Original Article

To determine the efficacy of ultrasonography in the evaluation of bone fill at the regenerate site for mandibular distraction osteogenesis over clinical and radiographic assessment– An in vivo prospective study

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ABSTRACT

Until date conventional radiographs and computed tomography are the preferred diagnostic modalities to monitor the distraction osteogenesis regenerate. But these techniques do not detect the ongoing osteogenic process; moreover they obligate the patient to serial radiation exposure. In addition, anatomic overlap and metal artifacts obscure the virtual findings. In contrast, ultrasound is a noninvasive, efficient and an inexpensive way to evaluate bone healing. This study was conducted to test the efficacy of ultrasound in evaluating bone healing at the mandibular distraction site. Twenty patients underwent mandibular distraction. The wounds were assessed with an orthopantomograph and an ultrasound at the end of latency, mid distraction, end of distraction and post distraction periods i.e. 6 weeks, 8 weeks and 4months. Estimates of bone formation, using a semiquantitative radiological, ultrasonographic and intraoperative surgical bone fill scores were made. The correlation between intraoperative and ultrasonographic bone fill scores was statistically significant at 0.602, a total of 26 of the 31 sites correlated. Corresponding correlation between intraoperative and radiographic bone fill scores was 0.332, and only 13 of the 31 sites correlated. The results indicate that ultrasound is potentially an accurate noninvasive technique that is most useful in assessing the mandibular distraction regenerate.

1. Introduction

Distraction osteogenesis is a unique form of clinical tissue engineering in which the clinician is able to guide the formation of new bone by mechanical means. The principles and guidelines for today's distraction protocol are mainly based on the studies and clinical trials of Dr. Ilizarov.^{1,2} It has now become an important tool for the maxillofacial surgeon due to its simplicity and versatility,

The duration of the consolidation period, however, as yet remains a debatable issue amongst the clinicians. Accurate assessment of the wound during the distraction phase and neutral fixation phase is important to document the progress of bone lengthening, assure stability of the device, determine the degree of bone formation in the distraction gap and the optimal timing for device removal.³

Current methods to assess healing of the mandibular distraction wound include clinical examination, plain radiography, and computed tomography. Serial radiographs and CT examination increase unnecessary radiation exposure to the patients.

In contrast to the above, Ultrasonography is an inexpensive,

efficient method of imaging that provides detailed assessment of bone formation across the defect with no radiation to the patient. Ultrasonic assessment of normal mature bone is limited by the inability of the ultrasound beam to penetrate the outer cortex, however newly formed bone, which is not completely remodeled and calcified, can be well evaluated with high-resolution linear ultrasound.⁵ This phenomenon allows the surgeon or radiologist to evaluate the quantity and distribution of the regenerate (Tables 1 and 2).

Ultrasound also is a real-time examination, one that can be adapted to the anatomy being examined. This allows interrogation of the mandibular distraction gap without interference from the distractors themselves. Thus the ease, minimal expense, lack of metal artifact, lack of the need for sedation of an otherwise uncooperative young patient and most importantly lack of radiation exposure makes ultrasonography a powerful tool for the assessment of bone healing.

The purpose of this study was to compare the efficacy of Ultrasonography as an assessment tool in comparison with radiographic and clinical examination in the evaluation of the mandibular distraction osteogenesis regenerate.

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Table 1

Bone fill scores at each interval of study.

BONE FORMATION	D0	D1		D2		D3				D4			D5			
		0	1	0	1	0	1	2	3	1	2	3	0	1	2	3
Count	33	33	0	31	2	17	13	2	1	22	9	0	17	13	2	1
Percent	100.0%	100.0%	0.0%	93.9%	6.1%	51.5%	39.4%	6.1%	3.0%	71.0%	29.0%	0.0%	51.5%	39.4%	6.1%	3.0%
Count	33	31	2	29	4	3	22	6	2	13	15	3	3	22	6	2
Percent	100.0%	93.9%	6.1%	87.9%	12.1%	9.1%	66.7%	18.2%	6.1%	41.9%	48.4%	9.7%	9.1%	66.7%	18.2%	6.1%
Count	66	64	2	60	6	20	35	8	3	35	24	3	20	35	8	3
Percent	100.0%	97.0%	3.0%	90.9%	9.1%	30.3%	53.0%	12.1%	4.5%	56.5%	38.7%	4.8%	30.3%	53.0%	12.1%	4.5%

Table 2

Beam penetration depth used as a monitoring measure for progressive bone fill at the intervals.

BPD	N	Mean	Std. Dev	Median	IQR
D0	0				
D1	0				
D2	2	4.750	0.7778	4.750	1.100
D3	20	10.745	22.9279	6.150	6.975
D4	31	5.052	3.3822	5.400	5.100
D5	31	0.474	0.9063	0.000	0.900

2. Materials and methods

A prospective study was conducted at a tertiary teaching hospital, a total of 20 patients were selected from the OPD of Dept. of Oral & Maxillofacial Surgery, requiring distraction osteogenesis of mandible (including horizontal, vertical, alveolar, transport distraction) for correction of their deformities.

Medically compromised patients, patients with osteoporosis and other osteopathies, pregnant patients, were excluded from the study.

Thorough case history taking and clinical examination of all patients were performed. Patients with a micrognathia and positive history of snoring were additionally evaluated with Polysomnography for assessment of their Apnoea: Hypopnoea Index (AHI) to determine the severity of Obstructive Sleep Apnoea (OSA).

2.1. Distraction appliances used

Bone-borne, intra oral, indigenously manufactured, internal devices were used for distraction.

In the first stage surgery, Placement of horizontal mandibular distraction was carried out under general anesthesia: A suitable pre-selected length of horizontal mandibular distractor was placed in the angle-body region of the mandible via submandibular incision bilaterally with each of its footplates being on either side of the osteotomy cut and fixed with corresponding screws.

A latency period of 5 days for adults and 3 days for children was followed. Distraction was carried out at the rate of 1 mm/day with 2, 360° turns, i.e. 0.5 mm for every turn every 12 h. Distraction was carried out till the full amount of desired reduction in overjet (in case of micrognathic patients) or till the completion of activation of the appliance was achieved and no further movement was possible.

The periodic radiological (Fig. 1) and ultrasonic (Figs. 2–5) assessments were carried out in the study as illustrated in the flow chart 1.

Removal of bilateral horizontal mandibular distractors / mandibular transport distractors under general anesthesia after clinically scoring the regenerate (Fig. 5).

2.2. Assessment parameters applied

2.2.1. Radiographic assessment

Serial ORTHOPANTOMOGRAPHIC images were taken [D₀–D₅] for

confirmation of device function and mandibular elongation. Assessment was done by blinded evaluators using a semi-quantitative 4-point scale as follows:

- 1 No bone fill
- 2 0% < bone fill < 50%
- 3 50% < bone fill < 100%
- 4 Complete bone fill

2.2.2. Ultrasonographic assessment

Images obtained on ultrasonographic assessment [from D₀ to D₅] were assessed by blinded evaluators and rated on a semi-quantitative 4-point scale as follows:

- 1 Complete through transmission of US waves with no echogenic material.
- 2 Partial transmission of US waves, echogenic material < 50%.
- 3 Partial transmission of US waves, echogenic material > 50%.
- 4 No through transmission of US waves, 100% echogenic material.

2.2.3. Intraoperative assessment at distractor removal

A 3- point scale was used by the operator as follows:

- 1 0% < bone fill < 50%
- 2 50% < bone fill < 100%
- 3 Complete bone fill in the gap with no segment mobility.

2.3. Statistical analysis

Data analysis was done with the help of SPSS Software version 15. Quantitative data is presented with the help of Mean, Standard Deviation, Median and IQR. Correlation among study parameters i.e. Ultrasonographic, OPG images and intraoperative assessment scores was done with the help of correlation coefficient.

Qualitative data is presented with the help of Frequency and Percentage table, association among study groups was assessed with the help of Chi-Square test.

3. Results

A total of 20 patients (11 males and 9 females) were included in the study with the number of distraction sites assessed being 33. Of the 20 patients, 13 patients were subjected to bilateral horizontal mandibular distraction (sites = 26) and 7 patients were subjected to transport distraction (sites = 7), the total no. of distraction sites thus being 33.

3.1. Assessment of beam penetration depth (BPD)

Beam penetration depth was used as a monitoring measure for progressive bone fill at the intervals (Tables 1 and 2). The mean BPD showed a progressive decrease from D₃ to D₅ interval (10.745 mm–0.474 mm) indicative of progressive bone fill hence suggesting an inverse relationship of BPD to the number of days of neutral

Fig. 1. USG at D0 (end of latency) shows osteotomy cuts seen as defects in hyperechoic regions (mandible) indicated by an arrow.

fixation.

An increase was seen in the mean BPD from 4.750 mm at D2 to 10.745 mm at D3, which was contradictory to our expectation of progressive decrease in BPD. This can be attributed to the increase in number of sites from $n = 2$ to $n = 20$ available for measurement of BPD.

The Spearman rank correlation between intraoperative and radiographic bone fill scores was 0.332. In 13 of the 31 sites, radiographic and intraoperative scores correlated. In the remaining 18 of the 31 sites, the radiographic score underestimated the amount of bone fill in the distraction gap relative to the intraoperative score. In none of the distraction sites, the radiographic score overestimated the amount of bone in the gap.

The Spearman rank correlation between intraoperative and USG bone fill scores was statistically significant at 0.602. In 26 of the 31 sites, the USG and intraoperative scores correlated. In the remaining 5 sites, the USG score underestimated the amount of bone fill in the distraction gap compared with the intraoperative rating.

Another finding that was noted during the study was that the amount of distraction achieved, as measured on USG, was lesser than the total number of days of distraction with the rate of 1 mm per day (17.958 ± 9.0264).

4. Discussion

Distraction Osteogenesis is a technique that uses the body's innate healing capacity to generate new bone and thus eliminate the need for bone grafts.

One of the greatest challenges of distraction and deformity correction is deciding when the bone has healed enough to remove the

distractor. Little is yet known with respect to the appropriate length of the consolidation period for the newly formed bone. Moreover, the rate of bony healing is difficult to predict as it differs from patient to patient. Thus we need improved methods for serial monitoring of the distraction regenerate so as to adjust the rate of distraction for each patient and also reduce the period of neutral fixation thus reducing the overall treatment time.

Till today no standard means of estimating the integrity of distraction regenerate is available. Serial radiographs have been traditionally used for monitoring the progress of distraction regenerate consolidation.^{4,6} However, the calcification needs to have progressed to a certain extent before it becomes evident on the radiograph. Nicholls et al⁵ showed that plain radiographs may not be accurate for measuring bony union. Furthermore, serial radiographs result in significant cost and radiation exposure.⁷

Computed tomography provides more detailed information on the quality (e.g., trabecular bone density) and quantity of bone in the distraction wound than other imaging modalities.^{3,8,9} The linear relationship between mean CT-values and calcium content has been well documented for several bones of the human body including the mandible.^{10,11} However, the increased radiation dose and cost of CT scans makes it difficult to justify their use.

Ultrasonography and ultrasonometry have been successfully used in orthopedic literature to be accurate measures in assessment of distraction wound. J W Young et al¹² showed that the sonographic appearance of new bone consists of echogenic foci within the distraction site and could be detected with sonography many weeks before its appearance on the radiograph.

HM Malde¹³ indicated the superiority of Ultrasonography over conventional radiographs in detecting early new bone formation,

Fig. 2. USG at D1 (mid-distraction) widening of hypoechoic region indicating no bone fill.

Fig. 3. USG at D3 (6 weeks post-op) reduction in the span of hypoechoic region indicating beginning of bone fill from osteotomy ends (score 1).

establishing cortical and medullary canal remodeling, detecting soft tissue complications at the distraction site and determining the presence of fluid collection at the distraction site, in patients with delayed consolidation.

Ultrasound showed a precise picture of all interesting items in distraction treatment. Although the value of radiographs is not obsolete completely, sonography was found to be a meaningful supplement in the clinical monitoring of callus distraction.

As plain radiographs underestimated bone formation compared with Ultrasound and intra-operative findings, Ultrasonography is an accurate noninvasive technique that may prove to be useful in assessing the mandibular Distraction regenerate in patients. Since the distraction regenerate is devoid of a cortical layer during consolidation, the Ultrasound waves can penetrate the site thus giving us valuable quantitative analysis of the bone fill in the distraction gap.^{14, 15}

In this study, we tried to assess the feasibility of using Ultrasonography as a means of assessing the mandibular distraction wound in 33 distraction sites, we found that USG scores correlated exactly with the intra – op findings at distractor removal in 26 sites as compared to only 13 sites in case of OPG scores. In the remaining 18 sites OPG underestimated the amount of bone fill as compared to only 5 in case of USG. Thus, reliability of USG to assess bone fill as compared to OPG is seen to be better in our study. Hence it may prove to be helpful in earlier termination of consolidation period and reduction in treatment time.

The amount of echogenic material in the distraction wound (bone) was seen to increase with the progress in the period of consolidation. Similar to the findings noted in the studies by Maria J. Troulis et al.¹⁴

In this study, we also used Beam Penetration Depth (BPD) as a measure of assessing bone fill at the distraction site ultrasonographically. Maturation of the distraction regenerate produced a change in its acoustic properties relative to that of the surrounding soft tissues.

The maximum benefit of BPD as a quantitative tool to evaluate the DO wound is derived from serial measurements at regular intervals. A spectrum of bone formation can be seen within the same distraction wound at any given point of time during the period of neutral fixation (consolidation period).

Our study also showed that, though a distraction rate of 1 mm per day was followed in the distraction protocol, the actual amount of distraction achieved (mean = 17.958, SD = 9.0264), as measured between the ends of the osteotomised segments on USG at the end of distraction, was always less than the number of days (mean = 20.95, SD = 10.002) for which the distraction was carried out.

5. Conclusion

Within the limits of our study, Ultrasonography was found to be a potential tool to serially evaluate bone formation at mandibular distraction sites. Ultrasonometry, used to obtain the beam penetration depths, is a useful method of assessing bone fill and hence accurately gauge the timing of distraction device removal.

These findings, coupled with the minimal expense, lack of metal artifact, lack of radiation exposure, and lack of the need for sedation of uncooperative young patients, make Ultrasonography a powerful adjuvant tool for assessment of bone healing and may decrease the number of serial radiographs required. However, the results of this study are to be interpreted with caution due to the limited sample size and a large scale study would always be advisable for better analysis so that the results are clinically more meaningful.

Conflict of interests

None.

Fig. 4. USG at D5 (4 months post-op) shows complete bone fill (score3).

Fig. 5. Removal of bilateral horizontal mandibular distractors under general anesthesia after clinically scoring the regenerate.

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