

# Does Guided Bone Regeneration Prevent Unfavorable Bone Shapes in Distraction Gap?



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**Purpose:** Complications related to distraction osteogenesis can cause degradation of newly regenerated bone. Additionally, an unfavorable shape of the regenerated bone at the distraction gap can reduce the quantity of regenerated bone. The aim of the present study was to report on the prevention of unfavorable shapes of regenerated bone using guided bone regeneration during distraction.

**Materials and Methods:** Bilateral alveolar distraction was performed in 10 beagle dog mandibles. One side of the mandible formed the experimental group and the other side served as the control group. In the experimental group, guided bone regeneration was performed simultaneously with distraction osteogenesis. In the control group, only alveolar distraction was applied. At the end of a 1-week latent period, all mandibles were distracted 10 mm (1 mm/day). After the distraction period, 3 months were allowed for consolidation. After consolidation, all the dogs were euthanized, and the shape of the regenerated bone was determined to be either favorable or unfavorable. Densitometric evaluation and area measurements were performed using computed tomography scans. Statistical evaluation was performed using the independent *t* test, with a significance level of  $P < .05$ .

**Results:** In the experimental group, no unfavorable bone shape developed in the distraction gap, and the new bone had a surface and volume similar to those of the segments. In contrast, in the control group, 4 mandibles had an unfavorable bone shape in the distraction gap and 4 showed favorable bone healing with no defect. The surface area of the regenerating bone in the experimental group was significantly greater than that in the control group. Also, the surface area differed significantly between the experimental and control groups ( $P < .05$ ). However, the densitometric values did not differ between the 2 groups ( $P < .05$ ).

**Conclusions:** Concomitant use of guided bone regeneration with distraction osteogenesis could be an optimal method for generating a favorable bone shape within the distraction gap.

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Currently, the surgical repair of deformities and defects in the maxillofacial region involves osteotomy procedures, free or pedicled bone grafts, and the use of allogenic and alloplastic materials. The principal

goal of these procedures is to achieve good function and esthetics. Distraction osteogenesis has been performed in maxillofacial surgery since 1992.<sup>1</sup> Since its first description by McCarthy et al,<sup>1</sup> it has been used

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increasingly, especially for the treatment of severe upper and lower jaw retrusion, mid-face advancement, augmentation of the vertical or horizontal size of the alveolar bone, treatment of cleft palate, reconstruction of the temporomandibular joint, and many other conditions.<sup>2,3</sup>

Nevertheless, some difficulties have been encountered during application of the distraction procedure. One problem encountered with distraction osteogenesis is an unfavorable bone shape in the distraction area, which occurs because the new bone generating in this area during and after distraction will not match the distraction segments exactly in terms of surface and volume. A few related studies have shown that this problem can arise from soft tissue invasion of the distraction gap or disruption of the integrity of the periosteum.

Chiapasco et al<sup>4</sup> observed this unfavorable bone shape in the distraction gap in patients undergoing alveolar distraction and reported that it occurred because of the advancement of the surrounding connective tissue toward the distraction gap, which resulted in decreased bone volume. Especially in implant applications, the inability to obtain a sufficient amount of bone will necessitate the use of autogenic or allogenic bone grafts in a second operation, leading to additional donor area morbidity and costs.

The aim of the present study was to determine whether resorption in the distraction gap after distraction could be prevented by performing guided bone regeneration (GBR) concurrently with distraction to achieve a favorable bone shape. We hypothesized that the application of covering membranes to the distraction gap would prevent fibroblast entry, thereby allowing only the accumulation of cells of osteogenic origin in the osteotomy area. The specific aims of the present study were to compare the bone density and measure the regenerated bone area of the distracted bone.

## Materials and Methods

The Erciyes University animal experiments local ethics committee approved the present experimental study.

### STUDY DESIGN

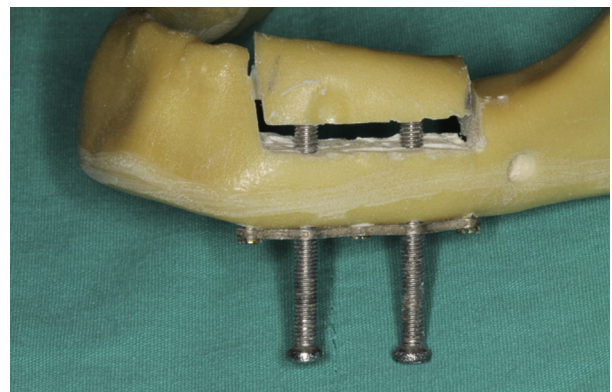
Ten adult male beagles of the same breed found to be healthy by veterinary examination were used in the present study. Their body weight ranged from 35 to 40 kg. Three months before distraction, 3 mandibular premolars were extracted bilaterally with the dogs under general anesthesia to prepare edentulous spaces for the distraction procedure. At 3 months after extraction, on 1 side of the lower jaw, alveolar distraction was performed, together with barrier membrane

application to cover the distraction gap. The specimens from this side constituted the experimental group (n = 10). On the other side of the lower jaw, the alveolar distraction procedure was performed alone. These specimens constituted the control group (n = 10). For distraction osteogenesis, we used a custom-made distractor (Fig 1).

All aspects of the procedure were performed in accordance with asepsis and antisepsis rules. Anesthesia was provided for all the dogs with ketamine hydrochloride (Ketalar, Eczacıbaşı, Turkey) at a dose of 10 mg/kg and xylazine (Rompun, Bayer, Germany) at a dose of 10 mg/kg, administered via intramuscular injection.

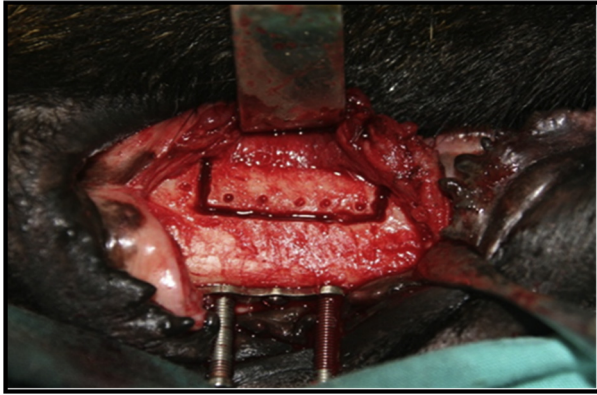
In the lower jaws of the dogs, the hair in the area where the distractor rods would come out was shaved. The operation area was cleaned using povidone iodine (Batticon, Adeka, Turkey). The operation began with creation of a 5-cm horizontal intraoral incision in the deepest area of the vestibule sulcus, from the level of the first molar. A mucoperiosteal flap was elevated toward the crest apex, preserving periosteal integrity. After identification of the accessory mental foramen in the anterior region, the vessel nerve package was cut by cauterization. After exposure of the distraction area, a vertical bone incision was made just anterior to the first molar using a thin fissure drill; however, the segment was not freed.

A segment to be distracted (thickness, 10 mm; length, 22 to 23 mm) was prepared, and distractors were placed (Fig 2). The custom-made distractors consisted of 2 rods (length, 35 mm; width, 3 mm), 3 miniscrews, and 1 miniplate with 5 holes (2 for the rods and 3 for the miniscrews). The rods were supported by the miniplate for segment elevation. First, the miniplate was fixed to the base of the mandible with the 3 miniscrews. Next, the basal segment was drilled for insertion of the rods and a transport segment (3-mm



**FIGURE 1.** Custom-made distractor, consisting of 2 rods, 1 miniplate, and 3 miniscrews to fix the miniplate.

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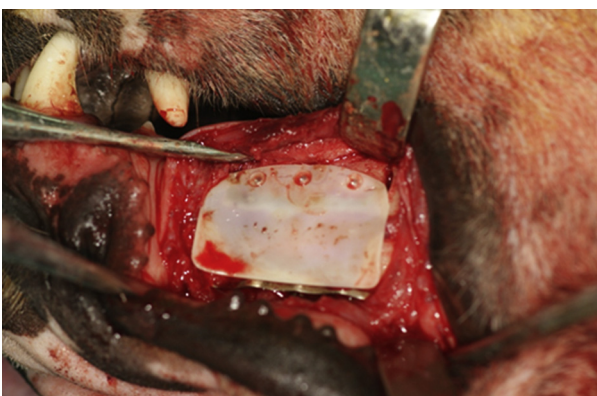
**FIGURE 2.** View after segment preparation and distractor placement on the mandible.

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length). After drilling, the rods were placed toward the basal and transport segments. The rod tips were placed extraorally through two 5-mm skin incisions. The transport segment was freed after distractor placement, the distractors were activated, and their function was checked.

Resorbable membranes of synthetic trimethylene l-lactide polyglycolide carbonate (Inion Ltd, Tampere, Finland) were placed to completely cover the segmented osteotomy area and extending to the base of the mandible. They were fixed to the transport segment with resorbable pins (Fig 3). The membrane was not fixed to the basal segment so that it could move with the transport segment.

In the control group, the distraction procedure was performed without application of the membrane. The incision site inside the mouth was closed by suturing the submucosa with 3-0 Vicryl and the mucosa with 3-0 silk suture.



**FIGURE 3.** Resorbable membrane fixed to the segment at the vestibule side. It slides with the segment during the distraction procedure.

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Postoperatively, the dogs were administered a prophylactic antibiotic (amoxicillin clavulanate, 20 kg/1 g; Synulox; Pfizer, San Diego, CA) and analgesics (meloxicam, 10 kg/0.4 g; Maxicam Bavet İlaç San, İstanbul, Turkey) for 7 days. The wound sites were irrigated with povidone iodine for 1 week.

After a 7-day latent period, 1-mm daily distraction was applied for 10 days. During the distraction period, no problem was encountered regarding activation of the distractors. The distracted alveolar segment was observed to advance inside the mouth in all 10 dogs.

After completion of distraction, 3 months were allowed to pass for consolidation. After this phase, the dogs were euthanized using high-dose intravenous sodium pentobarbital injection.

### STUDY VARIABLES

In the present study, the 2 predictor variables were the experimental and control groups. GBR was performed simultaneously with the distraction procedure to avoid unfavorable bone shapes and to prevent bone resorption at the distraction gap in the experimental group. In the control group, the distraction procedure was performed without GBR. The primary outcome variable was the shape of the regenerated bone, which was evaluated as favorable or unfavorable. A favorable shape was deemed to be flat regenerated bone, with no concave bone defect at the distraction gap. An unfavorable shape was deemed to be thin regenerated bone, with a concave bone defect in the distraction gap. Area measurements and densitometric values of the regenerated bone in the experimental and control groups were the other outcome variables.

### DATA COLLECTION

The obtained mandible specimens were scanned using computed tomography (CT), and densitometric and area measurements were performed using coronal sections. After placing the mandibles inside the CT device (QR SRL Co, Verona, Italy), pilot images were obtained. Using these pilot images, the areas that had been subjected to distraction in the mandible were identified, and 1-mm-thick continuous coronal sections were obtained of these areas. These sections were then transferred to the Mimics imaging program (Materialise, Leuven, Belgium). From the center of each distracted segment, 5 sections at 2-mm intervals were obtained. On these images, the borders of the callus areas were drawn and determined, and the surface area and density of these areas were calculated. The shape of the regenerated bone was assessed macroscopically and on the CT scans.

## HISTOLOGIC EXAMINATION

The specimens were fixed in 10% neutral-buffered formaldehyde, decalcified in 10% formic acid, and embedded in Paraplast (McCormick Scientific, St Louis, MO). The specimens were cut in the sagittal plane with a microtome set at 8  $\mu$ m. All the sections were prepared for microscopic examination with hematoxylin and eosin and Masson's trichrome staining.

## STATISTICAL ANALYSIS

The data obtained from the groups with and without membrane application were analyzed using SPSS software, version 10.0.1 for Windows (SPSS Inc, Chicago, IL). The statistical analyses began with evaluation of the distribution properties. To compare the groups, because the number of specimens in each group was less than 30, the Shapiro-Wilk test was used to evaluate the data distribution. This test showed that both the area ( $P = .086$ ) and the density ( $P = .841$ ) measurement data had a normal distribution. Because the data were distributed normally, the area and density measurements were compared between the 2 groups with and without membrane application using independent  $t$  tests. The level of statistical significance was set at  $P < .05$ . To calculate the method error in the measurements, the measurements were repeated in 8 randomly selected specimens by the same researcher, and the intermeasurement reliability coefficient was calculated.

## Results

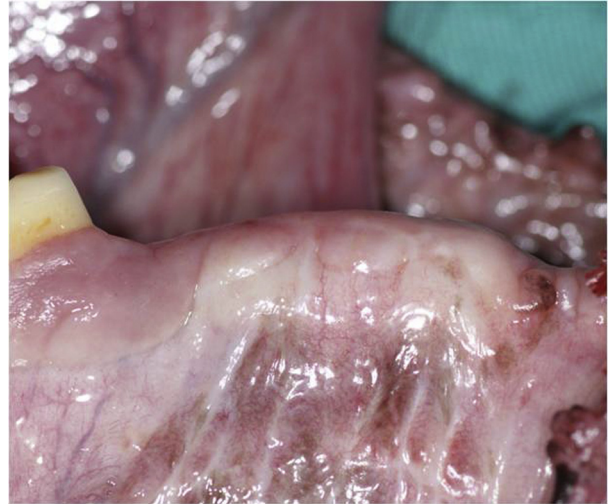
### CLINICAL FINDINGS

One dog died during the operation, likely of a complication from the general anesthesia. One dog developed infections in both alveolar distraction areas during the consolidation phase. These infections were treated and controlled after intense antibiotic treatment (amoxicillin clavulanate, Synulox; 20 kg/1 g; Pfizer), and local wound care was applied daily for 10 days. These dogs were excluded from the study, leaving 8 specimens for each group for analysis.

The dogs were weighed regularly, and no significant weight loss was observed. No problem was encountered during activation of the distraction apparatus. No signs of infection around the distractor screws were observed. None of the dogs showed segment or membrane exposure inside the mouth. The distracted segments were observed to rise markedly inside the mouth (Fig 4).

### MACROSCOPIC FINDINGS

New bone formation was observed within the distraction gap in the experimental and control groups. In the experimental group, no unfavorable bone shape was



**FIGURE 4.** Distracted segments were observed to rise markedly inside the mouth.

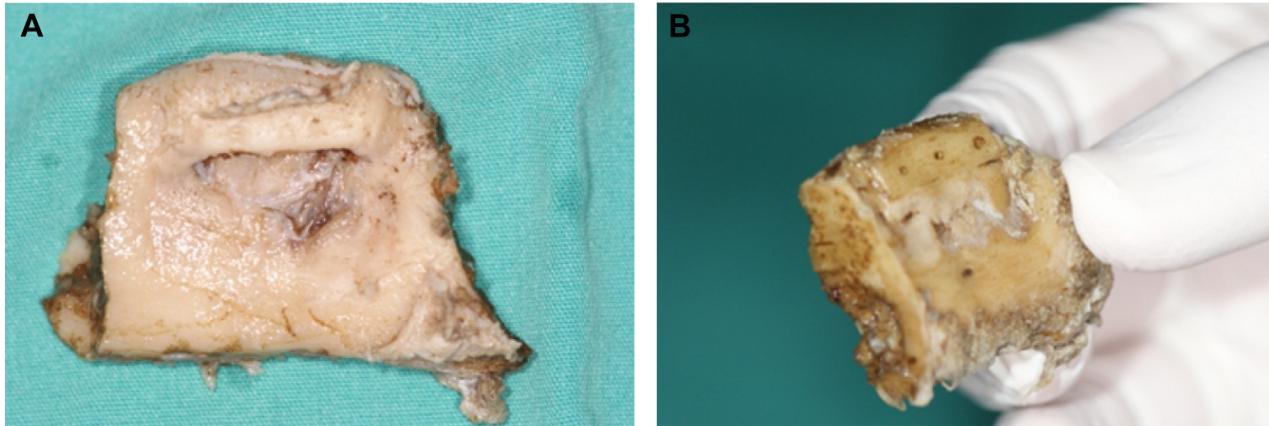
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observed in the distraction gap, and the new bone had a surface and volume similar to that of the segments. In the control group, 4 specimens had an unfavorable bone shape in the distraction gap and 4 had a favorable bone shape with no defect (Fig 5).

### RADIOLOGIC FINDINGS

The distraction gap could be observed in all the dogs. The borders of the new bone that had formed with the distraction procedure were identified, and densitometric and area measurements were performed (Fig 6). The favorable and unfavorable shapes of the regenerated bone in the control group and the smooth surfaces in the experimental group could be detected on the CT scans (Fig 7).

The callus area and density values determined from the CT sections obtained after the 3-month consolidation period were analyzed statistically. The callus area and density data were distributed normally, as determined by the Shapiro-Wilk test ( $P > .05$ ). The callus area and density values were compared between the groups with and without membrane application using variance analysis. The mean callus area was 68.75 mm<sup>2</sup> in the control group and 78.813 mm<sup>2</sup> in the experimental group. The surface area differed significantly between the experimental and control groups ( $P < .05$ ; Table 1). Specifically, it was greater in the experimental group, in which the membrane had been used. The mean density of the callus area was 1289.375 Hounsfield units in the control group and 1383.563 Hounsfield units in the experimental group. Statistical analysis showed no differences between the groups in the radiodensitometric measurements ( $P < .05$ ; Table 2).



**FIGURE 5.** A, The control group showed concave bone defect formation in the distraction gap. B, The experimental group showed bone healing with no defect.

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**HISTOLOGIC FINDINGS**

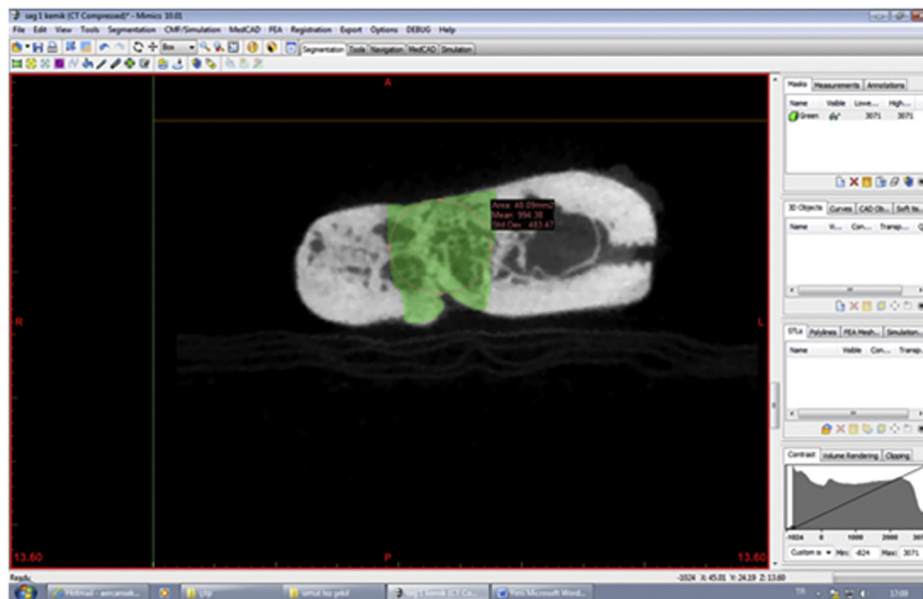
Examination of the specimens after the 3-month consolidation period showed that in both groups (with and without membrane application), cortical and spongy bone formation was almost complete in the distraction areas and calcification was continuing in the newly formed bone tissue. Osteon structures, indicators of mature bone, were observed in specimens from both groups.

**Discussion**

The purpose of the present study was to report on the prevention of unfavorable bone shapes in the distraction gap using GBR during distraction. The

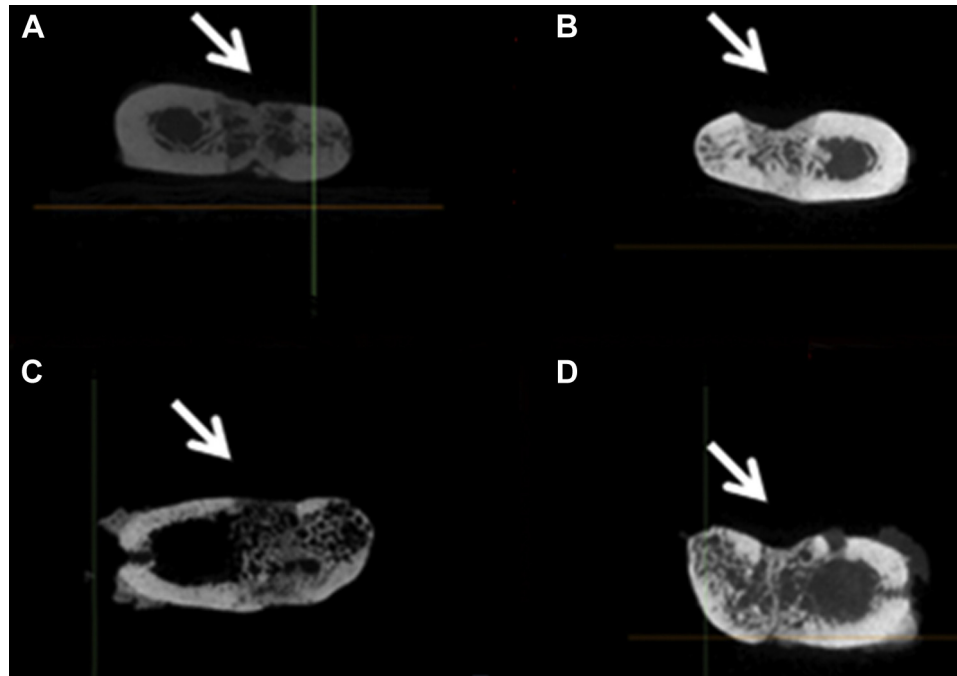
application of covering membranes to the distraction gap prevented fibroblast entry, thereby allowing only the accumulation of cells of osteogenic origin in the osteotomy area. The specific aim of the present study was to compare the density and area of the regenerated bone. New bone formation was observed within the distraction gap in the experimental and control groups. In the experimental group, no unfavorable bone shapes developed in the distraction gap. However, thinner and more unfavorable bone shapes were detected in the control group.

The distraction areas were significantly larger in the experimental group than in the control group; however, the bone density did not differ between the 2 groups. A membrane was applied to the distraction



**FIGURE 6.** Borders of the new bone that was formed with the distraction procedure were identified, and densitometric and area measurements were performed.

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**FIGURE 7.** Computed tomography images of mandibles in the *A,B*, experimental and *C,D*, control groups. Arrows show defect areas and nondefect areas of regenerated bone.

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area to prevent the surrounding connective tissue from invading this area in the experimental group. We observed no unfavorable bone shapes in the specimens in which the membranes had been applied, indicating that membrane application prevented such invasion. Additionally, the application of a membrane to the buccal surface of the distraction gap prevented the supply of nourishment from the vestibule periosteum to the newly formed bone. However, the study results showed no differences between the experimental and control groups in new bone formation, lamellar structure, or density measurements obtained from CT images. These results indicate that the

increased metabolic requirement within the distraction gap can be supplied adequately from the endosteal bone and lingual periosteum.

An unfavorable bone shape in the distraction area occurs from the inability of the new bone developing in the distraction gap to follow the distraction segments with the same surface and volume, during or after the distraction procedure.<sup>5-8</sup>

This unfavorable shape results in unwanted problems during the application of tooth implants, such as fenestration or dehiscence. These problems necessitate repair of the defect area using autogenic or allogenic grafts before implant application, which, in turn,

**Table 1. STATISTICAL RESULTS FOR DENSITY MEASUREMENTS FROM EXPERIMENTAL AND CONTROL GROUPS**

| Group        | Specimens (n) | Density Measurement |         |         |
|--------------|---------------|---------------------|---------|---------|
|              |               | Mean                | SD      | SEM     |
| Experimental | 8             | 1383.563            | 315.182 | 111.434 |
| Control      | 8             | 1289.375            | 348.549 | 123.231 |

Differences were not statistically significant at  $P = .58$  ( $P < .05$ ).

Abbreviations: SD, standard deviation; SEM, standard error of the mean.

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**Table 2. STATISTICAL RESULTS FOR AREA MEASUREMENTS FROM EXPERIMENTAL AND CONTROL GROUPS**

| Group        | Specimens (n) | Area Measurement |       |       |
|--------------|---------------|------------------|-------|-------|
|              |               | Mean             | SD    | SEM   |
| Experimental | 8             | 78.813           | 7.597 | 2.686 |
| Control      | 8             | 68.75            | 7.407 | 2.619 |

Differences were not statistically significant at  $P = .018$  ( $P < .05$ ).

Abbreviations: SD, standard deviation; SEM, standard error of the mean.

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results in increased morbidity and costs and further prolongation of the treatment duration. A limited number of studies of the treatment or prevention of bone defects occurring in the distraction area has been reported. For treatment of these defects, most investigators have recommended bone grafting in the defect area after the distraction procedure or concurrent treatment with GBR.<sup>9,10</sup>

Garcia Garcia et al<sup>9</sup> performed 17 alveolar distraction osteogenesis procedures in 12 patients and created a classification according to the morphology of the alveolar bone. In that classification, they also addressed the unfavorable bone healing occurring between segments at the vestibule surface. They reported the development of dehiscence or fenestration in implants placed in this area, caused by a concave bone surface, and recommended GBR for treatment of this condition. They noted that this type of bone healing is encountered frequently after distraction.<sup>9</sup>

In another study, Garcia Garcia et al<sup>10</sup> reported minor complications in 5 of 7 patients undergoing alveolar distraction osteogenesis. One complication, which they observed in 3 of 5 patients, was bone dehiscence or fenestration that caused exposure of the implants from the vestibule surface. In 1 of these 3 patients, the investigators attributed this bone defect to the loss of a fractured bone piece in the transport segment.<sup>10</sup> They reported that they could not determine an apparent reason for the occurrence of the other 2 defects. They treated these defects by covering them with resorbable membranes, which allowed for bone regeneration.<sup>10</sup>

Klug et al<sup>11</sup> performed vertical alveolar distraction osteogenesis in 10 patients who had an insufficient vertical bone height for implant application. Although the alveolar bone reached a sufficient height in all 10 patients, the investigators found that the distraction gap in the first 6 patients who had undergone this procedure did not have a straight bone surface at the buccal side. Instead, they had a concave surface between the segments, as previously stated.<sup>11</sup> Therefore, they covered the distraction area with a titanium membrane in the next 4 patients, which prevented the soft tissue from affecting the regenerating tissue within the distraction gap. They reported that on removal of the distraction apparatus and titanium membrane at the end of the 10-week consolidation period, they observed a straight cortical surface, rather than a concave surface, in the distraction area.<sup>11</sup>

Enislidis et al<sup>7</sup> performed alveolar distraction in 44 patients and detected defects at the vestibule surface and reduced bone volume because of these defects in 11 patients. Eight patients required additional grafting because of the defects, and no implant could be placed in 2 patients.<sup>7</sup> Unlike previous studies, the

present study focused on preventing the development of such bone defects in the distraction phase.

Investigators have associated these defects with injury to the periosteum on the buccal side of the distraction area during flap elevation and the related disturbance in nourishment of the distraction-related regenerating bone.<sup>12</sup> Block et al<sup>13</sup> reported that concave bone defects might develop because of compression of the distraction area by the surrounding connective tissue. Klug et al<sup>11</sup> stated that concave bone defects might occur when the neighboring connective tissue invades the distraction area if the periosteum at the vestibule area has been damaged during the operation.

Excessive changes in the bone and soft tissues during distraction also increase the local metabolic requirements. During distraction, blood flow is increased by 60 to 300% of normal, and this increase can continue during the consolidation period, with a flow rate 30 to 40% more than normal.<sup>14</sup> The requirement for this increased blood supply can be satisfied by the periosteum and endosteum. In the present study, the endosteum became the primary source of nourishment when no periosteum was present at the vestibule side. Several studies have shown that the effect of the periosteum on bone healing in the distraction gap is considerable. Kojimoto et al<sup>15</sup> performed a distraction procedure in the tibiae of 27 rabbits and investigated the effects of the periosteum and endosteum on bone healing in the distraction gap. For this purpose, they excised the periosteum at the osteotomy area in 1 group of rabbits, but not in the control group, and excised the endosteum at the osteotomy area in another group. They observed no marked effect on callus formation in the group in which the endosteum had been damaged. However, they observed that the callus formation was significantly disturbed in the group in which the periosteum had been excised, and bone elongation was unsuccessful in that group.<sup>15</sup> Thus, they concluded that preservation of the periosteum was essential for the success of distraction osteogenesis and reported that such preservation was more important than a carefully performed corticotomy.<sup>15</sup>

As demonstrated by these studies, the periosteum makes a significant regenerative contribution in distraction osteogenesis. However, it is not possible to perform the operation without traumatizing the periosteum in the vestibule area. Thus, the damaged periosteum will not always be able to protect the distraction gap adequately. In the present study, the membrane placed on the distraction gap functioned to physically protect the distraction area from surrounding soft tissue invasion and compression. Application of the membrane between the distraction area and the periosteum also prevented nourishment of

the callus in the distraction gap from the periosteum at the vestibule side. Thus, although new bone formation was not affected in the experimental group by membrane application, development of unfavorable bone healing was prevented. This also indicates that the vascular and, thus, blood element, supply originating from the endosteal bone and lingual periosteum can compensate for the lack of vestibular periosteum.

Application of a membrane for GBR will increase the cost of the procedure. In addition, manipulation and fixation of a membrane can require extra time during the operation and complicate the procedure. Moreover, the membrane type is important. The membrane used in the present study was a polylactic/polyglactin membrane, which became inflexible after the operation. Thus, poor adaptation of such a membrane will increase the exposure risk. However, GBR provided a favorable bone shape at the distraction gap, avoiding the need for any additional bone augmentation procedure after distraction, thereby decreasing the treatment time and cost and preventing the need for a second surgery for bone augmentation.

In conclusion, the results of the present study are significant because they demonstrate that the inappropriate healing that can occur after distraction can be prevented by the use of covering membranes. These results also show that the lack of periosteum can be compensated for by the endosteal bone when GBR is used during distraction osteogenesis.

Nonetheless, it would be a mistake to conclude from these results that the periosteum has no benefit in the distraction procedure. If GBR is not used during the procedure, it is very important to maintain the integrity of the periosteum because it can function as a natural covering membrane. In the future, to improve this procedure, alveolar distractors could be produced that contain membranes in their bodies, which might increase the ease of the procedure and decrease the incidence of related complications.

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