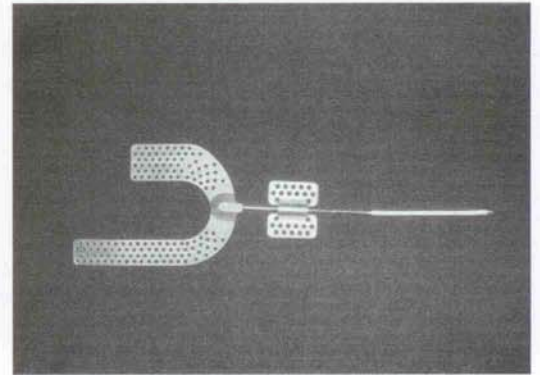


Fig. 4. Midface orbital frontal device (MOF) assembled. (Courtesy of W. Lorenz Surgical, Jacksonville, FL).

completely removing the superior limb into a maxillary-only distraction device. The maximum drive screw length is 40 mm. Conventional osteotomy techniques are used and complete mobilization of the proximal and distal segments must be achieved before device placement (Fig. 5). The proximal plate is placed parallel to the desired distraction vector. This will determine the maxillary occlusal plane. The distal plate is thermally contoured to the desired application and all excess material is removed. The distraction drive screw is passed through the scalp and engaged. Both sides are distracted at least 5 mm to ensure the completeness of the osteotomies and to rule out mechanical interferences. The authors have found that a three-dimensional sterilizable model can greatly aid in the planning process.

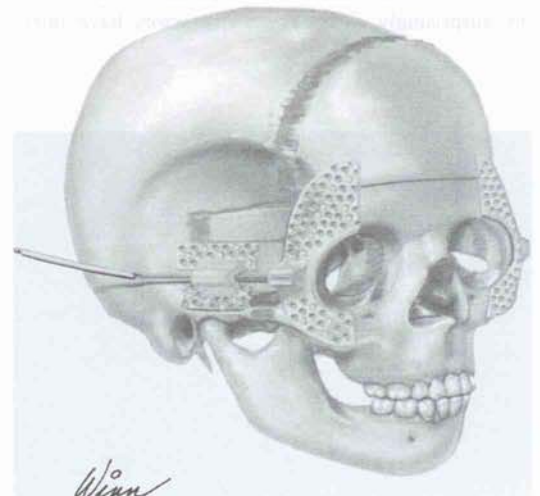


Fig. 5. Artists drawing of combined distraction of midface, orbits, and frontal bone using midface orbital frontal device.

Mandibular adolescent device (MA)

The mandibular adolescent device (MA) uses the same type of drive screw and thickness of plating as the MOF device (Fig. 6). It is designed to allow for mandibular distraction in adolescents. It comes in two design patterns. One has rectangular base and distal plates, which requires extensive customization, in situ, based on the individual morphology of the mandible. This is ideal for the irregularly shaped dysmorphic mandible. The second MA model features a smaller rectangular base and pentagonal distal plate designed to fit a normal mandible shape. This design requires minimal thermal contouring in situ. Both devices use the large diameter drive screw with up to 40 mm of length.

Mandibular pediatric device (MP)

The mandibular pediatric device (MP) is a smaller version of the mandibular adolescent device, designed to fit the pediatric mandible, generally above age 2 years. It uses the small diameter drive screw. A rectangular proximal plate and pentagonal distal plate can be thermally contoured to the mandibular curvature. It uses the small diameter drive screw and cable components. The maximum drive screw length is 30 mm.

Mandibular infant device (MI) is available in three different configurations (Fig. 7). The small diameter drive screw design is used. The three different designs allow for distraction of even the smallest mandible. When used with bicortical screws they are surprisingly rigid. These distractors have inter-

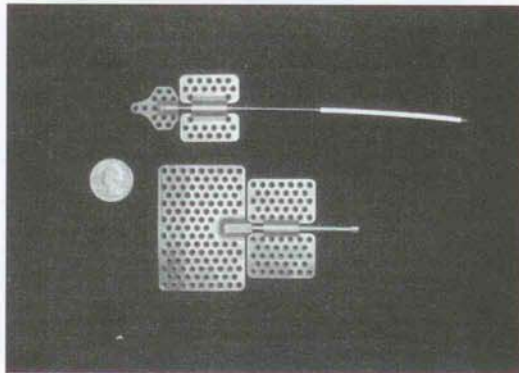


Fig. 6. MA (mandibular adolescent) devices with coin for scale. (Courtesy of W. Lorenz Surgical, Jacksonville, FL).

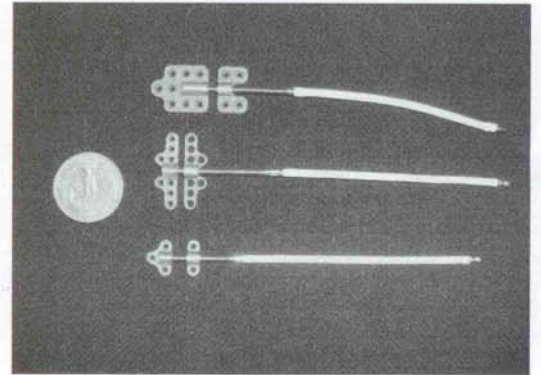


Fig. 7. MI (mandibular infant) devices with coin for scale. (Courtesy of W. Lorenz Surgical, Jacksonville, FL).

changeable parts and are generally used with 1.5-mm screws. The maximum drive screw length is 30 mm.

Clinical examples and technique

Each of the distractor designs has undergone numerous clinical applications. To date, the authors have

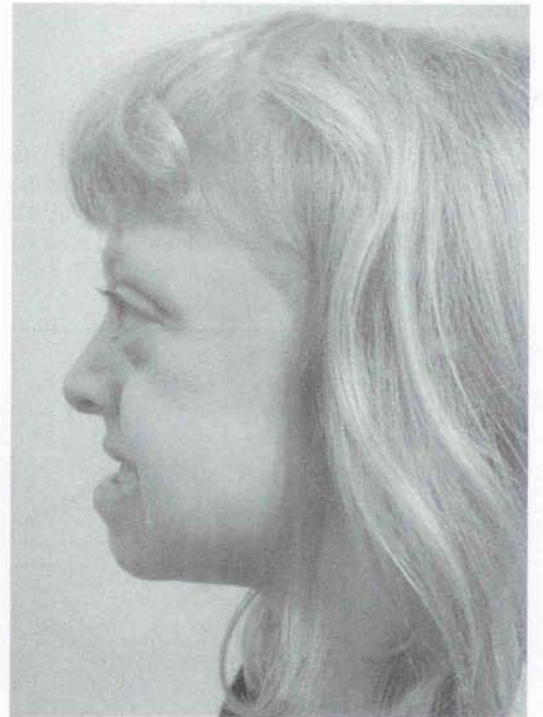


Fig. 8. Patient with Cruzon's and resultant midface hypoplasia, proptosis, and history of obstructive apnea and increased intracranial pressure.

had experience in 50 patients ranging in age from 5 days to 17 years with no major complications or morbidity. Several minor complications occurred early in the series. These included scalp granulomas when the proximal plates were placed along incision lines and skin irritation when plate edges were allowed to protrude beyond the underlying bone.

The MOF has been useful in cases of severe midface hypoplasia, such as is seen Cruzon's, Apert's, and Pfeiffer's syndrome. It is particularly useful when the entire maxilla, orbits, and frontal bones need to be advanced as a Monobloc (Figs. 8 and 9). The device is applied in the desired occlusal plane vector and can be shaped to fit the underlying bone through thermal bending in a water bath. Recently, life-sized three-dimensional synthetic models of the patient craniofacial skeleton have been used for preoperative treatment planning. The model can be sterilized and allows the devices to be thermally contoured to the shape of the patient's maxilla on the back table (Fig. 10). This saves time and allows for excess material to be trimmed before application to the patient. The device is optimally applied before making the osteotomy cuts and secured with at least six

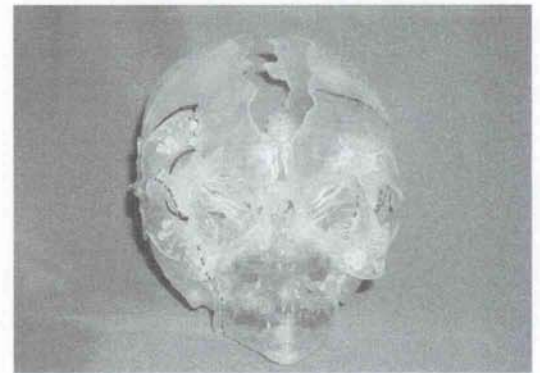


Fig. 10. Life-sized model from patient's CAT scan used to plan application of midface orbital frontal device.

proximal and six distal 2-mm diameter screws. The distraction drive screw is passed through a separate scalp incision and threaded through the proximal plate to the distal plate housing to insure proper alignment. The drive screw is then backed out and all osteotomies are completed. It is imperative that the surgeon mobilizes the Monobloc segment completely before activating the distraction devices. Once this has been done the distraction drive screw is inserted

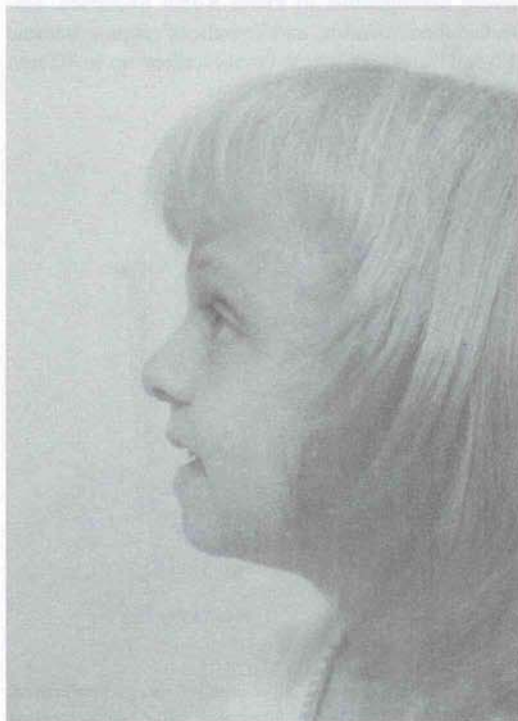


Fig. 9. Patient in Fig. 8 6 months after 35-mm distraction with midface orbital frontal device. Note correction of midface hypoplasia, and proptosis. Sleep apnea resolved.

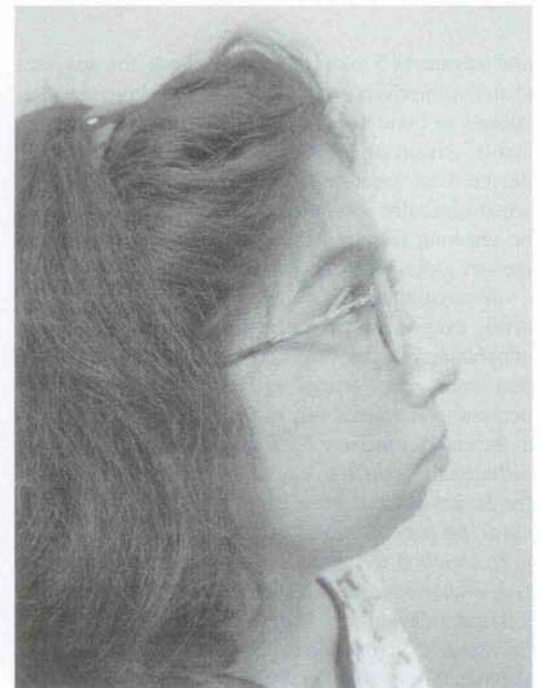


Fig. 11. Preoperative view of patient with severe retro-micrognathia and secondary airway compromise.



Fig. 12. Patient (in Fig. 11) 8 months after 25-mm mandibular distraction using MA device.

and advanced 5 mm. A careful check for any mechanical interference is made and the drive screw is backed to bone-to-bone contact. Up to 35.0 mm of stable advancement has been achieved with this device. Care must be taken that distraction is ended when clinically appropriate. The limiting factor may be reaching the desired occlusal relationship or the desired globe to lateral orbital rim relationship.

Because these MOF devices are extremely powerful, care must be taken to not produce severe enophthalmos or severe class II malocclusion. Note that even minor errors in determining the proper occlusal plane can result in fairly wide discrepancies at the anterior incisors. This magnification of occlusal disharmony is the result of the lever effect exerted by the device as the fulcrum point is at the distal plate. A checking plate or wire, as described by Denny et al [19], can limit the amount of distraction at the frontal and orbital levels. The gradual distraction process, 2.0 mm a day, after a 48-h latency period, allows for the brain to expand into the increased intracranial volume. The gradual distraction process avoids creation of dead space and potential infections of epidural fluid collections. In addition, a great deal of time is saved in not having to bone graft the advanced

segments. Once the distraction process has been completed a 4- to 6-week latency period is observed for bone consolidation. The patient is kept on a soft diet. The distraction drive screws are simply backed out in the office without anesthetic at the end of the consolidation period. The proximal and distal plates are allowed to resorb. Because of the thickness and volume of resorbable material present, the resorption process will take 4 to 6 months. During this time the plates may become palpable or visible under the scalp or skin. Early in the series, two patients developed small granulomas along their coronal incisions. The incisions were debrided and small amounts of fragmented plates that had worked their way to the surface were found. The proximal plates are now placed under the temporalis muscle to avoid further problems. This technique was applied to several patients with Apert's, Crouzon's, and Pfeiffer's syndrome with gratifying results. All patients who have had this device applied had severe preoperative obstructive sleep apnea; all had complete relief of their symptoms with distraction using the MOF device.

The MA, MP, and MI devices have been used in distraction of the mandible in various clinical situations. The most common applications are bilateral severe micrognathia in Pierre Robin Sequence, craniofacial microsomia, and Treacher Collins syndrome (Figs. 11 and 12). These devices allow up to 40 mm

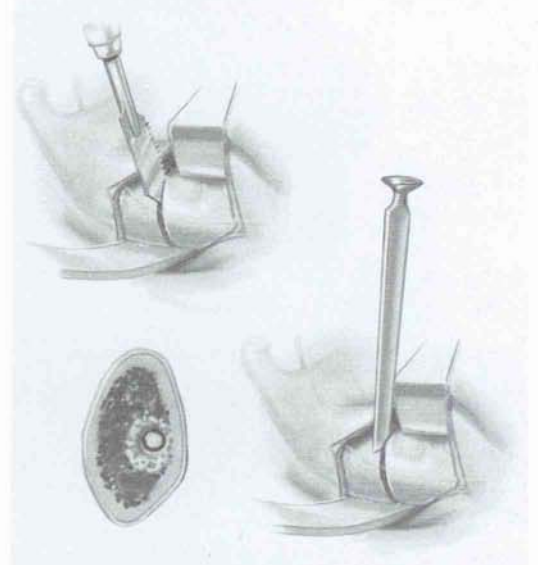


Fig. 13. Artists drawing of technique for circumferential monocortical mandibular osteotomy. *Top*: Reciprocating saw used to penetrate cortex only. Osteotomy made behind last tooth bud. *Bottom left*: Location of mandibular nerve in crosssection. *Bottom right*: Osteotomy completed with small osteotome.

of distraction for MA devices and 30 mm for the MP and MI devices. The technique for distractor placement was refined to minimize the danger of damage to the teeth, tooth buds, and inferior alveolar nerve (Fig. 13). In infants the available bone available for screw application may be limited, therefore accurate distractor placement and anchorage is essential. This is approached through a small incision approximately 2.0 cm below the angle of the mandible in adolescents, pediatric patients, and infants. This allows careful dissection under the platysma and retraction of the marginal mandibular nerve while exposing the ramus angle and body of the mandible in the subperiosteal plane. Once this has been done, the distraction cable is introduced through a separate pre- or postauricular incision, after determining the desired distraction vector. The osteotomy should be placed well behind the molars to allow room for anchorage. The entire distractor is fully applied, leaving a 5.0-mm gap for the osteotomy and screw anchorage between the proximal and distal plates. Whenever possible, bicortical screws are applied to maximize fixation. The distraction screw is then backed into the proximal plate and the monocortical circumferential osteotomy is performed. A thin reciprocating saw is used to go through just the outer cortex.

The osteotomy is carefully completed with a 4.0-mm osteotome and a bone spreader (Fig. 13). The neurovascular bundle can be preserved if care is taken to slowly divide the cortices circumferentially, gently spreading the bone edges. A life-sized synthetic model of the mandible showing the location of the tooth buds and neurovascular bundle can be manufactured from CAT scan digital data if it is available (Fig. 14). These sterilizable models have been useful for intraoperative plate molding and for

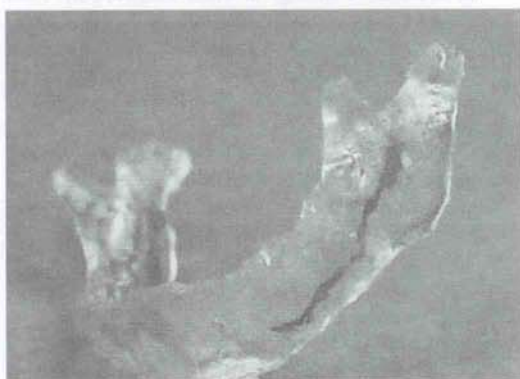


Fig. 14. Life-sized model of mandible from CAT scan showing location of mandibular nerve. This can be used to configure distraction plates in operating room.

planning the distraction vectors and device placement. Once the osteotomies have been completed, the drive screw is placed into the distal receiving compartment of the plate and the drive screw is turned at least 5.0 mm to ensure a complete osteotomy. A distraction rate of 2.0 mm a day is recommended after a 48-h latency period. The different MI designs can be applied to even small dysmorphic mandibles. If the bone mass allows, the MI plate holes can be overdrilled and 2.0 mm screws can be substituted for the 1.5 mm screws to allow for additional anchorage. These devices have been used successfully in 20 cases of severe retromicrognathia with airway obstruction secondary to Pierre-Robin Sequence [18]. The authors have been successful in avoiding or being able to remove the tracheostomy in 90% of the Pierre Robin patients treated with MI bone distractors. This may be the technique of choice for children with severe obstruction secondary to retromicrognathia [20,21]. All the devices have the unique feature that the drive screw is simply removed 4 to 6 weeks after the end of the consolidation period. This is done in the office, and no anesthetic or special instrumentation is required. There was initial concern about the stability of the devices in the rotational axis because the single-drive screw design does not provide for rotational stability. In practice, this concern has not been borne out. The masticatory muscles may act to prevent rotational instability during the distraction and consolidation process.

The ease of use, the multiple designs, and the one-stage nature of these devices will make them the device of choice for craniofacial distraction in the future. The ability to thermally contour the devices to almost any shape, coupled with the available three-dimensional models that can be sterilized, can certainly add an element of precision to craniofacial distraction. Despite the obvious advantages of single-stage resorbable distraction, several challenges remain. These devices provide linear single-vector distraction, which cannot be modified postoperatively. Any errors in aligning the distraction vector with the desired occlusal plane of distraction will be magnified at the incisor level as the distraction process proceeds. The authors are currently investigating coupling craniofacial distraction with active orthodontic therapy to adjust the distraction vector during the active and consolidation phases. Direct skeletal elastic traction, standard orthodontic appliances, if possible, and, in the young, the application of pinned palatal appliances with elastic traction are some of the methods currently under investigation. It has been shown that the bone regenerate is somewhat malleable during the consolidation phase, allowing for refinement of the final

occlusion even late in the distraction process [22]. This may add the valuable dimension of complete occlusal control to the current distraction techniques. If successful, it may allow a single-stage distraction process that goes far beyond the current large but inexact bone movements to one that provides predictable and stable occlusal results. The authors are in the process of developing a removable skeletal hook, which allows for placement of standard orthodontic rubber bands in patients who are not candidates for standard orthodontic appliances. The distraction device provides the gross bone advancement, while the orthodontic traction, applied by way of the skeletal hooks, guides the occlusion.

The future of distraction depends on ease of application, safety, cost-effectiveness, and the ability to produce a reliable and controllable occlusal result. It is hoped that one-stage resorbable devices, coupled with skeletal occlusal appliances, will be a positive step in the evolution of distraction osteogenesis.

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