

# What's new for the clinician?

Summaries of and excerpts from recently published papers

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Compiled and edited by V Yengopal

## 1. Single versus double miniplate fixation for mandibular symphysis and parasymphysis fracture: a prospective comparative clinical study.

Raut, R, Keerthi R, Vaibhav N, Ghosh A, Kateel SK. Journal of Maxillofacial & Oral Surgery 2017; 16: 113-117

Current patterns of maxillofacial trauma suggest that mandibular fractures occur two to three times more often than other facial fractures. Review studies reveal that motor vehicle accidents and interpersonal violence are the most common causes of mandibular fractures followed by falls and sports injuries.<sup>1</sup> The goals of treatment of mandibular fractures are trifold: restoration of premorbid occlusion, early return of function, and acceptable aesthetics (surgical correction of a disfiguring defect, or the cosmetic improvements). The basic sequence of management via open reduction requires four steps: restoration of premorbid occlusion, exposure of the fracture site(s), reduction of the fracture(s), and application of fixation. Restoration of the premorbid occlusion is typically done with application of intermaxillary fixation using Erich arch bars or intermaxillary fixation screws. Exposure can be done intraorally (commonly used for symphysis, parasymphysis, body and angle fractures) or extraorally (complex fractures or subcondylar injuries). Once the fractures are exposed and reduced, fixation is applied. The objectives of mandibular fracture management include the restoration of the pre-existing anatomical form, functional occlusion and facial aesthetics.

Two general treatment philosophies emerged for plate and screw fixation of mandibular fractures in the 1970s and 1980s.<sup>1</sup> The first is AO/ASIF philosophy, which promotes sufficient rigidity at the fracture site to prevent inter-fragmentary mobility during mandibular function.<sup>1</sup> A second philosophy (Champy principles) emphasizes "the ideal lines of osteosynthesis" in the mandible which uses noncompression monocortical miniplates in the region of optimal stress to neutralize tension. This principle prescribes the need for two plates for adequate fixation for fractures in the symphysis and parasymphysis region to ensure optimal balance of forces. Successful stabilization

### ACRONYMS

IMF: inter-maxillary fixation

AO/ASIF: Arbeitsgemeinschaft für Osteosynthesefragen/  
Association for the Study of Internal Fixation

of a fracture depends to varying degrees on at least two factors: the amount of bone contact and the rigidity of the fixation device.

Raut and colleagues reported on a trial which sought to compare the clinical efficacy and long term outcome of using a single 2.5mm (four holes with gap) miniplate and two 2mm miniplates (four holes with gap) in symphysis/parasymphyseal fractures.<sup>1</sup>

### MATERIALS AND METHODS

The study group comprised 30 patients with fractures of mandibular symphysis or parasymphysis region who reported to the Department of Oral and Maxillofacial Surgery at a Dental Hospital in India. Patients who were between 20-50 years old and had simple or compound (unfavourable) fractures in the symphysis or parasymphysis region of the mandible which were amenable to treatment using an intra-oral approach, were included in this randomized clinical trial. Medically compromised patients who were unfit for the procedure under general anesthesia; patients with comminuted fractures; patients with additional fractures at other sites on the mandible; patients with pan facial trauma; and edentulous patients were excluded from this study.

Thirty numbers were generated from a random sampling table and were then assigned alternatively into two groups—Group A and Group B. The patients were then asked to choose from the 30 random numbers that were generated and depending upon the number they chose they were allocated to one or other of the two groups.

**Group A:** Fracture in this group of patients was treated using a single 2.5 mm (four holes with gap) titanium miniplate fixed at Champy's 'neutral' zone.

**Jeff Yengopal:** BChD, MChD (Community Dentistry) Stellenbosch.  
Department of Community Dentistry, School of Oral Health Sciences,  
University of the Witwatersrand. E-mail: Veerasamy.Yengopal@wits.ac.za.

**Group B:** Fracture in this group of patients was treated using two 2 mm (four holes with gap) titanium miniplates fixed according to the principles of Champy's lines of osteosynthesis and zones of compression and tension.

All patients received one dose of antibiotic (inj. Amoxicillin + Clavulanic acid, 1.2 g) pre-operatively and Dexamethasone 8 mg pre-operatively which was later tapered down over a period of two days. All patients also received an orthopantomogram and an occlusal view of the mandible radiograph.

A standard vestibular incision was used in all patients to access the fracture site. The fractured segments were manipulated and reduced into position. Intra-operative inter-maxillary fixation (IMF) was done using Erich arch bars and 26 gauge stainless steel wires in all cases along with circumferential loop wiring using 26 gauge stainless steel wire to include 2 or 3 teeth on each side (as deemed necessary by the operator). Split arch bars were used when the operator deemed it was necessary for reduction. Fixation was done according to the group to which the patient belonged, with either a single 2.5mm titanium (4 holes with gap) miniplate and 2.5 x 8mm screws or two 2 mm titanium miniplates (4 holes with gap) and 2 x 8mm screws. Once fixation was done, the IMF was released. Closure was done in layers using 3-0 polyglycolic acid sutures (Vicryl®). The lower arch bar was kept in place for three weeks. Patients were given strict instructions to maintain proper oral hygiene. All patients were given oral Amoxicillin + clavulanic acid (625mg) twice a day for five days and Diclofenac sodium (50mg) + Paracetamol (325mg) thrice a day for three days post-operatively.

Clinical follow-up of all patients was done by an independent observer (blinded) at intervals of: first post-operative day, one week, 12 weeks and 24 weeks. Another independent observer was asked to evaluate the clinical findings at the above mentioned intervals. The following parameters were evaluated: Duration of surgery; Fracture segment mobility/mal-union; Paresthesia; Occlusion; Wound dehiscence and Time taken to return to normal function and diet.

## RESULTS

A total of 30 (24 males, 6 females) patients with a mean age of 32 years were selected for this study. The most common etiology was motor vehicle accidents (67%) followed by falls (17%). There were four cases of assault and one case of farm accident (borewell recoil injury). Mean duration of surgery in Group A patients was 27min and in Group B patients was 39min. Immediate post-operative reduction and stability achieved was comparable in both group of patients. Occlusion was deemed satisfactory in all but one patient (Group A) by both the evaluators. Post-operative malocclusion in that patient was corrected using elastics for a period of two weeks. This finding was statistically insignificant ( $P > 0.05$ ). In all patients, there was no fracture segment mobility noted post-operatively. Upper border or lower border splaying was not seen in either group. Five patients (1 in Group A, 4 in Group B) reported of post-operative paresthesia which resolved on its own after a mean period of 3 weeks. Four patients (all belonging to Group B) showed post-operative wound dehiscence and gaping which was statistically significant.

Radiographically, no discrepancies were noted with respect to reduction of fracture fragments achieved. However, Observer Two noted that in three cases (20 % of patients in Group B) the plate fixed at the superior end was close to the apices of the canine and the pre-molar which was not the ideal positioning desired.

## CONCLUSIONS

The researchers found that that a single 2.5 mm (four holes with gap) mini-plate provides adequate stability in symphyseal and parasymphyseal fractures with a relatively shorter operating time when compared with the conventional two plate fixation technique. Though miniplates are most commonly placed according to Champy's principle, symphysis/parasymphysis fractures can also be managed by placing a single stronger miniplate in Champy's neutral zone along with arch bars or dental splints, which act as effective tension bands to counter the forces, resulting in fewer potential complications like wound dehiscence and iatrogenic injury to the tooth roots.

## IMPLICATIONS FOR PRACTICE

The benefits of using a single miniplate for treating symphyseal and parasymphyseal mandibular fractures has been clearly shown in this trial. Clinicians should however note that the small sample of patients used warrant that these results be treated with caution.

## Reference

1. Raut, R, Keerthi R, Vaibhav N, Ghosh A, Kateel SK. Single Miniplate Fixation for Mandibular Symphysis and Parasymphysis Fracture as a Viable Alternative to Conventional Plating Based on Champy's Principles: A Prospective Comparative Clinical Study. Journal of Maxillofacial & Oral Surgery 2017; 16: 113-117.

## 2. The risk of thrombo-embolic events during dental extractions.

Sadhasivam G, Bhushan S, Chiang KC, Agarwal N, Vasundhar PL. *Journal of Maxillofacial & Oral Surgery* 2016; 15: 506-11.

Warfarin or antiplatelet agents such as clopidogrel (Plavix®), ticlopidine (Ticlid®), prasugrel (Effient®), ticagrelor (Brilinta®) and/or aspirin are commonly used in patients who have experienced a deep vein thrombosis (DVT) or pulmonary embolism, patients who have had an myocardial infarction and/or who have undergone cardiac stent placement.

There is general agreement that treatment regimens with these older anticoagulants/antiplatelet agents should not be altered before dental procedures.<sup>1</sup> A 2009 systematic review and meta-analysis found no increased risk of bleeding associated with continuing regular doses of warfarin in comparison with discontinuing or modifying the dose for patients undergoing single and multiple tooth extraction.<sup>1</sup> A 2013 systematic review found no clinically significant increased risk of postoperative bleeding complications from invasive dental procedures in patients on either single or dual antiplatelet therapy.<sup>1</sup> In a 2013 statement, the American Academy of Neurology recommended that patients undergoing dental procedures continue taking aspirin or warfarin for stroke prevention.<sup>1</sup> A 2015 systematic review of management of dental extractions in patients receiving warfarin determined that patients whose International Normalized Ratio (INR; a measure of the therapeutic index of warfarin) was in therapeutic range (i.e., 3.0 or less) could continue their regular warfarin regimen prior to the procedure.<sup>1</sup>

In February 2007, the American Heart Association, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, the American College of Surgeons, and the American Dental Association published their consensus opinion about drug-eluting stents and antiplatelet therapy (e.g., aspirin, clopidogrel, ticlopidine).<sup>1</sup> The consensus opinion states that healthcare providers who perform invasive or surgical procedures (e.g., dentists) and are concerned about periprocedural and postprocedural bleeding should contact the patient's cardiologist regarding the patient's antiplatelet regimen and discuss optimal patient management, before discontinuing the antiplatelet medications. Given the importance of antiplatelet medications post-stent implantation in minimizing the risk of stent thrombosis, the medications should not be discontinued prematurely.<sup>1</sup>

Some patients who are taking one of these or multiple anticoagulant medications may have additional medical conditions that can increase the risk of prolonged bleeding after dental treatment, including liver impairment or alcoholism; kidney failure; thrombocytopenia, hemophilia, or other hematologic disorders; or may be currently receiving a course of cytotoxic medication (e.g., cancer chemotherapy). In these situations, dental practitioners may wish to consult the patient's physician to determine whether care can safely be delivered in a primary care office.<sup>1</sup> Any suggested modification to the medication regimen prior to dental surgery should be done in consultation with and on advice of the patient's physician.<sup>1</sup>

There are very few studies in the literature comparing post-extraction bleeding in patients who continued anti-platelet therapy during extraction with that of the patients who discontinued the therapy and to a healthy control group and even less has been done to evaluate the difference between patients on monotherapy and dual therapy. Sadhasivam and colleagues from India (2016)<sup>2</sup> reported on a clinical trial that sought to evaluate the difference in post-extraction bleeding among an anti-platelet stopping group, an anti-platelet non-stopping group and a healthy control group and also related it to the type of therapy (mono/dual therapy).

### MATERIALS AND METHODS

A total of 300 patients requiring dental extractions were included in the study and were divided into three groups. Of these, 200 were on anti-platelet therapy (single/dual) for various cardiac ailments and were allocated randomly either into Group 1 or 2 whereas Group 3 comprised of 100 healthy patients not taking any haemostasis-altering medication. Hence, Group 1 (Non-stopping group) consisted of 100 patients (86 males and 14 females) who continued anti-platelet therapy during dental extractions; Group 2 (Stopping group) comprised 100 patients (88 males and 12 females) who discontinued anti-platelet therapy 3–5 days prior to dental extractions and resumed their medication 2 days post-extraction; and Group 3 (control group) included 100 healthy patients (45 males and 55 females) who were not on any haemostasis-altering medications.

Group 2 patients were referred to physician cardiologist for a written consent regarding discontinuation of anti-platelet therapy during dental extraction. All patients underwent estimations of bleeding time and clotting time on the day of extractions. Patients with a pre-operative bleeding time of more than 10min, a history of systemic conditions like liver disease, bone marrow disorders, patients who were on any hemostasis altering medications other than anti-platelet drugs, patients with a systolic blood pressure above 150mm of Hg or a diastolic blood pressure above 100mm of Hg and medically compromised patients who were not fit to undergo dental extraction procedures under local anaesthesia were excluded from the study.

Extractions (single or multiple teeth) were performed under local anaesthesia using 2% lignocaine hydrochloride with a vasoconstrictor (1:80,000 adrenaline). Following extraction, a pressure pack was given and patient was kept under observation. Presence or absence of bleeding at the extraction site was checked at 15, 30 min, 1, 24, 48 h and 1 week after extraction.

At the observed time intervals the extraction site was checked and bleeding that extended beyond the socket within 1 min was recorded as a positive result for bleeding at that time interval. In case of persistent bleeding beyond one hour, a local haemostatic agent (gelatin sponge) was inserted into the extraction socket in order to achieve haemostasis. After ensuring haemostasis, patients were discharged with postoperative instructions and were

prescribed amoxicillin 500mg and paracetamol 500mg, thrice daily for 5 days. They were advised to inform by person or through phone immediately in case of any post-operative bleeding.

Post-extraction bleeding was classified as immediate, late and very late. Immediate post-extraction bleeding was considered to be prolonged if it continued beyond 30 min in spite of the pressure pack. Late bleeding was considered to be clinically significant if it extended beyond 12 hours, or made the patient call or return to the surgeon or emergency department, or resulted in haematoma or ecchymosis within the oral soft tissues or which required blood transfusion. Very late bleeding was considered present if oozing occurred even after 24 hours.

## RESULTS

A total of 300 patients were included in the study. Groups 1 and 2 comprised of patients who either continued or stopped anti-platelet therapy during extractions and Group 3 served as control group comprising healthy patients. The two treatment groups were similar in terms of number of patients on monotherapy and dual therapy ( $p$  value = 0.102).

The bleeding time estimates among patients in Group 1 ranged from 1min and 10s to 3min (mean 1min and 32s), whereas in Group 2, this range was from 1min and 7s to 2min and 30s (mean 1min and 25s). Group 3 bleeding time values ranged from 1min and 20s to 2min and 10s (mean 1min and 27s). All these values were within acceptable limits and no statistically significant differences were observed among the three groups.

Events of single or multiple tooth extractions were also similar among the three groups.

Bleeding after 15min was present among 14 patients of Group 1 (14.0%), 17 patients of Group 2 (17.0%) and 3 patients of Group 3 (3.0 %); bleeding after 30min i.e., prolonged immediate post-operative bleeding was present among nine patients of Group 1 (9.0 %) and 15 patients of Group 2 (15.0%) whereas it was not seen in any patient of Group 3. Local pressure pack with gauze was used to control bleeding in required cases and bleeding was reassessed after another half an hour. Bleeding after one hour of extraction was present in nine patients of Group 2 (9.0 %) i.e., the group who had discontinued anti-platelet therapy before extraction whereas it was not seen in any other group. In these nine patients who continued to bleed even after pressure packing of one hour, gelatin sponge was packed into the extraction socket and patient was asked to bite on gauze placed over it. Haemostasis was achieved within a further half an hour in all nine patients and they were discharged uneventfully.

Statistical analysis revealed significant differences among the three groups with regard to bleeding after 15, 30 min and one hour with  $p$  values of 0.004, 0.000 and 0.000 respectively.

None of the patients in any group reported with bleeding after 24, 48 h and one week. Hence, there were no episodes of late or very late bleeding requiring additional haemostatic measures.

Among nine patients of Group 1 who presented with prolonged immediate post-operative bleeding, three were on monotherapy and six were on dual therapy and among 15 patients of Group 2, six were on mono-therapy and nine were on dual therapy. Hence, in both the groups, prolonged immediate post-operative bleeding was greater in patients on dual anti-platelet therapy when compared with patients on mono-therapy.

## CONCLUSIONS

The researchers concluded that dental extractions can be performed without the risk of significant post-extraction bleeding in patients on single or dual anti-platelet therapy. Although local factors like periodontal and peri-apical pathology might be responsible for increased post-extraction bleeding, it can always be controlled using local haemostatic measures. Hence, there is no need for interrupting the anti-platelet therapy prior to extractions as the risks clearly outweigh the benefits.

## IMPLICATIONS FOR PRACTICE

This huge clinical trial with a large sample size added to the weight of evidence from respected bodies such as the American Dental Association that there is little or no risk to patients who are on single or dual anti-platelet therapy who present for dental extraction. The most important point however, is to note that these decisions must be taken in consultation with the patient's physician.

## Reference

1. Oral Health Topics: Anticoagulant and antiplatelet medications and dental procedures. Available at <http://www.ada.org/en/member-center/oral-health-topics/anticoagulant-antiplatelet-medications-and-dental->.
2. Sadhasivam G, Bhushan S, Chiang KC, Agarwal N, Vasundhar PL. Clinical trial evaluating the risk of thromboembolic events during dental extractions. Journal of Maxillofacial & Oral Surgery 2016; 15: 506-11.