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Conservative treatment of a mandibular condyle fracture: Comparing intermaxillary fixation with screws or arch bar. A randomised clinical trial

B. van den Bergh [a, d, *], J. Blankestijn [b], T. van der Ploeg [c], D.B. Tuinzing [d], T. Forouzanfar [d]

[a] Department of Oral and Maxillofacial Surgery, Kennemer Gasthuis Hospital, P.O. Box 417, 2000 AK, Haarlem, The Netherlands
[b] Department of Oral and Maxillofacial Surgery, Medical Center Alkmaar, P.O. Box 501, 1800 AM, Alkmaar, The Netherlands
[c] Research Center Linnaeus Institute, Kennemer Gasthuis Hospital, P.O. Box 417, 2000 AK, Haarlem, The Netherlands
[d] Department of Oral and Maxillofacial Surgery/Oral Pathology, VU University Medical Center/Academic Centre for Dentistry Amsterdam (ACTA), P.O. Box 7057, 1007 MB, Amsterdam, The Netherlands

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ABSTRACT

Introduction: A mandibular condyle fracture can be treated conservatively by intermaxillary fixation (IMF) or by open reposition and internal fixation (ORIF). Many IMF-modalities can be chosen, including IMF-screws (IMFS). This prospective multi-centre randomised clinical trial compared the use of IMFS with the use of arch bars in the treatment of mandibular condyle fractures.

Results: The study population consisted of 50 patients (mean age: 31.8 years). Twenty-four (48%) patients were allocated in the IMFS group. Twenty-six (52%) patients were assigned to the arch bars group. In total 188 IMF-screws were used (5–12 screws per patient, mean 7.83 screws per patient). All pain scores were lower in the IMFS group. Three patients developed a malocclusion (IFMS-group: one patient, arch bars-group: two patients). Mean surgical time was significantly shorter in the IMFS group (59 vs. 126 min; $p < 0.001$). There were no needlestick injuries (0%) in the IMFS group and eight (30.7%) in the arch bars group ($p = 0.003$). One IMF-screw fractured on insertion (0.53%), one (0.53%) screw was inserted into a root. Six (3.2%) screws loosened spontaneously in four patients. Mucosal disturbances were seen in 22 patients, equally divided over both groups.

Conclusion: Considering the advantages and the disadvantages of IMFS, and observing the results of this study, the authors conclude that IMFS provide a superior method for IMF. IMFS are safer for the patients and surgeons.

1. Introduction

A mandibular condyle fracture is one of the most common fractures of the mandible (Marker et al., 2000; Motamedi, 2003; van den Bergh et al., 2012), and is mostly caused by falls, violence and traffic-accidents (Marker et al., 2000; van den Bergh et al., 2012). This kind of fracture can be treated conservatively by intermaxillary fixation (IMF) or by open reposition and internal fixation (ORIF). Although many studies have searched for the best and most suitable treatment, the issue remains controversial (Palmieri et al., 1999; Park et al., 2010; Sharif et al., 2010). In both types of treatment complications occur, such as deviation of the chin and/or facial asymmetry (Park et al., 2010; Yang et al., 2002; Bormann et al., 2009); reduced mandibular motility (Palmieri et al., 1999; Niezen et al., 2010); dysfunction of the temporomandibular joint (Silvennoinen et al., 1998; Gupta et al., 2012); ankylosis (Gupta et al., 2012); chronic pain (Chen et al., 2011); and malocclusion (Marker et al., 2000; Bhagol et al., 2011; Silvennoinen et al., 1998; Zachariades et al., 2006; Forouzanfar et al., 2013). When conservative treatment of a condylar fracture is preferred over ORIF, many modalities for obtaining IMF can be considered (e.g. arch bars, eyelets, interdental wiring or orthodontic braces). Whereas the use of arch bars is generally the treatment of choice, the use of interdentally placed screws (IMFS) is gaining popularity and is increasing.

* Corresponding author. Department of Oral and Maxillofacial Surgery, Kennemer Gasthuis Haarlem, P.O. Box 417, 2000 AK, Haarlem, The Netherlands. Tel.: +31 235453545.
E-mail address: b.vanden.bergh@kg.nl (B. van den Bergh).

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The use of these screws provides many benefits to both patients and surgeons (Gordon et al., 1995; Coburn et al., 2002; Roccia et al., 2005; Hashemi and Parhiz, 2011). Compared with arch bars IMFS are quick and easy to place, have relatively low costs, are ideal for use when teeth have been heavily restored and give reduced trauma to dental papillae and the oral mucosa. Furthermore, gingival health is easier to maintain and IMFS are easily and painlessly removed (Gordon et al., 1995; Coburn et al., 2002; Roccia et al., 2005; Arthur and Berardo, 1989; Ho et al., 2000; Laurentjoye et al., 2009; Onishi and Maruyama, 1996; Schneider et al., 2000; Hashemi and Parhiz, 2011). Related to this there is reduced risk of needlestick injury to the surgeon as the need for placing interdental wiring is absent (Laurentjoye et al., 2009), while operation time is considerably reduced compared with IMF techniques with arch bars (Roccia et al., 2005; Schneider et al., 2000; Rai et al., 2011; West et al., 2014). Several case reports and some retrospective studies support the usefulness of the IMFS technique (Onishi and Maruyama, 1996; Coletti et al., 2007; Gerlach and Schwarz, 2002; Jones, 1999). Complications relating to IMFS may occur. Potential surgical complications include the fracture of the screw on insertion, iatrogenic damage to dental roots, causing bony sequestra around the area of screw placement and loss of teeth (Coburn et al., 2002; Roccia et al., 2005; Hashemi and Parhiz, 2011). Postoperative complications include infection associated with screws, loss or loosening of screws, screws covered by oral mucosa, postoperative malocclusion and paraesthesia due to injury to the mental or inferior alveolar nerve (Hashemi and Parhiz, 2011; Coletti et al., 2007; Roccia et al., 2005; Coburn et al., 2002; Laurentjoye et al., 2009).

In 2011 a clinical trial was published in which the use of IMFS in maxillofacial trauma was compared with Erich arch bars (Rai et al., 2011). West et al. recently described a randomised clinical trial of 20 patients who were all treated for a mandibular fracture, but excluded patients with a condylar fracture (West et al., 2014). There is still a lack of prospective randomised clinical trials concerning the use of IMFS in oral and maxillofacial trauma, especially in condylar fractures.

The purpose of the present study is to compare the use of IMFS-screws with arch bars in the treatment of mandibular condylar fractures. In particular pain, the occlusal results, surgical duration, oral hygiene, mouth opening and intra- and postoperative complications/adverse side effects will be analysed.

2. Material and methods

A prospective multi-centre randomised clinical trial was conducted between May 2010 and July 2014. Patients were eligible when aged between 18 and 65 years, who had given written informed consent and required surgical treatment of a fractured mandibular condyle (with or without concomitant mandibular fractures). The study was performed in accordance with the Helsinki declaration and approved by the Ethics Committee of the VU University Medical Center Amsterdam and Medical Centre Alkmaar (reg. no. NL28831.029.09; 2009/311).

Exclusion criteria included: inability to give informed consent, known chronic pain syndrome, mental retardation or psychiatric abnormalities, concomitant maxillary or other facial fractures and known malignant disease. All patients provided written informed consent before surgical treatment.

2.1. Study protocol

After giving consent, patients were randomised by an assignment scheme that was generated from a table of random numbers. This table was developed, using a computer program developed for randomisation purposes. The randomised and sealed envelopes were opened by the surgeon the moment the patient was brought under general anaesthesia. Randomisation was to either IMFS study group or arch bars control group. Trial participants were blinded to group allocation until the end of the operation.

2.2. Procedure

The Food and Drug Administration-approved IMF-screws (Dual-Top H Screw, Jeil Medical, Seoul, Korea) were placed in the interproximal or edentulous spaces at the mucogingival junction. The screw insertion site was based on clinical and radiographic information. Screws were placed in locations that provided appropriate vectors to re-establish the pretraumatic occlusion and at an appropriate distance from root prominences. The intention was to orient the long axis of the screws at 90 degrees to the roots of the adjacent teeth. IMF was established by stainless steel wires through/around the placed screws in the maxilla and mandible. The arch bar was fixed by stainless steel wires around teeth from the incisors to the second molar (if available). IMF was established by fixing the mandible against the maxilla with stainless steel wires around the extensions of the arch bars. If fixation of the body of the mandible was necessary, KLS Martin 2.0-mm plates were used. The length of these plates and screws depended on the line of fracture. The plates were placed according to the Champy-theory.

2.3. Follow-up

The postoperative follow-up was the same as described in the treatment protocol for mandibular fractures as used in our department, i.e. every week postoperatively for 6 weeks. After 6 weeks the screws or arch bars were removed in an outpatient clinical setting without the use of analgesic medication or local anaesthesia. Loosened screws during the follow-up period would have been replaced in an alternative location under local anaesthesia if necessary. Dropout was observed and reasons for dropout were registered.

2.4. Outcome measures

The primary outcome measure was pain assessment. All patients were asked to rate their level of pain, three times daily (at 9AM, 3PM and 9PM) for 7 days on a 100-mm visual analogue scale (VAS). This scale was anchored by two extremes of pain: 'no pain' on the left and 'the worst possible pain' on the right end. At day 7 patients were asked to mark their average pain of the first week on a VAS scale with the same extremes. On day 3 and on day 7 patients were asked if the pain had changed in comparison with the first two days (7-point scale: 'maximally worse', 'a lot worse', 'mildly worse', 'equally painful', 'mildly improved', 'a lot improved' and 'maximally improved'). Six weeks postoperatively, when the IMFS or arch bars were removed, patients were asked to rate their pain immediately after and five minutes after removal on a 100-mm VAS.

Secondary outcome measures were the dental occlusion (rated as: pretraumatic occlusion, suboptimal occlusion or malocclusion); surgical treatment time (in minutes); oral hygiene (using a Likert scale: good, moderate, or poor oral hygiene); intraoperative complications/adverse side effects (e.g. needlestick injuries, screw-fracture on insertion, iatrogenic damage causing loss of teeth or bony sequestra around the area of screw placement, and/or damage to dental roots); postoperative complications/adverse side effects (e.g. infection associated with IMFS, loss of bone screws, screws covered by oral mucosa and/or paraesthesia due to injury to the mental or inferior alveolar nerve).