

CLINICAL AND RADIOGRAPHICAL EVALUATION OF THE USE OF HERBERT SCREWS VERSUS CONVENTIONAL MINIPLATES FOR FIXATION OF MANDIBULAR ANTERIOR FRACTURES (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

Objective: There are different treatment modalities for fixation of anterior mandibular fractures. Including bone plates, lag and Herbert screws. This study aimed to compare between using Herbert screw versus two conventional miniplates for anterior mandibular fractures fixation concerning timing of surgery, mouth opening, bite force recovery and bone density along the fracture line.

Materials and methods: A randomized controlled clinical trial was carried included twenty patients divided into two equal groups, 10 patients each. The study group received two Herbert screws for fixation of the anterior mandibular fracture, the control group received two conventional miniplates. Clinically operation timing, maximum mouth opening and bite force recovery were assessed. The bone density along the fracture line among both groups was recorded.

Results: The time taken using either techniques was statistically insignificant ($P= 0.156$). A non-significant difference was found concerning the maximum mouth opening at one week ($p= 0.505$). In following intervals, a significant difference was detected ($p < 0.001$). An increase in bite force recovery in both groups along all the follow up intervals was noticed; comparing all data between both groups, there was a statistically significant difference towards the study group ($p < 0.001$). Finally, a statistically significant difference was notable between both groups along the whole follow up period regarding the bone density ($p < 0.001$).

Conclusion: Herbert screws are found to be highly technique-dependent, requiring advanced surgical skills. Nonetheless, in terms of compression fixation, low cost, fewer devices and hardware required, and improved wound healing outcomes, they surpassed the other treatment modality.

KEYWORDS: Herbert screws, miniplates, mandibular fracture, parasymphseal fracture, symphyseal fracture.

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INTRODUCTION

The second most common facial injury in maxillofacial trauma is mandibular fractures. They represent 36-70 % of all facial injuries, according to multiple studies.⁽¹⁻³⁾

The most common sites involved during mandibular trauma are condyles and angle of the mandible. Although the prevalence of isolated anterior mandibular fractures is less common, its incidence ranging from 9%-57%. Malocclusion, enlargement of intergonial distance, dysphagia, speech, and esthetics difficulties are the most common clinical manifestations of anterior mandibular fracture.^(2,4)

The basic universal approach for treating a bony fracture is reduction and immobilization, which can be performed via a variety of surgical techniques. Treatment can be divided into two categories: closed reduction with intermaxillary fixation and open reduction with direct skeletal fixation. Open reduction can be done through an intraoral or extraoral approaches using transosseous wires, bone plates and fixation screws.⁽⁵⁾

Champy et al.⁽⁶⁾ advocated that miniplate osteosynthesis performed as soon as possible after trauma minimizes the overall rate of wound dehiscence and infection.

According to Cawood in 1991, inferior and superior borders fixation using conventional 2mm thickness miniplate has proven better outcome over traditional Intermaxillary fixation (IMF). He stated that the miniplate is simple to use, allows for exact anatomic reduction, and in most cases IMF is not required leading to faster recovery.⁽⁷⁾

The placement of miniplate along the osteosynthesis ideal's line counteracts distraction stresses that occur along the fracture plane during mandibular function.⁽⁸⁾ A second miniplate placed on the inferior border to withstand forces at the fracture line, according to Kroon et al,⁽⁹⁾ and Choi et al,⁽¹⁰⁾ would be better.

Moreover, the first use of lag screws in maxillofacial surgery was by Borns and Boering⁽¹¹⁾. They suggested using two lag screws to prevent rotation in mandibular fractures. A lag screw contains threads on the distal end as well as a smooth shank on the proximal part, which allows compression of both bony segments. The screw head will pass passively through the outer cortex of the proximal segment during rotation, allowing segments compression against one another without microfractures.^(12,13)

Herbert Fisher⁽¹⁴⁾ proposed a screw design for the treatment of scaphoid bone fractures in 1984, in which a cannulated headless screw with different pitch threads at both ends and a plain smooth shaft in the middle was used. It was demonstrated that using Herbert screw (HBS) enables appropriate bony segments compression overcoming the problems of lag screws, such as failure to establish compression, inability to estimate screw length, and distal segment mobility.⁽¹⁵⁾

Following fixation of mandibular fractures, the forces exerted during masticatory movements have received minimal attention. One of the components of the chewing process is the bite force. It rises with age starting in childhood, stays pretty consistent between the ages of 20 and 40 and then diminishes. The average maximal voluntary biting force measurement in healthy males is 50 pounds.^(16,17)

Therefore, the rationale of conducting this study was to compare between the use of Herbert screw versus two conventional miniplates in fixation of anterior mandibular fractures in terms of timing of surgery, bite force recovery and bone density along the fracture line.

MATERIALS AND METHODS

Study design and setting

This study was carried out as a randomized controlled clinical trial following the CONSORT guidelines for reporting clinical trials, in which 20

patients were chosen and operated under general anesthesia at the Oral and Maxillofacial surgery department, Faculty of Dentistry, Alexandria university. The university's ethical committee granted the necessary ethical approval. The nature of the study was explained to each patient, who signed their informed consent. All procedures used in studies involving human subjects complied with the institutional and/or national research committee's ethical requirements, as well as the 1964 Helsinki Declaration and its subsequent revisions or comparable ethical standards.

The Twenty patients assigned to the study presented with symphyseal or parasymphiseal mandibular fractures and were chosen thoroughly to fulfill the following eligibility criteria; the inclusion criteria included adult patients having an isolated unfavorable symphyseal or unilateral parasymphiseal mandibular fracture, of both gender and age ranging between 20-50 years, free of any bone disorders that may complicate normal bone healing and with proper oral hygiene. On the other hand, the exclusion criteria were patients contraindicated to general anesthesia, patients presenting with infection at the fracture site, or with an associated condylar fractures and patients not willing to return for follow up.

The selected patients were allocated randomly into two equal groups each consisted of 10 patients through the randomizer.org website. Group A:

(Study group), in which anterior mandibular fracture segments were exposed intraorally, properly reduced and fixed with a two Herbert screws. (Manufactured by DePuy Synthes Medical device company: Warsaw, US. www.depuyorth.com) (**Figure 1 a & b**). While, Group B: (Control group): in which anterior mandibular fracture segments were exposed intraorally, properly reduced and fixed with a two conventional miniplates (2.0-mm Leibinger System by Leibinger Stryker, Freiburg, Germany).

1. Preoperative evaluation

The patient's full medical history were taken included the basic personal information, as well as the trauma's history, past medical history, and current medications were all considered.

Then a thorough radiographic examination was performed; all patients were asked to present with a standard orthopantomogram and a computerized tomography (CT) to assess the degree and direction of displaced fractured segment, as well as to identify the fracture line and the bone density along the fracture.

The clinical evaluation also assessed the malocclusion and nerve impairment which were detected throughout an extraoral and intraoral inspection and palpation. Furthermore, maximum mouth opening were measured between the upper central incisor and the lower central incisor with digital callipers (Shanghai Afimao

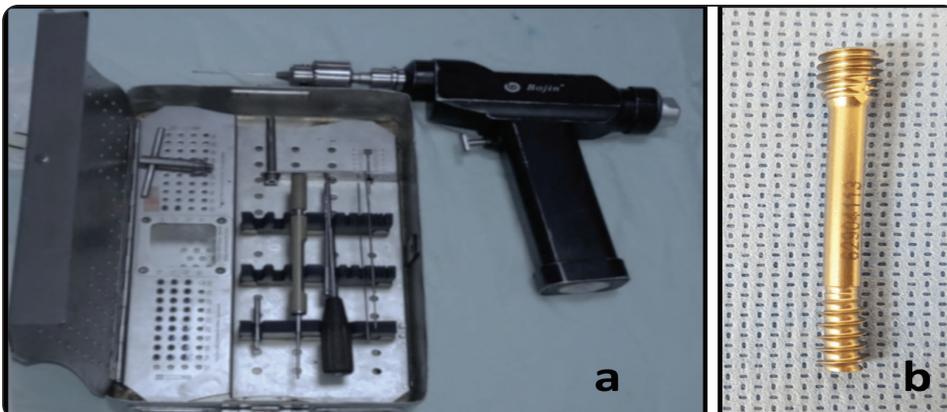


Fig. (1): a- Surgical kit for Herbert screw insertion. b- Herbert fixation screw.

Dental Industries Co., Ltd). (T0). Finally, a pressure indicating film (Pressurex®, Sensor Products INC, New Jersey, USA) is used to measure bite force. The pressure indicating film is a simple and unique instrument for revealing the force distribution and magnitude between any two touching surfaces.

2. Operative phase

All patients were operated at the Operating Room of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University under general anaesthesia and complete aseptic condition.

All patients were given an induction intravenous anesthesia and a muscle relaxant. A cuffed nasotracheal tube was then used to intubate patients. A pack was placed to prevent any blood, saline, or other fluids from entering the body and any object from aspiration into the airway.

The oral cavity was scrubbed with Betadine (Povidoneiodine, 7.5%, NileCo. for Pharmaceuticals and Chemical Industries) before wrapping the sterile towels all around the extra-oral surgical site. Teeth in the fracture line were managed by extraction or preservation, as determined by the preoperative

examination. Proper occlusion was regained, then intermaxillary fixation was done to all cases.

In all cases, an intraoral approach was used to get access to the fracture site. A conventional layered dissection of the mucosa, mentalis muscle, and periosteum was done to expose the fracture site. The mucoperiosteal flap was carefully raised, preserving the mental neurovascular bundle. Fracture sites were properly debrided using sharp bone curettes. Fragments were held and maintained in place using bone clamps to insure a proper reduction, with the alignment of the buccal cortex and inferior border which was confirmed visually in all cases.

For Group A (Study group): Two Herbert screws were placed intrabony along both inferior and superior borders of the mandible at the fractured site as follow: A 1.1mm Kirschner (K) Guide wire was drilled through the fracture line till it reached lingual cortex of distal segment. The screw length is determined using the depth gauge. Drilling is done with a 2mm cannulated spiral drill and the K-wire for guide. Herbert screw was finally inserted via a cannulated torque ranch screwdriver. **(Figure 2 a-d)**

For Group B (Control group): Two conventional

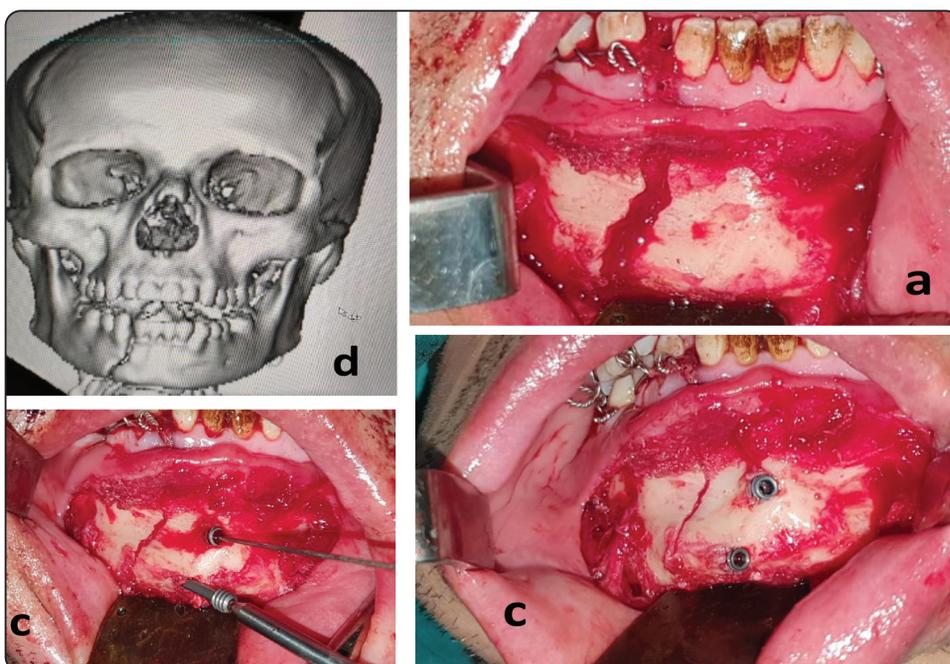


Fig. (2): a- 3D CT scan showing right mandibular parasymphyseal fracture (Study group). b- Clinical photograph showing the fracture line. c- Insertion of the two Herbert fixation screws. d- Fracture reduced and fixated by the two Herbert screws.

miniplates were placed on both inferior and superior borders of the mandible at the fractured site. (**Figure 3 a-c**)

For all cases, 4/0 and 5/0 Vicryl suture material (Johnson Int, Belgium) was used to close intra-oral incisions in layers. After the surgery, IMF was released and the occlusion was confirmed.

All patients in both groups were given antibiotics and nonsteroidal anti-inflammatory drugs twice daily for seven days (Cataflam 50 mg tablets, Novartis pharma AG, Basle, Switzerland; Augmentin 1 gm tablet, SmithKline Beecham pharmaceutical Co., England).

After surgery, a 0.12 % chlorhexidine mouthwash was used for 7 days (Hexitol mouthwash, the Arab medicine firm for pharmaceutical and chemical industries, Cairo, A.R.E).

3. Follow up and parameters of evaluation

Clinical evaluation:

Timing of Operation was measured intraoperatively for both groups using a stopwatch that was activated starting from performing the intraoral incision and stopped with the last suture for flap closure.

Maximum mouth opening was remeasured on the second day postoperative (T1), after the second week (T2), and at 3 months after the operation (T3).

The results were calculated in comparison to those obtained before the procedure

Bite force recovery was assessed by the pressure indicating film on the second day, after the second week, and after 3 months postoperatively. The measurements were compared to those taken before to the operation. The pressure indicating film is a Mylar based and is covered with a layer of microscopic microcapsules. When force is applied to the film, the microcapsules break, resulting in a high-resolution image with both instant and permanent pressure change over the “topographical” image area of contact. The two-sheet of Pressure Indicating Films is made up of two distinct polyester bases and is used to measure bite forces ranging from 2-100 kg. One has a layer of color-creating micro-encapsulated material, and the other has a coat of color-developing material. The patients were instructed to bite as hard as they could on both side of the pressure indicating film for 5 sec (**Figure 4 a & b**). The film was converted to a magenta hue quickly and permanently, with the intensity proportional to the level of force applied. To determine the force applied throughout the pressure indicating film, the following methods were used: The produced pressure indication films and the colour calibration swatch were scanned. The amount of pressure applied to the film was computed by comparing the colour density of the

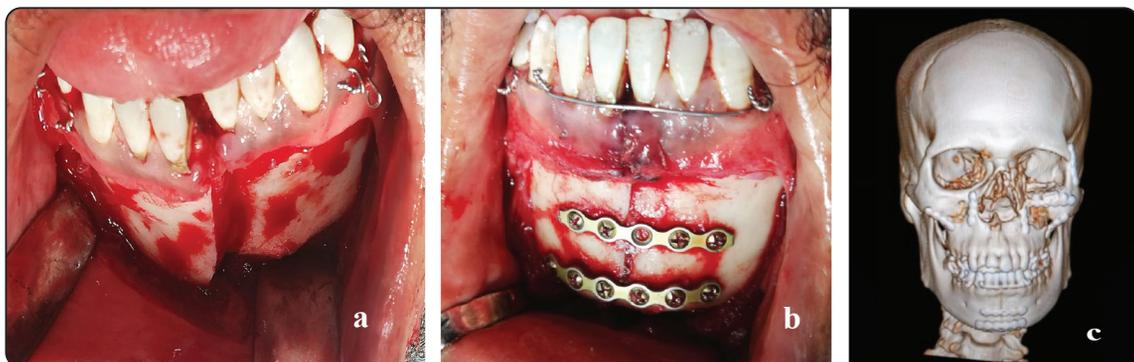


Fig. (3): **a-** Intra-operative view of a symphyseal mandibular fracture (control group) **b-** Intra-operative view of two conventional miniplates used for fixation of the symphyseal fracture. **c-** Post-operative 3D reconstructed CT showing the proper reduction and fixation of the fractured segments.



Fig. (3): **a-** Intra-operative view of a symphyseal mandibular fracture (control group) **b-** Intra-operative view of two conventional miniplates used for fixation of the symphyseal fracture. **c-** Post-operative 3D reconstructed CT showing the proper reduction and fixation of the fractured segments.



Fig. (4): **a-** pressure indicating film. **b-** bite force measurement using the pressure indicating film.

film to the colour pattern in Photoshop CS4; pixels to a specific surface area, which can then be calculated as: Force = Surface area x pressure. The bite force was measured and averaged at the fracture side's premolar area.

Radiographical evaluation

An immediate post-operative CT-scan was performed to examine fracture reduction from a buccal and lingual perspective, followed by a three-month CT-scan to assess mean bone density at the fracture line and compare it to the immediate post-operative CT scan. ⁽¹⁸⁾ The average bone density of the two CT scans done for each patient was calculated by taking 6 points at the location of the fracture line on the axial cut of the CT scans and measuring the value of bone density with a CT software. Hounsfield Unit was used for all measurements (HU). (**Figure 5**)

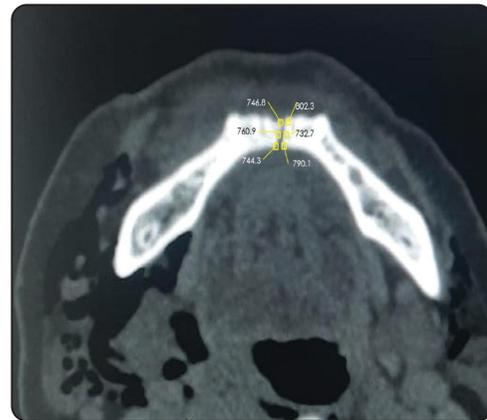


Fig. (5): Axial CT scan showing the measurements of average bone density around the fracture line by HU.

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). For continuous data, they were tested for normality by the Shapiro-Wilk test. Distributed data were expressed as range (minimum and maximum), mean, standard deviation and median Student t-test was used to compare two groups for normally distributed quantitative variables while ANOVA with repeated measures was used to compare between more than two periods, followed by Post Hoc test (Bonferroni adjusted) for pairwise comparisons. Significance of the obtained results was judged at the 5% level.

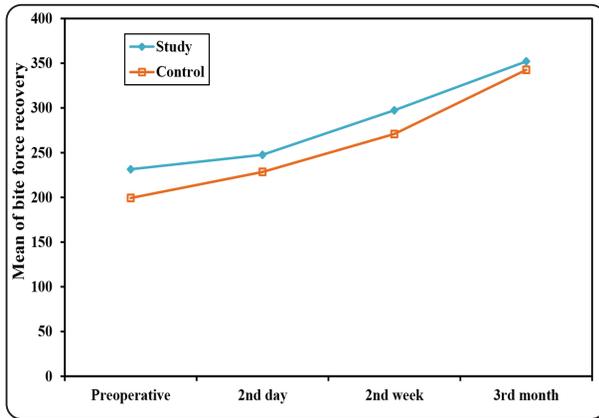


Fig. (7) Line chart graph comparing between the different studied periods according to bite force recovery in each group

Bone Density:

Bone density was calculated in Hounsfield unit HU from the CT scans for both groups preoperatively, immediate postoperatively and at 3 months postoperatively. Before surgery, the mean bone density within the study group was 761.4 ± 38.0 , on the other hand it was 766.4 ± 68.9 in the control group. Comparing both results together a statistically non-significant difference was found ($p= 0.844$). Immediately postoperative, the mean bone density calculated for the study group was 1378.0 ± 42.5 and 998.5 ± 68.9 for the control group. A statistical significant difference was found between both groups. Finally, at 3 months, an increase within the level of bone densities was observed; the mean bone density in the study group was 1637.8 ± 138.2 and 1218.2 ± 127.3 for the control group. A noted statistically significant difference was towards the study group ($p < 0.001$). (Table 2, Figure 8)

TABLE (2): Comparison between the different studied periods according to bone density in each group

	Bone density			P
	Preoperative	Immediate	3 months	
Study (n = 10)				
Mean \pm SD.	761.4 ± 38.0	1378.0 ± 42.5	1637.8 ± 138.2	$<0.001^*$
Median (Min. – Max.)	754.2 (714.5 – 810.5)	1390.6 (1300.7 – 1415.7)	1619.9 (1415.1 – 1905.6)	
Sig. bet. periods.	$p_1 < 0.001^*$, $p_2 < 0.001^*$, $p_3 = 0.001^*$			
Control (n = 10)				
Mean \pm SD.	766.4 ± 68.9	998.5 ± 68.9	1218.2 ± 127.3	$<0.001^*$
Median (Min. – Max.)	729.9 (703.5 – 898.2)	998.0 (889.7 – 1100.8)	1214.6 (1000.4 – 1419.5)	
Sig. bet. periods.	$p_1 < 0.001^*$, $p_2 < 0.001^*$, $p_3 = 0.002^*$			

SD: Standard deviation

F: F test (ANOVA) with repeated measures, **Sig. bet. periods** was done using Post Hoc Test (adjusted Bonferroni)

p : p value for comparing between the studied periods

p_1 : p value for comparing between Preoperative and Immediate in each group

p_2 : p value for comparing between Preoperative and 3 months in each group

p_3 : p value for comparing between Immediate and 3 months in each group

*: Statistically significant at $p \leq 0.05$

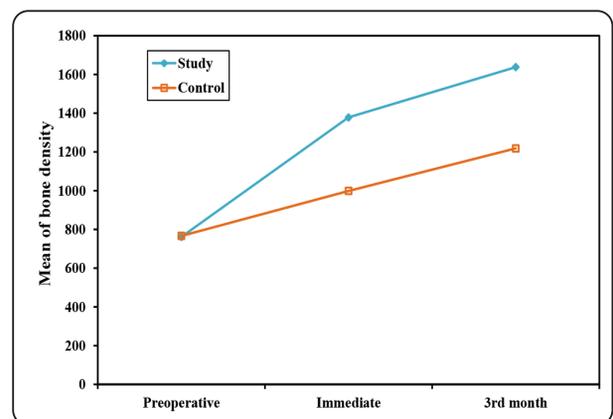


Fig. (8) Line chart graph comparing between the different studied periods according to bone density in each group

DISCUSSION

In the literature, there were a range of alternatives for reduction and fixation of anterior mandibular fractures, including lag screws, two miniplates, reconstruction plates, and arch bar with single miniplate or lag screw.

Twenty patients with anterior mandibular fractures (Symphyseal or Parasymphyseal) were chosen for this study. The ten study group patients had their mandibular fractures reduced and treated with two Herbert screws. The control group consisted of ten patients who had their mandibular fractures reduced and treated using two standard miniplates. According to Champy et al, the fracture site was exposed using an intraoral technique in both groups.⁽¹⁷⁾

In this current work, the major cause for mandibular fractures was road traffic accidents, which accounted for 80 % of the included cases. These results were similar to those reported by Yadav et al⁽¹⁸⁾ who observed that road traffic accidents were the etiological factor in 70 percent of cases.

In the study group, none of the treated cases showed signs of infection or wound dehiscence, however in the control group, only one case (10%) developed wound dehiscence during the first week of follow-up with no signs of suppuration. The wound was debrided and irrigated with normal saline and instructions were given to the patient concerning proper dental hygiene measures.

Our results were close to those gathered by Agnihotri et al.⁽²⁰⁾ who compared the efficacy of internal fixation for symphyseal fractures using either lag screws versus miniplates; they observed that 10% of patients treated with miniplates developed wound dehiscence with infection that necessitated plate removal.

In this research, the time of operation using two herbert screws for fixation was higher than using two miniplates. The mean operation time for the study group was 39 min and 36 min for the control group. These findings were in contrast to Schaff et

al.⁽²¹⁾ who stated that the time taken for lag screw placement was lesser than time taken for placement of two miniplates. This differences in results might be attributed to the difference in site of screws fixation, as they used the lag screws for fixation of angle fractures.

The degree of mouth opening was increased all over the study period within both groups. The statistical difference was only detected at the late stage of the follow up intervals, with more increase in maximum mouth opening in the study group. This difference may be attributed to the less traumatic procedure of Herbert screw placement in comparasion to this used for placement of the two miniplates. These results run parallel to Hughes⁽²²⁾, who found an increase in the degree of mouth opening in the lag screw group in contrast to the 3D plate group when used for fixation of anterior mandibular fractures.

The maximum bite force of an adult person is between 300 and 400 N.⁽²³⁾ In case of fracture, this magnitude is diminished⁽²⁴⁾. As a result, while attempting to assess the biomechanics of various fixation procedures, clinically relevant characteristics must be considered in order to provide useful information to the clinician; one of these characteristics are the bite force recovery.

Bite force was assessed using pressure sensitive sheets in this investigation. It is a very thin sheet that can conform to curved surfaces and is used to assess a patient's biting force and occlusal contact area. Shinogaya et al.⁽²⁵⁾ compared entire occlusal load by the aid of a pressure sensitive films versus traditional unilateral strain-gage transducer. They came to the conclusion that a pressure-sensitive sheets outperforms traditional measuring devices. Two variables have contributed to this result. Bite force can be assessed near to the intercuspal location, allowing for a more accurate estimation of bite force in normal situations and the load distribution across the dentition can be investigated simultaneously.

In the current study, both groups experienced an increase in biting force at successive follow-ups. The bite force difference was statistically significant. Our results agreed to a comparative study conducted by Bhatnagar et al. ⁽²⁶⁾ in which they concluded that the lag screw group had higher vertical biting forces after treatment of anterior mandibular fractures than the miniplate group. Furthermore, Mittal et al ⁽²⁷⁾ and Madsen and McDaniel ⁽²⁸⁾ found statistically significant differences in yield load and stiffness between the lag screw and other approaches. They further claimed that when molar loading was taken into account, the lag screw technique outperformed all other anchoring devices.

CT scans were taken before surgery, immediately after surgery, and three months later. For each CT scan, average readings from six sites near the fracture line were taken and bone density were calculated. The results of this study showed that the increase in mean bone density was statistically significant in between both groups from the immediate to 3 months postoperative period, indicating that fracture bone healing was progressing.

The bone density is significantly increased in the Herbert screw group than within the conventional miniplates group which may be related to the compression encountered along the fracture line following the reduction and fixation by the screw. Instead of the outer cortex being crushed by the head, axial compression in HBS is predicated on the existence of a differential pitch head, reducing the risk of outer cortex fracture during compression, which is a typical concern with Lag Screw placement. ⁽²⁹⁾ Because the HBS is a headless screw, it does not require the counter-sinking that is required for Lag Screw placement. ⁽³⁰⁾ Our results run in line with the results of the study performed by Kotrashetti and Singh ⁽³¹⁾ who recorded a statistically significant difference between Herbert fixation screws and lag screws regarding bone density along the fracture line.

The examined open reduction and internal fixation procedures showed comparable and good re-

sults in terms of fixation and stability of anterior mandibular fractures in the current investigation. Herbert screws were discovered to be extremely technique-dependent, necessitating advanced surgical abilities. Nonetheless, they outperformed the other procedures in terms of compression fixation, cheap cost, fewer devices and hardware required, and superior wound healing outcomes. Finally, the method of fixation chosen is determined by the precise indication of each case as well as the operator's experience and preferences.

CONCLUSION

Taking the results of this study into account, it can be stated that the two fixation techniques might be utilized interchangeably for anterior mandibular fractures fixation. while HBS is a technique-dependent treatment modality that necessitates surgical skills, it achieves higher compression of the fractured segments with less drilling than traditional miniplates. Also, it allows for a more favorable bone healing both from a clinical and a radiographic point of view. Additional research with a larger sample and a longer follow-up time is needed to confirm the findings of this study.

Conflict of interests:

The authors declare that there was no any conflicts of interest during conducting this research work.

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