Internal Distraction Osteogenesis With a Unidirectional Device for Reconstruction of Mandibular Segmental Defects

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Purpose: To present the authors' clinical experience with unidirectional internal distraction devices to reconstruct mandibular defects.

Patients and Methods: Five patients have been treated with mandibular distraction osteogenesis to reconstruct different acquired segmental defects. These mandibular defects (35 to 80 mm in length) were reconstructed by means of internal distraction devices with a transcutaneous activator. All the patients underwent complete resection of the affected bone and immediate placement of the distraction device on the remaining mandible.

Results: The results' analysis was based on clinical observation, postoperative radiographs, histopathologic findings and 3-dimensional computed tomographic scans. Successful distraction osteogenesis was achieved in 3 cases. In 1 case, extensive intraoral exposure of the device was observed, resulting in a failure of the procedure. One patient died of distant metastases 4 months after the resective surgery.

Conclusion: Because of the limited number of cases, this study is preliminary. However, considering the good experimental and clinical results, this new technique offers an alternative for patients with segmental mandibular defects in which, because of local or general reasons, a more aggressive procedure should be avoided.

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Although distraction osteogenesis (DO) has been widely used in long bones for several decades,[1] it is not until the 1990s that this technique became a common method in mandibular lengthening.[2,3] By means of this procedure, new bone is created after osteotomy followed by gradual separation of bony fragments. Mandibular reconstruction after bone loss is a great challenge. Grafts, flaps, and alloplastic materials have been used to reconstruct the mandible. Excellent results have been obtained by using microvascularized flaps in extensive defects,[4,5] but its use results in added morbidity, and costs are high. Recently, DO has been shown to be a successful technique not only in the surgical treatment of the congenital and acquired mandibular hypoplasia,[6,7] but also in the reconstruction of segmental mandibular defects.[8-10]

When compared with the extraoral technique, internal mandibular distraction has been shown to improve stability and optimal patient compliance.[6] Initial experimental studies have successfully used DO for the reconstruction of segmental mandibular defects,[11-15] even in previously radiated mandibles[16]; however, external devices have been used in the majority of these reports. Recently, our research group has obtained promising results in bone transport of the mandible with submerged devices in a canine model.[17]

The aim of this presentation is to show our preliminary series of bone transport by DO with a unidirectional submerged device to reconstruct different degrees of mandibular segmental defects.

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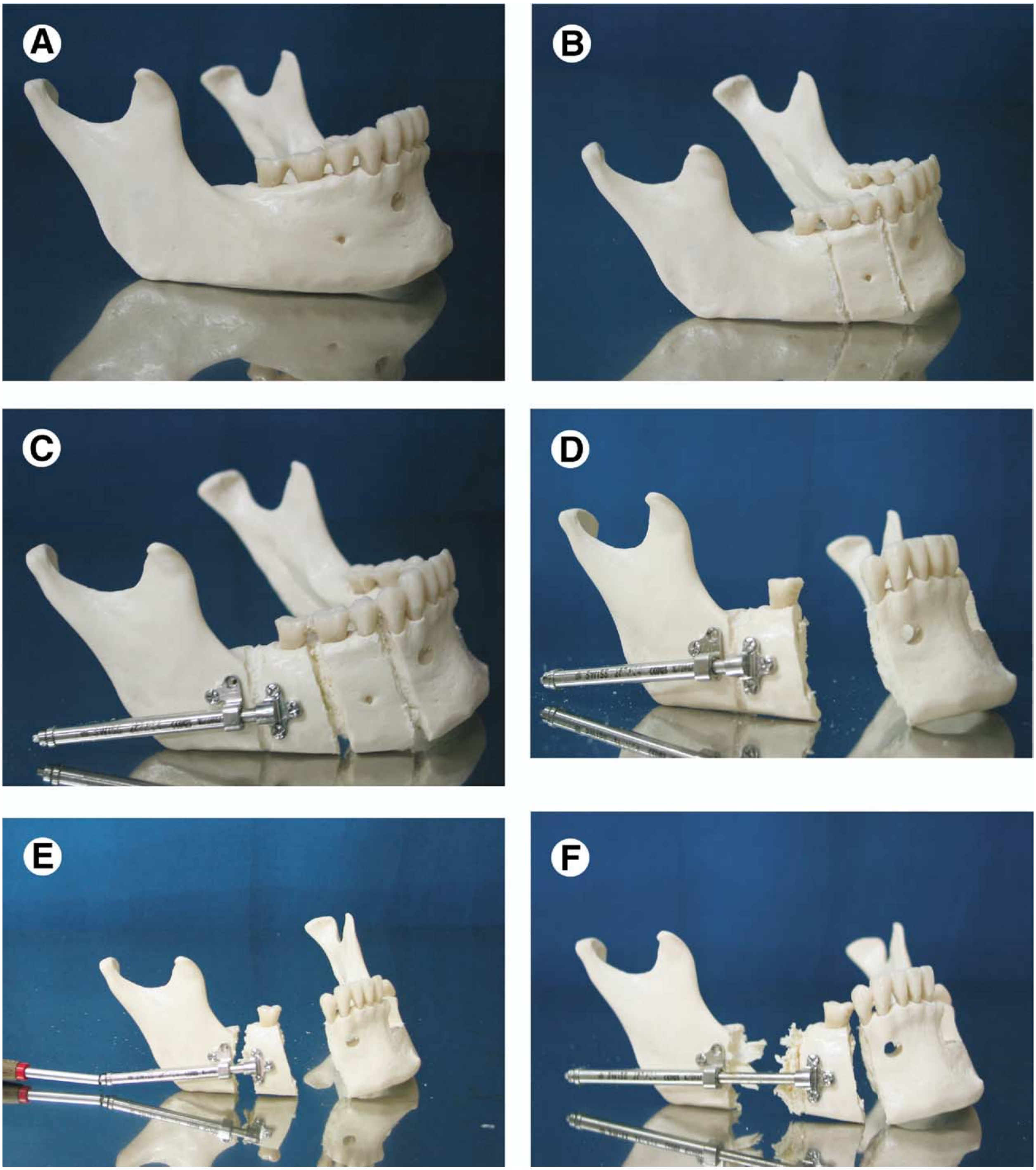

FIGURE 1. *A*, Mandible before treatment. *B*, Planning a segmental resection in the first premolar area. A reconstruction plate has to be secured to the bone before completion of the resection (not shown). *C*, Design of a proximal transport disk. Distraction device in place before completing the resection. *D*, Distraction device in place after completion of the resection. *E*, The osteotomy has been finally completed, creating the transport disk. The distraction device has been activated several millimeters to test that both bony fragments are completely separated. *F*, The transport disk is moved across the defect. The newly created bone will be formed starting from the bony edges towards the center of the osseous defect

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Material and Methods

Six submerged mandibular distraction devices with transcutaneous activator were used in 5 patients with different mandibular segmental defects. In 4 patients programmed for mandibular resection, bone transport was used to primarily reconstruct the defect (Fig 1). Detailed information about all patients concerning age, sex, diagnosis, stage of the disease, size and location of

Table 1. INTERNAL MANDIBULAR BONE TRANSPORT: PATIENT DATA

	Case 1 (JS)	Case 2 (MC)	Case 3 (BC)	Case 4 (DL)	Case 5 (LO)
Gender/age	M/67	F/78	M/48	F/50	M/66
Main diagnosis	SCC Floor of the mouth	SCC Tongue-floor of the mouth	SCC oropharynx (tonsilla)	Leiomyosarcoma left hemimandibular body	Mandibular osteoradionecrosis after radiotherapy SCC oropharynx (tonsilla)
Stage (pTNM)	IV	IV	IV	IV	–
Defect length (mm)/Site	46/hemimandibular body and symphysis	59/hemimandibular body	37/hemimandibular body	80/hemimandibular body	35/hemimandibular body and symphysis
Disk length (mm)	26	22	27	25	29
Amount of lengthening (mm)	19 (uncompleted)	15 (uncompleted)	37	80	35
Latent period (days)	10	10	10	10	10
Rhythm distraction (mm/day)	0,5	0,5	0,5	0.5	0,5
Consolidation period (wks)	0	22	12	12 in each period	20
Approach for placement	Extraoral, but activator intraoral	Extraoral	Extraoral	Extraoral	Extraoral
Device (location)	Gonial angle	Parasymphyseal	Body	Gonial angle	Parasymphyseal
Number of devices	1	1	1	2	1
Quality of bone (macroscopically)	Bad	Good, but distraction was not completed	Excellent	Excellent	Excellent
Quality of bone (microscopically)	None tested	None tested	None tested	Mature bone, lower density	None tested
Local treatment	Bone and surrounding soft tissue resection	Bone and surrounding soft tissue resection	Bone and surrounding soft tissue resection	Bone and surrounding soft tissue resection	Bone resection including cutaneous fistulae
Cervical treatment	Yes	Yes	Yes	No	No
Previous radiotherapy/dose	Yes/64 Gy	No	Yes/60 Gy (in another center)	No	Yes/60 Gy

Table 1. INTERNAL MANDIBULAR BONE TRANSPORT: PATIENT DATA (cont'd)

Gender	Case 1 (JS)	Case 2 (MC)	Case 3 (BC)	Case 4 (DL)	Case 5 (LO)
Radiotherapy post/dose	No	Yes/60 Gy during distraction	No	No	No
Complications	Failure, complete intraoral exposure and loosening of all screws	Distant metastases, bad general status Uncompleted distraction	Maximum oral opening decreased	Pain at the end of the distraction period Slight asymmetry	Partial intraoral exposure
Follow-up months since the resective surgery	15	4	29	43	37
Evolution	Death	Death	Alive, free of disease	Local relapse. New resective surgery	Alive, free of disease
Bone graft/donor site	No	No	No. A green-stick fracture was performed at the proximal stump	Yes/Iliac crest	No. A green-stick fracture was performed at the proximal stump

Abbreviation: SCC, squamous cell carcinoma.

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FIGURE 2. Case number 4. Initial 3-dimensional CT scan after the initial biopsy. A radiolucent area on the left hemimandibular body can be observed . Histopathologic diagnosis: primitive leiomyosarcoma of the mandible.

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the defect, amount of lenghtening, evolution, and duration of follow-up is summarized in Table 1.

Cases 1 to 3 were moderate to poorly differentiated squamous cell carcinoma (SCC) of the oral cavity. Case 4 presented with an asymptomatic radiolucent mandibular image in the panoramic radiograph (Figs 2-14). No pain, neurosensory disturbance, or other local and general symptoms were presented in the clinical history. Microscopic analysis revealed a malignant clear cell neoplasm of unclear origin. The block was sent to Dr Rosai (Chairman, Department of Pathology, Memorial Sloan-Kettering Cancer Center, New York, NY) to clarify the diagnosis.

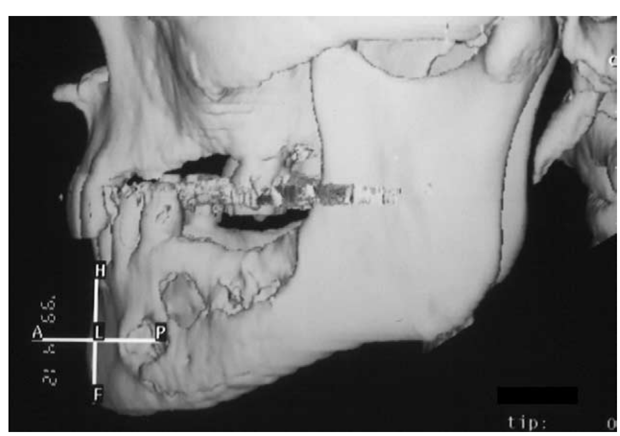

FIGURE 3. Preoperative 3-dimensional CT scan. Lateral view.

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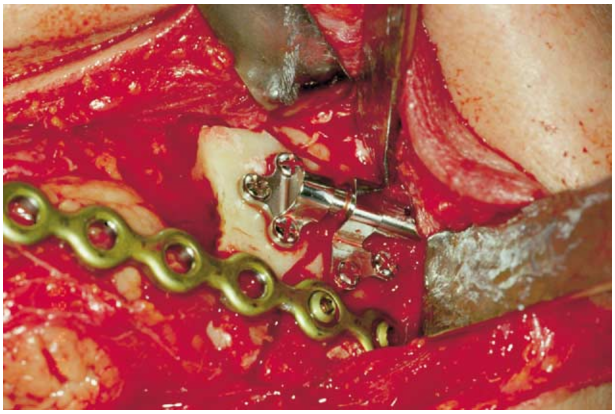

FIGURE 4. Intraoperative view after placement of the intraoral device and completion of the osteotomy. A trapezoidal design on the proximal remaining bone has been performed for the transport disk.

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A tomographic computed (CT) scan was included in the preoperative study to accurately appreciate the limits of the neoplasm, the existence of bone compromise, and lymphatic node metastasis. Panoramic radiographs were used as the image control tool during the distraction and consolidation periods.

The preoperative study showed no distant metastasis, and radical resective surgery was considered the first treatment option in every case. No palpable cervical nodes were found in neck examination but cervical metastases were evidenced on the CT scans in 2 patients. However, cervical lymph node dissection was considered to be necessary in the 3 cases with SCC of the oral mucosa, and it was performed during the same surgical procedure.

In all patients, an ablative surgery was performed through a submandibular approach, including wide bone and soft tissue margins around the tumor. The same approach was used to place the reconstruction plate and distraction device, and to design the bone transport disk. In 1 case (number 4), 2 consecutive distraction devices were used to restore the normal length of the mandibular body.

FIGURE 6. The activator of the device exits externally just below the auricular area, on the gonial angle. Only the activator of the device is allowed to project externally.

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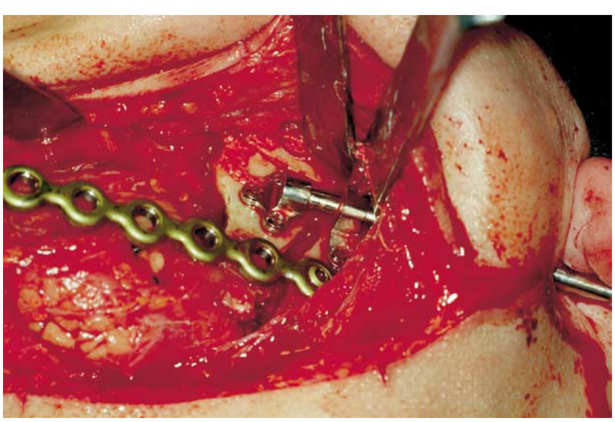

FIGURE 5. Activation of the internal distraction device intraoperatively. Note the separation of the bony fragments.

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FIGURE 7. Panoramic radiograph at the beginning of the distraction process.

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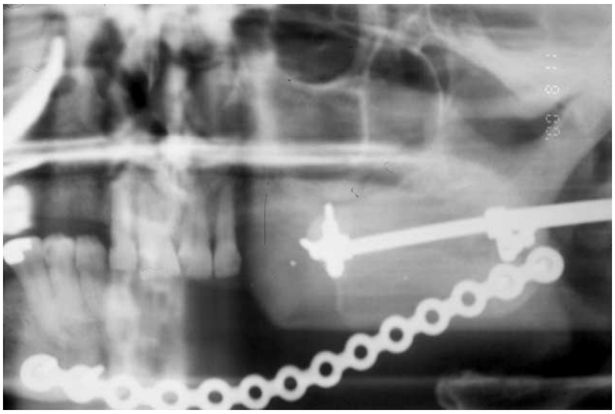

FIGURE 8. Panoramic radiograph during bone transport. Note the incomplete radiopacity between the proximal segment of the left hemimandible and the transport disk.

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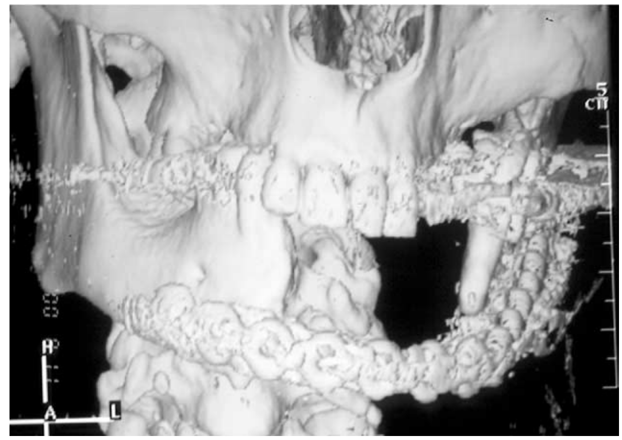

FIGURE 10. 3-Dimensional CT scan during the bone transport process. Note the transport disk and the bone gap.

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After an exhaustive analysis of each case, bone transport was considered the best treatment option because of local or general reasons; a more aggressive reconstructive method was dismissed.

Partial hemimandibulectomy, including the symphysis in several cases, produced a variable segmental mandibular defect. This defect was bridged with a reconstruction plate (Leibinger, Freiburg, Germany) before completing the osteotomy.

At this time the bone transport disk is designed. An osteotomy is performed proximal to the defect to create a variable transport disk. The unidirectional distraction device (Fig 1) used in this study (AO Synthes, Oberdorf, Switzerland) was originally designed to lengthen the ascending ramus of the mandible.[7] The maximal length allowed by this distraction device is 40 mm. The body of the distraction device was fixed bicortically with 4 screws (1.5 mm in diameter and 10 to 14 mm in length), 2 screws in each side of the osteotomy. The anterior 2 screws fixed the movable part of the distraction device to the transport disk. The posterior 2 screws were fixed to the posterior and stable part of the mandible (Fig 1).

After fixation of the distraction device the osteotomy was completed with a small osteotome, to ensure the correct position of the bone fragments. Activation of the distraction device was tested by twisting the screw several mm (Fig 5), before returning it to its original position (Fig 4). This maneuver allows control of bleeding from the proximal osteotomy.

Soft tissues were sutured in layers, maintaining the periosteum to cover the body of the distraction device, the plate, and the osteotomy line. The distrac-

FIGURE 9. Panoramic radiograph after completion of the consolidation period and removal of the distraction device.

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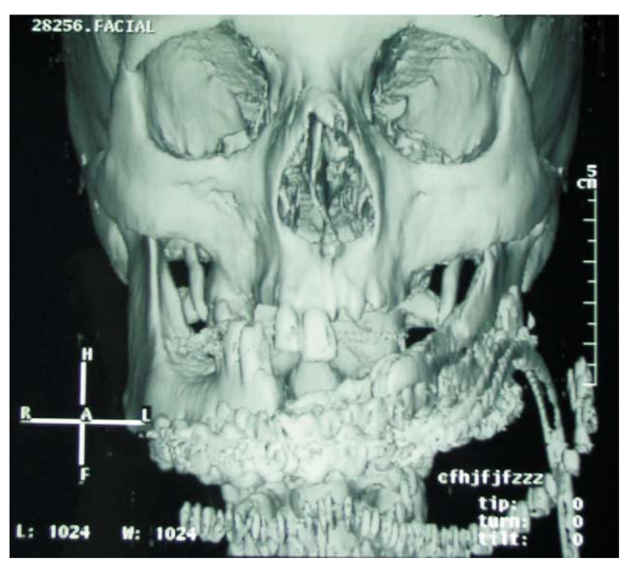

FIGURE 11. Three-dimensional CT scan of the same patient showing the newly generated bone immediately after removal of the distraction device.

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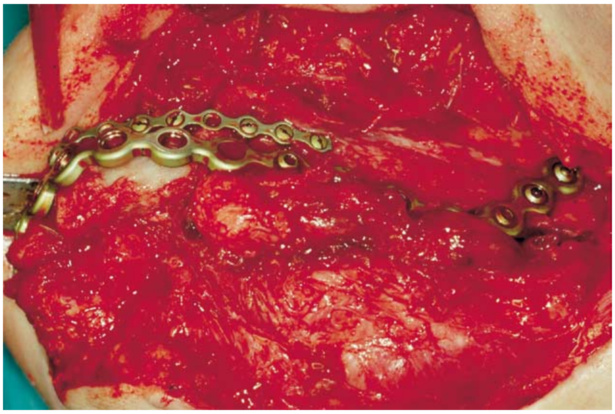

FIGURE 12. Intraoperative view after the distraction process. Note the continuity of the whole mandible. Osteosynthesis is completed with miniplates. The reconstruction plate is left in place.

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tion activator was passed percutaneously, right below the ear (Fig 6) or in the cheek area (see case number 5: Figs 15-22).

The design of the bone transport disk depended on the quality of the remaining mandibular bone and the degree of the defect (Fig 18). Correct positioning of the device is time-consuming but important because it will define the distraction vector. Distraction was initiated on the 10th postoperative day to continue twice a day, a total of 0.5 mm daily. Once the distraction was finished, a variable period of bone consolidation was established. The distraction device was removed under general anesthesia, through the same cervical incision, whenever new bone formation was radiographically confirmed.

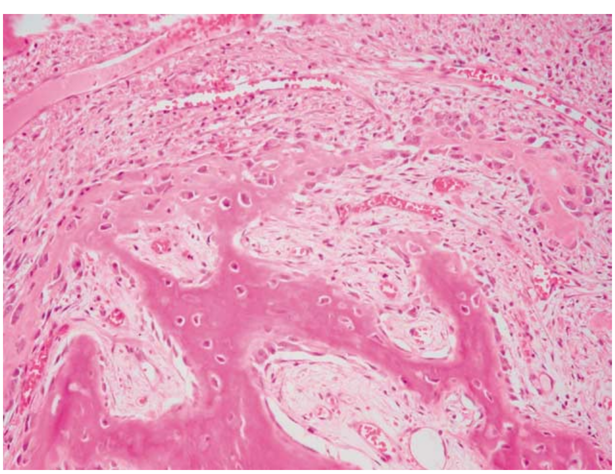

FIGURE 13. Microscopical analysis of the newly created bone in case number 4.

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FIGURE 14. Lateral view of the same patient showing a good facial contour.

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Results

Surgical margins of the tumor were microscopically free of disease in all cases. In 4 cases the diagnosis was

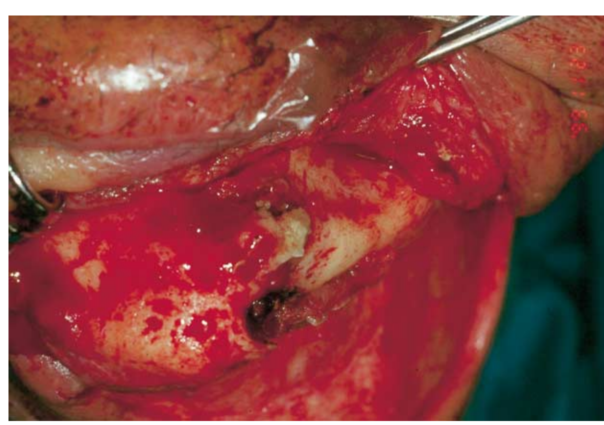

FIGURE 15. Intraoperative view of case number 5. Wide surgical exposure of the affected bone through a cervical approach. Note the extensive area of osteoradionecrosis of the mandible.

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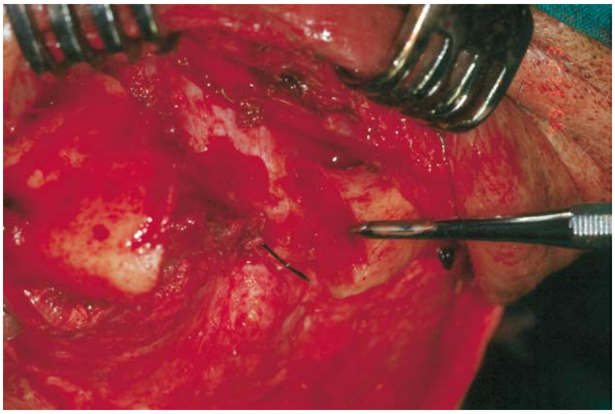

FIGURE 16. Segmental mandibular defect after resection of the necrotic bone.

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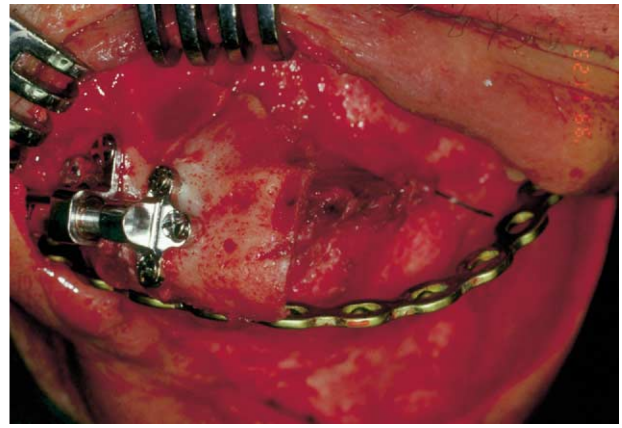

FIGURE 18. Reconstruction plate and distraction device in place. A rectangular disk has been designed on the remaining healthy bone. It will be transported across the defect.

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SCC of the oral mucosa; in case number 4 a new histopathologic study was performed by Dr Rosai, which concluded a low-grade leoimyosarcoma, a rare tumor. Examination of the whole piece of hemimandibulectomy allowed the histopathologic diagnosis. This patient showed the largest mandibular defect, 80 mm in length. This is why 2 consecutive distraction procedures were necessary. The first distraction period was uneventful, achieving a total of 40 mm of new bone (the maximal length of the device) and 14 weeks later, the patient underwent another successful distraction. Some acute pain was experienced by the patient at the end of the second distraction period.

Complete bone regeneration of the surgically created gap was successful in 3 of 5 patients. One patient (case number 2) died of distant metastases 4 months after the resective surgery; in this case, distraction was not completed because of the deteriorated general status of the patient. Another patient (case number 1) showed a complete intraoral exposure of the distraction device; therefore, he was returned to the operating room, where he underwent removal of the device. The reconstruction plate was left in place to bridge the defect.

For the 3 cases in which distraction was successful, the minimum follow-up period after removing the distraction device was 30 months. No premature consolidation or pseudoartrosis was observed. There were no problems with oral nutrition while the distraction devices were in place. The buried distraction device allowed the patients to carry out their normal activities without discomfort.

The quality of the new bone was tested during the second operation in every case, but a biopsy was taken in only 1 case (case number 4). Macroscopically, the quality of the newly created bone was con-

FIGURE 17. The piece of bone was 35 mm in length.

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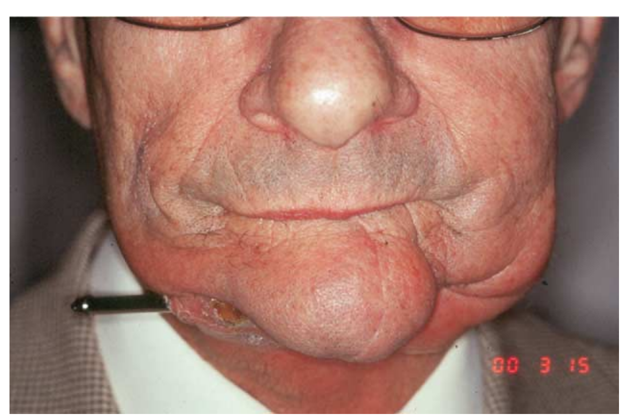

FIGURE 19. The activator of the device exits externally in the cheek area.

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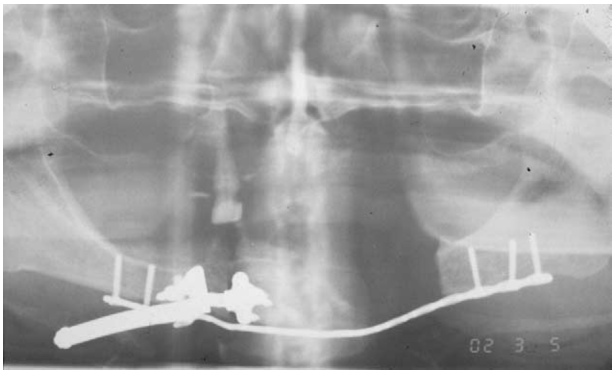

FIGURE 20. Postoperative panoramic radiograph. Note the size and shape of the bone transport disk.

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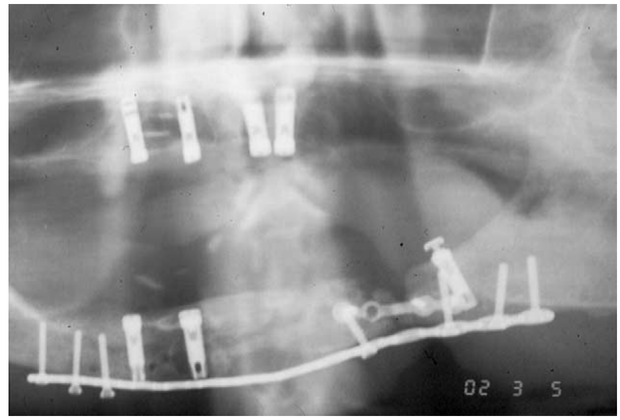

FIGURE 22. Panoramic radiograph after completion of the consolidation period and after removal of the distraction device. Osseointegrated implants have been used to complete prosthodontic rehabilitation.

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sidered to be good or excellent by the surgeons when compared with the adjacent bone. The regenerated segment was comparable in diameter with the transport disk. The exact location of the junction between the regenerated and the preexisting bone could not be determined. Microscopically, the distracted bone was analyzed in case number 4; histologic examination of the biopsy confirmed the presence of mature bone deposition along the mandibular defect (Fig 13).

Unfortunately, case 4 suffered from local recurrence 16 months after the removal of the second distraction device, and an ablative surgery was performed to resect the distracted bone. In this case, a microvascularized fibular flap was used to reconstruct the defect.

Case 5 was successfully treated with osseointegrated implants in both jaws (Fig 22).

RADIOGRAPHIC EXAMINATION

Immediately after surgery, all the devices were shown to be in the right position. At the end of the distraction period, the panoramic radiography showed that the regenerated bone had the same density as the surrounding soft tissue. After 8 to 12 weeks the entire gap showed progressive calcification in the 3 patients in which distraction was completed (Fig 8). Panoramic radiography served as vector control during the active distraction period (Fig 21).

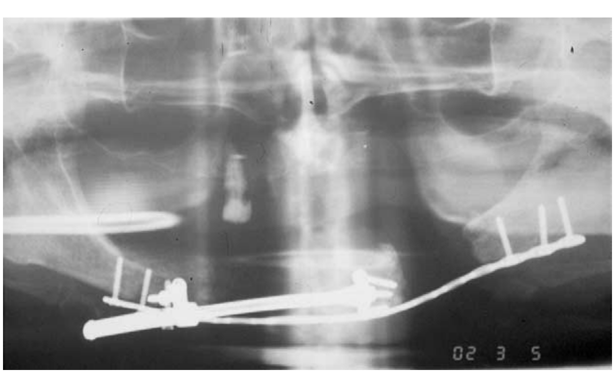

FIGURE 21. Panoramic radiograph during the distraction process.

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In the 2 unsuccessful cases, the gap remained radiolucent during the whole follow-up period.

Three-dimensional CT scans were taken in some patients to evaluate the newly created bone (Fig 11).

Discussion

Although microvascularized procedures are widely used for mandibular reconstruction, several limitations are associated with unhealthy high-risk patients and donor site morbidity. DO, when indicated, provides an alternative method to these conventional techniques. Distraction is applied across osteotomy of the bone to achieve lengthening without additional bone transplantation. In this manner, the mandibular gap can be replaced by new bone grown from the remaining mandible.

The regenerated segment is similar in diameter with the transport disk in every case. The anatomy of the newly created mandible is more favorable than the one achieved by other mandibular reconstructive techniques. This fact is important when osseointegrated implants will be placed in the new bone. Even though experience is restricted to 1 case in this study, it seems that osseointegrated implants can be successfully used in this bone.

Because of the rapid development of DO with worldwide acceptance of its benefits, a variety of different devices, each with its own inherent engineering and application limitations, is commercially available.

However, DO through internal devices is the only method currently used in our department because of its reliability.[7] Internal distraction, compared with the external distraction, offers several advantages in mandibular lengthening[6]:

The stability of the internal distraction is excellent.
Infections and dehiscences are rare.
A higher tolerance and comfort.
Internal devices are less prone to trauma and unesthetic scars.

Internal mandibular DO has shown to be effective to treat congenital or acquired mandibular hypoplasias and it is being widely used.[7,18-20] However, external devices are still used for reconstructing segmental defects.[8-10] Only a few reports about segmental mandibular regeneration by means of submerged distraction devices could be found.[21]

A recent experimental study[17] shows the possibility to use internal distraction devices to reconstruct segmental mandibular defects in a canine model. In this clinical series, a similar surgical method has been performed in our patients.

Our results suggest that the intraoral device can be used as an alternative method for mandibular reconstruction, even in patients with large segmental defects.

Moreover, the distraction mechanism with an external activator allows an easier access for activation compared with other submerged mechanisms with intraoral and transmucosal activators. Because of this, there is no communication between the area of bone regeneration and oral cavity. This isolation protects the area from oral bacteria contamination and reduces the risk for dehiscence. In our series, a complete intraoral dehiscence was observed in the unique patient in which an intraoral approach was performed to place the device. This is why a cervical submandibular approach is recommended for placement of the devices in all cases.

The absence of pins through the skin of the face right above the distracted zone can represent another advantage. Even though the effects of radiotherapy over DO are not completely known, an experimental study suggests that the existence of previous radiotherapy does not have negative effects on the regenerative process.[16] If further studies show that postoperative radiotherapy does not affect the process, internal distraction, with the transcutaneous activator away from the distraction site, may become the technique of choice. However, further studies are necessary to assess if the need for postoperative radiotherapy may limit the use of this technique.

Distraction technology has to be refined to develop newer devices based on experimental studies and clinical applications like the ones presented in this report. The requirement for bone grafting may be minimized by using devices that allow longer distractions, for example, to reconstruct the entire hemimandibular body by means of a unique distraction device. The technical limitation of the distraction device used in this study forced us to use 2 consecutive devices in 2 different surgical steps, to fill up an 80 mm-segmental defect

On the other hand, the distraction device used in this study for bone transport is completely rigid and the adaptability of the plates and principal body of the device is minimal. Therefore, after completing the osteotomy, the transport disk tends to move and place itself parallel to the proximal segment of the mandible. This is important especially in the areas where the mandible curvature changes, for example, in the symphysis. In these situations, it may be necessary to perform a green-stick osteotomy when the distraction device is removed, with the aim of modifying the direction of the newly created bone. Adaptability of the device to the outer cortical is desirable to allow the maximal stability and to reproduce the curvature of the mandibular anatomy. For these reasons, a technical improvement of the distraction device is mandatory.

The process of DO for mandibular lengthening involves careful preservation of buccal periosteum and minimal dissection of the lingual periosteum.[6] However, during oncologic surgery, a wider dissection of the mandible is often necessary. In the current study the internal device was placed in a subperiosteal plane in all the cases. This fact, however, did not seem to have a negative influence on the osteogenesis.

The period of passive fixation, which allows the healing of the soft tissues, periosteum, and bone marrow is longer than the one recommended in mandibular lengthening.[7] Bone transport was initiated 10 days after the implantation of the distraction device; however this may vary depending on the patient's age (younger patients require shorter periods)[21] and diagnosis. No premature consolidation was observed after this period, ensuring a safe healing of all tissues before distraction of the mandible.

A distraction rate of 1.0 mm/day has been considered optimal in the majority of previous reports addressing DO of the hypoplastic mandibles.[3,6,7,18-20] However, a slower rate (0.5 mm/day) with the same rhythm (twice a day) has been considered necessary in this kind of patient with previous radiotherapy and/or large tumoral resections in which the periosteum has suffered extensive detachment.

For a successful distraction of a transport disk in the mandible, the following criteria should be satisfied:

Enough remaining bone to ensure absolute stability of the distraction device and the reconstruction plate. Stability is one of the most important factors for optimal osteogenesis.[17]

Bicortical fixation of the screws is important to allow a rigid fixation of the device to the bone, minimizing the movement of the disk during distraction.

At least a 10-day interval between the completion of surgery and initiation of distraction.

Because of the limited number of cases, this study is preliminary. This technique has been used in only 5 patients, representing 5% of the mandibular reconstructions in 3 years. Conventional surgical procedures are still indicated in the majority of cases; bone transport only represents a promising alternative. In spite of this, and considering the good experimental and clinical results, this new technique offers an option for patients with different degrees of mandibular defects in which, for local or general reasons, a more aggressive procedure should be avoided.

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