Title: BONE TRANSPORT RECONSTRUCTION DEVICES AND METHODS

Abstract: Disclosed are devices and methods used to grow bone. The methods use distraction osteogenesis to grown new osteocytes. Preferred embodiments can be used to fill a gap in the mandible after surgical excision. In some embodiments, an intraoral reconstruction plate fixes the bone stumps on both sides of a bone gap. In other embodiments, the reconstruction plate is fixed to a single bone stump. In a middle segment of the reconstruction plate overlying a bone gap, a transport bone disc is carried on a transport unit that moves along a rail on an outer surface of the reconstruction plate.
BONE TRANSPORT RECONSTRUCTION DEVICES AND METHODS

This application claims the benefit of U.S. provisional application No: 60/552,272 filed 03/11/2004 and U.S. application No. 10/970,108 filed 10/21/2004.

FIELD OF THE INVENTION

Disclosed are devices and methods used to grow bone. The methods use distraction osteogenesis to grow new osteocytes. Preferred embodiments can be used to fill a gap in the mandible after surgical excision. In some embodiments, an intraoral reconstruction plate fixes the bone stumps on both sides of a bone gap. In other embodiments, the reconstruction plate is fixed to a single bone stump. In a middle segment of the reconstruction plate overlying a bone gap, a transport bone disc is carried on a transport unit that moves along a rail on an outer surface of the reconstruction plate.

BACKGROUND OF THE INVENTION

Segmental resection is a basic component of the surgical treatment of malignant mandibular tumors. Incidence of oral cancer in the US is 7.7/100,000 (30,000 case/year). Surgical resection may be followed by radiotherapy or chemotherapy. Definitive treatment of many of the more common benign tumors may also require segmental resection due to high incidence of local recurrence after simple curettage or intra-lesional excision. These tumors include ameloblastoma, myxoma, giant cell granuloma and recurrent keratocyst. Blast injuries and high impact trauma to the mandible may lead to segmental bone loss either directly or due to
surgical debridement. Segmental bone loss may also result from repeated surgical debridement for treatment of chronic osteomyelitis of the mandible.

All these conditions require reconstruction of the lower jaw, including the bone, the gingiva and the teeth. After resection of malignant tumors, more soft tissue reconstruction is often necessary. This may include the floor of the mouth, the tongue, the cheek, the chin, in addition to adequate soft tissue covering of the major vessels of the neck following neck dissection. This has always been a challenging task. In spite of the wide variety of reconstruction methods, none of them is completely satisfactory.

The general aim of oral reconstruction is to restore both the normal physiology and the facial aesthetics. Physiological functions include the maxillo-mandibular occlusion, mastication (jaw dynamics), deglutition, mandibular continuity, sensibility of the mucosa, sufficient alveolar ridge height and thickness, lip competence and speech. Esthetic goals include the general appearance of the reconstructed soft-tissue, facial symmetry, restoration of dentition, and preservation of the lower facial dimensions.

The principle current reconstruction methods include mandibular reconstruction plate with or without bone grafting. Traditional mandibular reconstruction plate is a rigid titanium bone plate that connects the remaining bone stumps after segmental excision. The maxillo-mandibular central occlusion has to be achieved first by intermaxillary wire fixation. The plate prevents displacement of bone segments, soft-tissue collapse, and preserves facial symmetry.

Soft-tissue reconstruction is then carried out to provide the proper covering and lining of the plate. This is usually the first of two reconstruction steps. The second step, definitive bone reconstruction, is often delayed to allow for radiotherapy to take place, eliminate the possibility for local recurrence or simply not to add to the longevity of the first operation. However, some
surgeons prefer to do primary bone reconstruction at the same setting provided that no radiotherapy is needed and no recurrence is anticipated. Others, however, prefer not to do the definitive bony reconstruction at all. Although good aesthetic results were reported with reconstruction plate alone with no bone replacement, this deprives the patient of having any restoration of occlusion, not even a removable lower denture.

During the second stage of reconstruction, the gap is explored, and the whole width of the tumor bed as well as the edges of the remaining bone is dissected. This step is often technically difficult due to extensive fibrosis, loss of anatomical planes and landmarks, and the possibility of vascular injury that can result in serious bleeding or injury to the oral mucosa. Communication with the oral cavity due to mucosal breaks during dissection has a high chance of resistant postoperative infection. After complete dissection, the plate is removed and the bone graft (either vascularized or non-vascularized) is inserted in its place. The procedure is lengthy and highly demanding especially when microvascular techniques are used. The overall outcome of this technique, with either primary or secondary bone reconstruction was less than satisfactory.

Failure rate of metal plate with bone graft was between 16-29%, while complication rate varied from 45-81%. Some factors were found to be more related to graft failure, the most important of which are the amount of intra-operative blood loss and the occurrence of recipient site complications (e.g. fistula and infection).

Disadvantages of free non-vascularized bone graft include graft resorption, high incidence of failure due to resistant infection, especially with primary reconstruction, insufficient amount of bone for large gaps and donor site morbidity. Except for iliac crest graft, the harvested bone mass was not sufficient neither for osseointegrated implant insertion nor carrying a
removable lower denture. Disadvantages of free vascularized bone graft (free flaps) are discussed in the next section.

A substitute for the reconstruction plate has been a titanium mesh, which is shaped according to the gap after tumor excision, and then it is filled with bone graft either immediately or at a later stage. Although the mesh does have to be removed after reconstruction, it still requires the use of large amount of autogenous bone graft, and has a high failure rate mainly due to resistant infection necessitating removal of the prosthesis. Again, rehabilitation of jaw function was not achieved by this method. The tendency towards definitive reconstruction of bone as a part of the primary surgery is growing over the years. However, achieving acceptable results with primary reconstruction methods was never an easy task.

The use of non-vascularized bone graft during primary reconstruction is not advised due to high incidence of failure. The description of microvascular techniques in the early seventies provided more options for primary reconstruction of the mandible. Over the years, many designs for vascularized osseomyocutaneous flaps for mandibular reconstruction were reported; the most popular of which are the vascularized fibula, scapula and iliac crest. They had better functional results, with the possibility to carry tooth restorations for full mouth rehabilitation, and the ability to reconstruct large and composite defects, even in growing patients.

In spite of their promising success rate, free vascularized flaps have high rates of complications, especially medical complications, which may be as severe as postoperative death. These highly demanding techniques, which require specialized surgical team; definitely add to the longevity and complications of the primary surgery. In an average procedure of tumor resection with free fibular graft mandibular reconstruction, two surgical teams are operating
simultaneously for more than 10 hours. Considering the general condition of the cancer patient, reconstructive surgery should be as brief and less invasive as possible.

Other disadvantages of vascularized tissue transfer include the donor site morbidity. Leg pain, ankle instability have been reported with the vascularized fibula; hernias, hip pain, and anesthesia of the lateral thigh with vascularized iliac crest; and limitation of shoulder range of motion with vascularized scapula. Additionally, the characteristics of each flap design limited its use only to specific defects.

**Distraction osteogenesis in mandibular reconstruction**

Distraction osteogenesis is a process of new bone formation between two bone segments, when they are gradually separated by incremental traction. This pattern of bone elongation allows the surrounding soft tissues to adjust to the new skeletal dimensions through the series of adaptive changes called distraction histiogenesis. Active histiogenesis has been shown to occur in various soft tissues including skeletal muscles, nerves, blood vessels, periodontal ligament, and gingiva. The result will be the synthesis of new bone with a cover of periostium and soft tissues (mucosa, muscles, etc.) as well as new vascular and nerve supply.

Using this technique, bone defects in long bones could be reconstructed without bone grafting, but by surgically separating a bone segment (transport disc) from one, or both edges of the remaining bone and gradually distracting this segment in the direction of the opposite bone edge. New bone will develop behind the distracted segment filling the gap until it reaches the docking site. Recent results of mandibular reconstruction using this principle were very promising. Newly formed bone proved to have normal architecture (inner cortex, outer cortex, and medulla), dimensions, and 80-100% of normal mechanical properties when examined after 8 weeks of consolidation.
Distraction devices designed for reconstruction of mandibular bone defects had two forms. The first is a uni-or-multidirectional distraction device mounted on, or combined with reconstruction plate. The second is an extra-oral titanium arch with movable units anchored to mandibular bone segments through steel pins.

5  **Distraction devices mounted on, or combined with reconstruction plate**

Each of these devices is composed of a distraction device, which is either mounted on (connected to) the plate, or totally separate from it. The distraction device can be uni-directional or multi-vector; extra-oral or intra-oral. However, in addition to the technical problems associated with device assembly and application, the distraction devices had a completely independent function to the reconstruction plate. While the reconstruction plate takes the curved shape of the original mandible, the distraction device carries the transport segment towards the docking site guided by the linear vector of the distraction device irrelevant to the course of the reconstruction plate. In other words, the fixative function of the reconstruction plate was separated from the new bone formation, even when the two device components were physically connected. In addition, the length range of the regenerate is limited by the length of the device, which makes it unable to reconstruct large mandibular defect especially those crossing the midline.

**Extra-oral bone transport devices**

In our experience with this design, it proved to be simple, fast, with minimal interference with bone segments, wider range of distraction for angle-to-angle reconstruction. However, its disadvantages included poor control of the transport disc, pin-tract infection, pin extrusion, and retrusion of the newly formed bone in case of anterior reconstruction.
SUMMARY OF THE INVENTION

Disclosed are devices and methods used to grow bone. The methods use distraction osteogenesis to grown new osteocytes. Preferred embodiments can be used to fill a gap in the mandible after surgical excision. In some embodiments, an intraoral reconstruction plate fixes the bone stumps on both sides of a bone gap. In other embodiments, the reconstruction plate is fixed to a single bone stump. In a middle segment of the reconstruction plate overlying a bone gap, a transport bone disc is carried on a transport unit that moves along a rail on an outer surface of the reconstruction plate.

In some embodiments, for the mandibular bone transport reconstruction plate, the transport track is the shaft of the reconstruction plate itself and not a separate device mounted on it. In other words, the transport unit glides on the middle segment of the plate itself. Therefore, the plate functions both as a rigid mandibular reconstruction plate and a bone-transport distraction device. In preferred embodiments, the transport unit moves along the serrated groove on the surface of the middle segment of the plate by direct activation of a screw within the unit case. The screw threads interact with the serrations on the groove when the screw is turned pushing the whole unit in one direction, either forwards or backwards, according to the direction of screw turning. In further embodiments, the foremost thread on the activation screw is sharply cut so that, while rotating, it cuts its way through any tissue growth that may be covering the serrations on the plate surface groove. In further embodiments, the transport unit has a sloping edge to act as a dissector through the soft tissues as the unit is moving. In further embodiments, the transport unit can be disassembled and removed after the end of distraction, while the plate itself can be retained in place for as long as desired. In further embodiments, the transport unit is
attached to the transport disc by 1.7mm screws arranged in an alternating fashion, so that fewer screws can provide appropriate stability.

In some embodiments, the devices can be used for any distraction procedure, such as mandibular lengthening, and not only for reconstruction of a bone gap. In further embodiments, the transport unit can by advanced using a screw, or another mechanism, whether it may be manually controlled or automatic. In further embodiments, the plate and/or the screws can be made of titanium or another material. In further embodiments, the number and size of fixation screws can be variable. In further embodiments, methods use the devices in other bones of the body.

In some embodiments, the bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track; and 2) two ends configured for fixing at least one end of the device to a bone segment; and b) a transport unit configured for gliding over said transport track comprising a casing for attaching a transport bone disc to the transport unit. In further embodiments, the casing has a sloping leading edge. In further embodiments, the casing is attached to the transport bone disc by a screw. In further embodiments, the casing is attached to the transport bone disc by screws arranged in an alternating fashion.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track with serrated grooves; and 2) two ends configured for fixing at least one of the ends to a bone segment; and b) a transport unit comprising 1) a casing for attaching a transport bone disc; 2) a activation screw with threads; wherein when the activation screw is turned the screw thread interact with the serrated grooves
and the transport unit moves along said transport track. In further embodiments, the activation screw has a foremost thread and the foremost thread is sharply cut.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track with serrated grooves; and 2) two ends configured for fixing at least one of the ends to a bone segment; b) a transport unit comprising 1) a casing for attaching a transport bone disc, 2) an activation screw with threads and a head; and c) a flex cable; wherein when the activation screw is turned the screw thread interacts with the serrated grooves; the transport unit moves along said transport track; and the casing is configured so that the head of the activation screw can be configured in forward and backward orientations reversing the movement of the transport unit in relation to the direction of rotation of the flex cable.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track with serrated grooves; and 2) two ends configured for fixing at least one of the ends to a bone segment; and b) a transport unit comprising 1) a casing for attaching a transport bone disc said casing comprises two halves; 2) an activation screw with threads wherein when the activation screw is turned, the screw thread interact with the serrated grooves and the transport unit moves along said transport track. In further embodiments, a connecting screw attaches the two halves. In further embodiments, interlocking segments attach the two halves.

In some embodiments, a method comprises: i) providing a transport bone disc, first and second bone segments, and a bone transport device comprising: a) a bone reconstruction plate comprising 1) a middle segment having a transport track; and 2) two ends configured for fixing the device to said first and second bone segments; and b) a transport unit comprising a casing for
attaching a transport bone disc, wherein the transport unit moves along the said transport track; ii) attaching the bone transport disk to said casing; and iii) fixing the ends of the bone reconstruction plate to said first and second bone segments; and iv) moving the transport unit along said transport track. In further embodiments, the method further comprises: v) detaching the casing from the transport bone disc; and vi) removing the transport unit from the transport track. In these embodiments, the bone reconstruction plate functions as a distraction device.

In some embodiment a device consists of a first piece and a second piece; said first piece comprising a bone reconstruction plate comprising 1) a middle segment having a transport track; and 2) two ends configured for fixing the device to bone segments; and said second piece comprising a transport unit configured for gliding over said transport track, said transport unit comprising a casing for attaching a transport bone disc.

In some embodiments, a system comprises: first and second bone segments and a bone transport device comprising: a) a bone reconstruction plate comprising 1) a middle segment having a transport track; and 2) a first end fixed to said first mandibular bone segment and a second end fixed to said second mandibular bone segment; and b) a transport unit configured for gliding over said transport track, said transport unit comprising a casing for attaching a transport bone disc.

In some embodiments, a device comprises: 1) a plate configured for fixing the device to the bone; 2) a middle segment of the plate configured to overly a bone gap, and 3) a transport bone disc connected to a transport unit wherein the transport unit is configured to move along an outer surface of said plate.

In some embodiments, a method comprises a) providing: i) an animal comprising of a bone and skin and ii) a device comprising: 1) a plate configured for fixing the device to the bone;
2) a middle segment of the plate configured to overly a bone gap; and 3) a transport bone disc connected to a transport unit wherein the transport unit is configured to move along an outer surface of said plate; b) inserting the said plate under the skin of the animal; and c) fixing the device to said bone. In further embodiments, the method comprises the steps of: d) detecting the size of a bone in said animal, and e) configuring said plate to grown bone of a desired dimension.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track; and 2) two ends configured for fixing at least one end of the device to a bone segment; and b) a transport unit configured for gliding over said transport track comprising a casing for attaching a transport bone disc to the transport unit. In further embodiments, the casing has a sloping leading edge. In further embodiments, the casing is attached to the transport bone disc by a screw 5.0 millimeters or less long, preferably less than 2.0 millimeters long. In further embodiments, the casing is attached to the transport bone disc by screws 5.0 millimeters or less long that are arranged in an alternating fashion, preferably less that 2.0 millimeters long.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track with serrated grooves; and 2) two ends configured for fixing at least one of the ends to a bone segment; and b) a transport unit comprising 1) a casing for attaching a transport bone disc; 2) a activation screw with threads; wherein when the activation screw is turned the screw thread interact with the serrated grooves and the transport unit moves along said transport track. In further embodiments, the activation screw has a foremost thread and the foremost thread is sharply cut.

In some embodiments, a bone transport device comprises: a) a bone reconstruction plate comprising 1) a middle segment having a transport track with serrated grooves; and 2) two ends
configured for fixing at least one of the ends to a bone segment; b) a transport unit comprising 1) a casing for attaching a transport bone disc, 2) an activation screw with threads and a head; and c) a flex cable wherein when the activation screw is turned the screw thread interacts with the serrated grooves; the transport unit moves along said transport track; and the casing is configured so that the head of the activation screw can be configured in forward and backward orientations reversing the movement of the transport unit in relation to the direction of rotation of the flex cable.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1: Illustrates Bone Transport Reconstruction Plate with a transport unit superimposed on the beginning of the rail (middle section).

FIG 2: Illustrates a cross section in the inner segment of a plate (rail portion).

FIG 3: Illustrates the transport unit with an activation screw.

FIG 4: Illustrates the composition of an activation screw.

FIG 5: Illustrates a cross section in a transport unit.

FIG 6A: Illustrates a Bone Transport Reconstruction Plate in place on the mandible before distraction is started.

FIG 6B: Illustrates a Bone Transport Reconstruction Plate in place while distraction is proceeding and new bone is being formed behind the transport disc.

FIG 7. Illustrates construction of one device with two halves of a transport unit, a threaded screw, and a bone transport reconstruction plate.

FIG 8A: Illustrates the Bone Transport Reconstruction Plate bent in a horizontal direction.
FIG 8B: Illustrates the Bone Transport Reconstruction Plate bent in a vertical direction.

FIG 9: Illustrates checkpoint osteotomy technique.

FIG 10A: This is the histological appearance of active new bone formation in the defect after distraction osteogenesis in a live goat.

FIG 10B: This is a lateral X-ray showing calcified new bone within the defect after distraction osteogenesis in a live goat.

DETAILED DESCRIPTION:

Disclosed are devices and methods used to create new bone. The methods use distraction osteogenesis to grow new osteocytes. Preferred embodiments can be used to fill a gap in the mandible after surgical excision. In some embodiments, an intraoral reconstruction plate fixes the bone stumps on both sides of a bone gap. In other embodiments, the reconstruction plate is fixed to a single bone stump. In a middle segment of the reconstruction plate overlying a bone gap, a transport bone disc is carried on a transport unit that moves along a rail on an outer surface of the reconstruction plate.

Theses devices can be used to create new bone to fill a gap in the mandible after surgical excision. They use the rigid bone reconstruction plate as distraction device. In some embodiments, the reconstruction plate fixes the bone stumps on both sides of the bone gap by large (2.3-2.7mm, bicortical titanium bone screws). In the middle segment of the plate overlying the bone gap, the transport bone disc is carried on a transport unit that moves along a rail on the outer surface of the reconstruction plate when a screw within the unit is activated.

In one embodiment, a device is composed of a traditional titanium mandibular reconstruction plate (see figure 1) with a middle segment (2) that functions as a straight track
over which a transport unit can be moved from one end of the track to the other. The middle segment of the plate can overly a bone gap resulting from surgical bone removal for any reason.
The two ends of the plate are stabilized to the bone segments on both sides of the gap with 2.3-2.7 titanium screws. The transport unit is stabilized to a bone disc cut out from one of the two bone segments to move it gradually (e.g. at a rate of 1mm/day) until it reaches the other bone segment.

The outer surface of the middle segment has a serrated groove (3) so that the movable transport unit (4) can glide over it in one direction if a screw within it (6a and 6b) is turned clockwise, and glide back in the opposite direction when the gear is turned anti-clockwise (see figures 1-5). Activation of the screw within the transport unit is carried out through an activation flex cable (not shown) that is fixed to the head of the activation screw (6a). Rotation of the flex cable causes the screw to rotate to the same degree. This rotation will cause the transport unit to move in the direction of bone transport for a calculated distance (e.g. one millimeter of linear movement for each 360 degree rotation of the activation rod). The screw can be oriented so that the head faces either forwards or backwards, reversing the movement of the transport unit in relation to the direction of rotation of the flex cable.

The inner surface of the middle segment of the plate has an undercut (fig 2) so that a countersink, or a lip, in the transport unit (fig 5) fits into it for stabilization during the transport process. As soft tissues will be covering the device throughout the procedure, the leading edge of the movable transport unit is sloping (4b) to dissect through the tissues covering the plate and to minimize resistance to the movement of the transport unit beneath them. The thread of the screw is cut at its foremost end to be able to cut through any soft tissue growth that may be covering the serrations on the rail.
The transport unit is composed of two halves attached at the middle (4f) either by two connecting 1mm screws, or by interlocking snap segments (not shown). The plate is secured to the bony stumps on either sides of the bone gap by 3 to 4 titanium 2.3-2.7 mm screws (1) that are inserted bicortically, while the movable unit is secured to the transport bone segment (transport disc) through two, at least 3 hole-each, titanium miniplates (5) that hold 1.7 mm titanium miniscrews. The holes in the miniplates are arranged in an alternating fashion forming a small sheet with at least three holes on each side of the transport unit.

One of the devices is curved. The curved device may be used when the bone gap involves the anterior portion of the mandible or when the bone gap involves the vertical ramus of the mandible. One device may contain both a horizontal and a vertical curve. One device is customized to the exact dimensions of the patient’s original mandible. A model of the mandible can be synthesized by a milling machine based on reconstructed serial radiographic images of the mandible.

The following examples are provided in order to demonstrate and further illustrate certain preferred embodiments and aspects of the present invention and are not to be construed as limiting the scope thereof.

**Example 1: Surgical procedure:**

First, the maxillo-mandibular occlusion is maintained by intermaxillary wire fixation to maintain jaw relations. The appropriate length of the transport segment should be estimated before surgery and a number of plates with different lengths should be available during surgery to choose from. The device can be fixed to the mandibular bone stumps either before or after removal of the tumour segment by three bicortical screws on each side as in traditional reconstruction plate, leaving out approximately 2cm of bone at the edge of one of the two bone
segments, classically the posterior segment, so that it can be separated and fixed to the transport unit. After tumor resection, the transport unit is fixed to the potential transport block (transport disc) through the two miniplates (5) either before or after its separation. If immediate reconstruction is planned, a bicortical osteotomy to separate the transport segment is carried out during the same surgery. However, the surgeon may decide to delay the osteotomy according to the condition.

During the delay period, the device will function as a traditional reconstruction plate: stabilizing the bone segment, maintaining the maxillo-mandibular occlusion, preventing soft tissue collapse, and preserving the facial symmetry. Due to its intra-oral design, we expect the patient will tolerate it as comfortably as the traditional reconstruction plate. Reconstruction plates could be retained for years with minimal inconvenience to the patient.

Osteotomy is a procedure that takes around 15-30 minutes to complete. If delayed, it can be done under sedation and local anesthesia on an outpatient basis, as with the subsequent daily activation of the device. The buccal cortical plate is cut using an ultra thin micro saw and the osteotomy is then completed through the lingual cortex by a sharp osteotome. Care should be taken not to exert much force on the transport unit during bone separation. It may be helpful to take out the 3 screws of the upper plate in order to have some degree of mobility in the transport segment during separation. After complete separation of the segment, at least 4 secured mini-screws in total are preferred for the stability of the transport segment. The lingual mucosa should not be dissected at any time during the procedure to maintain the blood supply of the separated bone segment. The wound is then closed so that the activation cable protrudes through the mucosa into the oral cavity when the wound is closed. After 5-7 days of latency, activation of the device is started. Distraction rate is 0.5 mm/12 hours.
Distraction is continued until the transport segment reaches the docking site. As the bone disc is transported, new bone is formed behind it to gradually fill the gap, according to the well-established principles of distraction osteogenesis. When the transport disc reaches the docking site (at the edge of the other bone segment), the device should be retained in place for a few weeks, depending on the amount of distraction, until the newly formed bone consolidates and is able to sustain chewing forces or carry implants. Bone grafting may still be needed to promote bone union at the docking site. In this case, freshening of bone edges and the addition of small pieces of cancellous bone are usually sufficient.

**Example 2: Checkpoint Osteotomy**

According to this technique, points of maximum curvature are identified on the cast model of the patient's mandible. These points are considered as checkpoints for bone transport. Gradual transport proceeds until the transport segment checks into the first checkpoint on the track. Then, distraction is stopped and the bone is left to consolidate. After consolidation, the transport segment is re-osteotomized and distraction restarts until the next checkpoint.

**Example 3: Transport Unit Against the Forces of Tissue Resistance**

This study was carried out to compare the effect of different screw lengths and orientations in bone on the stability of the transport unit and the transport bone segment during distraction. Pig mandible was chosen for this study because of the availability of several pig mandibles, and because of its adequate vertical height and the relatively short roots of teeth, providing a large area of flat bone that was used to test the bone transport unit multiple times on different areas of the bone. The bone transport unit was fixed to the cadaver pig mandible at the same anatomical orientation as it would be fixed during actual bone transport surgery. Six 1.7 mm titanium screws were used for fixation of each unit to the bone. The bone
was then mounted on a linear loading machine that applies up to 100 N of vertical load. The bone was mounted so that the vertical load was in the anticipated direction of soft tissue resistance to the movement of the unit during distraction.

Six groups were compared (3 specimens each). In the first group, the bone transport unit was stabilized on each side by three 5 mm screws vertically inserted into the bone. In the second group, the unit was stabilized by three 9 mm screws vertically inserted on each side. In the third group, the unit was stabilized by three 9 mm screws diagonally inserted on each side. In the fourth and fifth groups, 4 screws symmetrically orientated on each side of the unit stabilized the unit. For the sixth group, each side was secured with 4 screws that were orientated such that the leading edge was secured with 2 screws, the middle edge was secured with 1 screw and the trailing edge was secured with 1 screw.

The unit resisted vertical loading before failure. In the first three groups, failure happened when the screws started to be pulled out. In the fifth and sixth group, failure occurred when the plate neck was bent. Based on the preliminary data, the following modifications were made to increase stability of bone transport. The leading edge of the transport unit was modified so that it has both vertical and lateral slopes to disperse the force of soft tissue resistance (Fig. 7). The mini-plates that fix the transport unit to the transport bone segment were modified so that each has a relatively thin “stem” connecting the screw portion to the transport unit (Fig. 7). This stem serves as a stress absorber, giving more space for angular screw insertion, and enables proper contouring of the screw portion of the plate to conform to the surface of the bone. The number of screw holes was increased to 4 on each side. The shape of the screw hole portion was accordingly modified (Fig. 7). This disperses the tissue resistance force and aligns four screws, instead of two, at the leading edge of the plate to provide more stability. The optimum direction
of screw insertion was found to be when screws were angulated forwards and outwards. This direction provided the maximum resistance to extrusion force and prevented caving in of the transport unit over the plate, which can increase the frictional resistance to the advancement of the transport unit.

5 Example 4: Device Operation on a Cadaver Goat Head

On a cadaver adult goat’s head, the mandible was dissected out and split in half at the symphysis. On each half mandible, a simulation surgery was carried out. First, a bone segment was cut and removed from the middle of the mandibular body. After shaping to conform to the bone surface, the reconstruction plate was fixed to the bone stumps on either side of the gap, after which a transport bone segment was excised from the edge of the posterior mandibular stump. The transport unit of the device was then fixed to the transport bone segment. The device was then activated all along the distraction track until the transport segment reached the docking site at the edge of the anterior mandibular bone stump. The procedure was repeated for the opposite side of the mandible.

The information gained from the in-vitro testing include that: the dimensions of the device were appropriate for the goat mandible and the plates could fit the bone surface; it is feasible to create osteotomies after placement of the bone transport reconstruction plate on the bone, injuring the very long roots of goat’s molar teeth by the mini-screws can be avoided, it is possible to carry intact teeth in the transport segment without the need to extract them and rigid bone fixation can be assured.

Activation of the transport unit was smooth along the full length of the distraction track. The transport segment maintained its vertical orientation throughout the distraction process. The transport segment was excised from the posterior mandible, which has a greater vertical height
than the anterior part of the mandible. Therefore, as the transport bone segment advanced forwards, it interfered with the normal occlusion, possibly compromising the chewing ability of the goat. This motivated us to performing crown reduction of the teeth carried on the transport segment with appropriate root canal treatment to avoid unnecessary pain or discomfort to the animal. The activation rod was replaced by a flexible cable connected to the rear of the screw. The cable exits the surgical wound after closure and is activated from outside making activation easier.

Example 5: Distraction Osteogenesis in a Live Goat

The device as depicted in figure 7 has been tested in four live goats. The surgical approach started with a submandibular incision extending below the whole length of the lower border of the mandible and curving upwards at the mandibular angle to create a redundant soft tissue flap. Subcutaneous dissection was carried out to improve the mobility of the skin flap so that it provided adequate cover when the device was inserted. The periosteum was incised and raised to expose the lateral surface of the mandible. The reconstruction plate was shaped to fit the surface of the mandible and then fixed preliminarily by one screw at each end without tightening, to maintain the correct dimensions and stability of the mandible. Two bicortical osteotomies were then carried out to excise and remove a bone segment. Next, another bicortical osteotomy was done to obtain the bone transport segment. This separated the bone transport segment from the posterior mandibular bone stump. It was partly accomplished using a reciprocating saw for the buccal cortex. A sharp osteotome was used in the lingual cortex to prevent injuring the periosteum.

The transport segment was then secured to the transport unit with four, 1.7 mm, screws inserted diagonally on each side. 2.7 mm screws were then added to the reconstruction plate to
stabilize the mandibular stumps. Closure was done in layers so that the activation cable exited through the sutures.

Active distraction was started on the fourth or the sixth day after surgery (two animals each) at 1 mm/day. Distraction was continued until the transport segment reached the docking site in two animals. In the other two animals, distraction had to be stopped due to premature bone healing. Examination of the mandible of the first two animals at necropsy revealed that: all screws were stable with no extrusion; on both sides of the gap as well as the transport segment were still rigidly fixed, and a mass of hard tissue was found bridging the gap with the device embedded within it. We had to break though the mass with bone nibbling forceps to retrieve the device.

The device provides stability for the bone segments, even against the peculiar pattern of goat’s chewing movements that was expected to apply significant lateral as well as vertical stresses to the transport bone segment.

**Example 6 Increasing Rate of Osteogenesis**

The device provides stability for the bone segments, even against chewing movements applying lateral as well as vertical stresses to the transport bone segment. Because of the rigid stability of the device, decreasing the latency period (greater than 1 mm/day) avoids premature consolidation of bone (such as between 1.1 to 2.5 mm/day, preferably 1.5 mm/day) decreasing the force required to dislodge the device from newly formed bone mass and decreasing patient recovery time.
CLAIMS

We Claim:

1. A bone transport device comprising:
   a) a bone reconstruction plate comprising
      1) a middle segment having a transport track; and
      2) two ends configured for fixing at least one end of the device to a bone segment; and
   b) a transport unit configured for gliding over said transport track comprising a casing for attaching a transport bone disc to the transport unit.

2. The bone transport device of claim 1 wherein the casing has a sloping leading edge.

3. The bone transport device of Claim 1 wherein the casing is attached to the transport bone disc by a screw less that 5.1 millimeters long.

4. The bone transport device of Claim 3 wherein the casing is attached to the transport bone disc by screws less than 5.1 millimeters long that are arranged in an alternating fashion.

5. A bone transport device comprising:
   a) a bone reconstruction plate comprising
      1) a middle segment having a transport track with serrated grooves; and
2) two ends configured for fixing at least one of the ends to a bone segment; and

b) a transport unit comprising

1) a casing for attaching a transport bone disc;

2) a activation screw with threads;

wherein when the activation screw is turned the screw thread interact with the serrated grooves and

the transport unit moves along said transport track.

6. The bone transport device of claim 5, wherein the activation screw has a foremost thread and the foremost thread is sharply cut.

7. A bone transport device comprising:

a) a bone reconstruction plate comprising

1) a middle segment having a transport track with serrated grooves; and

2) two ends configured for fixing at least one of the ends to a bone segment;

b) a transport unit comprising

1) a casing for attaching a transport bone disc,

2) an activation screw with threads and a head; and

c) a flex cable

wherein when the activation screw is turned the screw thread interacts with the serrated grooves;
the transport unit moves along said transport track; and

the casing is configured so that the head of the activation screw can be
configured in forward and backward orientations reversing the movement
of the transport unit in relation to the direction of rotation of the flex cable.

8. A bone transport device comprising:

a) a bone reconstruction plate comprising

1) a middle segment having a transport track with serrated grooves; and

2) two ends configured for fixing at least one of the ends to a bone
segment; and

b) a transport unit comprising

1) a casing for attaching a transport bone disc said casing comprises two
halves;

2) an activation screw with threads

wherein when the activation screw is turned, the screw thread interact with the
serrated grooves and

the transport unit moves along said transport track.

9. The bone transport device as in claim 7 wherein the two halves are attached by a
connecting screw.

10. The bone transport device as in claim 7 wherein the two halves are attached by
interlocking segments.
11. A method comprising:

i) providing a transport bone disc, first and second bone segments, and a bone transport device comprising:

a) a bone reconstruction plate comprising

1) a middle segment having a transport track; and

2) two ends configured for fixing the device to said first and second bone segments; and

b) a transport unit comprising a casing for attaching a transport bone disc, wherein the transport unit moves along the said transport track;

ii) attaching the bone transport disk to said casing; and

iii) fixing the ends of the bone reconstruction plate to said first and second bone segments; and

iv) moving the transport unit along said transport track.

12. The method of claim 11 further comprising:

v) detaching the casing from the transport bone disc; and

vi) removing the transport unit from the transport track.

13. The method of forming mandibular bone of claim 11 wherein the bone reconstruction plate functions as a distraction device.

14. A device, consisting of a first piece and a second piece;
said first piece comprising a bone reconstruction plate comprising

1) a middle segment having a transport track; and

2) two ends configured for fixing the device to bone segments; and

said second piece comprising a transport unit configured for gliding over

said transport track, said transport unit comprising a casing for attaching a

transport bone disc.

15. A system comprising: first and second bone segments and a bone transport device comprising:

10  a) a bone reconstruction plate comprising

1) a middle segment having a transport track; and

2) a first end fixed to said first mandibular bone segment and a second end

fixed to said second mandibular bone segment; and

b) a transport unit configured for gliding over said transport track, said transport

unit comprising a casing for attaching a transport bone disc.

16. A device comprising:

1) a plate configured for fixing the device to the bone;

2) a middle segment of the plate configured to overly a bone gap, and

20  3) a transport bone disc connected to a transport unit wherein the transport unit is

configured to move along an outer surface of said plate.

17. A method comprising:
a) providing:
   i) an animal comprising of a bone and skin and
   ii) a device comprising:
       1) a plate configured for fixing the device to the bone;
       2) a middle segment of the plate configured to overly a bone gap;
       and
       3) a transport bone disc connected to a transport unit wherein the
          transport unit is configured to move along an outer surface of said
          plate;
   b) inserting the said plate under the skin of the animal; and
   c) fixing the device to said bone.

18. The method of claim 17 further comprising the steps of:
   d) detecting the size of a bone in said animal, and
   e) configuring said plate to grown bone of a desired dimension.