Introduction of a New Removable Adjustable Intraoral Maxillary Distraction System for Correction of Maxillary Hypoplasia

Alvaro A. Figueroa, DDS, MS,* John W. Polley, MD,* and Alexander L. Figueroa, DMD†

Abstract: Distraction osteogenesis has become a treatment alternative to treat severe craniofacial skeletal dysplasias. A rigid external distraction device has been successfully used to advance the maxilla as well as the maxillary, orbital, and forehead complex (monobloc) in children as young as 2 years, adolescents, and adults. For this severe group of patients, the technique has been found to be simpler and safer than traditional surgical methods. Maxillary and midfacial advancement through distraction has been found to be extremely stable in the patients in whom the technique was used.

The authors introduce an intraoral distractor for those patients requiring a moderate maxillary advancement. The advantages of the device include ease of insertion, vector adjustability, reactivation capabilities, and no need for second procedure for its removal.

The above approaches have provided predictable and stable results. A detailed description of the device, necessary orthodontic and surgical procedures, case reports, and cephalometric outcomes are presented. The techniques can be applied alone or as an adjunct to traditional orthognathic and craniofacial surgical procedures.

Key Words: Distraction osteogenesis, cleft, maxillary hypoplasia, removable intraoral maxillary distractor

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Cleft patients with maxillary hypoplasia present a challenge to the reconstructive team. Treatment of these patients with traditional approaches (orthognathic surgery) may not provide the desired immediate and long-term goals as they may have compromised vascular supply and secondary scarring of the maxilla due to previous lip and palate surgery. In addition, some of these patients may have pharyngeal flaps or pharyngoplasties that may make the advancement of the maxilla even more difficult. On occasion, the maxillary hypoplasia can be quite severe, making it difficult to correct only with maxillary surgery but also requiring mandibular surgery in an otherwise normal mandible if traditional orthognathic surgery is used. If the deformity is present at a young age, those children will have to wait for skeletal maturity to undergo corrective treatment, as traditional techniques are not recommended for young growing cleft patients. This in turn places the children at a psychologic disadvantage during their important formative years.

Since the introduction of distraction osteogenesis in the craniofacial skeleton by McCarthy et al, the technique has now been applied throughout the craniofacial skeleton. It has been reported that a significant percentage of cleft patients benefit from maxillary advancement. Furthermore, patients treated with conventional orthognathic surgery have a high degree of relapse. Therefore, seeking other treatment modalities to treat this group of patients is a significant clinical priority

Molina and Ortiz-Monasterio were the first to suggest maxillary advancement using distraction osteogenesis by means of applying traction with an orthopedic face mask and elastics after a maxillary corticotomy. Although their approach seemed promising, the results were disappointing. We then developed the use of an external cranially fixed halo as a point of anchorage to advance the maxilla that was connected through the dentition by an intraoral splint and surgical wires to the distraction system mounted on the halo device. The use of this technique has provided impressive outcomes in patients who otherwise would have been difficult to manage with traditional orthognathic surgery. Clinicians around the world have now successfully used the rigid external distraction (RED) technique. As experience has been gained with the RED technique, it has been applied not only to cases with cleft-related deformities, but also to patients with dentofacial deformities and severe craniofacial syndromic deformities. The results obtained with the technique have been close to ideal from the functional, aesthetic, and occlusal perspectives. The above approaches have provided predictable and stable results. A detailed description of the device, necessary orthodontic and surgical procedures, case reports, and cephalometric outcomes are presented. The techniques can be applied alone or as an adjunct to traditional orthognathic and craniofacial surgical procedures.

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Figure 1. Frontal (top A, B, C) and profile (bottom D, E, F) photographs of a 16-year-old girl patient with Crouzon syndrome undergoing monobloc advancement with RED (left), before (center) and after (right) treatment. Note significant improvement in facial balance and esthetics. The intraoral pretreatment (G) and posttreatment (H) photographs demonstrate the correction of the anterior crossbite and class III relations obtaining ideal occlusal and functional results. The cephalometric radiographs before (left) and after (right) treatment (I) demonstrate the establishment of normal maxillomandibular relations, improvement in airway dimension, eye protection, and soft-tissue balance. (Orthodontic treatment for this patient was provided by Dr C. Lynn Hurst, San Antonio, TX).
moderate cleft cases that apparently could be managed with orthognathic surgery have an increased risk for complications with the traditional approach. In addition, it may help to alleviate some of the obvious psychosocial concerns that might affect a patient wearing an external device.

Distraction systems used for the gradual advancement of the maxilla and mandible have been classified as tooth-borne (using only the teeth to support the distractor and mainly used for segmental movements); bone-borne (using bone to support the distractor to the anchor and the intended segment to be moved; used to

FIGURE 2. Frontal (top A, B, C) and profile (bottom D, E, F) photographs of a 15-year-old boy with repaired right cleft lip and palate undergoing maxillary advancement with RED (left), before (center) and after (right) treatment. Note improvement in facial balance and esthetics. The intraoral photographs (G) before (top) and after (bottom) treatment demonstrate correction of anterior crossbite and class III relations obtaining ideal occlusal and functional results. The cephalometric radiographs before (left) and after (right) treatment (H) demonstrate the establishment of normal maxillomandibular relations and soft-tissue balance.
Even recently described hybrid systems require a second maxillary (malar) buttress plate. Removable AIM Distractor vertical bar has in its upper or cranial end 3 threads for securing it into the buttspace plate. The upper part of the bar is very strong to resist failure. The lower part of the vertical bar has a threaded lockable extension rod for vertical adjustability. In its ends, it holds a hinge attachment to secure the actual distractor. This attachment is serrated to allow for vector adjustability of the actual distractor and has a safety screw to hold the distractor (it cannot be removed from its housing to prevent accidental loss in the operating field).

3. The distractor proper has a movable part that attaches to the dentition by means of either a superior or inferior plate. The teeth are used to receive the distraction forces; used to move complete skeletal segments containing the maxillary-mandibular dentition or just movement of an osseous-dental segment).

The REMOVABLE AIM DISTRACTOR

The removable adjustable intraoral maxillary distractor (patent pending; KLS Martin LP, Jacksonville, FL) consists of 3 parts (Fig. 3):

1. The maxillary (malar) buttress plate with 2 components; a cranial vertical one to fix the plate to the anterior maxillary-zygomatic wall and a caudal horizontal extension with 2 to 3 threaded holes for supporting the second part of the distractor (the vertical bar).

2. The vertical bar has in its upper or cranial end 3 threads for securing it into the buttspace plate. The upper part of the bar is very strong to resist failure. The lower part of the vertical bar has a threaded lockable extension rod for vertical adjustability. In its ends, it holds a hinge attachment to secure the actual distractor. This attachment is serrated to allow for vector adjustability of the actual distractor and has a safety screw to hold the distractor (it cannot be removed from its housing to prevent accidental loss in the operating field).

3. The distractor proper has a movable part that attaches to the dentition by means of either a superior or inferior plate. The teeth are used to receive the distraction forces; used to move complete skeletal segments containing the maxillary-mandibular dentition or just movement of an osseous-dental segment).

The RED system is classified as an external hybrid (bone-tooth) device as it uses the cranium as anchorage, and the intended moving part is advanced via forces applied to the dentition by means of an intraoral splint.

The main disadvantage and objections to the bone-borne devices are that they have to be removed through a second operation. Even recently described hybrid systems require a second operation to remove the anchor footplates from the bone.

Learning from the simplicity, stability, and predictability offered by the RED system, we have developed a new intraoral hybrid (bone-tooth–borne) device that allows adjustability of the system to fit different maxillary sizes. It also offers adjustability of vectors during the distraction process. It offers sufficient rigidity to mobilize the osteotomized maxilla and does not require the need for a second operation for its removal. This device is a removable adjustable intraoral maxillary (AIM) distractor.

**Intraoral Splint**

An intraoral splint to connect the distractor to the dentition needs to be manufactured. Ideally, the intraoral splint is prepared and secured in the patient’s mouth a few days before surgery.

This can be made of acrylic and wired to the teeth. The acrylic wafer needs to have wire loops or other strong mechanical systems attached to it for wiring to the teeth and securing the distractor. If the acrylic wafer is thick enough, it can directly be secured with skeletal fixation screws. Because most of our patients are prepared beforehand with orthodontic treatment, we prefer the use of a splint either soldered or wired to the orthodontic appliance. We use a 0.045 stainless steel wire bent around the perimeter of the arch and bent in a way that it will clear the orthodontic brackets. Multiple hooks are soldered to the base wire for wire fixation of the plates attached to the distractor. The posterior end of the splint is either soldered to the orthodontic band or inserted through the headgear tube on the band and secured with wires from the band hook to the most posterior hook soldered onto the intraoral splint. In patients without
orthodontic appliances, a custom-made or commercially available segmental arch bar can be secured to the teeth and the loops of the arch bar used to secure the distractor plates with surgical wires. Another reason we prefer not to use an acrylic splint is that it interferes with assessment of the occlusion as distraction proceeds.

**Surgery**

Careful patient selection is based on clinical, functional, and radiographic evaluations completed before the patient is scheduled for a Le Fort I osteotomy and distractor placement. After the soft-tissue incisions and exposure of the maxillary walls, the malar anchorage plate with the vertical bar in place is fitted to the maxilla. Care must be taken to position the vertical bar at about the level of the first molar with the attachment joint for the distractor located at the level of the tooth gingival junction. The vertical bar must be placed 3 to 5 mm lateral to the molar. The plate is then temporarily secured with 1 screw, and the outline of the plate and screws is marked with indelible marker. The procedure is repeated on the opposite side. The osteotomy is outlined to ensure that it will not interfere with placement of the plates. The plates are removed, and a standard Le Fort I osteotomy is completed with pterygoid and septal disjunction. The surgeon must ensure complete mobilization of the maxilla but without extensive down-fracturing. The previously bent and fitted plates are then permanently secured with as many screws as necessary, the vertical threaded bar is screwed into place, and the distractor is attached at the appropriate vertical and lateral position with the safety screw. Based on the anatomy of the patient, the surgeon decides if the upper or lower plates attached to the distractor will be used for fixation. The plates that are not used are then removed with plate cutters. The distractor plate is then simply secured to the intraoral splint by means of surgical wires or screws. The distractors are activated to assess advancement of the maxilla. The distractors are then returned to their original position, and the soft tissues are closed in a routine fashion, leaving the vertical bar of the distraction system exiting through the vestibular incision (Fig. 4). The patient receives standard antibiotics and pain control medications. On the day after surgery, the patient is given a liquid diet and is instructed to be on a soft diet on the second postoperative day. Stereolithographic models can be helpful in the planning stages to select plate size, prebend them, and outline the desired osteotomy (Fig. 5).

**Distraction Protocol**

After a 5- to 7-day latency period, the activations are initiated at a rate of 1 mm/d (2 turns a day). If the distractor is fully extended and the patient still requires additional advancement after full activation, the wires or screws connecting the distractor plate to the wire or acrylic splint are cut. The distractor is backed or rewound. The distractor plate is again secured with surgical wires or screws to the surgical splint, and the distraction is continued until the desired advancement is achieved.

During or after distraction, the patient can use elastics with a class III vertical component to assist in achieving an ideal occlusal result (Fig. 6). If it becomes necessary to adjust the vector or if the patient is exhibiting a tendency for an anterior open bite, the vector can be changed by cutting the surgical wires attaching the distractor to the intraoral splint and also by loosening the screw in the hinge connection between the vertical bar and the distractor. The distractor is then redirected in the appropriate vector, the hinge screw is tightened, and the distraction plate is rewired to the splint (Fig. 7).

If at the end of the anteroposterior correction there is an open bite, the clinician can detach the distractor from the splint and give the patient elastics, acutely mold the regenerate, and in the new corrected position rewire the distractor plates to the splint. This will provide horizontal and vertical stability during the consolidation phase. Active elastics can also be used during the consolidation phase (Figs. 6, 11C). The consolidation period depends on the degree of advancement and age of the patient. The distractors can be kept until it is noted that the maxilla is firm, and radiographically, there is sufficient bone deposition in the pterygomaxillary region. An orthopedic face mask after distractor removal can also be used to ensure added stability (Fig. 11C).
The distraction vector can be simply changed by cutting the wire connecting the metal dental splint to the distractor plate. The hinge screw is loosened (center), the distractor repositioned and rewound, the hinge screw is tightened, and the distractor is rewired to the metal dental splint.

Removal of the Distraction Device

After consolidation, the device is removed in the office setting by disconnecting the surgical wires or screws from the intraoral splint. The screw connecting the distractor to the hinge is loosened to remove the distractor. The vertical arm is then held by its thicker diameter with a medium-size needle holder and twisted counterclockwise until it is completely detached from the buttress plate and removed through the vestibular incision. The procedure is repeated on the contralateral side. Rarely, the wound needs sutures, but it can be closed if necessary with 1 or 2 interrupted sutures under local anesthesia (Fig. 8). The buttress plate is left behind as it is fabricated using biocompatible grade metal (Figs. 10D, 11D and E).

CLINICAL REPORT

Patient 1

A 20-year-old woman with maxillary hypoplasia secondary to left unilateral cleft lip and palate presented for treatment (Figs. 9A–D). Her treatment plan included extraction of tooth no. 5 as she was missing tooth no. 10. After orthodontic alignment of the arches, she required fistula closure and bone grafting through a Le Fort I access without advancement. This was followed by maxillary advancement surgery with a removable AIM distractor. After obtaining soft-tissue access for a Le Fort I osteotomy, the right and left buttress plates of the distractor were properly fitted and marked. The Le Fort I osteotomy was completed, the buttress plates were secured, and the distractors were attached in the proper vector to the vertical arm of the distractor and were wired to the orthodontic splint attached to the dentition. As soon as the desired occlusal changes were achieved (correction of anterior crossbite and obtaining class II molar relations), the distractors were maintained in place for a period of 10 weeks until consolidation of the maxilla was observed. Class III elastics and an orthopedic face mask were used to ensure stability of the newly achieved maxillary position. As this patient was one of the first ones to undergo this procedure, a decision was made to remove the distractors and buttress plates in the operating room. The patient obtained ideal skeletal, aesthetic, occlusal, and functional results.

Patient 2

The next case is that of a 21-year-old man with a repaired bilateral cleft lip and palate who presented with secondary maxillary hypoplasia and class III skeletal and dental relations with anterior and bilateral buccal crossbites (Figs. 10A–D). Because he was congenitally missing teeth no. 7 and 10, extraction of teeth no. 21 and 28 became necessary to achieve adequate occlusal relations. After orthodontic alignment of the dental arches, the patient was scheduled for a Le Fort I maxillary advancement using removable AIM distractors. After obtaining correction of the negative overjet, the patient underwent a consolidation period of 10 weeks with the distractors in place. After consolidation, the distractors were removed in the office without the need for local anesthesia or sutures for the small opening on the line of the vestibular incision. The patient underwent class III elastics and orthopedic face-mask therapy, as well as finishing orthodontic treatment. The postoperative results reveal ideal skeletal, aesthetic, occlusal, and functional results. It can be seen on the cephalometric radiograph that the buttress plates remained in position after removal of the distractor.

Patient 3

A 12-year-old girl presented with maxillary hypoplasia secondary to right unilateral cleft lip and palate with class III skeletal and dental relations and anterior and posterior crossbites (Figs. 11A–E). She was congenitally missing tooth no. 10, and tooth no. 7 was diminutive. A decision was made to extract tooth no. 7 and finish her occlusion with class II molar and canine relations. After orthodontic alignment, she underwent a Le Fort I advancement with removable AIM distractors. After obtaining a favorable anteroposterior maxillary relation, the distractors were left in place for 8 weeks and were removed in the office without the need for local anesthesia or sutures to close the vestibular openings. Class III elastics and an orthopedic face mask were used to ensure stability of the newly achieved maxillary position. The postoperative results reveal ideal skeletal, aesthetic, occlusal, and functional results. It can be seen on the posttreatment cephalometric and panoramic radiographs that the buttress plates remained in position after removal of the distractor.

RESULTS

To date, 11 patients have had maxillary advancement with the removable AIM distractor. Of these, 10 had clefts, there was a female patient who underwent mandibular setback at the time of maxillary

FIGURE 7. The distraction vector can be simply changed by cutting the wire connecting the metal dental splint to the distractor plate (left). The hinge screw is loosened (center), the distractor repositioned and rewound, the hinge screw is tightened, and the distractor is rewired to the metal dental splint (right).

FIGURE 8. The distractors are removed in the office setting after disengaging the distractor from the splint and the vertical bar. The vertical bar is simply unscrewed through the small vestibular incision and pulled out (left). The soft-tissue defect heals without suturing (right).
osteotomy and AIM distractor placement, and there was a noncleft male patient with moderate maxillary hypoplasia. The age range of the sample was between 9 and 21 years (mean, 15.8 years). Cephalometric measures were conducted to assess the changes in maxillary anterior and vertical position, secondary changes in mandibular position, and postoperative stability. Radiographs were obtained before (T1), immediately after (T2), and at least 6 months (T3) after completing treatment. Two patients did not have T3 radiographs, and
FIGURE 10. Facial photographs (A) before (top) and after treatment (bottom). Note improvement on facial profile and lip/nose relations. Intraoral photographs (B) before (top) and after (bottom) treatment. Note correction of anterior and posterior crossbites. This patient was missing teeth no. 7 and 10; therefore, extractions of teeth no. 21 and 28 were carried out to obtain adequate arch coordination. Intraoral photographs (C) demonstrating the close relation of the distractors (arrows) relative to the dentition (left and right). The metal dental splint with soldered hooks (center) is used to wire the distractors. Note that the right distractor was wired with the upper plate, and the left one to the lower plate (oblique arrows). Also note the vertical bar emerging through the vestibule (upper arrow) and the bone anchorage screws used to further secure the splint with suspension wires. Cephalometric radiographs (D) obtained before (left), during (center), and after (right) treatment. Note improvement of skeletal, dental, and soft-tissue relations. The removable AIM distractors are clearly seen during active treatment. After treatment, the anterior crossbite has been corrected, and the buttress plates remain (right, oblique arrow). Note position change of the maxillary third molars and eruption into newly created space.
FIGURE 11. Facial photographs (A) before (top) and after treatment (bottom). Note improvement on facial profile and lip/nose relations. Intraoral photographs (B) before (top) and after (bottom) treatment. Note correction of anterior and posterior crossbites. This patient was missing teeth no. 7 and 10; therefore, the molars and canines were finished with class II relations. Immediately after removal of the AIM distractors (C), the patient underwent face mask (left) and class III elastic therapy (right) to detail the occlusion and enhance stability. Note suspension wires from the bone anchorage screw used to enhance rigidity of the intraoral splint. Cephalometric radiographs (D) obtained before treatment (left), after orthodontic preparation (center), and after (right) completion of treatment. Note improvement of skeletal, dental, and soft-tissue relations. After treatment (right), the anterior crossbite has been corrected, and the buttress plates remain. In the panoramic radiographs (E), note normal eruption of the maxillary second molars after treatment (horizontal arrow). The patient was congenitally missing all third molars. Oblique arrow points to the left buttress plate after treatment.
FIGURE 12. Cephalometric landmarks, planes (sella-nasion [S-Na] plane, MP, and vertical line through S perpendicular to S-Na plane), angles (S-N-A, S-Na/MP), and measurements (perpendicular distance to A point from the S vertical line, direct distance from Na to A point, and dental overjet).

the posttreatment follow-up period for the remaining 9 patients ranged from 6 months to 2 years (average, 1.2 years). The cephalometric measurements included changes in S-N-A angle, changes in the vertical (direct distance between Na and A point) and horizontal (perpendicular distance between A point and a vertical line through S and perpendicular to the S-Na plane) position of A point, changes in overjet, and changes in mandibular plane (MP) angle (Fig. 12). Paired t-tests between the different times points were conducted for all the measurements as well as a repeated-measures analysis of variance for the 9 patients who had radiographs for the 3 time points. Between T1 and T2, the S-N-A angle changed 4.8 degrees \( (P < 0.001, \text{from 76.9 to 81.7 degrees}) \). The horizontal position of the A point to the S-N vertical changed 5.6 mm \( (P < 0.001, \text{from 51.2 to 56.8 mm}) \). The vertical position of the A point to the S-N plane changed nonsignificantly only 0.5 mm (from 55.8 to 56.3 mm). The overjet changed 8.8 mm \( (P < 0.001, \text{from -6.9 to +1.9 mm}) \). The MP angle decreased significantly 2 degrees \( (P < 0.01, \text{from 40 to 38 degrees}) \). The changes for the 9 patients with posttreatment radiographs between T2 and T3 were small and nonsignificant. The significance for the mean differences was similar when comparing changes between T1 and T2 and T1 and T3. This indicated stability of the initially obtained changes during the follow-up period. Minimal changes in the MP angle and obtaining an ideal overjet and overbite are indicative of adequate vector control with the removable AIM distractors (Tables 1 and 2).

**DISCUSSION**

Cleft patients with significant maxillary hypoplasia were in the past treated with orthognathic surgery. However, orthognathic surgery in cleft patients has yielded less than acceptable results with reported high degrees of relapse.\(^{4-8}\) In addition, it is known that Le Fort I surgery in cleft patients has a higher incidence of morbidity including avascular necrosis with its severe consequences.\(^{26}\) For the above reasons, distraction now has been accepted as a treatment alternative for patients with cleft-related maxillary hypoplasia.

Various techniques for maxillary distraction are currently used. For patients in whom the maxillary deficiency is quite severe and involves the infraorbital and paranasal regions, the technique of rigid external distraction has proven extremely successful. However, in milder cases, rigid external distraction may seem to be intimidating to some clinicians and also to patients who are not properly informed about the benefits of this technique. Therefore, for milder or noncleft patients in whom distraction is indicated, a hybrid (bone-tooth–supported) distractor has been developed. The benefit of this internal distractor over others that are commercially available\(^{25,28,29}\) is the fact that it is relatively easy to place, it allows for vector alterations during the distraction process, and more importantly, it does not require a second operation to remove the distractor.

The observed disadvantages of this internal system are that in cases with limited oral access or severe bone hypoplasia, the placement can be complicated or not possible. In addition, it leaves a plate behind after the distractor is removed. Leaving hardware attached to the maxillofacial bones is of no clinical consequence as this is done on a routine basis during conventional orthognathic surgery and has been done without negative consequences for many years. Another potential disadvantage of this and other internal systems is that the osteotomy design needs to be below the anchor plate. In some instances, the position of the buttress plate can limit the height of the osteotomy; otherwise, the dental roots could be damaged. This osteotomy design is able to correct an anteroposterior deficiency mainly below the floor of the nose. A deficiency involving the paranasal and infraorbital regions may require the use of an external distractor.

The advantages of the AIM distractor system are as follows: it is intraoral; it is easily activated by the patient or caregiver; and there is no risk to the dental roots as the caudal part of the system is anchored to a splint attached to the dentition, so there is no need to use screws for fixation of the device close to root structures.

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\( n = 9 \).

Bonferroni correction for multiple comparisons. Significance level = 0.05. Dif indicates difference between means.

### TABLE 2. Abbreviated Table for Repeated Measures Analysis of Variance, Comparing Values Obtained in the 9 Patients Who Had Radiographs at the 3 Time Points (T1, T2, and T3)

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<td>0.681</td>
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<td>0.081</td>
</tr>
</tbody>
</table>

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Removable AIM Distractor

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system permits adjustability of the vector during the distraction process, and because the distractor can be easily returned to its closed or inactive position, it can be reactivated, allowing for additional distraction distance. In the consolidation period, it acts as a fixation device. The attachment of the distractor to the teeth is easily removed, allowing reactivation and molding of the regenerate with elastic therapy. The device is well designed and relatively small and causes no discomfort to the intraoral tissues in the postoperative period, during the distraction process, or during the consolidation period. Finally, the system can be removed simply in the office setting without the need for local anesthetic and without the need for a second operation.

CONCLUSION
An intraoral distraction system for cleft and noncleft patients who require a mild to moderate maxillary advancement is introduced. It is a relatively easy and simple system to apply, activate, and remove. Its effectiveness is demonstrated by the presented case reports and cephalometric outcomes. The use of this hybrid system for the management of cleft related maxillary hypoplasia provides surgeons with an additional tool to treat this difficult group of patients.

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