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COMPARATIVE STUDY BETWEEN THE EFFECT OF SHOCKWAVE THERAPY AND LOW-INTENSITY PULSED ULTRASOUND (LIPUS) ON BONE HEALING OF MANDIBULAR FRACTURES (CLINICAL & RADIOGRAPHIC STUDY)

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ABSTRACT

INTRODUCTION: Low-intensity pulsed ultrasound (LIPUS) and extracorporeal shock wave therapy (ESWT) are the different forms of acoustic mechanical waves that might promote bone healing by stimulating bone growth in long or other bones .the aim of this study is to evaluate the effect of adjuvant LIPUS and ESWT in healing of patients with fresh mandibular fractures.

Subjects and Methods: this study was a randomized controlled clinical trial , twenty one patients (12 males, 9 females) aged from 20 to 40 years with fresh mandibular fractures treated with closed reduction and maxillary mandibular fixation (MMF) were prospectively enrolled into this study with ethical approval and informed consent .Those patients were randomly assigned in three treatment groups ,each of seven patients . Group I received a single treatment with 4000 impulses of focused ESWT, group II received 18 sessions of LIPUS for 20 min while group III received neither represented the control group . Clinical assessment together with radiographic follow-up using cone beam computed tomography (CBCT) at 1.5 and 3 months were done for all patients postoperatively.

RESULTS: there was statistically significant difference in bone density between three groups in different times after six weeks and after three months as bone density higher in group I (ESWT) than in groups II,III

CONCLUSIONS: Focused ESWT appeared to be more effective than LIPUS or nothing as an adjuvant treatment of adults with fresh mandibular fractures.

KEYWORDS: Low intensity pulsed ultrasound, extracorporeal shock wave therapy, mandibular fracture.
RUNNING TITLE: ESWT and LIPUS effects on mandibular fracture healing.

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INTRODUCTION

Mandibular fractures are the most common fractures found between craniofacial injuries. (1-3). Accounting for 23-97% of all facial fractures worldwide (4). The fracture is "breach in the continuity of bone" (5). It requires a force of about 70g to 100g to produce a mandibular fracture (6). The mandibular bone is the strongest and largest facial bone (7), it has a main role in the aesthetics and the functional occlusion (7,8). the patterns and etiology varies from one country to another dependent on socioeconomic,cultural,and environmental issues(9-12). road traffic accident is the most common etiological factor followed by violence and direct trauma (13). The bulk of mandibular fractures occur in young males from 21 to 30 years old (14).

The managing of mandibular fractures may be problematic to achieve an aesthetically practical progress. An appropriate administration is essential to reconstruct the structure, shape, form and function of unhurt status (15). Postoperative illness is the most serious disadvantage following oral and maxillofacial surgery. This consist of pain, trismus, inflammation and contamination disturbing patients' quality of life and emotional well-being (16).

Treatment of maxillofacial fractures depends up on using open or closed techniques for the reduction, fixation and rebuilding of standard occlusion. Before fracture reduction, temporary Inter-maxillary Fixation (IMF) with correct registration of occlusion is essential (17).

Conventional management of undisplaced or slightly displaced mandibular fracture by IMF is consequently still a viable option. Inappropriately, it requires a prolonged period of immobilization which causes discomfort, weight loss, malnourishment, and most significantly can compromise airway function in case of gagging. Consequently, the need arose for the use of an innovative technique towards the reduction of the postoperative IMF period; a treatment method that may has a major effect on fracture healing period is Low-Intensity Pulsed Ultrasound (LIPUS) which has a supportive effect on bone healing and the reduction of fracture healing time (18-23), Several studies have strongly backed the evidence that Extracorporeal Shock Wave Therapy (ESWT) has a optimistic effect to induce bone regeneration. It was concluded that ESWT combined with intermaxillary fixation can be an real treatment for faster fracture healing and even for the reduction of complications combined with fracture healing (24-30). So this clinical trial effort to compare between the effect of Extracorporeal Shock Wave Therapy and Low-Intensity Pulsed Ultrasound on healing procedure of fresh mandibular fractures.

The null hypothesis of this study is that there is no significant difference in mandibular fracture healing in the clinical and radiographic parameters after application of Low-Intensity Pulsed Ultrasound (LIPUS) or Extracorporeal Shock Wave Therapy (ESWT)

MATERIALS AND METHODS

This study was a randomized controlled clinical trial .It included twenty one adults with fresh mandibular fractures selected from the outpatient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Egypt, and from the Emergency Ward of the Alexandria Main University Hospital. Faculty of Medicine, University of Alexandria, Egypt. A full informed consent was signed from all participants and this study was formally approved by the Ethics Committee of the faculty of dentistry, Alexandria University. With the following ID:[IORG No. 0008839 ,November 2016.

For all patients a through history was recorded in a standardized format. All patients were free of any systemic or bone disease. Patients presenting with infection, burn and scar in the skin of relevant working area or with any contraindication to ESWT, LIPUS or CBCT were excluded. Furthermore, all fractures were single non-displaced fresh mandibular fractures treated with closed reduction and maxillary mandibular fixation (MMF) using Erich arch bar or eyelet wiring fixed using 24 gauge wire.**(Figure1.A,B)** The pre-operative evaluation was based on clinical, extra-oral, intra-oral examination and standard Orthopantomogram. In all patients, standard principles of surgical preparation, reduction, fixation and suturing were followed. MMF was placed for 3-6 weeks and oral hygiene was maintained by 0.2% chlorhexidine oral rinses. Warm fomentation, antibiotics, anti- inflammatory and analgesic drugs were administered for 5-7 days following surgery. Patients were instructed for careful oral hygiene measures, discontinue smoking and avoid biting on any tough food and rest. In addition soft, fully liquid, high protein, high calorie diet was given for all patients for 4 weeks postoperatively. A minimum post-operative follow-up period of 3 months was necessary.

Post-operatively, those patients were randomly assigned in three treatment groups, each of seven patients. Group I (the ESWT group): received a single session of high energy electrohydraulic shock wave therapy the day after closed reduction (4000 impulses; 0.35mJ/mm2) energy flux density per impulse and frequency range from 4 to 6 Hz under regional anaesthesia. Determination of the fracture line was done firstly intra orally by dental probe by help of panoramic x-ray and marked extra orally by marker pen to fix the applicator of the Orthowave 180c® over the middle portion of the pre marked line, with continuation of an analgesic on the same day of the session.**(Figure1,C)**

Group II (the LIPUS group): received 18 sessions of Low-intensity pulsed ultrasound therapy via Sonopuls 692 Enraf-Nonius with frequency of 1MHz, intensity 1.50 W/cm2 applied externally over the area of fracture line, starting from the day after closed reduction and repeated three times weekly for six weeks with considering analgesic if required on the day of the session. **(Figure1,D)**

Group III (the control group) received neither represented were treated with closed reduction and MMF by arch bar or eyelet wiring without exposure to shockwave or Low-intensity pulsed ultrasound.

Clinical follow-up was carried out after 24 hours, at 1, 4, 6, and 12 weeks postoperatively. For assessment of pain, oedema, tenderness, discharge at the site of the fracture , looseness of the MMF, maintenance of proper occlusion and normal jaw movement after MMF removal as well as stability of the segment and nerve function. Postoperative Pain was determined through a 10-point Visual Analogue Scale (VAS); (0- 1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe).

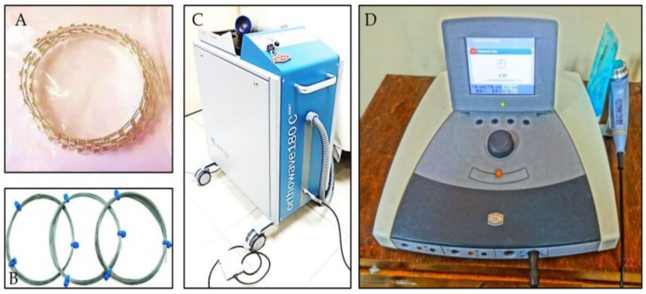

Figure (1):
(A) Erich arch bar.
(B) 24 gauge stainless steel wire.
(C) Orthowave 180c®.
(D) Low- intensity pulsed ultrasound Device

Postoperative radiographic follow-up evaluation was done using Cone beam computed tomography (CBCT) with J.Morita R100 cone beam 3D imaging system (Morita 3DX; J Morita Mfg corp., Kyoto, Japan). The scan was done with field of view (FOV) W 100mm X H 80 mm. The volume was reconstructed with 0.250 mm isometric voxel size. The tube voltage was 90 kVp and 8 mA, Exposure time was 20 seconds. The image was analyzed using OnDemand3D™ software (Cybermed Inc.) CBCT analyzing software. A standard 5 mm thickness cut was selected for all measurement. A Bone Density measurement icon was used at the region of interest (ROI) to give a reading in a gray scale by means of (6 points at each ROI). The mean bone density at the site of fracture was calculated by measuring the bone density at 6 points distributed inside the fracture line then taking their mean values to determine the mean bone density at 1.5 and 3 months postoperatively. In addition to estimate the adequacy of the reduction of the fractured section and the improvement of healing process.

Statistical analysis of the data

All the obtained data was statistically analysed and presented in tables, graphs and charts using the IBM Statistical Package for Social Science (SPSS)* version 13.0 software.

The chi-square test was applied to determine any significant differences in pain, occurrence of complications, mean bone density between the patients at different follow up phases.

RESULTS

The study involved 21 patients; 12 males and 9 females, their age ranged from 20 to 40 years with a mean of 28.52 ±5.50 years. Road traffic accident is the most common etiological factors of mandibular fractures in 71.4% of patients, interpersonal violence in 23.8% and fall in 4.8 %.

The anatomic positions of mandibular fractures were parasymphysis in 38.1%, the body in 47.6% and ramus in 14.3% of patients. No complications were observed except for slight gingival inflammation and bleeding after MMF in immediate postoperative period.

Regarding pain intensity, it was observed during the first 24 hours after treatment that the mean value of pain score using VAS in group I was 8.14±0.69, group II was 7.71 ±0.76 while in the control group III it was 7.86±0.69. But this difference was not statistically significant as p value =0.500 ($p \leq 0.05$).

One week later, a statistically significant decrease in pain was observed in group I (2.86±1.07), group II (4.86±0.90) as well as in group III (6.0±0.58) p value = 0.001 ($p \leq 0.05$). However, the decrease of pain in group I was statistically significant in comparison to either group II and III (p1=0.032*, p2<0.001*respectively) but not on comparing groups 2 and 3 (p3=0.094)**.** The mean VAS of pain score in group I was 1.2±0.31 at week 4 postoperatively with signs of clinical union, 3.12 ±0.67 in group II while in the control group III it was 5.56±0.71. Signs of clinical union were achieved in 71.4% of group II by week 6 and in 57.1% of group III by week 6.**(Figure 2 ,Table 1)**

At one and half months postoperatively, the mean bone density in group I was 1145.7 ± 166.5 voxel value (VV), group II was 535.9 ±190.5VV while in control group III it was 803.05 ± 197.8VV, the difference between the three groups was found to be statistically significant (p = 0.001 ;$p \leq 0.05$). Significant higher mean bone densities was found in group I compared to either group II or III (p1<0. 001*, p2=0.025*respectively). At three months postoperatively, the mean **bone** density was 1472.3 ± 24.09 VV in group I, 612.5 ± 92.4 VV in group II and 960.0± 198.0 VV in the control group III, again the difference between the three groups was found to be statistically significant (p =0.001; $p \leq 0.05$). **(Figure 3,Table 2)**

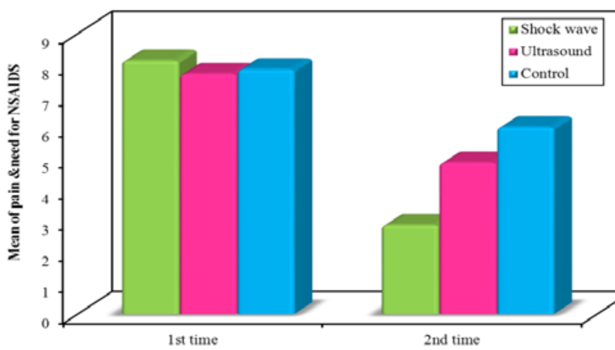

Figure (2): Descriptive analysis of the three studied groups at two times according to pain (n=21).

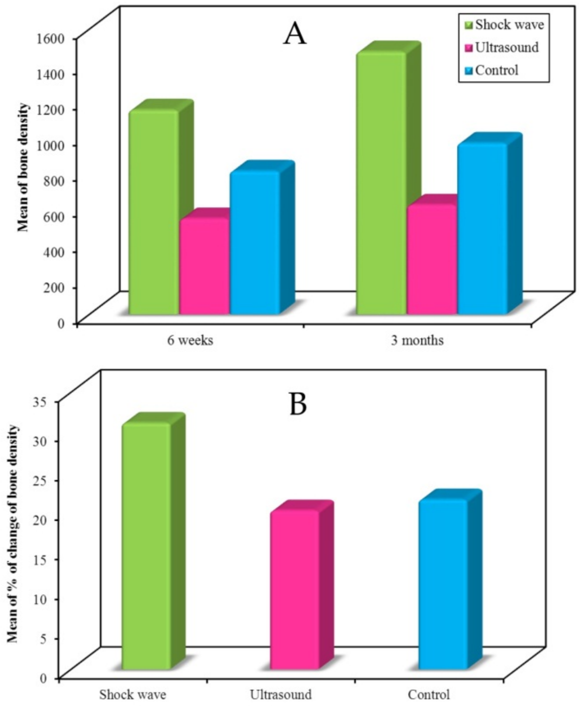

Figure (3): (A) Descriptive analysis of the three studied groups at two different periods of time according to bone density (n=21). **(B)** Distribution of the studied groups at two different times according to % of change of bone density (n=21)

The percentage change in the bone density after the one and half to 3 months' postoperative measurements was not statistically significant comparing the three groups. This means that group I with the use of ESWT attained a statistically significant higher bone densities at one and half months post-operatively than the other two groups and this effect was maintained at 3 months period.**(Figure4,5,6,Table 3)**

Table (1): Distribution of the studied cases at two periods according to pain (n=21)

Pain	1st time	2nd time	Z	p
Shock wave				
Min. –Max.	7.0 –9.0	2.0 –4.0		
Mean ±SD.	8.14 ±0.69	2.86 ±1.07	2.379*	0.017*
Median	8.0	2.0		
Ultrasound				
Min. –Max.	7.0 –9.0	4.0 –6.0		
Mean ±SD.	7.71 ±0.76	4.86 ±0.90	2.392*	0.017*
Median	8.0	5.0		
Control				
Min. –Max.	7.0 –9.0	5.0 –7.0		
Mean ±SD.	7.86 ±0.69	6.0 ±0.58	2.414*	0.016*
Median	8.0	6.0		

Z: **Wilcoxon signed ranks test**
p: p value for comparing between the studied periods
*: Statistically significant at $p \leq 0.05$

Table (2): Distribution of the studied groups at two times according to bone density (n=21)

Bone density	6 weeks post operatively	3 months post operatively	Z	p
Shock wave				
Min. –Max.	855.9 - 1334.5	1430 - 1495		
Mean ±SD.	1145.7 ± 166.5	1472.3 ± 24.09	2.366*	0.018*
Median	1150.17	1480.0		
Ultrasound				
Min. –Max.	364.3 –930.8	505.9 –760.7		
Mean ±SD.	535.9 ±190.5	612.5 ±92.4	1.352	0.176
Median	494.3	622.0		
Control				
Min. –Max.	376.2 - 957.28	526.2 –1100.6		
Mean ±SD.	803.05 ± 197.8	960.0 ±198.0	2.366*	0.018*
Median	833.83	1020.5		

Z: **Wilcoxon signed ranks test**
p: p value for comparing between the studied periods
*: Statistically significant at $p \leq 0.05$

Table (3): Distribution of the studied groups at two different times according to % of change of bone density (n=21)

% of change of bone density from 6 weeks to 3 months	Shock wave (n=7)	Ultrasound (n=7)	Control (n = 7)	H	p
Min. –Max.	7.15 – 71.81	-18.28 – 40.07	9.76 – 39.86		
Mean ±SD.	31.11±21.22	20.04±19.88	21.44 ± 9.92	0.742	0.690
Median	28.68	18.52	18.09		

H: H for **Kruskal Wallis test**
p: p value for comparing between the studied groups

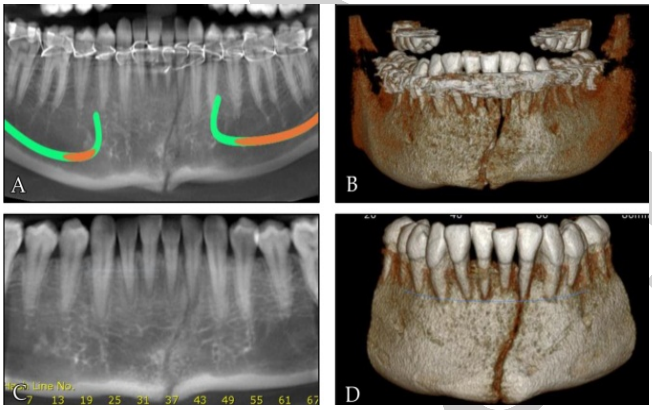

Figure (4): A 31-year-old male patient with left parasymphyseal fracture treated with closed reduction and MMF then received one session of ESWT. a,b panoramic and 3D CBCT sections I.5 months post-operatively showing early signs of fracture healing . c,d panoramic and 3D CBCT sections 3 months post-operatively showing progression of bone healing.

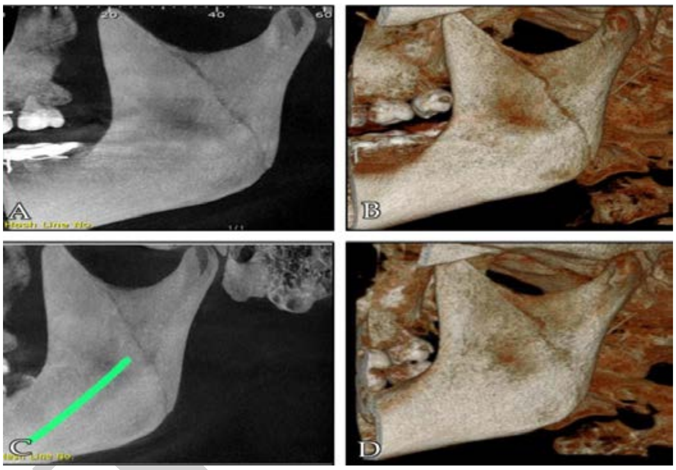

Figure (5): A 27-year-old female patient with left ramus fracture treated with closed reduction and MMF then received 18 sessions of LIPUS. a,b panoramic and 3D CBCT sections I.5 months post-operatively showing early signs of fracture healing ,c,d panoramic and 3D CBCT sections 3 months post-operatively showing progression of bone healing

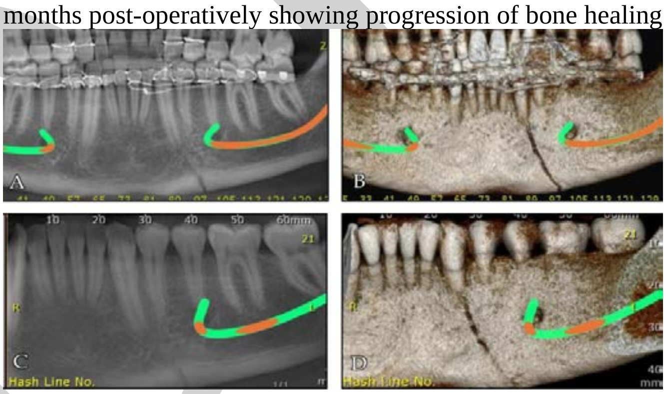

Figure (6): A 35-year-old male patient with left parasymphyseal fracture treated with reduction and maxillary mandibular fixation, a,b panoramic and 3D CBCTsections I.5 months post-operatively showing early signs of fracture healing ,c,d panoramic and 3D CBCT sections 3 months post-operatively showing progression of bone healing .

DISCUSSION

In the musculoskeletal coordination, the biomechanical environment shows an important role in restoring, conserving, and restoration of the fractured bone to meet its functional demands. Built on this fundamental idea, many connective tissue remodeling rules have been proposed to explain the repair procedure and their biological responses. When the normal healing and remodeling environment is compromised or lacking, reliable and active biological or biophysical stimulation may be necessary (31).

In an effort to reduce immobilization period thereby facilitating early return to function with slight sickness, there were lots of ways and studies about how to accelerate bone healing to ensure the patients quick recovery which includes return to work, regeneration and family life. Augmentation of skeletal repair can be done by physical stimulation therapies. There are a large number of devices that are sold under the category of bone growth stimulators these modalities are attractive because they are less aggressive. The two main types of physical stimulation therapies used in fracture healing include low intensity pulsed ultrasound, and extracorporeal shock wave therapy. In animal models, these shockwaves have biological properties by forming free and oxygen radicals, which lead to the construction of a number of different growth factors. In previous studies, the authors settled that extracorporeal shock wave therapy may excite the healing process as it produces physiological effects and biological healing processes, bone remodeling, anti-inflammation and increases bone mass concentration, in delayed unions or nonunion. So in our study we tested the effect of both devices on the healing of mandibular fracture, the extracorporeal shockwave for group I (study group), and low intensity pulsed ultrasound for group II (study group) and no application of physical stimulation therapy for group III (control group) (32,33).

In our study we dealt with 21 Patients suffering from mandibular fractures in different sites divided randomly in 3 equal groups, each group involved of seven patients.

In the first group I (study group) the fractures were closely reduced, treated with maxillary mandibular fixation (MMF), and followed by receiving a solitary session of high energy electrohydraulic shockwave therapy (2000-4000 impulses of frequency ranged from 1-5 pulses per second at approximately 20 minutes).

It had been hypothesized that the extracorporeal shockwaves caused micro trauma or micro fracture and encouraged neovascularization through hematoma formation which would increase osteoblast or fibroblast action. Focused shockwave affects small precisely defined area carrying more energy which invades deeply in tissues to increase local blood current and stimulates inflammatory response to promote tissue curing according to **Wang, et al.,** (24).

The second group II (study group) consisted of seven patients with mandibular fracture which was closely reduced and fixed with maxillary mandibular fixation (MMF), and then underwent 18 sessions for 20 minutes of Low-intensity pulsed ultrasound 3 times weekly. It has a frequency of 1 MHz, pulse frequency/duty cycle 100 Hz/50%, and an intensity of 1.50 W/cm2 continuous.

In the year 1996 Yang et al ,mentioned that the low intensity pulsed ultrasound improves fracture healing by stimulating earlier synthesis of extracellular matrix protein, the aggrecan in cartilage, possibly altering chondrocyte maturation through endochondral bone formation path (34).

The third group III (control group) in which the fractures were closely reduced and fixed with maxillary mandibular fixation (MMF), by using Erich arch bar and 24 gauge stainless steel wire deprived of any physical intervention.

In our study, patients were selected randomly lying within the age range from 20 to 40 years old with a mean of 28.52 ± 5.50 years old. This is higher than **Sakr, et al.,** who reported in **2006** a mean age of 22 years old and also higher than **Melek and Sharara,** who announced in **2016** that the mean age of patients subjected to maxillofacial trauma is 25.56 ± 14.04 years old (35,36).

These results may be owing to the fact that young adults represent a large mass in our country and they vigorously participate in outdoor activities without caring about safety rules such as seat belts in cars and wearing crash helmets at what time riding motorbikes.

In the existing study, most fractures were sustained by men as 57.1% of patients were males and 42.9% were female which indicate that, the incidence of male affection was more than female affection which is consistent with most of the studies, the high ratio in our country might be because the females drive vehicles less commonly and more carefully than males. This is in agreement with other studies showing a male predilection in maxillofacial fracture as in **Natu et al., and Sakr et al., and Melek and Sharara** (13,35,36).

Regarding the etiology of mandibular fracture in our patients, road traffic accidents (RTAs) were found to be the most prominent cause of fractures accounting for 71.4% of the cases followed by inter personal violence 23.8%, and fall 4.8%, which is in agreement with **Sakr et al., Natu et al.,** and **Melek and Sharara,**

Causes of road traffic accidents (RTAs) may be due to high speed vehicles on high ways, driving of drunk and addict drivers on motor ways, and using mobile phones while driving with non-compliance with traffic laws (13,35,36).

While in **2006, Sakr et al., mentioned that** the second cause of maxillofacial injuries was fall followed by inter personal violence (IPV). The sport related injuries seem to be increasingly involved in the cause of maxillofacial trauma (36).

However in our cases the most frequent affected site was the body of the mandible (47.6%), followed by parasymphyseal region (38.1%), whereas this is mostly regarding to the fact that lower canines having longer roots than adjacent teeth, the fact that makes the bone in this area weaker and more liable to fracture. These results are mismatched with Sakr et al., (36) who found that the angle was the most common site and with Melek and Sharara, (35) who found that parasymphyseal region is the most commonly affected site.

Closed Reduction and fixation of fractured mandibular segments were done with administration of local anaesthesia to apply the Ivy loop or Erich arch bars using 24 gauge wires; this was done for all patients in the three groups. In group I, patients were administered local anaesthesia due to the pain associated with high energy extracorporeal shock wave therapy. But in groups II and, III anaesthesia was not necessary. So there was significant difference between the three groups in administration of anaesthesia as p value =0.001 ($p<=0.05$).

Concerning the postoperative pain, the latter was assessed using a visual analogue scale (VAS). There was no significant difference between the three groups at the first 24 hours postoperatively where the mean value of pain score 7.9± 0.7 in the three groups, and was treated by using diclofenac potassium orally 50 mg twice daily for five days. After one week, pain score was measured again by using VAS and the mean value of pain score in group I (study group) which was subjected to shock wave session became 2.86 ± 1.07. For group II (study group) the mean value of pain score became 4.86 ± 0.90 after 3 sessions of low intensity pulsed ultrasound, where in group III (control group) the mean value of pain score became 6.0±0.58.This difference was statistically significant where the pain decreased markedly after one week in case of group I. This may be explained by the fact that extracorporeal shock wave improves the blood circulation and has a proven analgesic effect (37,38).

In this study, radiographic follow up demonstrates a strong correlation between gray- scale values of CBCT images and bone densities. This has implications for potential quantitative radiological approaches to determining bone density from CBCT images. The mean bone density of group I was higher than groups II and III, but the percentage change of the bone density was not statistically significant comparing the three groups.

Our results show that the use of the extracorporeal shock waves in the treatment of fractures of the human lower jaw is better as its applicator produces shock waves which are single high amplitude sound waves generated by electrohydraulic that provides a deeper penetration (up to 5cm) than that of conventional ultrasound therapy. Shockwave has shown to be a less time consuming (20 minutes for one single session) than the low intensity pulsed ultrasound (20 minutes per day 3 times weekly for 6 weeks) (39,40).

In conclusion ESWT application on the fracture site of mandibular fracture may be useful in acceleration of the fracture healing and our study could be the setting stone for further studies & researches as to the best of our knowledge, it is the first time for using shockwave therapy in the management of jaw bone fractures. So we reject the null hypothesis of this study.

CONCLUSION

From this study, the following points could be concluded:

Extracorporeal shock wave therapy is safe and effective therapy for fracture healing as it increase bone mass density, advance blood perfusion and metabolism of the surrounding soft tissue in addition to an pain-relieving effect. So it may be helpful in acceleration of fracture mandible.

Our study is the first time for using shockwave therapy in the treatment of jaw bone fractures, and the promising results should encourage the implementation of more studies to confirm the value of this treatment modality.

The authors declare that they have no conflicts of interest.

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