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Original Research Article

Comparative evaluation of self-tapping and self-drilling screws in mandibular inter-foraminal fractures: A randomized controlled clinical trial

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Abstract

Background: Over the past century, there have been several stages of development in the management of maxillofacial fractures. The various screws' designs should also be taken into account in order to accomplish this.
Aim: To evaluate the efficacy of Self-tapping and self-drilling screws in mandibular inter-foraminal fractures.
Materials and Methods: Using a convenience sample technique, patients were divided into two groups of ten each. Self-tapping screws were used to treat the patients in Group A. Screws that self-drill were used to treat the patients in Group B.
Results: By the end of the first week following surgery, seven patients in group A had stable occlusion, while three patients experienced mild occlusion abnormalities. Following surgery, all ten patients who received self-drilling screws had 100% stable occlusion. he end of the first month, we observed more stability in group B, and no patient displayed splaying of fractured fragments, resulting in 100% stability of fractured fragments in patients who received self-drilling screws for plate fixation.
Conclusion: The current experimental clinical study's findings show that self-drilling screws, which require less operating time and armamentarium, have better mechanical qualities than self-tapping screws for fixing fractures. But in the dense anterior mandibular bone, the technique-sensitive self-drilling screw needs more driving force.

Keywords: Intermaxillary fixation, Self-tapping screws, Self-drilling screws, Drill-free screws, Mandibular inter-foraminal fractures.

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1. Introduction

Internal fixation for maxillofacial surgery was developed initially for mandibular fractures, and was then applied to mid and upper face fractures, continuity defects, and subsequently to facial osteotomies. In 1949, Davis put forth three basic aims of ORIF as immediate active movement of muscles and joints in the affected region, complete restoration of body form and direct union of bony fragments without the formation of visible callus.[1]

Since various screw designs are available in the literature that mandate to know the potential of each type of screw.[2] Mainly two generations of screws were introduced, first generation screws were monocortical or bicortical and self-tapping that required a hole to be drilled that are smaller in diameter than the screws. The disadvantages for these screws included bone necrosis and risk of damage to the roots through major or minor contact.[3] The second-generation bone screws were found to overcome the limitations of these first-generation screws thus overcoming the need of drilling and also it can be used as both self-tapping and self-drilling.[4]

In case of self-tapping screws, they shear at bone level while insertion thus accumulating the bone particles in the thread causing binding and hindering of insertion. While in case of self-drilling screws the lower shaft is conical with small engraved cutting flutes hence bone particles are cleared away as the screw is inserted.

Self- tapping screws are further subdivided into thread-forming and thread-cutting screws. The former forms its thread by elastic-plastic deformation or by local destruction of the bone, the latter by cutting through the bone and simultaneously performing the function of a tap.[5]

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The cutting tip geometry of Self-drilling screws (SDS) were polygonal, it had a tapered shank behind the polygonal tip. These characteristics are intended to achieve immediate gripping of the bone with slight axial pressure and the triangular shaft a simultaneous drilling and removal of the drilling debris.[6] Self-tapping screws are more commonly used in the field of Oral and Maxillofacial Surgery for fixation of jaw fractures whereas, literature search for self-drilling screws highlights its usage as IMF screws but not for fixation of fractures. Hence our study aims to evaluate the efficacy of Self-drilling screws in fixation of mandibular fractures.

The objectives of the study are as follows:

1. To assess the occlusion at maximum intercuspation by bimanual examination
2. To assess the stability of the fractures segments by digital manipulation.
3. To determine screw loosening or screw distortion through intra-operative visual examination.
4. To deduce the time lapsed to fasten the screw; from reduction to fixation of the segments.

2. Materials and Methods

2.1. Study design

The study was a prospective, interventional, and randomised controlled study.

2.2. Study setting

Department of Oral and Maxillofacial Surgery, Faculty of Dental Sciences (FDS), XXXX

2.3. Study population

Patients reporting to FDS, Department of Oral and Maxillofacial Surgery, Dept. of Emergency and accident services XXXX.

2.4. Sample size

Based on the findings of previously published literature, using power of 80% and alpha error of 5%, sample size was estimated to be 10 in each group.

2.5. Inclusion criteria

All patients reporting with Inter-foraminal fractures in the mandible requiring open reduction and internal fixation, and are ready to give consent for the study.

2.6. Exclusion criteria

Patients with HIV, HBsAg and Uncontrolled Diabetes Mellitus.

Patients with ASA III and IV.

2.7. Ethical clearance

Obtained by the Institutional review board on University Ethics Committee for Human Trials Approval Certificate (UECHT).

2.8. Randomization

Patients were randomized into 2 groups using the lottery method.

Group A: Patients undergoing internal fixation with the help of miniplate fixation with self-tapping screws.

Group B: Patients undergoing internal fixation with the help of miniplate fixation with self-drilling screws. There were 10 patients in group A and 6 patients in group B.

All the patients in both the groups were hospitalized prior to the surgery and underwent routine investigations for general anaesthesia. Patients were given prophylactic I.V antibiotics (amoxicillin- 1.5 gm 3 times/day).

2.9. Surgical procedure

Exposure of the fracture site was done using vestibular incision, after reduction to anatomical position, fixation was done using titanium miniplates and self-drilling screws (group B patients) (2x6 mm screws and a drill bit of 1.7mm dimension) after carefully skeletonising the mental nerve bilaterally. Those patients with associated condylar fractures, arch bar with IMF was placed for 21 days.

2.10. Follow up

The patients were assessed clinically at immediate post-operative period, 1 week and at 1-month post-operative period. Radiographic assessment for reduction of fractured fragments and placement of screw position was done through the OPG. Clinically the incision site was seen for any signs of infection indicating screw loosening. Screw distortion was radiographically evaluated through post-operative OPG one month after the surgery.

2.11. Parameter analysis

1. Occlusion: Stable – 0
   Deranged – 1
2. Stability: Stable – 0 (Less than 0.5mm splaying of the fracture fragments upon bi-digital manipulation).
   Unstable: 1 (More than 0.5mm splaying of fracture fragments upon bi-digital manipulation).
3. Screw loosening & distortion: Present – 1
   Absent – 0
4. Time lapsed to fasten the screw (recorded in minutes)

All the patients were followed up in the time period of 1 week and 1 month.

2.12. Statistical analysis

Statistical Package for Social Sciences [SPSS] for Windows, Version 22.0 Released 2013 Armonk, NY: IBM Corp., will be used to perform statistical analyses.

3. Results

The parameters checked intraoperatively before fixation, a week after fixation, and a month after fixation were occlusion and stability of the fracture segments. The screw distortion and screw loosening were checked intraoperatively and time elapsed was calculated from the time of screw placement till complete fixation of the fracture segments.

Preoperatively none of the group had stable occlusion as both the groups included displaced fractured fragments. In group A 7 patients showed stable occlusion post operatively by the end of 1st week while 3 patients had mild disturbances in occlusion. Thus, at the end of 1st week the results showed 70% stability of occlusion in patients receiving self-tapping screws. Further at the end of 1st month the percentage of stability was increased up to 90% with 9 patients having stable occlusion. **(Table 1-18)**

In contrast to group A, it was found that patients in group B did not show any disturbance in occlusion at the end of first week and also by one month. All the 10 patients receiving self-drilling screws had stable occlusion post operatively (group B) (100%). **(Table 1-18)**

Figure 1: Basic maxillofacial trauma kit

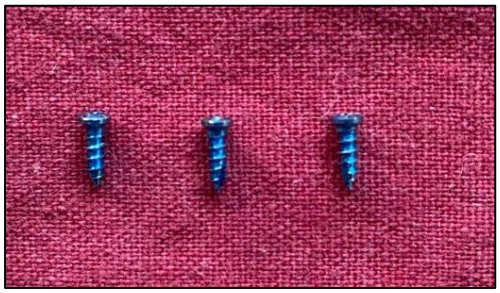

Figure 2: Self-drilling screws

Figure 3: OPG showing mandibular right para-symphysis fracture

Figure 4: Post-operative OPG showing adequately reduced fracture segments –self-drilling screws

Figure 5:

Table 1: Comparison of intra operative, 1st week and 1st month with status of stability of occlusion in two groups (self-tapping and self-drilling) by Cochran Q test

Groups	Status	Intra operative	%	1st week	%	1st month	%	Q-value	p-value
Self-tapping	Stable	0	0.00	7	70.00	9	90.00	14.8888	0.0005*
	Unstable	10	100.00	3	30.00	1	10.00		
	Total	10	100.00	10	100.00	10	100.00		
Self-drilling	Stable	0	0.00	10	100.00	10	100.00	20.0000	0.0001*
	Unstable	10	100.00	0	0.00	0	0.00		
	Total	10	10.00	10	100.00	10	100.00		

*p<0.05

Table 2: Comparison of intra operative, 1st week and 1st month with status of stability of occlusion in two groups (self-tapping and self-drilling) by Cochran Q test

Groups	Status	Intra operative	%	1st week	%	1st month	%	Q-value	p-value
Self-tapping	Stable	0	0.00	7	70.00	9	90.00	14.8888	0.0005*
	Unstable	10	100.00	3	30.00	1	10.00		
	Total	10	100.00	10	100.00	10	100.00		
Self-drilling	Stable	0	0.00	10	100.00	10	100.00	20.0000	0.0001*
	Unstable	10	100.00	0	0.00	0	0.00		
	Total	10	10.00	10	100.00	10	100.00		

Table 3: Comparison of two groups (self-tapping and self-drilling) with status of stability of fracture fragments at intra operative, 1st week and 1st month by Fisher exact test

Times	Self-tapping	%	Self-drilling	%	Total	p-value
Intra operative						
Stable	0	0.00	0	0.00	0	1.0000
Unstable	10	100.00	10	100.00	20	
1st week						
Stable	8	80.00	10	100.00	18	1.0000
Unstable	2	20.00	0	0.00	2	
1st month						
Stable	9	90.00	10	100.00	19	1.0000
Unstable	1	10.00	0	0.00	1	
Total	10	100.00	10	100.00	20	

Table 4: Comparison of two groups (self-tapping and self-drilling) with status of screw loosening and distortion by Fisher exact test

Screw loosening & distortion	Self-tapping	%	Self-drilling	%	Total	p-value
No	8	80.00	9	90.00	17	1.0000
Yes	2	20.00	1	10.00	3	1.0000
Total	10	100.00	10	100.00	20	

4. Discussion

The self-tapping screws were first introduced by Arthur and Berardo et al in 1989 and later modified by Carl Jones with a Capstan shaped head design. He suggested the use of threaded titanium screws of 2mm diameter and 10 to 16mm in length. Screws with a capstan type head are vital because they keep wires and elastics far from either the gingival tissue. These screws are easy to install and have less hazards of needlestick injuries than traditional procedures, resulting in a shorter operating time from one hour to 15 minutes.[7]

In orthopaedic and maxillofacial surgery, rigid internal fixation as well as osteosynthesis are commonly used. Until quite recently, the two most common Non self–tapping (pretapped) screws and self–tapping screws were used for plate fixing. The non-self-tapping or pre-tapped screw includes a screw insertion procedure where an initial hole is drilled first, then threads are created in the bone with a tap. Following that, a screw is placed into a hole drilled in the bone.[8] While the self-tapping screw refers to a screw insertion technique in which no pre drilling of screws is required and the screw is directly inserted into a predrilled hole without tapping a screw thread. The literature mentions about various advantages of self-tapping screws when compared to pre tapping screws decreased operating time being the principle advantage, these screws are also compared with their pull-out strength and do not damage the bone on insertion. In cases of pre tapped screws damage to the bone could contribute to bony necrosis and screw loosening which is avoided in self-tapping screws.[9] These screws were made in an attempt to avoid some of the issues that come with screw hole drilling. The most common issue is heat damage that happens during the pilot hole drilling process. Infection, hardware loosening, and non-union are some of the associated risks in self-tapping screws taking thermal damage into consideration. Damage to subjacent nerves and tooth roots and even breakage of drill bits that requires retrieval have also been described. In cases of cancellous and thin bones such as in thin maxillary/orbital bone, pre drilling of screws can lead to the need for replacement screws of slightly larger diameter to be used as emergency ("bail-out") screws.[10,11]

Introduction of self-drilling screws (SDS) have overcome all such disadvantages. The SDS has a corkscrew-like design, with a sharp point and threads that trace a rotating axis all the way towards the screw head. This innovation allows screws to be inserted without the need for a pilot hole to be drilled first. During application, a cutting flute drilled into the screw theoretically permits bone fragments to be ejected onto the surface. As a result, the screw's design may result in reduced operational time, suppressing the growth fatality from pilot-hole placement (since no holes are drilled), and increased holding power, particularly in thin cortical bone areas.[11-13] The use of a rechargeable screwdriver in this approach tends to make the process even more automated. Given cortical bone's relatively low tensile strength the insertion of SDS (sans drilling an initial hole) into cortical bone appears to be difficult without generating deleterious consequences to the neighbouring bone.[8,14,15]

Self-tapping screws in miniplate osteosynthesis have some potential disadvantages which include damage to the nerves, roots or tooth germs, thermal necrosis of bone and drill bit breakage. Recently developed drill free screws avoid these problems. Complication using self-tapping intermaxillary fixation screws includes fracture of the screws on insertion, iatrogenic damage to teeth and bony sequestrum around the areaof screws placement. If the screws are left in place postoperatively this overheating can cause thermal necrosis of bone around the screw and lead to loosening.[12,14]

5. Conclusion

Results of previous experimental studies such as finite element analysis and histological studies from the literature and as well as the results of present experimental clinical study highlights that the self-drilling screws possess better mechanical properties in terms of screw retention and fracture fragments stability utilizing minimal armamentarium and lesser operative time than self-tapping screws in fixation of fractures except that is technique sensitive which demands extra driving force in the dense anterior mandibular bone. Selecting an appropriate screw driver, accurate loading of screw and fastening perpendicular to the bone surface helps in ease of screw insertion thus minimizing the operative time and distortion of screw physically.

6. Source of Funding

None.

7. Conflict of Interest

None.

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