

HERBERT BONE SCREW VERSUS LAG SCREW IN THE TREATMENT OF ANTERIOR MANDIBULAR FRACTURE (RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: The most common type of trauma is the mandibular fracture with various fixation modalities. One of these modalities is the use lag screw and Herbert cannulated bone screw.

OBJECTIVES: Comparison of the clinical and radiographic results of Herbert bone screw (HBS) with conventional Lag screws in anterior mandibular fracture.

MATERIALS AND METHODS: Twelve patients were randomly allocated into two groups each including six patients. Group 1 received Herbert bone screw, and group 2 received Lag screw. Follow up visits after 24-hours, one, four, six and twelve weeks for clinical assessment. After twelve weeks, a radiographic examination was conducted to measure the mean bone density along the fracture line.

RESULT: After twelve weeks, both groups showed normal occlusion, no intra-fragmentary mobility, no wound dehiscence or infection, normal sensory function and decreased pain intensity level which was statistically significant (p value <0.0001). By comparing post-operative 12 weeks to pre-operative values, the mean bone density showed a statistically significant improvement in values in both groups 1 (p <0.001) and 2 (p<0.0001).

CONCLUSION: HBS is comparable to gold standard lag screw with similar outcomes in anterior mandibular trauma. Yet, HBS shows higher compressive feature than LS. Also countersinking is not necessary during HBS insertion unlike LS.

KEYWORDS: Herbert bone screw, Lag screw, Mandibular fracture.

RUNNING TITLE: Herbert versus lag screw in anterior mandibular fracture.

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INTRODUCTION

The main goal in management of mandibular fracture is to regain normal function and esthetic (1). Principles of open reduction and internal fixation were endorsed by Arbeitsgemeinschaft für

Osteosynthesefragen (AO/ASIF) (2). According to Schenk and Willenegger researches, primary bone healing can only be achieved with rigid fixation (3). The concept of axial compression principle was introduced by Luhr through compression plating that shows the benefit of better adaptation and early

function. This was achieved using Lag screw with less time and armamentarium used (4).

Brons and Boering were the first to use lag screws 1970 in maxillofacial surgery. They stated that according to the biomechanics of the area of the fracture where using at least two screws were necessary to avoid rotational movement (4).

Lag screws compress the segments to each other through rotation, however this technique has limitations such as the possibility of fracture of the proximal segment and the head of the screw is not flushed with the bone surface (5).

In 1984, Herbert and Fisher advocated the use of Herbert bone screw as a minimally invasive technique in fractured scaphoid bone and to avoid the disadvantages of lag screws (6). Using the same principle as in lag screw, the Herbert Bone screw differs in its geometry that it has two heads with different diameters and different pitch length and has a blank shaft in between (7). Unlike lag screw that utilizes the head to cause the compression, the differential pitch pulls the segments towards each other (8). This study was carried out to compare between HBS fixation and Lag screw fixation in symphyseal and parasymphyseal fracture.

MATERIALS AND METHODS

A randomized clinical study was conducted, which was carried out after receiving ethical approval from the Alexandria University Faculty of Dentistry's Research Ethics Committee.

Patients

The participants in this study were twelve patients with anterior mandibular fractures who were chosen from the Emergency Department of Alexandria University Teaching

Hospital. Before the procedure, all patients signed an informed consent form at Alexandria University's Faculty of Dentistry's Oral and Maxillofacial Surgery Department. All of the participants were adult males.

The patients were selected following these bases:

Inclusion criteria:

- Symphyseal or para-symphyseal fracture.
- Recent trauma.
- Noncomminuted fracture.
- Displaced fracture that require open reduction and internal fixation.
- Patient age from 20 – 40 years.

Exclusion criteria:

- Evidence of infection.
- Pathologic fracture.
- Old fracture.
- Comminuted fracture.
- Medically compromised patient.

Prior to surgical operation using the traction osteosynthesis principle with Herbert Bone Screw (HBS) or Lag Screw, all patients signed an informed consent form (LS). Patients were randomly allocated using computer-based site (www.randomizer.org) into two groups, each with six patients, with group 1 receiving Herbert Bone Screw (HBS) and group 2 receiving Lag Screw (LS).

Materials

A true Lag screw designed with threads in the distal end of the screw with a smooth shank at the proximal end. This creates compression force that leads to reduction of intra-fragmentary mobility. The screw head is 2 mm in diameter with shank 1.8mm in diameter comes with different length from 16 to 30 mm. (Provo care medical Corporation Company: Germany) (Figure 1 A) The Lag screw compresses bone segments by first engaging the head of the screw in the outer cortex, then rotating the screw to apply further compression. A common disadvantage of this screw is weakening and fracture of the proximal segment while screw tightening. Also, the fact that the head serves as a wedge and cannot be flushed with the bone limits using this screw. (9)

Herbert cannulated bone screw is a cortical cannulated bone screw made of Titanium alloy that shows excellent biocompatibility, strength and corrosion resistance. The screw has two threaded heads and a smooth, blank central shaft. (DePuy Synthes Medical device company: Warsaw, US) (Figure 1 B) The leading head is designed with longer pitch distance and smaller diameter while the trailing end is designed with larger diameter and smaller pitch distance. This screw was introduced to overcome the disadvantage of Lag screw head as the headless screw will be flushed with bone surface eliminating the need of countersinking. Unlike Lag screw, HBS compresses the bone segment and due to the differential pitch. The cortex is pulled out as the leading end threads engage the inner cortex, and compression is gradually induced as the trailing end threads engage the outer cortex. (9)

Methods

1) Pre-operative assessment and examinations

Full detailed history was collected from the patients. A full clinical, intra-oral and extra-oral, examination was performed to observe by inspection any swelling, ecchymosis, bleeding, step deformity, soft tissue laceration, hematoma formation, occlusal disturbances and mandibular deviation during opening and closing of the mouth, as well as any step

deformity, tenderness, segmental mobility and changes in bone contour by palpation.

The extend of fracture line, degree of displacement and involvement of vital structures at the fracture site was determined with the help of pre-operative computerized tomography (CT) scan (Figure 2) The mean bone density was estimated using CT software to measure bone density at six points along the fracture line. The pre-operative, immediate post-operative, and 3-month post-operative mean bone density are then calculated using their average. Hounsfield Units (HU) were used for all measurements.

2) Surgical phase

Prescription of Cefotaxime 1 gm/12 hours (Cefotax, E.I.P.I.C.O, Egypt) pre-operatively as prophylactic antibiotics was done to prevent post-operative infection. All patients were given general anesthesia with nasal intubation during the procedure. Swabs with povidone iodine solution (Betadine 7.5 percent; Purdue Products L.P) and sterile towels were used to prepare the surgical site. With an intra-oral vestibular incision, after Maxillo-Mandibular Fixation (MMF), the fracture line was exposed and manually reduced, holding the bone segments in place and visually evaluating the reduction by aligning the buccal cortex and inferior border.

A 1.1 Kirschner wire was drilled to the opposing cortex of the distal bone segment in group 1, and the length of the screw was measured with a depth gauge. A 2 mm spiral drill was used with K wire guidance, followed by Herbert Bone Screw insertion using a cannulated torque shank screw driver. (Figure 3 A).

In group 2, a 1.6 mm pilot drill was used to drill through the both bone segments of the fracture line, then a 2 mm spiral drill was used in the proximal segment. To allow the screw head to be flush with the bone surface, countersinking was done with a rose head bur. Inserting 2mm lag screw with screwdriver. Following Champy's line osteosynthesis, a second screw was inserted in the same manner to prevent fracture segments from rotating. (Figure 3 B) Occlusion of all patients was then checked and MMF was removed. Preparing wound site for closure by irrigating with normal saline solution, suturing with Vicryl suture material (Johnson & Johnson Int. European Logistics Centre, Belgium)

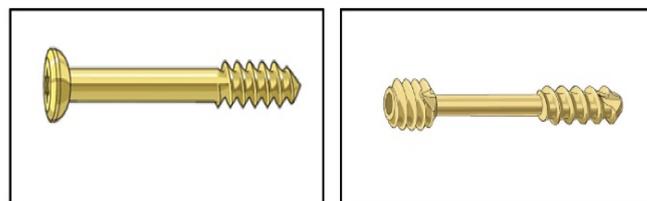


Figure (1): Lag screw (A), Herbert bone screw (B).

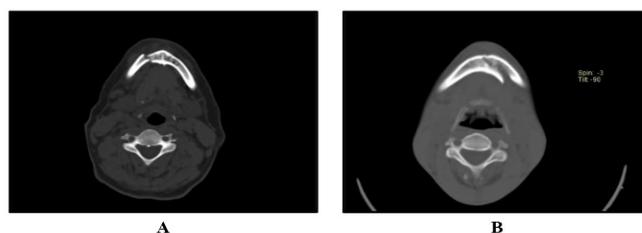


Figure (2): Computerized tomography (CT) scan displacement of fracture.



Figure (3): Surgical placement of (A) Herbert screw (B) Lag screw.

3) Post-operative phase

All patients received post-operative medication including Intravenous cefotaxime 1 gm/12 hours for the first day followed by Amoxicillin + clavulanate 1 gm (Augmentin 1gm: GlaxoSmithKline, UK) twice daily for the next 5 days, Metronidazole 500mg (Flagyl 500mg: GlaxoSmithKline, UK) every eight hours for 5 days, α -chemo-trypsin (Lourquin France, packed by Amoun pharmaceutical CO.S.A. E-Egypt) ampoules as anti-edematous once daily for 5 days, Diclofenac potassium 50mg (cataflam 50mg: Novartis-Switzerland) every eight hours for 5 days and Chlorhexidine (Hexitol 125mg/100ml, concentration 0.125%: Arabic drug company, ADCO) antiseptic mouth wash. Patients were advised to follow a soft diet and maintain good oral hygiene for one month.

Follow up phase

Clinical assessment of post-operative pain using 10-points visual analogue scale (VAS). On a scale of 0 to 10, patients were asked to rate their postoperative pain and discomfort (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe). Nerve function was assessed by asking patient if there is any alteration in sensation (subjective assessment) and by using dental probe with pressure to detect sensory nerve change (objective assessment). Intra-fragmentary mobility was checked using bi-manual palpation along the fracture line. Wound healing and occlusion status were visually examined, and any abnormalities were recorded. (10)

An immediate post-operative CT-scan was used to measure fracture reduction from the buccal and lingual perspectives, and a three-month CT-scan was used to determine mean bone density at the area of fracture line and correlate it to the immediate post-operative CT-scan. (Figure 4).

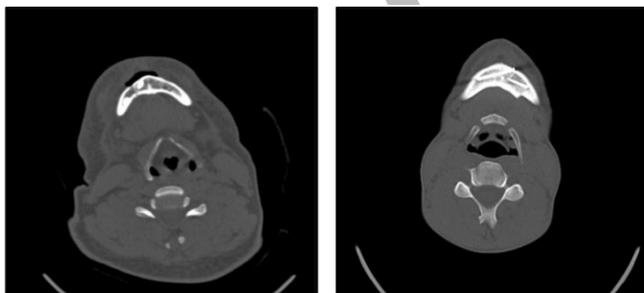


Figure (4): Postoperative Computerized tomography (CT) scan.

4) Statistical analysis

Normality was checked using descriptive statistics, plots (histogram and box plot) and Shapiro Wilk test. Age, Bone density and Pain scores readings were presented using mean

and standard deviation. All qualitative variables were presented using count and percentage.

Bone density at each time point and percent change in bone density were compared between groups using independent t test. Pain scores at each time point were compared using Mann Whitney u test. All qualitative variables were compared using Chi Square test.

Differences between each time point within groups were compared using One Way Repeated measures ANOVA regarding the bone density while Friedman test was applied to compare the pain scores. Significance level was set at 0.05. Data was analyzed using IBM SPSS statistical software (version 25).

RESULTS

All twelve patients in this study required open reduction and internal fixation with traction osteosynthesis using Herbert Bone screws and Lag screws. In both groups, all of the patients were men. Patients in both groups ranged in age from 20 to 43 years old, with a mean of 29.83 ± 9.08 years in group 1, while in group 2 a mean of 28.33 ± 11.14 . Fracture distribution in this study was 50% para-symphyseal (n=6) and 50% symphyseal fracture (n=6) in both groups. Patients presented with only anterior mandibular fracture (AMF) were (33.3%) in group 1 (n=2) and (50%) in group 2 (n=3) while patients presented with associated fractures were (66.7%) in group 1 (n=4) and (50%) in group 2 (n=3).

All of the cases examined were followed for 12 weeks post-operatively. As compared to the 24h postoperative values, both cases in both groups experienced a statistically significant decrease in pain intensity score based on the Visual Analogue Scale (VAS) during the follow-up duration (P value <0.0001). Post-operative occlusion in group 1 showed abnormal occlusion in one case in early follow up period in comparison to two cases in group 2. With the use of elastic traction and MMF, all cases regained normal occlusion by the end of the follow-up period.

Among study participants, 16.7% in group 1 (n=1) recorded impaired lower lip paresthesia and 50% of group 2 (n=3). All cases in both groups had regained normal sensory function by the end of the follow-up period. Six patients in group 2 showed wound dehiscence (n=2) at the first week of follow up, which was treated by irrigation and oral hygiene instructions. By the end of follow up period, wound healed by secondary intention. None of the patients in group 1 developed wound dehiscence, and both groups didn't record wound infection. 66.7% (n=4) of patients showed slight intra-fragmentary mobility at the first 24 hour follow up postoperative that progressively decrease till it disappeared completely at fourth week follow up in group 2 while in group 1 no intra-fragmentary mobility was detected. (Table 1)

Table (1): Intra-fragmentary mobility between the Herbert screw group and Lag screw group

	Herbert screw (n=6)	Lag Screw (n=6)	Test P value
	n (%)		
No	6 (100%)	4 (66.7%)	X ² =2.400 0.455
Yes	0 (0%)	2 (33.3%)	

When comparing the immediate postoperative recorders to the preoperative value in group 1, a statistically significant

increase in mean bone density was observed ($P=0.001$). The percentage of change was $92.36\pm 32.69\%$. On the other hand; an insignificant increase was recorded when comparing the 12 weeks post-operative records with the immediate values ($P=0.103$). Yet the overall increase in mean bone density recorded from baseline to 12-week post-operative was statistically significant ($P=0.001$) with a percentage of change $112.32\pm 39.49\%$.

Regarding the values in group 2, there was a statistically significant increase in the mean bone density in the immediately post-operative values ($P=0.0001$) with a $62.34\pm 6.28\%$ percent of change from the preoperative records. A continues significant increase in the mean bone density after 12 weeks was recorded ($P<0.0001$) with $88.98\pm 13.27\%$ percent change in bone density. Overall increase in mean bone density from base line to 12-week post-operative was statistically significant ($P= 0.006$) with a percent change 88.98 ± 13.27 . (Table 2,3).

Table (2): Mean and standard deviation of Bone density across time intervals between the Herbert screw group and Lag screw group

	Herbert screw (n=6)	Lag Screw (n=6)	P value
Baseline	737.82 (74.27)	701.08 (19.05)	0.864
Immediately Postoperative	1400.77 (131.90)	1137.38 (27.81)	0.012*
12 weeks Postoperative	1548.33 (212.12)	1323.70 (76.96)	0.147

*Statistically significant difference at p value <0.05

Table (3): Percent increase in bone density between the Herbert screw group and Lag screw group

	Herbert screw (n=6)	Lag Screw (n=6)	P value
Baseline - Immediately PO	92.36 (32.69)	62.34 (6.28)	0.200
Baseline - 3 Months	112.32 (39.49)	88.98 (13.27)	0.218

DISCUSSION

Management of anterior mandibular fracture in literature shows variety of options for reduction and fixation, such as lag screws, double miniplates, reconstruction plates and using arch bar with single miniplate or lag screw (11-13). These are classified to be rigid or functionally stable methods as they allow early function and decreases the intra-fragmentary mobility. Choosing one modality over the other depends on the availability of the instruments, the condition of the fracture line, the clinical state and the surgeon preference (14).

As there is not enough studies that shows superiority of one modality over the other, some considered Lag screw osteosynthesis as the standard treatment of choice with better functional stability, minimal intra-fragmentary mobility, low cost and fast application (11, 12, 14). Moreover, it permit better reduction due to elimination of lingual gap comparing with the use of miniplates. Though, the use of miniplates is more common as they require less technical skills and less technique sensitive (12). A new method of rigid fixation was introduced by Herbert and Fisher in 1984 in management of scaphoid bone fracture. The

design used was a headless cannulated screw with differential pitch threads of both leading and trailing heads and a blank smooth shaft in between producing immense inter-fragmentary compression. Therefore, providing a rigid fixation (7).

There are insufficient studies in literature regarding the use of HBS in anterior mandibular fracture, hence the aim of this study was to evaluate and compare the aftermath of HBS and LS in fixation of anterior mandibular trauma.

All participants in this study were male. The mean patient age in group 1 (Herbert screw) was 29.83 years, while the mean patient age in group 2 (lag screw) was 28.33 years. This was similar to a study done by Brade et al who recorded that a higher incidence of mandibular fracture in India in young adult male (15). A main reason for this is the higher incidence of RTA cases, caused mainly by young adult male. Fracture site distribution among the study participants were equally distributed 50% symphyseal fracture and 50% Para symphyseal fracture.

In group 1 it was found that 16.7% of the cases presented with post-operative malocclusion in comparison with group 2 33.3% of the cases showed post-operative malocclusion which was treated in both groups with elastic traction for 14 days as recommended in a previous study done by Hyde et al., where elastic traction was used in 10% of the patients. to regain pre-morbid occlusion for 10 days post operatively (16). Only group 2 demonstrated intra-fragmentary mobility in 33.3 percent of the cases during the early follow-up period. This may be due to the Herbert screw's differential pitch, which causes further compression between bone segments. Absence of mobility after 6 weeks post operatively was recorded. This maybe correlated to a study done by Ardary et al., who stated that the factors affecting fixation stability are the number of the screws used, screw placement technique and the screw holding power which is influenced by the cortical bone's thickness (17).

Post-operative pain during follow up period showed decrease in intensity level according to Visual Analogue Scale, where mean value was 5.33 for both groups after 24-hour post operatively. After one week, there was significant decrease ($P=0.044$) in pain for both groups. Overall, there was statistically significance decrease in pain level throughout six weeks follow up period ($P=0.0001$) yet, no significant difference between HBS and LS in pain recovery was recorded. This may be due to the rigid fixation and decrease the intra-fragmentary mobility which in turn decrease pain and discomfort of the patient.

Similar results were recorded in different studies done by Bhatnagar et al., (2013) (18) and Kotrashetti and Singh (2017) (19). While Kotrashetti and Singh recorded faster recovery of pain in cases treated using HBS than those treated using LS, Bhatnagar et al recorded that patients treated with LS recovered faster than those treated with miniplates. This likely may be due to less drilling needed and less hardware used for stable fixation, thus less pain recorded by patients.

During the first follow-up period, altered sensory function was recorded in 16.7% in group 1 and 50% of group 2 (first week). At the end of the follow-up period, all patients had fully recovered and restored normal nerve function (12 weeks). This may be correlated with the study done by Iizuka and Lindqvist, who reported that 58.3 % of the cases with pre-operative sensory disturbance were associated with displaced fracture (20).

Neither infection nor wound dehiscence was recorded in group 1, while in group 2 33.3% developed wound dehiscence in the first follow up period (one week) without infection. Irrigation with sterile saline was done and instruction of careful oral hygiene were given to the patient. The wound healed later with secondary intention process. A comparable outcome was recorded by Agnihotri et al., (12) who reported 10% of patients treated with LS developed wound dehiscence that healed with secondary intention and 10% of the patient received Miniplates suffered from wound dehiscence with infection requiring plate removal. Regarding to these results a debate arises that a better outcome may be associated with internal positioning of traction osteosynthesis hardware to prevent hardware exposure. Other factors affects wound healing are the forces applied by mentalis muscle, suturing technique, infection and poor oral hygiene (14).

To measure mean bone density three CT scans were taken. Pre-operative, immediate post-operative and 3 months follow up CT scan. Average reading of six points in the vicinity of the fracture line were taken and calculated for each CT scan. Regarding radiographic isodensity values, increase in bone density was recorded immediately post operatively in both groups were mean value for group 1 was (1400.77) and for group 2 (1137.38). Increase in mean bone density was statistically significant from base line to the 3 months follow up period were $P= 0.001$ for group 1 and $P<0.001$ for group 2. The difference in the mean bone density between the HBS and LS was not statistically significant, unlike the results of the research done by Kotrashetti and Singh (19) who recorded a statistically significant difference between HBS and LS. This may be due to difference in case selection as in this study only anterior mandibular fracture was included while Kotrashetti and Singh included all types of mandibular fracture. Another cause maybe the use of modern CT scan to obtain bone density values not panoramic radiographs.

Axial compression in HBS is based on the presence of a differential pitch head, rather than the outer cortex being compressed by the head, minimizing the possibility of outer cortex fracture during compression, which is a common problem with LS placement. (21) The design of HBS as a headless screw does not necessitate the need for countersinking that is a must in case of LS placement. (22)

The use of HBS leads to faster healing in comparison with Lag screw. This may be due to less bone drilling and the elimination of countersinking step needed in Lag screw. Although difference was not statistically significant, the differential pitch in HBS leads to less intra-fragmentary mobility. Yet, HBS require high surgical skills as it is a technique sensitive procedure.

CONCLUSION

HBS is equivalent to the gold standard lag screw in the management of anterior mandibular fractures with identical outcomes, despite being a technique-sensitive treatment modality that necessitates higher surgical skills. HBS, on the other hand, outperforms the LS in terms of achieving higher compression forces with less drilling amount. Unlike lag screws, the HBS has a higher compressive feature due to the differential pitch distance in the leading head and trailing head, which results in higher intra-fragmentary compression. Improper countersinking is a problem faced during the installation of Lag screws, which creates cracks in the cortical bone supporting the screw head, weakens the bony

buttress, and reduces compression forces. However, since HBS is a headless screw that does not involve countersinking, none of these limitations appear while using it.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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