Research Code

Radiographic and Clinical Evaluation of Three-Dimensional Delta Plate in Internal Fixation of Mandibular Sub-condylar Fractures.

(Longitudinal Study)

Research Protocol
Submitted to the Department of Oral and Maxillofacial Surgery

Faculty of Dentistry, Ain Shams University.

In partial fulfillment of the requirements of Masters' degree in Oral and Maxillofacial Surgery.

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2019
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2023

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I.Abstract:

Management of Sub-condylar fractures has been debatable for years, some surgeons advocate closed management if the situation permits, to avoid the complications associated with open reduction and internal fixation (ORIF). Nowadays, there are meticulous approaches and novel osteosynthesis systems that facilitate its open management but many of these systems need more research work to evaluate its efficacy.

In this study we intend to examine the efficacy of 3D delta plates from the radiographic and clinical point of view. This Single arm study will include 14 cases of trauma having mandibular sub condylar fractures, in which open reduction and internal fixation are indicated. After selecting patients according to the inclusion criteria, all patients will undergo open reduction and rigid fixation. Fracture will be stabilized using 4 hole, 2.0 mm 3-D Delta titanium plates using pre-auricular or retromandibular incision.

Postoperative clinical examination will be carried out on day three, day seven, one month and after three months. Postoperative radiographic examination will be performed immediately postoperative by CT scan.

II. Background:

The incidence of mandibular condylar fractures is estimated to be 17.5–52% making it the most seen mandibular fracture (1–4) sub condylar fractures are commonly encountered when the fracture is unilateral. However, in case of bilateral fracture pattern, the condylar heads are the ones that are fractured (5).

The reason for the high incidence of mandibular condyle fracture is attributable to the binding of the mandibular ramus with high stiffness and mandibular condyle head with low stiffness ((6) causative factors include physical trauma, road traffic accidents, violence, fall, sports, and gunshot wound. Internal causative factors include osteomyelitis, benign or malignant tumor, and muscular spasm during electric shock treatment (7).

The management of condylar fractures is highly controversial and includes observation, closed treatment, and open reduction. It depends on multiple factors such as the age of the patient, the co-existence of other mandibular or facial fractures, is it unilateral or bilateral, the level and displacement of the fracture, the stage of dentition and dental occlusion, the facilities in the area, patient's mental and physical conditions ((8).

Closed management of condylar fractures has lots of long-term complications like pain which is considered the most common complaint. In addition to esthetic problems like facial asymmetry due to shortening of ramus especially with unilateral fractures ((9). Moreover, Temporomandibular diseases such as ankylosis, internal derangement of the temporomandibular joint (TMJ) and mouth deviation could happen. Nevertheless, Closed management is essential in some cases like simple patterns of fractures when occlusion is achievable, putting into consideration that patient's compliance, mental and physical status are crucial for successful treatment (8). Its main benefit (when indicated) is the avoidance of facial nerve injury, However, facial nerve injury risk is decreased as the operator's experience and skill increase(10) .

Indications for ORIF include bilateral fractures(relative), severe dislocation (> 10 degrees), other facial fractures affecting the occlusion, foreign bodies, lateral displacement of the condyle, and condyle displacement into the middle cranial fossa(11), mandibular nerve paraesthesia(12). Condylar fractures can be reached through trans -facial or intraoral approaches (13,14) .Singh et al (15) published the largest blinded, randomized controlled trial comparing open techniques with closed management; they concluded that both treatment options carry promising outcomes. However, the surgically treated group showed better results in all objective and subjective functional outcomes except for occlusion.

The gold standard osteosynthesis system is the use of two miniplates fixation secured with four screws each (16). However, some drawbacks such as; difficult accessibility that elongates operation time especially in higher fractures the use of double miniplates is associated with risk of facial nerve injury and subsequent facial nerve palsy. Moreover, the little amount of bone that is always encountered at the proximal part of the fracture (17).

Recently, Osteosynthesis devices with various shapes and sizes as single L, Y plate, or 3-D plate are used for the management of condylar fractures. Manufactures tend to develop such systems to gain outcomes similar to that of the conventional 2 mini-plate system regarding functional stability and rigidity with less cost, less complications and less effort(17).

Several studies were conducted on three-dimensional plating systems such as Rhomboid, Trapezoid and Delta shaped plates that yielded good outcomes (17–21). One study claimed that trapezoidal condylar plate is convenient for low sub condylar fractures because of its wide dimensions, On the other hand, delta plate is suitable for both high and low sub condylar fracture. ((22–24)

The aim of this study is to evaluate the versatility of three-dimensional delta plate in reduction and fixation of this type of fracture in adult patients presented with unilateral sub-condylar fractures for primary ORIF. The results will be analyzed by radiographic assessment of proper anatomical reduction and measurement of vertical ramus height. In addition to, clinical outcomes of pain with jaw movements and measurement of all mandibular movements range.

III. Research Question:

What are the radiographic and clinical outcomes of using three-dimensional Delta plate for primary open reduction and internal fixation of unilateral subcondylar fractures in adult patients?

PICOTS Elements:	
Patient/Problem	Adult patients presenting with unilateral sub condylar fracture, with or without concomitant facial or mandibular fractures.
Intervention	Primary ORIF using three-dimensional delta plate
Comparator	-
Outcome	Pain, posterior facial height, anatomic reduction, mouth deviation.
Time	3 months follow up
Setting	Faculty of Dentistry-Ain Shams University

IV. Aim of the Study, Research Objectives and Clinical Relevance Aim:

The aim of the study is to assess the efficacy of the delta plate in fixation of sub condylar fractures by radiographic evaluation of anatomic reduction and vertical ramus height and clinical evaluation of pain with jaw movements and range of mandibular movements.

Outcomes:

Primary outcomes: 1-Anatomic Reduction
2-Posterior Facial Height

Secondary outcomes: 1-Pain
2-Mandibular Movements.

Clinical Relevance:

Delta plate provides functionally stable osteosynthesis. In addition to, less periosteal dissection, and easier reduction and fixation of small fragments combined with the advantages of a smaller plate size, less cost and adequate stiffness (19,23).

V. Hypothesis:

Delta plate doesn't provide an added advantage over the other Osteosynthesis methods of Sub condylar fixation.

VI. Ethical consideration

Open reduction and internal fixation of sub condylar fractures is accompanied with complications such as facial nerve injury, parotid gland fistula, permanent scar, infection, pain, edema, and difficulty in mastication following surgical procedure.

Risk of Facial injury can be decreased by choosing the appropriate incision and meticulous dissection of the tissues.

Parotid gland fistula is avoided by suturing of parotid capsule or by retroparotid-retromandibular approach whenever possible.

Permanent scar is best minimized by minimal tissue trauma, suturing in layers then the skin will be sutured by Prolene 6-0, Topical antibiotics and topical silicone gel will be prescribed.

Risk of Infection is reduced by post-operative antibiotic.

Post-operative analgesics and anti-inflammatory medications will be given to control pain and edema.

Mastication force is enhanced by physiotherapy.

Patients are allowed to withdraw from the trial whenever they want to. In this case, they will be surgically managed by conventional plating systems. All patients will be fully informed about the procedures. The risks and benefits will be thoroughly explained to them. No surgery will be performed without written consent.

All personal information and data of the patients will be preserved, maintained and stored in a special filing system available in the department. It will not be exposed to anyone that is not included in the surgical team.

The research ethics committee, Faculty of Dentistry Ain Shams University, will review the research plan.

VII. Study Design:

Longitudinal study.

VIII. Materials and Methods:

14 patients having unilateral sub condylar fractures will undergo open reduction and internal fixation by a single 4-hole miniplate 3D Delta plate. The dimensions of this plate are 1.0 mm thick, 20mm long, 5mm wide at top and 14 mm wide at the base. At the top of the plate is an arm with two longitudinally arranged holes, two more holes form the 2 corners of the base of the plate.

Study Setting:

Department of oral and maxillofacial surgery in the Faculty of Dentistry, Ain Shams University.

Sample Size Calculation:

The sample size was estimated based on research published by Manoj et al. study (2015) regarding fracture fixation by trapezoidal 3D plate in India, by fixing alpha at 0.05 (5%) and beta at 0.05(5%), the minimal sample size is 10 patients to be included. To avoid drop out the sample was increased to 14 patients(25).

Eligibility criteria

Inclusion Criteria:

1-Patients at or over 18 years.

2-Unilateral sub condylar fractures.

Exclusion Criteria:

1- Bilateral sub condylar fractures

2-Pediatric patients.

3-Intracapsular fractures

4-Patients with Uncontrolled systematic conditions.

Justification for Exclusions:

-Most clinical and radiographic assessments of bilateral sub condylar fractures are dissimilar to that of unilateral ones.
-The management of pediatric patients is totally different from that of adults.
-Intracapsular fractures is best treated by endoscopic approach or conservatively managed
-Patients with Uncontrolled systematic conditions are unfit for surgery.

Pre-operative Assessment:

All patients will undergo radiographic assessment with Computed Tomography to assess the level of the fracture, degree and direction of displacement and shortening of ramus height by comparing the two sides.

All patients will undergo clinical evaluation of pain, mandible deviation on opening and closing, measurement of mandibular movements.

All patients will undergo pre-operative anesthetic evaluation which includes medical and surgical history, physical examination, investigations, risk assessment, consent and pre-medication.

Surgical Procedure:

All patients will undergo open reduction and internal fixation under general anesthesia.

The Fracture will be exposed either extraorally (submandibular or retromandibular or endaural approaches). The incision will be chosen according to the level of the fracture.

Fracture will be reduced; occlusion will be re checked then it will be fixated by 2.0 mm 3D Delta mini plates and anchored by 4 screws of 7-9 mm length.

Immediate post-operative medications:

All patients will take painkillers, anti-inflammatory, antibiotics and steroids.

Follow up:

Radiographic outcomes: The following will be measured on CT:

1-The vertical ramus height will be done by comparing the two sides from the glenoid fossa to the inferior border of the ramus on CT.

2- Accuracy of anatomical reduction detected on coronal and axial sections.

Radiograph will be taken immediately post-operative.

Clinical outcomes:

1- Assessment of pain by Visual Analogue scale.
2- Mandibular movements by a ruler:

-Lateral mandibular movement by measuring the horizontal distance between upper central teeth midline to the lower central teeth midline.

-Protrusive mandibular movement by measuring the transvere distance between upper central teeth midline to the lower central teeth midline.

-Maximal mouth opening by measuring the vertical distance between upper central teeth midline to the lower central teeth midline.

Follow up notes will be taken on day three, day seven, one month and Three months postoperatively.

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IX. Statistical Analysis:

Regarding the continuous date, the T dependent test will be used to assess the statistical data. Regarding the discrete data, Chi Square test will be used to assess the statistical data significance, using SPSS Software.

X. Funding of the Study:

The research study will be self-funded by the operator. No internal or external funding will be shared in this study.

XI. References:

1. Zachariades N, Papavassiliou D, Papademetriou I, Koundouris I. Fractures of the facial skeleton in Greece. A retrospective study covering 1791 cases in 10 years. J Maxillofac Surg. 1983 Jun;11(3):142–4.
2. Bochlogyros PN. A retrospective study of 1,521 mandibular fractures. J Oral Maxillofac Surg. 1985 Aug;43(8):597–9.
3. Zachariades N, Papavassiliou D. The pattern and aetiology of maxillofacial injuries in Greece. A retrospective study of 25 years and a comparison with other countries. J Craniomaxillofac Surg. 1990 Aug;18(6):251–4.
4. Silvennoinen U, Iizuka T, Lindqvist C, Oikarinen K. Different patterns of condylar fractures: an analysis of 382 patients in a 3-year period. J Oral Maxillofac Surg. 1992 Oct;50(10):1032–7.
5. Zachariades N, Mezitis M, Mourouzis C, Papadakis D, Spanou A. Fractures of the mandibular condyle: a review of 466 cases. Literature review, reflections on treatment and proposals. J Craniomaxillofac Surg. 2006 Oct;34(7):421–32.
6. Fridrich KL, Pena-Velasco G, Olson RA. Changing trends with mandibular fractures: a review of 1,067 cases. J Oral Maxillofac Surg. 1992 Jun;50(6):586–9.
7. Choi KY, Yang JD, Chung HY, Cho BC. Current concepts in the mandibular condyle fracture management part I: overview of condylar fracture. Arch Plast Surg. 2012 Jul;39(4):291–300.
8. Kang DH. Surgical management of a mandible subcondylar fracture. Arch Plast Surg. 2012 Jul;39(4):284–90.

9. Ellis E, Throckmorton G. Facial symmetry after closed and open treatment of fractures of the mandibular condylar process. J Oral Maxillofac Surg. 2000 Jul;58(7):719–28; discussion 729-30.

10. Tandon S, Verma V, Rashid M, Srivastava S, Singh AK, Sharma NK. Is the facial nerve at risk following surgical correction of mandibular condylar fracture: A systematic review and meta-analysis. Natl J Maxillofac Surg. 2022 Aug;13(Suppl 1):S1–10.

11. Miloro Michael, Larsen P.E, Ghali G.E. Peterson's Principles of Oral and Maxillofacial Surgery. Fourth.

12. Nys M, Van Cleemput T, Dormaar JT, Politis C. Long-term Complications of Isolated and Combined Condylar Fractures: A Retrospective Study. Craniomaxillofac Trauma Reconstr. 2022 Sep;15(3):246–52.

13. Moloro Michael, Ghali G.E., Larsen PE. Peterson's Principles of Oral and Maxillofacial Surgery . fourth. 2022. 649–670 p.

14. Kommers SC, Boffano P, Forouzanfar T. Consensus or controversy? The classification and treatment decision-making by 491 maxillofacial surgeons from around the world in three cases of a unilateral mandibular condyle fracture. J Craniomaxillofac Surg. 2015 Dec;43(10):1952–60.

15. Singh V, Bhagol A, Goel M, Kumar I, Verma A. Outcomes of open versus closed treatment of mandibular subcondylar fractures: a prospective randomized study. J Oral Maxillofac Surg. 2010 Jun;68(6):1304–9.

16. Huang CM, Chan MY, Hsu JT, Su KC. Biomechanical analysis of subcondylar fracture fixation using miniplates at different positions and of different lengths. BMC Oral Health. 2021 Dec 1;21(1).

17. Albogha MH, Mori Y, Takahashi I. Three-dimensional titanium miniplates for fixation of subcondylar mandibular fractures: Comparison of five designs using patient-specific finite element analysis. J Craniomaxillofac Surg. 2018 Mar;46(3):391–7.

18. Ashor M, Salah A, Shindy M, Selim H, Metwaly S, Behairy G. Clinical and radiographic outcomes of rhomboid plate in management of subcondylar fractures: prospective randomized controlled trial. Egypt. J. Oral Maxillofac. surg. 2018 Jan 1;9(1):1–5.

19. Ahuja SA, Galinde J, Asnani U, Mistry YA. Comparative Evaluation of Clinical Outcomes Using Delta Plates and Conventional Miniplates for Internal Fixation of Mandibular Condylar Fractures in Adults. J Oral Maxillofac Surg. 2018 Jun;76(6):1255–66.

20. Lauer G, Haim D, Proff P, Richter G, Pradel W, Fanghänel J, et al. Plate osteosynthesis of the mandibular condyle. Ann Anat. 2007;189(4):412–7.

21. Albogha MH, Mori Y, Takahashi I. Three-dimensional titanium miniplates for fixation of subcondylar mandibular fractures: Comparison of five designs using patient-specific finite element analysis. J Craniomaxillofac Surg. 2018 Mar;46(3):391–7.

22. Lata J, Verma N, Mahajan S. Evaluation of Efficacy of 3-Dimensional Delta Versus Trapezoidal Condylar Plates in Internal Fixation of Mandibular Subcondylar Fractures: A Clinical Study. The Traumaxilla. 2019 Apr;1(1):11–21.

23. Sikora M, Sielski M, Stąpor A, Chlubek D. Use of the Delta plate for surgical treatment of patients with condylar fractures. J Craniomaxillofac Surg. 2016 Jul;44(7):770–4.

24. Sarkar A, Banerjee L, Ghosh S. Efficacy of Delta Plate in Condylar Fracture: a Case Series with Review. J Dent (Shiraz). 2023 Mar;24(1):71–5.

25. Chaudhary M, Pant H, Singh M, Vashistha A, Kaur G. Evaluation of trapezoidal-shaped 3-D plates for internal fixation of mandibular subcondylar fractures in adults. J Oral Biol Craniofac Res. 2015;5(3):134–9.