Endosseous alveolar distractor (LEAD™) in the management of residual alveolar ridge resorption

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Abstract

Background Lack of sufficient alveolar bone height or width is one of the most frequent problems in the dental rehabilitation of the edentulous patient.

Methods A prospective study to evaluate the efficacy of an endosseous alveolar distractor (LEAD™) in managing residual alveolar ridge resorption was carried out. The complications related to the surgical procedure and the quantitative changes in the regenerate over a 6 month period following distraction were studied in 13 cases with alveolar ridge atrophy.

Result Desired ridge augmentation was achieved in 11 cases. In 2 cases the distraction failed. Some unusual complications were encountered.

Conclusion The LEAD™ alveolar distractor produces consistent augmentation of the alveolar bone but is confronted with stability issues.

Keywords Distraction osteogenesis · Alveolar augmentation · LEAD™

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Introduction

The alveolar ridge is entirely dependent on the teeth to maintain its functional morphology. Teeth may be lost as a result of periodontal disease, or may be extracted due to other causes. Causes of alveolar bone loss include periodontal disease and other pathological processes, trauma, tumour resections and congenital deformities. Strategies for facilitating prosthetic rehabilitation in atrophic alveolar ridges include

- Alteration of the soft tissue attachments in relation to the alveolar ridge
- Increasing the height of the residual ridge

Soft tissue procedures that were popular are vestibuloplasty [1] and the lip switch [2] with their modifications. Augmentation of the ridge height facilitates the placement of longer implants. Techniques currently available are autologous bone grafts [3,4], reconstruction using biomaterials, augmentation of the floor of the maxillary sinus [5], dental nerve transposition [6], guided bone regeneration [7] and procedures such as the visor osteotomy [8].

Distraction osteogenesis is form of tissue engineering that induces new bone formation by the gradual stretching of the reparative callus that forms around bone segments interrupted by osteotomy or fracture. This stretching process is gradual, allowing maintenance of blood flow [9]. The bone regeneration involves two processes: osteogenesis – callus formation and generation of new bone; and histiogenesis – inducing soft tissue growth, i.e. mucoperiosteum, nerves and blood vessels [10,11].

Distraction osteogenesis has also become an established technique for alveolar ridge augmentation. The technique involves mobilization of a healthy bone segment (the transport segment) from the basal bone, but retaining attachment via the lingual mucoperiosteum. A mechanical device, the alveolar distraction device, is used for gradual, controlled transport of a mobilised alveolar segment. When the desired repositioning of the bone segment is achieved, the distraction device is left in a static mode to act as a fixation device.

Materials and method

This prospective clinical study was carried out at the Oral and Maxillofacial Surgery division of the Department of Dental Surgery, Armed Forces Medical College, Pune between January 2005 to December 2006; to evaluate the efficacy of an endosseous alveolar distractor (LEAD™) in the augmentation of the atrophic alveolar ridge. The quantitative change in the regenerated alveolar bone was studied using orthopantomographs over a period of 6 months following distraction. Procedural complications were recorded during the period.

Study population

Partially or completely edentulous patients, who were considered unsuitable for prosthetic dental rehabilitation on account of poor residual ridge form, were selected for treatment (Fig. 1).

Those patients with a minimum edentulous span of 8 mm were included while; those with medical compromise,

known history of metal allergy, tobacco habits, flabby or scarred tissue overlying the residual ridge and local factors such as poor periodontal condition were excluded. A total of 13 patients were selected. This included 6 males and 7 females aged between 30 to 62 years. 10 cases were partially edentulous and 3 cases were fully edentulous. The atrophic ridge was located in the mandible in 9 cases and the maxilla in 4 cases. Intraoral Periapical (IOPA) radiographs of edentulous segments and Orthopantomogram (OPG) were taken for each patient to determine vertical height of alveolar bone, distance between the alveolar crest and superior aspect of the inferior alveolar canal, the position of teeth and the inclination of their root apices.

The amount of distraction required, was determined utilising tracings made on the OPG (Fig. 2). The desired alveolar augmentation was given by the distance between the deepest part of the edentulous alveolar crest and the height of the adjacent interdental bone on both sides of the edentulous span. In case of completely edentulous cases, augmentation to a height that would permit placement of dental implants was considered the baseline for augmentation. This was measured from the inferior mandibular border to the alveolar crest between the mental foramina. Posterior to the mental foramen the distance from the inferior alveolar canal to the crest was used.

The distraction device

The LEAD™ system is an intraoral, endosseous distraction system typically used prior to the placement of endosseous dental implants. The distraction device has three components – a threaded distraction rod, a transport plate and a base plate.

The threaded distraction rod has a hexagonal head and a threaded shaft ending in an unthreaded tip. When rotated, the threaded Transport Plate travels along the lead screw, resulting in vertical movement of the transport bone segment attached to this plate (Fig. 3).

The transport plate is essentially a three holes plate one of which is threaded to receive the distraction rod (Fig. 4).

The base plate is very similar to the transport plate except that it does not have a threaded hole (Fig. 4). It receives the apical end of the lead screw and acts as a bushing to prevent intrusion of the screw into the bone as it is activated.

The device is activated by turning the threaded rod with the Ratchet/Adapter assembly.

Surgical procedure

After clinical evaluation alveolar ridge augmentation was carried out in all patients using the LEAD™ system. 11 cases were done under local anaesthesia. 2 cases were carried out under GA.

Mucoperiosteal flap was elevated through a horizontal incision placed on the outer aspect of the alveolar ridge spanning the length of the edentulous area to be augmented, to expose the labial cortex. The dissection avoided elevation of the flap at the crest of the ridge, especially near the periodontal attachment of the adjacent teeth (Fig. 5).

A micro-sagittal saw was used to establish vertical osteotomies through both the labial and lingual cortices 1mm clear of the adjacent roots from the alveolar crest downwards 1cm towards the basal bone. A third horizontal osteotomy was then placed apically, joining the vertical osteotomies and outlining the transport segment.

Before mobilization of the transport segment, a 2mm pilot hole was drilled through the osteotomised segment for placement of the lead screw. The drill was passed through the crestal stab incision in the mucosa without reflection of a flap. Final release of the segment was carried out by wedging an osteotome into the horizontal osteotomy.

The transport plate was then introduced between the transport segment and the basal bone through the horizontal osteotomy. The distraction rod was turned through the threaded hole on the transport plate. Once engaged to the transport plate, the distal tip of the threaded rod was placed through one of the holes on the base plate.

Both plates were bent through 90° - the transport plate occlusally and the base plate apically; and attached to the buccal or labial aspect of the bone using 1.2 mm screws (Fig. 6). The distractor was activated through a couple of turns to verify its unimpeded action. Once the movement was found to be satisfactory the distractor was deactivated and the mucoperiosteal flap sutured back in place using interrupted 4-0 black braided silk sutures.

Distraction protocol

The distraction protocol involved latency period of 7 days followed by activation of

the device at a rate of 1mm per day in two instalments. After completion of bone transport, the lead screw was left in place for 1 month after which it was removed by rotating in the counter clockwise direction (Fig. 7). The transport and stabilizing plates were removed 10–16 weeks later at the time of implant placement.

Postoperative assessment

Postoperative orthopantomograms were taken during the latency period to verify the distractor position and then at 4 weeks and 6 months after distraction to quantify the degree of ossification of the regenerate (Fig. 8). The radiographic analysis consisted of obtaining the amount of the Vertical Bone Gain (VBG) in each radiograph. The magnification factor of each panoramic radiograph was accounted for.

Results

The aetiology of the alveolar deficiency was trauma in 3 cases, post-extraction in 4 cases and periodontal disease in 6 cases. The procedure was carried out in the anterior region in 10 cases and, in the posterior region in 3 cases. The average distraction required per case was 8.5 mm (7 to 14 mm). The average span of the distracted bone was 21.3 mm with a range of 9–54 mm.

In 12 cases a single device was used and in 1 case with an edentulous mandible 2 distractors were placed after creating a long span transport segment extending just beyond the mental foramen on either side. In the other 2 fully edentulous cases distraction was carried out in the anterior segment alone.

11 cases had satisfactory clinical outcome with improved ridge height. Radiographic evidence of new bone formation was evident at the end of 8 weeks in 8 cases and at 3 months in 3 cases.

Two cases (15.4%) had undesirable outcomes. In one patient sequestration of the transport segment occurred during the consolidation phase. This left him with inadequate bone for creating a fresh osteotomy for distraction. In the other patient the transport plate fractured on the third day of distraction.

In two patients the distraction rod came loose within 3 days of placement of the device. Both cases required repositioning of the device as a second procedure under local anaesthesia.

Fig. 1 Preoperative photograph of a 31-year-old patient with teeth loss secondary to periodontal disease

Fig. 2 Preoperative assessment on a panoramic radiograph to assess the approximate bone augmentation required. The outlines of the atrophic alveolar ridge and adjoining teeth are traced. The mid-sagittal reference line is constructed and the ideal position of the alveolar crest is drawn. The distance between the ideal crestal position and the actual position measured parallel to the MSR gives the approximate augmentation required

Fig. 3 The distraction rods 17.5 mm and 31.5 mm

Fig. 4 The base plate (top) and the transport plate: note that one hole of the transport plate is threaded to receive the distraction rod

Fig. 5 The transport segment osteotomised but not mobilised. The attachment of the crestal mucoperiosteum has not been violated

Fig. 6 The distraction device after fixation. The apical end of the distractor sits passively in one of the holes of the base plate

Fig. 7 The distraction rod removed at the end of the consolidation phase

Fig. 8 Post distraction radiographic OPG to determine the vertical bone gain

In one patient taken up for distraction of the anterior mandibular alveolus, the transport segment with the attached distraction rod was displaced lingually and apically under the influence of the genial muscles during his recovery from general anaesthesia. Repositioning of the transport segment and stabilisation using an acrylic splint in the form of a lingual plate was carried out under local anaesthesia 5 days later. After 7 days the splint was removed and distraction carried out without further problems.

In distraction of the anterior mandibular segment the depth of the lingual sulcus did not improve in any of the cases. There were no instances of loss of vitality of adjacent teeth, premature consolidation or acute infection in relation to the device.

Discussion

In all subjects of our study the clinical parameters of the edentulous alveolar bone span and degree of atrophy matched other similar studies. Hon-Lay Wang and Khalaf AI-Shammari gave a therapeutically oriented classification for ridge deficiency, known as HVC [Horizontal Vertical and Combination] classification based on type of deficiency of alveolar ridge. Vertical defects of medium (4–6mm) and large size (>7mm) were indicated for ridge augmentation by alveolar distraction [12]. All patients had large vertical defects according to the HVC classification.

Widest clinical studies have been performed on 3 alveolar distractor designs:

TRACK extra-bone distractors [13,14], LEAD intra-bone distractor [15], and DISSIS implant-distractor [16]. The ultimate aim of alveolar distraction is the restoration of anatomical and functional form for prosthodontic rehabilitation. In our study the anatomical objective was not achieved after the distraction process alone in 5 cases. 3 cases required additional alveoloplasty to round off knife-edge bony alveolar ridges. Repositioning of the lingual muscular attachments was carried out in two fully edentulous cases for deepening the lingual vestibule.

The surgical technique and distraction protocol followed in our study is in line with existing protocol on alveolar distraction. Jorge Cano et al. have reviewed

Table 1 Clinical parameters and vertical bone gain achieved in individual cases

Sl. No.	Age (Years)	Sex	Region	Aetiology	Edentulous span considered for distraction (mm)	Distraction (mm)		Follow-up months
						Required	Achieved	
1.	62	Female	Mandible anterior	Post extraction	33	8	7	14
2.	32	Female	Mandible anterior	Periodontal disease	13	7	7	13
3.	21	Male	Maxilla anterior	Trauma	9	7	6	12
4.	53	Male	Mandible anterior	Trauma	26	10	10	7
5.	57	Female	Mandible posterior	Post extraction	12	8	0	7
6.	42	Female	Mandible anterior	Post extraction	54	8	7	6
7.	57	Male	Mandible anterior	Trauma	35	14	12	6
8.	35	Female	Maxilla anterior	Periodontal disease	11	7	6	7
9.	50	Male	Mandible posterior	Post extraction	13	7	0	6
10.	33	Female	Maxilla anterior	Periodontal disease	14	7	6	8
11.	59	Male	Mandible posterior	Periodontal disease	12	8	6	9
12.	46	Male	Mandible anterior	Periodontal disease	24	9	9	10
13.	52	Female	Maxilla anterior	Periodontal disease	21	10	9	8

the literature on various alveolar distraction procedures and elucidated their indications, applications, procedures and limitations [17].

Suhr MA et al. studied technical considerations in distraction osteogenesis and described immediate early and late complications [18]. Complications that may arise during alveolar distraction have been classified by García AG et al. into three groups:

1. Problems arising during surgery, generally related to osteotomy and distractor placement
2. Complications arising during distraction, including incorrect direction of distraction and soft-tissue complications
3. Complications arising after distraction, due to defective bone formation.

Uckan et al. reported bleeding in cases of deep osteotomy, and pain and significant resorption of the distracted fragment in distractions of more than 10 mm. Klug et al. [19] Gaggl et al. [16] and Nocini et al. have described other complications, including dysesthesia of the mental nerve and mandibular fracture [20]. The complications noted in this study included sequestration of the transport segment, fracture of the transport plate and inadequate stability of the device particularly in the mandibular anterior region. This problem occurred consistently in all cases where distraction was carried out in the mandibular anterior region. There was

excess mobility of the distraction rod in the immediate postoperative phase. This reduced on initiating the distraction. Rachmiel et al. [15] have also, in a study that carried out alveolar ridge augmentation on 14 patients using the LEAD™ device, suggested some relative instability in the device.

Radiographic evidence of new bone formation (end of 4 weeks in 3 cases and at 6 months in all) in our series is consistent with other studies [21].

The limitation of this study is the small size of the study population hence statistically significant results cannot be derived in terms of complication rates and other study parameters. However it does lend itself for meta-analysis by virtue of the standardised protocol used.

Conclusion

The endosseous system, accomplishes the desired magnitude of distraction. We however faced certain problems during the distraction process. These included:

1. The distraction vector being influenced by the soft tissue attachments particularly mandibular anterior region
2. The device was not being stable enough during the latency period to prevent dislodgement in three cases
3. No significant change in the lingual vestibular depth as the soft tissue attachments were also transported along with the transport segment

4. The need for secondary procedures like alveoloplasty obtaining the ideal ridge form

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