Assessment of Mandibular Distraction Regenerate Using Ultrasonography and Cone Beam Computed Tomography: A Clinical Study

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Abstract

Distraction osteogenesis (DO) is becoming a popular method of reconstruction for maxillofacial bony deformities or defects secondary to trauma or surgical tumor ablation. However, the technique is very sensitive in terms of the rate and rhythm of distraction. Because of this, there is a need for monitoring of the distraction regenerate during the distraction as well as the consolidation period. The present study was conducted to assess the regenerate using two imaging modalities, namely, ultrasonography (USG) and cone beam computed tomography (CBCT) to determine their relative efficacies and to weigh their clinical usefulness in assessment of DO regenerate. The study was conducted on 12 patients (18 sites) who underwent mandibular distraction for correction of facial deformities. The results showed that overall USG correlated better with the condition of regenerate ($r = 0.606$) as compared with CBCT ($r = 0.476$). However, USG was less effective as compared with CBCT in assessing the regenerate once corticomedullary differentiation occurred in the bone.

Keywords

- ▶ distraction osteogenesis
- ▶ ultrasonography
- ▶ CBCT

Distraction osteogenesis (DO) is the biological process of new bone formation between the surfaces of bone segments that are gradually separated by incremental traction.¹ This technique is based on the law of tension–stress,² which states that gradual traction on living tissues creates stresses that can stimulate active growth of the tissues involved. The whole process of DO is technique sensitive. The type of tissue formed in the distraction gap depends on the rate of distraction as a too slow rate may lead to premature consolidation and a faster rate may lead to fibrous tissue formation in distraction gap rather than bone.^{3–5} Furthermore, delay in removal of the distraction device beyond consolidation period leads to increased chances of pin tract infection along with associated pain and inconvenience for the patient. Hence, this process requires continuous monitoring during the distraction as

well as the consolidation period. Thus, for regular assessment of the distraction process, various imaging modalities have been used in the past including radiographs, ultrasonography (USG), and computed tomography (CT).

Conventional radiography which was one of the first used modality for this purpose⁶ leads to unnecessary exposure of the patient to radiations and was unable to detect bone formation in early stages as only soft tissue callus is present with minimal mineralization.

To overcome these problems, USG was thought as an alternative and was found beneficial in satisfactorily assessing the distraction gap in several studies.^{7–12} However, the main disadvantage for USG is the need for an expert sonologist for proper interpretation of the images due to unfamiliarity of the maxillofacial surgeons with the USG images. Also, USG has been found unsatisfactory in accurate assessment of

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lengthening once the corticomedullary differentiation occurs in the distraction regenerate.¹²

Recently, CT has been used for the regenerate monitoring as it provides a cross-sectional view of the distraction gap. Roth et al found this technique accurate in volumetric assessment of the mandibular distraction regenerate.¹³ However, the high radiation dose associated with CT is a cause of concern for its use, especially in young patients. Thus, there is a need for an imaging modality which can assess the wound accurately with minimum radiation dosage and at the same time being simple in interpretation for the surgeon. With the advent of cone beam CT (CBCT) which is a commonly used imaging modality in the field of dental medicine, it has become possible to image the maxillofacial region with significantly less radiation exposure. In a study by Hashimoto et al, the CBCT device was found to produce better images than medical helical CT at a much lower radiation dose,¹⁴ which is comparable to a full mouth Intra Oral Peri Apical (IOPA) radiograph series.¹⁵ Owing to these advantages of CBCT over conventional CT, the authors decided to explore the efficacy of CBCT in the assessment of mandibular distraction gap and compare it with USG.

The purpose of the current study was to assess the mandibular distraction regenerate by USG and CBCT and to correlate their findings with the clinical condition of regenerate at the time of distraction device removal. The study was based on null hypothesis and the authors believed that there would be no difference between the two modalities.

Materials and Methods

The study comprised 12 patients (7 males and 5 females) with an age range of 6 to 20 years (mean = 12.2 years) who required mandibular lengthening for the correction of facial asymmetry, retrognathia, or obstructive sleep apnea (OSA). Total 18 sites (6 bilateral and 6 unilateral cases) were addressed. Patient suffering from any kind of systemic disease, for example, metabolic disorders, endocrinal disturbances, bone/connective tissue disorders, and smokers were excluded from the study.

All the patients and guardians were informed about the radiation exposure associated with the treatment procedure and informed written consent was taken. The study protocol was approved by the Institutional Ethical Committee.

In all the patients, distraction was done with a semiburied unidirectional distraction device (Synthes, Switzerland GMBH) with the port placed extraorally.

Distraction Protocol

Activation of the distraction device was done at a rate of 1 mm per day after a latency period of 3 days for children younger than 12 years and 5 days for older than 12 years and a rhythm of twice daily for the number of days corresponding to desired lengthening. The duration of consolidation period was considered as twice the number of distraction days as per the protocol followed by Pensler et al¹⁶ and Troulis et al.¹⁷ The devices were then planned for removal.

Assessment

Postoperative assessment was done with the help of clinical examination, USG and CBCT. The semiquantitative score scales were adopted and modified according to the study conducted by Troulis et al.¹¹

Ultrasonographic Assessment

An experienced ultrasonographer performed the USG examination using a 10 MHz linear transducer probe machine (Siemens Acuson Antares, Shenzhen, China). The US beam was oriented perpendicular to the bone surface and a real-time survey was done to find the best site of bone formation which was used for assigning the score.

USG was done on:

- Seventh postdistraction day to check for early mineralization changes in the distraction gap
- At the completion of distraction
- At the completion of consolidation period (a day before the planned distractor removal).

In all the sites, the sharp osteotomy cut ends were seen clearly in the USG at the completion of distraction period. The distance was then measured linearly. It acted as a baseline for assessing the amount of bone formed at the end of consolidation period.

The semiquantitative score was given at the end of consolidation period as follows:

- 0: Complete throughout transmission of US waves, clear gap margins, no echogenic material.
- 1: Partial throughout transmission of US waves, identifiable gap margins, < 50% echogenic material.
- 2: Partial throughout transmission of US waves, partially obscured gap margin, 50 to 100% echogenic material.
- 3: No throughout transmission of US waves, invisible gap margins, 100% echogenic material.

Cone Beam Computed Tomography Assessment

CBCT images for all study subjects were obtained with K9500 equipment (Carestream Healthcare India (P) Ltd., New Delhi, India) in the normal resolution dental mode at 90 kV, 10 mA. A single scout image, that is, lateral view was taken in accordance with the patient's position, and a 360-degree scan was acquired afterward. The total scan time was 11 seconds. The time required for the reconstruction of volumetric images after the patient's complete exposure was approximately 1 minute.

Study images were reconstructed from the volumetric dataset, in planes perpendicular to the selected tooth axes. True and oblique axial, coronal, and sagittal images with a thickness of 0.2 mm and an interval of 0.2 mm were obtained. Cross-sectional images with a thickness of 0.2 mm and an interval of 1 mm were also prepared.

CBCT assessment was done as follows:

- At the completion of distraction period
- At the completion of consolidation period (a day before the planned distractor removal).

The semiquantitative score for the regenerate was given at this stage as follows:

- 0: No bone formation in the gap
- 1: > 0 but < 50% bone fill
- 2: 50 to 100% bone fill
- 3: Complete bone fill in the gap.

Third party image processing software (Ondemand 3D, Cybermed Inc., Seoul, Korea) was used for reproducible superimposition or fusion of the first and second CBCT volumetric datasets of the same patient to verify the semi-quantitative scores.

Intraoperative Assessment at the Time of Distraction Device Removal

At the time of distractor removal, the surgeon clinically evaluated the bone by probing at multiple sites in the distraction gap and the stability of the mandible was also recorded. Surgeon's comments were then translated into a semiquantitative score as follows:

- 0: Only soft tissue in the gap with gross mobility across the segment
- 1: > 0 but < 50% bone fill in the gap with mild to moderate mobility
- 2: 50 to 100% bone fill in the gap with mild mobility
- 3: Complete bone fill in the gap, no mobility across the segment.

As the clinical condition and stability of the distraction regenerate are actually visible to the surgeon during surgical device removal, the scores given at this time were considered as gold standard. Since the distraction device removal and scoring in all cases was done by the same surgeon, the bias in intraoperative assessment that could have occurred due to surgeon variability was avoided.

Correlation between USG and CBCT scores at the end of consolidation period and clinical scores were obtained using Spearman correlation coefficient.

Results

In the present study, the amount of distraction ranged from 11 to 28 mm (mean = 20.22 mm) and the duration of consolidation ranged from 28 to 64 days (mean = 41.6 days). There was one exception to the consolidation period where in one patient undergoing genial distraction, the duration was extended 8 days beyond the planned duration due to accidental fracture at osteotomy site during distraction (► **Table 1**). In one patient undergoing asymmetric advancement, the duration of consolidation of the side undergoing more distraction was considered.

Complete bone formation was found in only 10/18 sites on clinical assessment at the time of distraction device removal where a score of 3 was given. In rest of the eight sites, either no or incomplete bone formation was seen where scores were given accordingly. In sites where no bone formation was seen, the distraction gap was found to be filled by fibrous tissue. It probably suggests that a consolidation period of twice the

duration of distraction is not sufficient for complete mineralization of the regenerate. Such patients were managed with postoperative maxillomandibular fixation.

With ultrasonographic monitoring, bone formation was visible in the distraction gap as early as 1 week after distraction in 14 out of 18 sites. In only 3/18 sites, complete cortical bridging of distraction gap was noticed (score = 3), whereas in 2/18 sites, no bone formation was noticed in distraction gap (score = 0). In rest of the 13 sites, the scores varied from 1 to 2 depicting intermediate bone formation (► **Table 1**).

USG scores correlated completely with clinical scores in 7/18 sites. In 8/18 sites, it underestimated the bone formation, whereas in 3/18 sites, clinical bone formation was overestimated by USG (► **Fig. 1**). Out of the seven sites where USG and clinical scores completely correlated, three had complete bone formation (score = 3), two had no bone formation (score = 0), and the rest two sites had intermediate levels of bone formation (scores 1 and 2).

With CBCT monitoring, in 11/18 sites scores completely correlated with clinical scores. Out of these 11 sites, 8 had complete bone formation (score = 3), 2 had no bone formation (score = 0), and 1 site had intermediate bone formation (score = 2) (► **Fig. 2**). CBCT score in the rest seven sites were as follows: 3 at two sites, 2 at one site, 1 at one site, and 0 at three sites.

Statistical Analysis

Statistical analysis was done using Spearman correlation coefficient. It revealed that USG scores correlated well with clinical scores ($r = 0.606$) with a one-tailed p value of 0.0038 as compared with CBCT ($r = 0.476$) with a one-tailed p value of 0.0231. This finding was quite surprising because CBCT correlated in more number of sites as compared with USG. The possible reason for this might be the high amount of disparity among CBCT and clinical scores in sites where correlation was not seen. This disparity might be due to the artifacts produced by the distraction device which made assessment of distraction gap difficult, especially in early and intermediate mineralization stages.

Discussion

The main aim of assessment of the regenerate in the "distraction period" is to ascertain whether bone formation is taking place properly or not, so that the rate of distraction can be adjusted accordingly, if required. On the contrary, regular appraisal of the distraction gap during the "consolidation period" is also equally critical. It helps in deciding the appropriate time of removal of the distraction device and thus avoiding complications associated with either premature removal or longstanding hardware in vivo. Conventional radiologic evaluation was the only mode of detecting bone formation in earlier days.⁶ However, radiographs failed to detect bone formation during early stages of distraction and associated radiation exposure was also a matter of concern. In search of a new imaging modality for assessment of distraction site, USG was used during DO done for limb lengthening by Young et al.⁷ In their study, they found that new bone

Table 1 Table showing detailed clinical, USG, and CBCT scores of each patient

S. No.	Age/sex	Diagnosis	Treatment	Amount of distraction		Consolidation period in days	USG score		CBCT score		Clinical score	
				Right	Left		Right	Left	Right	Left	Right	Left
1	19/M	Retrognathia due to B/L TMJ ankylosis	Bilateral corpus distraction	23	23	46	0	1	0	0	0	0
2	20/F	Asymmetry due to TMJ ankylosis	Unilateral corpus distraction	26	-	52	2	-	2	-	2	-
3	15/F	Asymmetry due to TMJ ankylosis	Unilateral corpus distraction	-	20	40	-	1	-	3	-	3
4	16/M	Retrognathia due to B/L TMJ ankylosis	Bilateral corpus distraction	24	24	48	0	2	3	3	0	0
5	6/M	Retrognathia due to B/L TMJ ankylosis	Bilateral corpus distraction	11	20	40	1	2	1	3	2	3
6	6/F	Asymmetry due to TMJ ankylosis	Ankylosis release and condylar transport distraction	-	21	42	-	3	-	2	-	3
7	10/M	Asymmetry due to condylar hypoplasia	Condylar transport distraction	16	-	32	2	-	3	-	3	-
8	20/F	OSA due to B/L TMJ ankylosis	Genial distraction	14	14	28	1	2	0	0	1	1
9**	15/M	OSA due to B/L TMJ ankylosis	Genial distraction	28	28	64	2	3	3	3	3	3
10	6/F	Asymmetry due to TMJ ankylosis	Unilateral corpus distraction	-	19	38	-	2	-	0	-	3
11	11/M	Retrognathia due to B/L TMJ ankylosis	Bilateral corpus distraction	18	18	36	1	3	3	3	3	3
12	12/M	Asymmetry due to TMJ ankylosis	Unilateral corpus distraction	-	17	34	-	2	-	3	-	3

Abbreviations: CBCT, cone beam computed tomography; OSA, obstructive sleep apnea; USG, ultrasonography.

**S. No. 9.

Fig. 1 Graph showing correlation between USG and clinical scores. USG, ultrasonography.

formation could be seen many weeks before sonograms as compared with radiographs. In addition to this, in one site, it was possible to visualize developing cyst in distraction site which was not possible with radiographs. Due to this advantage of detecting early changes occurring in distraction sites, it was possible to treat them sooner before the process of bone formation got adversely affected. The use of USG in craniofacial distraction has also been reported by various authors with encouraging results.⁸⁻¹² It enjoys the benefit of being noninvasive, no radiation hazard to the patient, inexpensive, widely available¹⁰ and not subject to radiographic magnification.¹² However, at the same time, it also has some limitations which include nonfamiliarity of USG images to the surgeons and the difficulty in obtaining images in the early postoperative period due to hindrance caused by tissue edema.¹³ Thus, in the present study, the first USG was done 1 week after the start of distraction and during this time, the edema usually regresses and the authors did not encounter much difficulty in obtaining images of the distraction gap.

Ultrasonography Monitoring

USG monitoring in the present study revealed few specks of echogenicity in the distraction gap as early as 1 week after starting of the distraction. As the distraction continued, the number and size of echogenic foci increased in the distraction gap, which were later aligned parallel to the direction of distraction. The distraction gap was found to be of "v" shape in most sites following 1 week of distraction (→ **Fig. 3**). Gradually, the "v" shape changed to "u" shape as the distraction continued and this "u" turned shallow gradually like a saucer, during the consolidation period. It probably suggests that bone formation in distraction gap occurs from the periphery toward the center and from the base toward the superficial surface.

Troulis et al¹¹ reported that USG images show complete cortication across the distraction gap as the bone formation gets completed. However, the authors failed to see the same in all except three sites. The USG images of distraction gap failed to show complete cortication even at sites where a complete

Fig. 2 Graph showing correlation between CBCT and clinical scores. CBCT, cone beam computed tomography.

Fig. 3 USG image showing the typical “v” shape of the distraction gap at 1 week after starting of distraction. USG, ultrasonography.

Fig. 5 USG image of the distraction site shown in ►Fig. 4. Despite complete clinical bone fill, complete cortication in the distraction gap is not seen in the USG image. USG, ultrasonography.

clinical bone fill was seen at the time of distraction device removal (►Figs. 4 and 5).

Cone Beam Computed Tomography Monitoring

CBCT is a commonly used imaging modality which has gained enormous popularity in the field of dentomaxillofacial imaging since its introduction in 1999.¹⁸ The associated radiation dose varies from 29 to 477 μ Sv which is approximately 1.3 to 22.7% of comparable conventional CT.¹⁹ CBCT has been used widely in imaging of fractures, bony deformities, impacted teeth, temporomandibular joint (TMJ), and 3D cephalometry in orthodontics.²⁰ In the present study, its use has been explored to assess mineralization in the distraction gap.

The finding suggested that CBCT scores completely correlated with the clinical scores in 11/18 sites. In 5/18 site, CBCT underestimated bone formation, while in the rest 2/18 sites, bone formation was overestimated (►Fig. 2). Out of the 11/18 sites where CBCT scores completely correlated with clinical scores, 8 were those which had complete bone formation

(score 3), while 2 had no bone formation (score 0) and 1 site had intermediate level of bone formation (score 2). It indicates that CBCT is able to accurately show either complete or no bone formation at all, but in the intermediate levels of bone formation, it does not have same accuracy. This inability of CBCT to detect early bone changes in the distraction site might be attributed to this technique being a radiographic modality which requires at least 30 to 60% mineralization or demineralization for the new bone to be evident radiographically.^{20–22} However, once the corticomedullary differentiation occurred, it was very well seen on CBCT images (►Figs. 6 and 7). Overall, there were 10/18 sites where complete bone formation was found in the distraction gap intraoperatively at the time of distraction device removal. Out of these, eight sites were accurately detected by CBCT while USG could detect only three of them. Therefore, in the present study, CBCT was found to detect complete bone fill more accurately than USG, which might prove beneficial in decision making regarding the timing of removal of the distraction device after the

Fig. 4 Clinical picture showing complete bone fill in the distraction gap at the time of distraction device removal.

Fig. 6 CBCT image of distraction site shown in ►Fig. 4 at the end of distraction period. CBCT, cone beam computed tomography.

Fig. 7 CBCT image of distraction site shown in ►Fig. 4 at the completion of consolidation period. Cortical bridging in the distraction gap can be well appreciated. CBCT, cone beam computed tomography.

completion of bone formation in distraction gap. A main disadvantage of CBCT is that one cannot assess the bone density using this technique. However, in a recent in vitro study, Mah et al²³ showed that the gray levels in CBCT can be used to derive the Hounsfield units and thus, density of the regenerate can also be assessed by this imaging modality. This proposed algorithm by Mah et al can be applied in future studies on CBCT.

Conclusion

On comparing the results of present study, the authors found that neither CBCT nor USG can effectively assess the distraction regenerate throughout the whole distraction and consolidation period. USG was found more beneficial in the early stages of regenerate maturation to detect initial mineralization and any changes in the immature distracted bone, whereas CBCT was more valuable in depicting the changes once the bone formation reached near completion. Thus, the authors concluded that a combination of both USG and CBCT might prove useful at varying intervals of consolidation. Another observation which was made during the present study was that twice the duration of distraction is not a sufficient period for complete mineralization of distraction regenerate. Thus, a longer consolidation period dictating the device removal may be considered.

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