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Article *in* Tissue Engineering Part B Reviews · December 2009

DOI: 10.1089/ten.TEB.2009.0502 · Source: PubMed

Uriel Zapata
Universidad EAFIT

Mohammed Elsalanty
Augusta University

Paul C Dechow
Texas A&M University Baylor College of Dentistry

Lynne A Opperman
Texas A&M University College of Dentistry

TISSUE ENGINEERING: Part B
Volume 16, Number 3, 2010

DOI: 10.1089/ten.teb.2009.0502

Biomechanical Configurations of Mandibular Transport Distraction Osteogenesis Devices

Uriel Zapata, M.Sc., Ph.D.,[1,2] Mohammed E. Elsalanty, M.D., Ph.D.,[3]
Paul C. Dechow, Ph.D.,[2] and Lynne A. Opperman, Ph.D.[2]

Mandibular bone transport (MBT) distraction osteogenesis devices are used for achieving reconstruction of mandibular defects in a predictable way, with few complications, less complexity than other alternative surgical procedures, and minimal tissue morbidity. However, selection of appropriate MBT device characteristics is critical for ensuring both their mechanical soundness and their optimal distraction function for each patient's condition. This article assesses six characteristics of currently available MBT devices to characterize their design and function and to classify them in a way that assists the selection of the best device option for each clinical case. In addition, the present work provides a framework for both the biomechanical conception of new devices and the modification of existing ones.

Introduction

A MYRIAD OF MANDIBULAR BONE TRANSPORT (MBT) devices are being developed or are already being used for creating bone in the mandible (Table 1), making it difficult to choose the most appropriate device to use. The literature shows that there is a good understanding of how device position and vector of distraction affect the ability to conduct MBT effectively; however, there appears to be a dearth of understanding as to how the device mechanism of action, its method of anchorage, and its relation to the soft tissues influence the eventual outcome. This review article informs the reader of the types of devices that are available and discusses the importance of understanding their biomechanical mechanisms, both for improving device design and for choosing the most appropriate device for achieving successful MBT outcomes.

Distraction osteogenesis is a surgical technique for the growth of new bone through the application of tensile stresses to a preexisting tissue laying between two bone ends. This technique of skeletal regeneration generally involves four stages[1,2]: (1) creation of a full osteotomy or a corticotomy, (2) latency period or callus formation between two bone ends, (3) distraction period or bone formation by callus stretching, and (4) consolidation or new bone tissue maturation. Although distraction osteogenesis was first popularized by Ilizarov in the mid-20th century to correct long bone defects,[3,4] its application was extended to the distraction of the membranous bones of the craniofacial skeleton by Snyder *et al.* in 1973. They removed 15 mm of bone in canine mandibles, generating a severe crossbite that was then reopened with an external distraction device (Fig. 1).[5]

The mandibular distraction procedure was further developed by Michieli and Miotti.[6] They performed bilateral distraction in two dogs, using an external tooth-borne device to lengthen the mandible by 15 mm. Based on their histologic and microscopic results, they suggested the first mandibular distraction operative protocol in humans, involving a latency period of 1 week after osteotomy, an activation rate of 1 mm on alternate days, and a minimum consolidation period of 45 days for every 15 mm of distraction.[6] Since previous animal studies showed the high potential of mandibular distraction osteogenesis to correct deformities, the first clinical distraction osteogenesis application in the human mandible was reported in 1992 by McCarthy *et al.*,[7] using an extraoral distraction device. They applied monofocal distraction techniques to four children with mandibular hypoplasia by using either unilateral or bilateral treatment. Costantino *et al.*[8] first reported the clinical use of bifocal distraction of the mandible in one patient by using an external custom-made distraction device to correct a 40 mm defect.

Procedures for distraction osteogenesis of the mandible can be classified into two main groups: monofocal distraction osteogenesis and transport distraction osteogenesis.[9] Monofocal distraction involves the separation of two mandibular bone segments at a single osteotomy site (Fig. 2A)

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[1] Mechanical Engineering Department, Eafit University, Medellín, Colombia.
[2] Texas A&M Health Science Center, Baylor College of Dentistry, Dallas, Texas.
[3] Medical College of Georgia, Department of Oral Biology, Augusta, Georgia.

Table 1. Mandibular Bone Transport Device Classification Is Based on the Activation System, the Relative Position of the Device, the Anatomical Position of the Defect, Vector Components of the Distraction, and the Activation Mechanism

		Relative position		*Anatomical defect position*				*Distraction vector*			*Bone transport*		*Activation mechanism*		*Observation*		
Activation mechanism	*Reference*	*External*	*Internal*	*Condyle*	*Ramus*	*Body*	*Symphysis*	*Unidirectional*	*Bidirectional*	*Multidirectional*	*Bifocal*	*Trifocal*	*Manual*	*Automatic*	*Animals*	*Humans*	*Gap size (mm)*
Power screw	23	X				X		X			X		X		X		25
	30	X					X		X			X	X		X		50
	1	X				X		X			X		X		X		20
	8	X							X		X		X			X	40
	45	X				X		X			X		X			X	15–35
	29	X				X	X		X			X	X			X	60
	26	X				X			X		X		X		X		51
	22	X				X	X		X		X		X			X	30–80
	54	X				X			X		X		X			X	35–50
	32	X					X			X	X	X	X			X	79
	28	X					X		X			X	X		X		—[a]
	18		X			X		X			X		X		X		20
	9		X			X		X				X	X			X	43
	17		X			X	X		X		X		X			X	40–70
	15		X			X		X			X		X			X	35–80
	19		X			X		X			X		X			X	40
	20		X			X		X			X		X			X	40
	21		X			X		X			X		X			X	25–60
	31		X				X		X			X	X		X		25–30
	42		X			X		X			X		X		X		30
Spring	55		X			X		X			X			X	X		15
	24		X			X		X			X			X	X		8
	25		X			X		X			X			X	X		40
Traction wire	16		X			X	X		X		X		X			X	50
	14		X		X				X		X		X		X		30
Hydraulic	27		X			X		X			X			X	X		15
Rack and pinion	2	X			X	X			X		X		X			X	65
	56	X				X	X			X	X		X			X	90

[a] Defect length was ranged from canine to canine; X, indicates device capabilities.

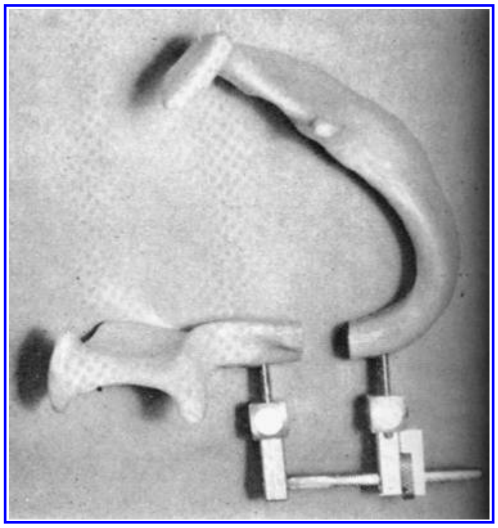

FIG. 1. External mandibular distraction appliance first used by Snyder *et al*. in a mandibular canine distraction procedure through a technique similar to monofocal distraction of the human mandible. Reproduced with permission from Snyder *et al.*[5]

and is widely used for bone lengthening to correct craniofacial deformities,[10] such as mandibular widening to correct dental crowding,[11] sutural expansion at the maxilla and skull,[12] mandibular or midface advancement,[13] and treatment of unilateral craniofacial microsomia.[7]

Bone transport distraction osteogenesis is used for the reconstruction of segmental defects by means of the incremental movement of one (bifocal distraction) (Fig. 2B1),[14–27] two (trifocal distraction) (Fig. 2B2),[9,28–32] or three (quadrifocal distraction) (Fig. 2B3)[32] viable bone segments, called "transport discs," across a defect. Bone transport osteogenesis is generally performed in the mandible. Such defects can result from surgical removal of cancers, chronic bone infections, blast injuries, and gunshot wounds.

Trifocal transport distraction requires half the time of bifocal transport distraction for the same mandibular bone defect. The transport disc, used in MBT, is cut from one or two ends of a mandibular segmental defect and is fixed to the transport unit of the distraction device to be moved at the desired rate until it reaches either the distal native side or its opposing disc counterpart (docking site), where it bonds by osteogenesis.[28] In general, MBT technique selection depends on the size of the defect.[33]

Although MBT has many advantages over conventional bone grafting, it presents several difficulties in selection of a

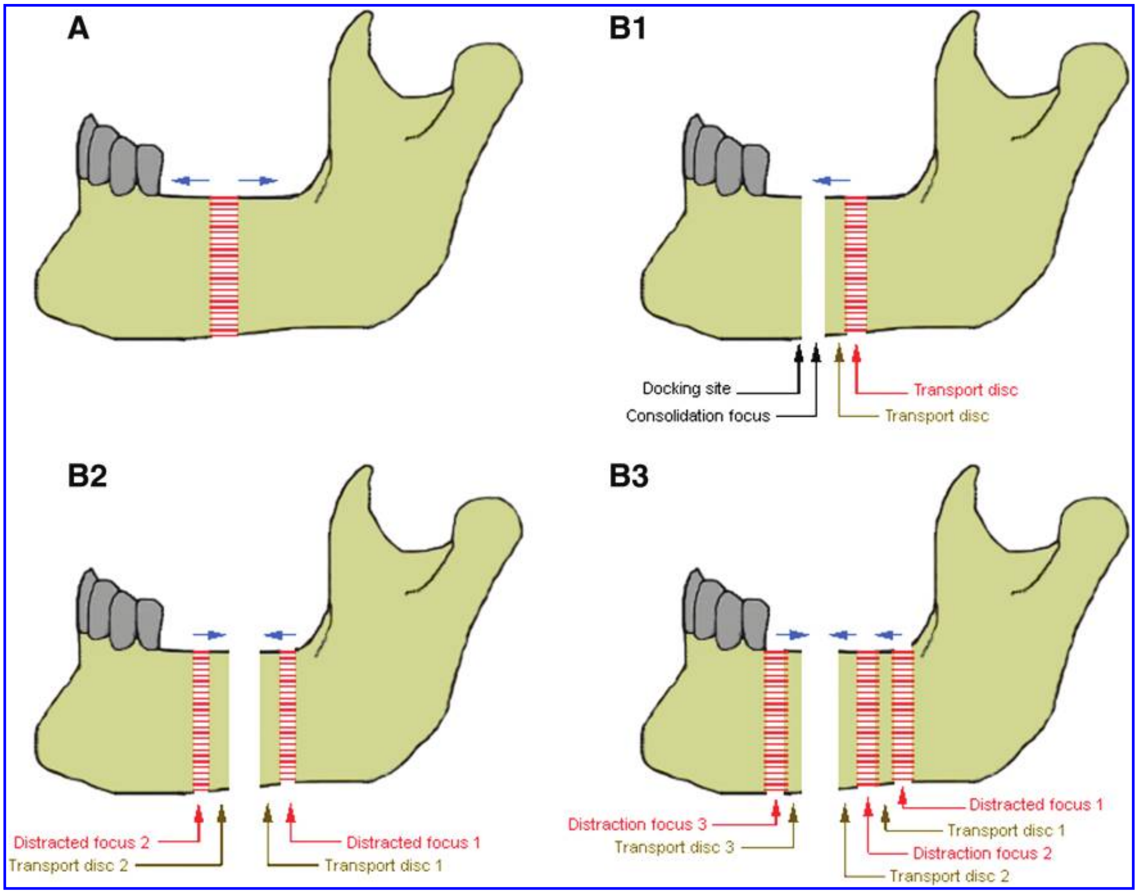

FIG. 2. Two variations of mandibular distraction osteogenesis. (**A**) Monofocal distraction osteogenesis creates bone between two corticotomy surfaces that are moved apart. Transport distraction osteogenesis generates new bone within a segmental defect by moving one transport disc or bifocal distraction osteogenesis (**B1**), two transport discs or trifocal distraction osteogenesis (**B2**), and three transport discs or quadrifocal distraction osteogenesis (**B3**). Color images available online at www.liebertonline.com/ten.

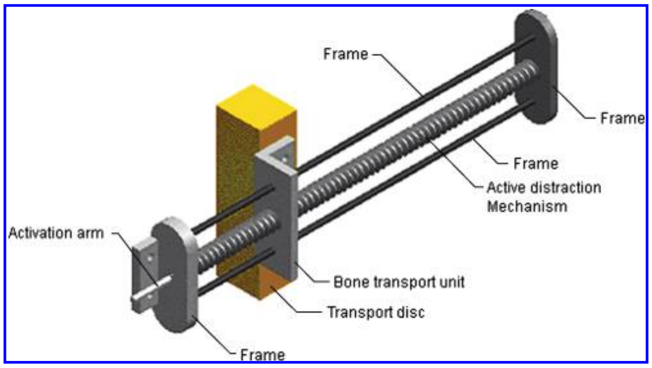

FIG. 3. The basic bifocal BTO device configuration contains an activation distraction mechanism, the bone transport unit, the activation arm, and the frame, which is constructed of two longitudinal bars that provide both a guide and stability for the bone transport unit and two support plates that provide the support for the active distraction system and the fixation ends. Color images available online at www.liebertonline.com/ten.

suitable device with consideration of each defect, the activation vector, the osteotomy site, and the appropriate patient condition. Inspite of the proven success of the MBT technique, problems still persist, such as soft tissue dehiscence, occurrence of occlusal disturbances, bone transport segment losing orientation, premature consolidation, regenerate deficiency, docking site nonunion, and failing devices.[34] Although several mandibular distraction devices have failed,[13,32,35–37] paradoxically, no studies have examined both device design and biomechanical characteristics.

Biomechanical Classification of MBT Devices

MBT devices are conceptually designed in four parts (Fig. 3): the frame that provides mechanical stiffness, strength, and support to the other components, along with protection to the new bone tissue and fixation ends; the bone transport unit that provides support to the transport disc of bone, allowing it to move between the two bone edges; the distraction activating mechanism that transforms energy into movement to displace the transport unit; and the activation arm that transfers the external energy to the distraction activating mechanism. Although MBT devices have a wide variety of designs,[38] they can be classified based on six criteria.

The anchoring tissue

The manner in which the ends of the MBT device are attached to the hard tissues defines the rigidity of fixation that provides mechanical stability to the device. Bone-borne anchorage is achieved using cortical screws, mini-implants, or implants that are fastened fully into the cortical bone to provide the most stable anchorage condition.[39] Tooth-borne anchorage is solely supported by the teeth and therefore produces dental tipping that could lower the MBT's direct effect on the mandible.[6,11,40,41] Finally, bone-tooth-borne (hybrid) anchorage simultaneously attaches to both the teeth and the cortical bone.[40] Tooth-borne and hybrid-borne MBT devices can potentially damage the teeth and the gingiva. Bone-borne MBT distraction devices produce the greatest skeletal effect, because most of the distraction force is applied directly to the distraction segment.[40] In general, most of the MBT devices use the bone-borne anchorage system to provide both stability and stiffness.

The relationship with the cutaneous tissues

MBT devices can be internal,[9,14–21,24,25,27,31,42] if the bulk of the device is buried beneath the cutaneous tissues, or external,[1,8,22,23,26,28–30,32,43–45] if the device uses transcutaneous pins to attach to the bone (Fig. 4). Depending on the specific device design, internal MBT devices, sometimes called intraoral devices, have excellent stability, favorable patient compliance, low infection rates, leave no scars, and may contribute to soft tissue expansion.[13,46,47] Eating and maintaining oral hygiene can be problematic in patients using internal devices,[46] and they need at least an additional minor surgical procedure to remove the device.[47] However, new resorbable materials are becoming available to build internal devices.[48]

External MBT devices, sometimes called extraoral devices, are usually preferred when complicated three-dimensional bone reconstruction is required.[32,49] However, fixation pins sometimes lose their stability, because they are not able to overcome soft tissue resistance and regenerate bone opposition during distraction.[50] In addition, pin-tract infection is common[51] and cutaneous scars result from the pin use.[52] External devices can enable unidirectional, bidirectional, and multidirectional distraction,[53] whereas internal devices, in

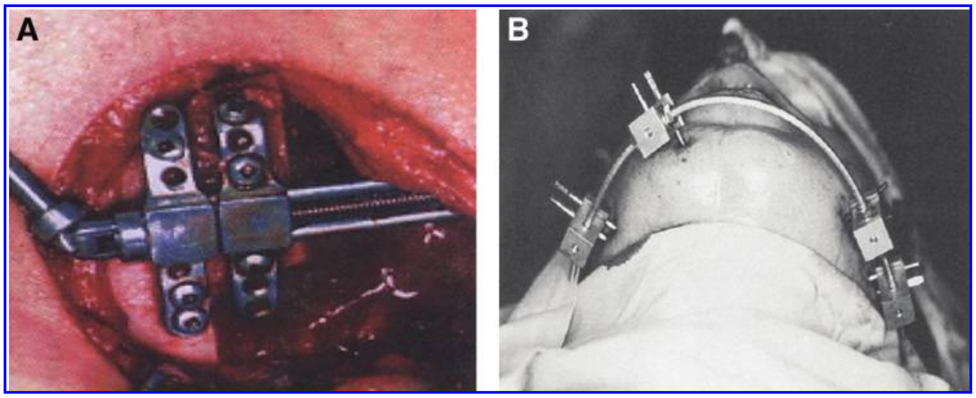

FIG. 4. Mandibular bone transport (MBT) device position relative to the skin. (**A**) Internal MBT device. Reproduced with permission from Wang *et al.*[9] (**B**) External MBT device. Reproduced with permission from Sawaki *et al.*[29] Color images available online at www.liebertonline.com/ten.

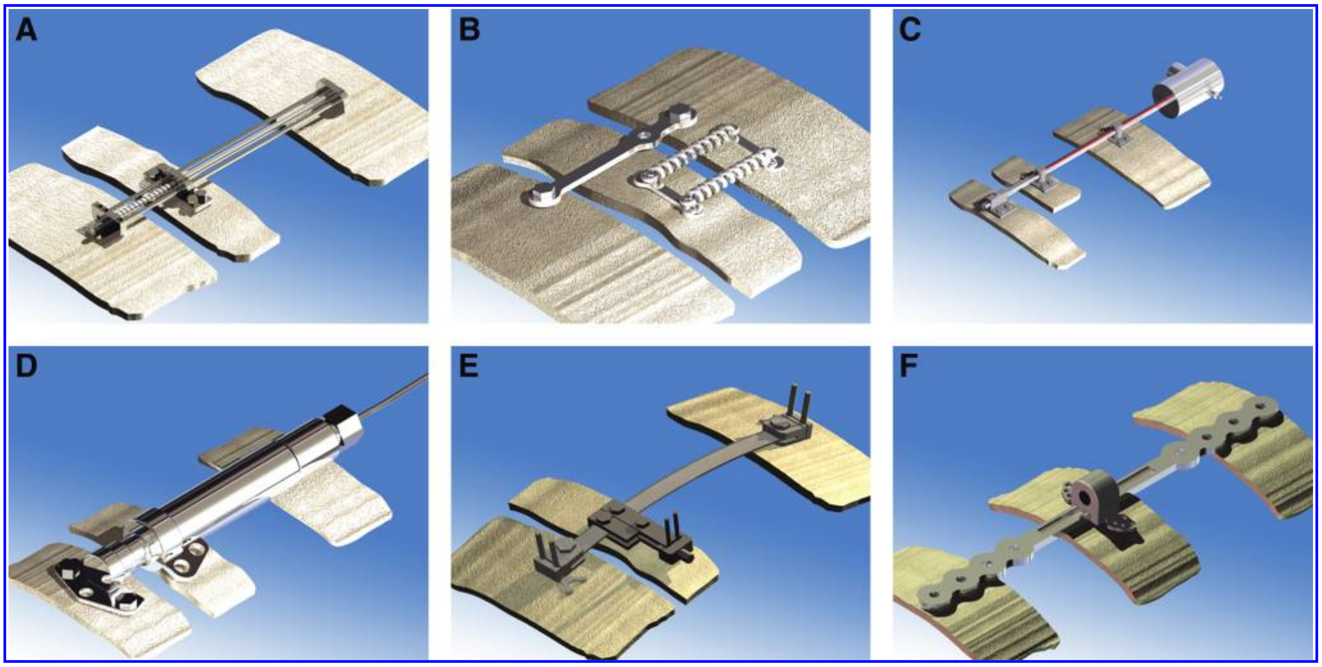

FIG. 5. MBT active mechanism. (**A**) A power screw system with female nuts, based on a prototype by Zapata. (**B**) A spring system, based on the design from Ref.[24] (**C**) A wire system, based on the design from Zhou *et al.*[14] (**D**) A hydraulic system, based on the design from Ayoub *et al.*[27] (**E**) A rack and pinion system, based on the design from Kramer *et al.*[75] (**F**) A power screw system with patterned band, based on a prototype by Elsalanty. Color images available online at www.liebertonline.com/ten.

almost all the cases, can perform only unidirectional and bidirectional distraction (Table 1).[47,49]

The activating mechanism

Active distraction mechanisms exist in a great variety of designs, and most of them are based on five basic principles (Fig. 5): power screw,[1,8,9,15,17–23,26,28–32,42,45,54] spring,[24,25,55] traction wire,[14,16] hydraulic,[27] and rack and pinion.[2,56]

The power screw activation system, also called screw lead activation system, translates torque into linear force to be used to distract the mandibular bone by matching an external helical threaded screw with either a negative or female threaded nut with the same thread form (Fig. 5A) or a band with the same pattern of holes (Fig. 5F). Several MBT devices based on power screw activation are unable to reproduce the curvature of the mandible, because they produce unidirectional distraction by moving the transport unit parallel to the screw (Table 1).[1,9,15,18–21,23,42,45] It is possible to improve their design to generate bidirectional MBT by adding complementary moveable mechanisms[31] performing complementary steps that include the rotation of the distraction device[57] or bending either the track[8,30] or the screw.[22,26]

The power screw activation system needs one[17,21,28,58–60] or two[9,61] complementary guide bars to form a stable frame and ensure an efficient function. However, it is also possible to achieve MBT without guide bars, by using devices complemented with a titanium reconstruction plate.[1,15,18–20,22,26,29,42,45] Most of the power screw activation systems without guide bars are built to accomplish monofocal distraction on the mandible.[13,62,63] Power screw activation systems with one and two complementary guides are mechanically more stable than power screw activation systems without guides or supporting reconstruction plates. The average length that can be distracted by using internal MBT devices with power screw activation systems is 40 mm,[9,15,18–20,47] and 50 mm of distraction by using external MBT devices.[26,30,54]

A novel MBT device, which combines the power screw activation mechanism with the stabilizing reconstruction plate to form a bone transport reconstruction plate unit, has recently been developed.[42] Combining the MBT and reconstruction plate reduces the size of the internal device and increases the stability of the transport unit. Curving the reconstruction/bone transport plate will allow this device to conduct monofocal bone transport across the mandibular midline or bifocal bone transport to meet at the midline (Fig. 5F).

The spring activation system is an elastic system that produces constant external loads by deforming itself. It is unique in that it does not have an activation arm, because the external energy is stored within a preformed superelastic shape memory alloy (SMA) that allows the system to deliver a continuous force directly on the callus without external activation.[24,25] However, the first activation of the spring, after the latency period, requires an operative process to release the activation mechanism.[64]

Spring activation mechanisms can be either a uniform coiled wire[24,35,65] or a bent wire with different conformations.[25,55,66,67] Bent springs (Fig. 5B), sometimes called arch springs, are unable to follow a linear distraction vector, because their asymmetric shape produces a caudal distraction force component,[64] whereas MBT devices based on coiled spring activation systems tend to produce unidirectional distraction.[24,65] Coiled springs are only effective over short distraction lengths, because the distraction load produced by the alloy tends to be constant for a small range of spring deformation.[68] Body temperature changes also can affect the distraction force magnitude in SMA like Nitinol™.[24,64] An MBT length up to 40 mm was achieved in canine models by using a bent spring.[25]

The traction wire activation system is based upon the basic mechanism for traction loads that are able to produce unidirectional, bidirectional, and multidirectional MBT (Fig. 5C). However, for both bidirectional and multidirectional MBT, the traction wire system needs either a guide or a housing to provide a track for the wire. The guides or the housing help solve some of the MBT limitations related to the defect length, the external mandibular curvature, and the position of the defect.[16] Most of the time, a rail, which has the same shape as the external contour of the mandible, is used to slide the transport unit along and to guide the traction wire.[14] The activation of the traction mechanism can be performed by either a conventional screw rod[16] or a rod within a cylinder.[14] MBT lengths up to 50 mm have been achieved by using this activation system.[16]

The hydraulic activation system is composed of three sealed parts: the hydraulic activation mechanism, the remote control, and the flexible noncompressible hydraulic tube that connects them.[69] The hydraulic cylinder, the tube, and the remote control are filled with uncompressible fluid to power the movement of the piston.[70,71] The hydraulic activation mechanism (Fig. 5D) is based on the principle of a hydraulic pump, which is composed of two parts, the hydraulic cylinder and the piston. The hydraulic system is activated by an injector that works through a remote control device to apply either continuous or incremental pressure on the piston and produce similar distraction frequencies.[69–71] However, the hydraulic pressure of the activation system is variable during the distraction period, for both continuous and especially incremental activation processes.[70,72]

In general, the hydraulic activation system does not have a constant relationship between pressure applied at the remote control and the amount of disc displacement, except if both the hydraulic activation system and the remote control have the same internal diameter.[69,71,73] This activation system has been mainly used for monofocal distraction by attaching the cylinder and the piston directly to the edges of the bone and taking advantage of the relative displacement between them.[70–73] The device has also been used for MBT by using a titanium reconstruction plate to stabilize both mandibular segments (Fig. 5D), fixing the cylinder to one side of the defect and projecting the transport unit attached to the end of the piston.[27] However, this telescopic process tends to be unstable with increasing defect length. The maximum MBT length achieved by using this active mechanism was 15 mm.[27]

The rack and pinion activation system is made up of a circular pinion that perpendicularly engages the cogs on a gear bar to convert rotational movement into linear movement and produce displacement of the transport unit (Fig. 5E). Few MBT devices have been reported to be using this active system,[2,56] although another device was reported for calvarial bifocal distraction, wherein a bone graft was used as the transport disc.[74,75] The maximum bifocal distraction length reported was 90 mm.[56]

The distraction vector

The vector of distraction is related to the orientation of the new bone produced by the MBT device (Fig. 6). Vectors can be unidirectional[1,9,15,17–21,23,24,27,42,45,76] if the MBT device provides linear distraction in the same direction as the MBT device orientation. Alternately, the vector can be bidirectional[2,8,14,16,17,26,28–31,77,78] if the MBT device provides two distraction direction components. Most of these devices are called curved or curvilinear MBT devices. Finally, the vector can be multidirectional[16,22,29,32,44,79,80] if the MBT device provides up to three distraction direction components. Multidirectional MBT devices that are used to correct complex mandibular defects are external distraction devices (Table 1) that are mounted on a U-shape rod that not only provides support but also allows bidirectional transport of the bone segments. The third distraction vector component is produced by a vertical element of the device that permits mandibular contour definition. The multidirectional MBT devices are able to perform both bone transport over longer distances and bone transport in the symphyseal region of the mandible.[32,56]

Most internal MBT devices only provide unidirectional distraction in which the new bone generated does not follow the original curved shape of the mandible; however, several internal MBT devices have been designed to provide bidirectional distraction.[14,16,17,31]

Device position

The device position corresponds with the site of the mandibular defect location according to Urken's classification (Fig. 7).[81] Defects can be located on the condyle,[82,83]

FIG. 6. Distraction vector activation in MBT devices. (**A**) Unidirectional (KLS Martin, Jacksonville, FL), reproduced with permission from Sacco and Chepeha.[76] (**B**) Bidirectional, reproduced with permission from Hibi and Ueda.[16] (**C**) Multidirectional (www.globalmednet.com/do-cdrom/Clinical/Transp/Klein/kl001.htm). Color images available online at www.liebertonline.com/ten.

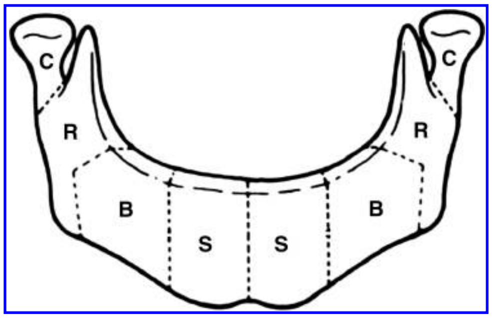

FIG. 7. MBT device relative position with respect to the mandibular bone defect. C, Condyle; R, Ramus; B, Body; S, Symphysis. Adapted from Urken *et al.*[81]

ramus,[47,84] body,[1,15,18,19,24,42,45] or symphysis.[17,28,30–32,56,57,85] Although the condyle, ramus, and body anatomical positions are able to receive either unilateral or bilateral MBT devices, most of the MBT devices are applied to only one side of the mandible,[14–17,25] and only one MBT device has been successfully used bilaterally.[28,54] According to reports in the literature, most of the MBT devices for use across the symphysis are external (Table 1). Currently, few internal MBT devices for the symphysis have been tested in animal[31] and human[16,17,57] subjects, because the reconstruction of the curved mandibular symphysis is challenging. In addition, most of the monofocal internal distraction devices that have been applied at the human symphysis are used to obtain mandibular widening.[85]

Although restoration of the condyle-ramus complex requires bidirectional MBT devices to reconstruct its curved anatomical shape,[2,54] several monofocal distraction devices have been applied for the reconstruction of the condyle-ramus unit in a process that is used to unidirectionally project the posterior part of the condyle. This method is often incorrectly referred to as an MBT process.[37,82,83,86] In contrast, reconstruction of segmental bone defects of the mandibular body has been mainly accomplished by using unidirectional MBT devices,[19,42] whereas few devices have been designed to reconstruct the slightly curved lateral aspect of the mandibular body.[1,16] Examination of the literature reveals that no internal devices have been reported for the reconstruction of the mandibular symphysis, although several external MBT devices provide either bidirectional[26,31] or multidirectional reconstruction of this anatomical part.[56]

Activation mechanism

The activation mechanism is the means by which the MBT device receives external energy through the activation rod, which usually emerges from the mucosa (transmucosal), the skin (trascutaneous) in the internal devices,[18,21] or directly at the device in external systems.[22,26] The activation mechanisms can be either manual[1,2,8,9,14–21,23,28–32,42,45] or automatic (Fig. 8).[87–91] Manual activation mechanisms are operated by doctors or the patients using a tool similar to a screwdriver or a wrench that is inserted into the end of the activation arm. Manual activation involves two different and complementary components: (1) the frequency or the number of activation steps a day and (2) the rate or the distraction length that is achieved each day by the movement of the MBT system. Manual activation varies from one or two steps for rates between 1 and 2 mm/day[92] to frequencies between 4 and 5 steps for a rate of 1 mm/day.[90]

Automatic distraction activation can be provided by a motor-driven system that supplies an electromechanical micro-incremental frequency,[91] by an electro-hydraulic pump that provides a continuous hydraulic pressure,[27,69,71] or by an SMA spring that provides constant force to generate MBT disc displacement.[24] In internal MBT devices, the activation component tends to be distant from the surgical site. If activation is via a flexible cable that connects the device and the automatic control-power unit mechanically, the mechanism is vulnerable at the connections.[91] It is also important to remember that the further the activating mechanism is from the transport mechanism, the lower is the translation of the activation force into forward motion. This is especially problematic in external devices, because the activating mechanisms on external devices are only indirectly attached to the bone.[92]

Discussion

Both monofocal distraction and bone transport distraction techniques are used to create bone regenerate; however, there are distinct differences between these two methods. Monofocal distraction is generally used to correct skeletal defects, whereas bone transport is used to correct skeletal deformities. Monofocal distraction requires that the two stumps of bone begin, in direct contact with one another, to generate new bone while separating the bone stumps. In contrast, bone transport uses discs of bone cut from the ends of the segmental defect to be transported across the gap. The

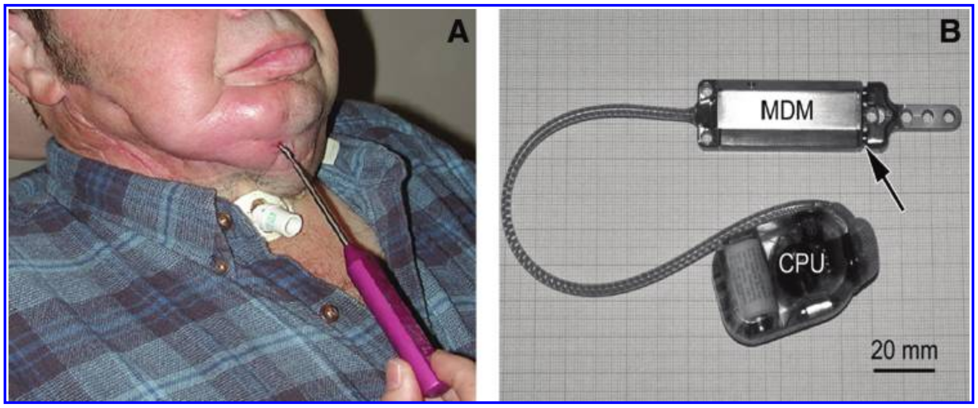

FIG. 8. MBT activation mechanism. (**A**) Manual activation of the device, reproduced with permission from Spagnoli.[21] (**B**) Electromechanical activation system with expandable transporting rods (arrow), reproduced with permission from Ploder *et al.*[91] Color images available online at www.liebertonline.com/ten.

bone transport technique has a docking site or place where the transport disc meets its opposing counterpart at the end of the activation process.[54] Monofocal distraction does not have tissue discontinuities, whereas bone transport often has concomitant soft tissue losses. Bone transport has five stages instead of the four monofocal stages, adding a docking site osteogenesis stage[8,20,26,30] after the distraction period and in parallel with the consolidation period. These basic differences support the necessity of independent and special device designs for both monofocal distraction and bone transport distraction.

The clinical patient's defect characteristics must be the basis for determining the selection of the optimal device to accomplish most of the bone distraction requirements.[21] Based on the biomechanical description and classification of MBT devices presented here, an optimal device should have the following characteristics. MBT devices should be internal to lessen scar formation and small to improve patient comfort and reduce soft tissues stress. Further, the devices should be stable, with the use of a strong frame and ends attached directly to the bone to diminish shear stresses within the new bone. The devices should follow the initial vector plan, with an activation system that allows distraction without patient intervention and either bifocal or multifocal distraction abilities to restore the curvilinear continuity of the newly formed bone when reconstructing the facial contour.

Based on the variety of device options described in the present classification system, new MBT device designs can combine a multitude of options to produce devices optimized for specific defect characteristics. Future MBT device designs are likely to include new material options like composites and are likely to increase the number of devices using resorbable materials. In addition, future MBT device designs can incorporate biophysical and biochemical stimulation factors developed to accelerate bone formation, abbreviate the consolidation period, and reduce complication risks.[93] Finally, it is likely that MBT device designers will consider including drug delivery options within the device's conception.

Acknowledgments

This work was supported by NIH/NIDCR grants R43 DE017259-05, R42 DE015437-03, and a fellowship from Departamento Administrativo de Ciencia, Tecnología e Innovación COLCIENCIAS-Colombia.

Disclosure Statement

The bone transport reconstruction plate device described[42] was invented by M.E.E., and the patent is assigned to a company (Craniotech ACR Devices, LLC) owned by M.E.E. and L.A.O.

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Address correspondence to:
Lynne A. Opperman, Ph.D.
Texas A&M Health Science Center
Baylor College of Dentistry
3302 Gaston Ave.
Dallas, TX 75246

E-mail: Lopperman@bcd.tamhsc.edu

Received: July 21, 2009
Accepted: December 3, 2009
Online Publication Date: January 21, 2010