Condylar Fractures of the Mandible

Treatment, Function and Anatomy

Florine M. Weinberg

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Treatment, Function and Anatomy

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ABBREVIATIONS LIST

CBCT	Cone beam computed tomography
CCT	Controlled clinical trial
CT	Closed treatment
IMF	Intermaxillary fixation
MAI	Mixing ability index
MAT	Mixing ability test
MFIQ	Mandibular function impairment questionnaire
MIO	Maximum interincisal opening
MMF	Maxillomandibular fixation
MMO	Maximum mouth opening
MRI	Magnetic resonance imaging
OLVG	Onze Lieve Vrouwe Gasthuis
ORIF	Open reduction and internal fixation
OT	Open treatment
PROMs	Patient reported outcome measurements
ROM	Range of motion
UMCU	University Medical Centre Utrecht
VAS	Visual analogue scale

CHAPTER 1

General introduction

ANATOMY

The adult human body consists of 206 bones that fulfill various functions. They provide attachment for muscles and form joints for movement, ensure upright stability and protection of vital organs like the brain, heart and lungs.[1] The skull consists of the neurocranium, that contains 8 bones which surround the brain, and the viscerocranium, that contains 21 bones which form the face. These bones form the midface, auditory ossicles, hyoid bone and the mandible.[1]

The mandible is the strongest and largest of these facial bones and is the only bone of the skull that is movable. It consists of a body, rami, and coronoid- and condylar processes. It protects facial organs, nerves and blood vessels and houses the lower teeth. The mandible is attached to major muscle groups, as well as ligaments that make up the temporomandibular joint. The temporomandibular joints, both left and right, connect the condylar parts of the mandible to the temporal bone by synovial articulation with an articular disc. This bilateral joint functions together as one unit and allows essential movement of the mouth which is crucial for speech, laughing, yawning, and mastication.

Because of its prominence in the face, the mandible, zygoma and nose are the most fractured maxillofacial regions. Despite being the strongest facial bone, the condylar parts of the mandibles are vulnerable and the mandible is often fractured in two places because of its half-round shape.[2–4]

TREATMENT OF FRACTURES IN HISTORY

The oldest evidence of a mandibular fracture is believed to originate from a papyrus of the seventeenth century before Christ. However, it is thought to be a copy from the original of at least a thousand years earlier. This Egyptian papyrus described the examination, diagnosis, and treatment of fractures of the mandible (Fig. 1). At the time, the Egyptians did not consider it possible to treat compound fractures or patients who eventually suffered from fever, therefore many patients received no treatment at all and death was inevitable.[5–7]

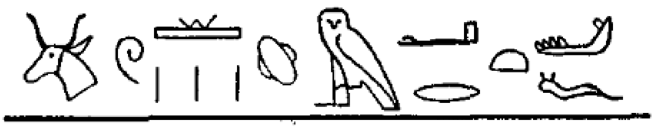

Figure 1. “Instructions Concerning a Fracture in His Mandible” [6]

In ancient Greece, 400 before Christ, Hippocrates realised the importance of establishing maximum occlusion in treatment management for obtaining healing in a good position. He was the first to describe reduction of the fracture followed by immobilisation through the use of circumdental gold or linen thread combined with loose external bandaging.[7,8] Fixation of not only the teeth anterior and posterior to the fracture, but also to the opposite jaw was first mentioned in 1275 in Italy. Until the nineteenth century, most fracture treatment, however, involved some form of external bandage or wrap, occasionally used in conjunction with a bridle wire.[6]

The greatest progress of development of treatment methods in trauma was made during periods of battle and war. Hippocrates already advised those who desired experience in the treatment of injuries to follow the armies into the battlefield.[6]

MEDICAL DEVELOPMENTS IN GENERAL

Multiple developments caused a medical and surgical revolution over time.
Setting fractures was not such a problem, but internal surgery remained a last resort because of the high risks. The main problems were pain, infection and blood loss.
In the early 19th century, scientists began to experiment with anaesthetics to sedate the patient. The first gas used was nitrous oxide, however, it was suitable for pulling teeth but could not be used for longer operations.[9] In 1846, ether was used first in America by the dentist William Morton (1819-1868). It was very effective for sedation but was flammable and damaged the lungs. In 1847, James Simpson (1811-1870) first used chloroform successfully.[9]
Accompanied by sedation, one of the first reports of endotracheal intubation to secure the airway during surgery comes from the American paediatrician Joseph O'Dwyer (1841–1898). The improvement of endotracheal tubes to meet the demands of maxillofacial surgery was done by Ivan W. Magill (1888–1986) and Edgar S. Rowbotham (1890–1979).[9] Ironically the use of chloroform initially led to a period where the death rate went up. This was because with patients unconscious, operating time increased as more difficult invasive surgery was attempted.[9]
Unfortunately, patients still died from blood loss and infections. Until the acceptance of germ theory in the 1860s, surgeons did not take any precautions to protect open wounds from infection. They did not wash their hands before operating, sterilise their equipment or clean the operating table. This began to change in 1867, when Semmelweis (1818–1865) and Lister (1827–1912) introduced the use of antiseptics on wounds, bandages and medical instruments.[10] The discovery of the micro-organism *Penicillium notatum* by Alexander Fleming (1881–1955) was the beginning of a major medical breakthrough. During World War I, he noticed that antiseptics seemed unable to prevent infection, particularly in deep wounds. Eventually, in 1940, the first paper demonstrating the antimicrobial value of penicillin was published.[10]
Since the beginning of World War I and the development of X-ray examination, diagnosis

of fractures have become more accurate and frequent.[11] Early X-ray machines, invented in 1895 by Wilhelm Roentgen (1845-1923), were of enormous proportions and found only in the most advanced hospitals. During the war, Madame Marie Curie (1867-1934) invented a mobile X-ray unit to be used at the battlefield which made a large contribution to treatment of soldiers.

MAXILLOFACIAL DEVELOPMENT

The specialty of maxillofacial surgery was significantly advanced during World War I because of the huge number of casualties with facial trauma due to trench warfare.[12] New Zealand surgeon Harold Gillies (1882-1960) met the French-American dental surgeon Charles Valadier (1873-1931) at No. 13 Stationary Hospital in Wimereux in France in 1915, where the latter had established the first British Plastic & Jaw Ward during the war.[12–14] Both recognised the skills and potential of the French surgeons in reconstructing the mutilated faces but also identified the need for progress in the specialty. Valadier developed treatment techniques to deal with the problems of facial trauma. He advocated early primary closure of wounds and retention of teeth; even those in the fracture line. Gangrene was combatted with frequent irrigations of sterile water under pressure.[13] However, infection remained a major problem of all wounds until development of antiseptics and antibiotics as described above. On the other side of the war, German physicians like the pioneer surgeon August Lindemann (1880-1970) were the first to establish a multidisciplinary approach to maxillofacial injuries including teams of surgeons, dentists and dental technicians.[12]

Since the invention of Marie Curies mobile X-ray units, mandibular condylar fractures in particular were diagnosed more frequently, because this type of fracture was often overlooked when occurring combined with other maxillofacial fractures before.[6] As a result of the war, the treatment of mandibular fractures was reformed by fixated full arch bars on the mandible and the maxilla for maxillomandibular fixation. The goal was to attain normal occlusion for healing of the fracture in anatomical position.[6] For condylar fracture in particular, in the nineteenth century, the importance of anatomical reposition of the fracture was studied.[15] Based on experience, it was believed that the average time of healing was five weeks.[16–18] Inadequate treatment led to ankylosis and limited motion of the mandible in case of immobilisation during a long time, or an open bite in case of fixation in malocclusion.[19] Therefore functional treatment by short or no immobilisation with early active mobilisation of the mandible was promoted by all who thought that immobilisation was unnecessary, inadvisable and resulted in incomplete function.[6] However, this frequently resulted in non-union of the fracture.[18] Different methods to increase vertical dimension were introduced around the 1930s in order to correct shortening of the ramus caused by the fracture and the elevator muscles of the mandible.[6]

Some surgeons believed a condylectomy was the only operative option because of their experience with ankylosis in case of suboptimal reduction.[20] In 1925 operative reduction of the dislocated condyle by intra oral incision and manually pushing back the fragment into the fossa was advised.[21] In 1938 a pulling back technique with a sharp hook through pre-auricular incision of a medially dislocated fracture was introduced.[22] These first operative techniques were carried out without internal fixation and therefore a postoperative period of maxillomandibular fixation was necessary.[21,22]

In maxillofacial surgery, the interest in internal rigid fixation began with the treatment difficulties of fractures of the edentulous mandible, as maxillomandibular fixation was not possible.[23] In 1886 the surgeon Hansmann (1852-1917) was the first to develop and describe subcutaneous fixation of bone fragments with a plate- and screw-system in general.[24] These first plates did not allow approximation of the bone fragments and as necrosis occurred when both fracture ends were kept apart by the plate, the fracture gap grew wider.[24] The first compression plate for osteosynthesis with slot-like holes could approximate the fracture ends after the screws had been inserted and was presented by the Belgian general surgeon Danis (1880-1962) in 1949. Having introduced this form of primary stability, Danis learned that many of the fractures treated in this way healed without the radiological signs of callus formation and named it ''primary'' bone healing.[24]
The technique of open surgery combined with rigid internal fixation was further developed and popularised by the Swiss Arbeitsgemeinschaft für Osteosynthesefragen (AO) (translated to Association for the Study of Internal Fixation, ASIF) in Europe in the 1970s.[25] The basic principles of internal rigid fixation call for primary bone healing under conditions of absolute stability, which is necessary for direct fracture healing.[25] Therefore rigid internal fixation has to neutralise all forces (tension, compression, torsion, shearing) developed during functional loading of the mandible to allow for immediate function.[23]
In the late 1960s miniplates were established next to compression osteosynthesis of the mandible by Michelet (1931-2005) and further developed by Champy (born in 1926) in the 1970s.[26,27] With these miniplates, the path of static compression switched to that of dynamic compression. They could be placed along the tensile trajectories and secured with monocortical screws instead of the bicortical screws that were used before. The dimensions of the miniplates could be kept small as they only had to cope with tensile stress, however, often a second plate was needed. The Champy Miniplates ensured that small postoperative corrections of occlusion remained possible by chewing forces and guiding elastics. This was a major positive development compared to rigid fixation plates, which often resulted in malocclusions.[27] Postoperatively, strict maxillomandibular immobilisation was not necessary in most patients.[24] Around the year 2000 a mini-locking-system was introduced with a stability three times higher than conventional miniplates. This plate is located closer to the bone, but does not have intimate contact, so the term ''internal fixation'' appears to be appropriate. Further development resulted in titanium 3D plating systems in 1992 by Farmand to meet the requirements of semi-rigid fixation with lesser complications.[28] This "3D" plate resists the forces in three directions, namely, bending, shearing, and torsion, hence the name 3D. Instead of two miniplates, now only one 3D plate was necessary. The

stability is gained over a defined surface area and is achieved by its configuration and not by thickness or length.[29,30] Trapezoidal 3D plates were developed to meet these bio-functional demands in the condylar region. The large free areas between the plate arms and minimal incision and dissection permit good blood supply to the bone.[29] Thus, it uses lesser foreign material, reduces the operation time and overall costs of the treatment.[29]

CONDYLAR MANDIBULAR FRACTURES NOWADAYS

Of all mandibular fractures, 20 to 52% are fractures of the mandibular condyle.[31,32] The aetiology is variable and depends on the region in the world, social status, age and gender.[33,34] In several studies traffic accidents were the most common cause and (electric) bicycle-related injuries account for an important proportion.[33] Other important causes in literature are assaults, falls, sport accidents and “other causes” such as work-related injuries. A number of different classifications for mandibular condyle fractures are used in common clinical practice, which leads to confusion. Examples of different classification systems are: ABCM-classification of condylar head fractures, Spiessl and Schroll, classification according to Lindahl and MacLennan’s classification.[35–37] Condylar fractures are not homogenous and have been subdivided by these numerous and partly contradictory classifications. So far, it is very difficult to perform reliable comparisons between studies, including meta-analyses. To compare studies and their outcomes in literature, a relevant classification system should be easy to understand, and be easy to recall. A conventional way to classify these fractures is according to reproducible anatomical landmarks, subdividing the condylar process into condylar base, the condylar neck, and condylar head fractures. In 2014, the AO updated the AO Comprehensive Injury Automatic Classifier (AOCOIAC), which allows for a precise anatomical description of condylar base, neck and head fractures identified according to specific landmarks and reference lines (Fig. 2).[38]

Besides the bony aspect of condylar fractures, injury of the surrounding soft tissue is frequently accompanied.[39,40] As functioning of the condylar bone is made possible by the structures of the temporomandibular joint, healing of these soft tissues may play a role in rehabilitation of the patient.[40] Alterations in position, shape and form of TMJ structures due to trauma may interrupt the function of this integrated mechanism, apart from the bony injury.

Therefore, ideal outcome of treatment of a condylar fracture would be early mobilisation and optimal oral and masticatory functioning for the patient. This means restoration of occlusion, unrestricted mouth opening and range of motion of the mandible, and no pain. Further, the treatment should be minimally invasive, preferably without (surgical) complications, and a short period of recovery for patient’s comfort.

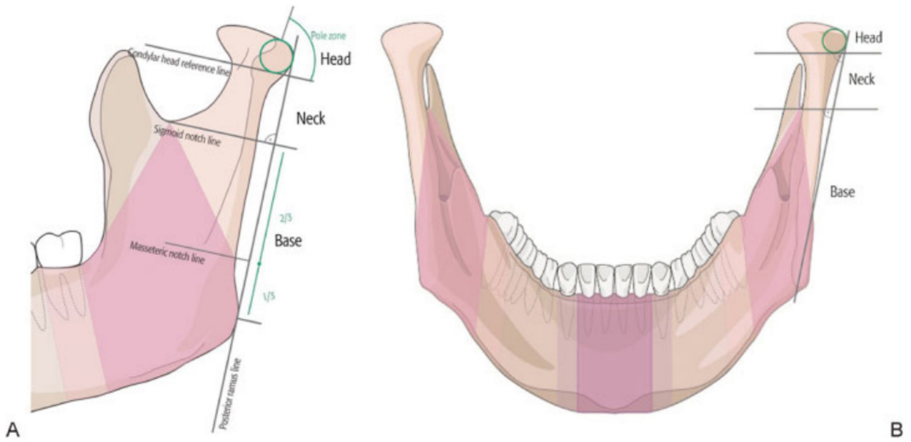

Figure 2. The Comprehensive AOCMF classification System.[38]

CLOSED TREATMENT

As detailed above, for decades closed treatment was the first choice of treatment because of the advantages in terms of decreased costs and no potential surgical complications.[41] Closed treatment refers to any treatment that does not involve open treatment. A distinction can be made between expectant and closed treatment.[41] Expectant treatment is treatment with strict soft diet prescription and/or exercise instructions.[41] However, in most cases, the treatment of fractures consists of a period of maxillomandibular fixation, called closed treatment: in case of condylar head fractures to reduce pain in the first week, and in case of condylar neck and base fractures to restore occlusion. Potential complications of closed treatment include malocclusion (particularly open bite), reduced posterior facial height, facial asymmetry, chronic pain, and reduced mobility of the mandible.[41]

Examples of types of maxillomandibular fixation are wires or elastics fixated on Erich arch bars or applied on bone screws or continuous wiring as described by Obwegeser.[42,43] Further suspension wires on the paranasal, zygoma, frontal and mandibular areas are known. Compared with arch bars, bone screws 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.[42] Furthermore, oral health is easier to maintain and bone screws are easily and painlessly removed.[42] Potential complications include iatrogenic damage to dental roots with potential loss of teeth, infection, loss or loosening of the screws, screws covered by oral mucosa, and paraesthesia due to injury to the mental or inferior alveolar nerve.[42]

OPEN TREATMENT

Since the introduction of 3D-imaging and (semi-)rigid internal fixation plates and screws, an open approach to treat condylar fractures of the mandible in adult patients became more and more favourable.[44] The main advantage of open treatment is the ability to restore anatomical position of the mandibular condyle.[45] Further, open treatment can prevent complications caused by maxillomandibular fixation, such as breathing problems and severe nutritional imbalance.[45] It will also potentially allow immediate mobilisation of the joint.[45] The most concerning surgical complication is damage to the facial nerve, other surgical complications are sialocele, damage of the great auricular nerve, loosening or fracture of the internal fixation plates, haemorrhage and a visible hypertrophic scar.[44] Complications similar to complications for closed treatment include malocclusion, pain, reduced mouth opening, restricted range of motion of the mandible and infection.
There are two main open techniques; the extraoral and the intraoral technique. For the extraoral technique, depending on the level of the fracture and the direction of the dislocation different approaches are described in literature: retromandibular, pre-auricular, submandibular, peri angular and other approaches.[45] The intraoral technique is often endoscope-assisted. Compared with extraoral approaches, the endoscopically assisted technique have the advantages of invisible intraoral scars in social interaction, the scar of entering the endoscopic trocar is small, and the risk of facial nerve damage seems to be minimal.[46] However, intensive training in endoscopic techniques and therefore a learning curve, and handling of the specialised instruments is needed before the transoral approach can successfully be performed.[46,47]

MASTICATORY FUNCTIONING

In case of condylar trauma where not only the bony part, but also the surrounding soft tissues are injured, masticatory functioning has probably changed. Masticatory functioning is defined as the act of chewing food. It represents the initial stage of digestion. During mastication, the food bolus is broken down into pieces, mixed with saliva containing amylase and prepared for digestion. These various cyclic movements are produced by the coordinated contraction of the muscles of the jaw, tongue and face. Further collaboration with the teeth, periodontal supportive structures, temporomandibular joints, the palate, the salivary glands and tactile (neurologic) feedback are required. It is an activity that is usually automatic, although it can be easily controlled. Masticatory functioning can be changed by antalgic restrictions and malocclusion, but also by possibly altered anatomical position, decreased biteforce, sensory changes, altered or inhibited range of motion of the mandible and joints, persisting malocclusion, and loss of dentition. These changes have direct influence on the coordination within the masticatory system and compensatory patterns will possibly occur.[48]

The degree of masticatory deficits after condylar trauma can be measured through masticatory performance and masticatory ability.[49–51]

Masticatory performance is the objective efficiency of this mastication functioning, which can be assessed by different methods, such as comminution tests, two-coloured chewing gum and paraffin wax tests. A validity and reliability study showed that chewing on a two-coloured paraffin wax tablet is a reliable test.[52] The mixing ability test (MAT) is such a test, which assesses the comminution of a bolus over a standard number of chewing cycles.[49–51]

Masticatory ability is a patient-reported outcome (PRO) of mastication functioning. It reflects the expectations and quality of life of the patients by taking the psychological and emotional adjustment of the patient in their daily life into account. This can be an advantage over measurement of objective outcomes alone. Questionnaires measuring influence on general quality of life are for example the RAND-36 questionnaire, the Short-Form-36 (SF-36), the Hospital Anxiety and Depression Schedule (HADS), and the General Health Questionnaire (GHQ).[53,54] Subjective efficiency of the impairments related to the oral cavity are tested in various departments with several questionnaires, such as the Oral Health Impact Profile (OHIP) questionnaire and the Mandibular Function Impairment Questionnaire (MFIQ).[55–57] In recent studies, the MFIQ has been used to measure subjective masticatory ability in condylar trauma patients.[58,59] Since objective functional outcomes of the treatment do not necessarily correspond with PROs, it is important to keep both of them in mind when treating a patient for its condylar trauma.[60]

OUTLINE OF THIS THESIS

The overall aim of the studies in this thesis is to get insight in the different treatment modalities for mandibular condylar fractures and the influence of these fractures on masticatory functioning and anatomy.

CHAPTER OVERVIEW

<u>Chapter 2 - Articular soft tissue injuries in mandibular condyle fractures</u>

The primary aim was to appoint what kind of soft tissue injuries appear after mandibular condylar fractures. The secondary aim was to investigate the influence of soft tissue injuries on oral functioning in adults and if there is a relation between soft tissue injuries and oral functions. The third aim was to get insight into the used MRI settings to visualise the damaged tissues for future use in research and clinical use.

In this systematic review, the literature was searched for a relation between soft tissue injuries after mandibular condylar fractures and masticatory functioning. Further, insight into MRI settings for future use in research and clinical use is given.

Chapter 3 - Reproducibility and validity of Mixing Ability Test

The aim of this study is to determine, on the one hand, the test-retest reproducibility (reliability, measurement error and agreement) of the mixing ability test (MAT), and, on the other hand, the construct validity of the MAT in relation to the mandibular functioning impairment questionnaire (MFIQ) concerning patients with mandibular condylar fractures. We hypothesise that the reproducibility of the MAT will be sufficient (ICC ≥ 0.7) and that the construct validity would be at least moderately correlated (≥ 0.60).
This study focused on the test-retest reproducibility (reliability, measurement error and agreement) of the MAT and the construct validity of the MAT in relation to the MFIQ in patients with unilateral mandibular condylar fractures.

Chapter 4 - Long-term masticatory performance and ability

The first aim was to find explanatory demographic and clinical variables for masticatory performance and ability in patients who received closed treatment for unilateral condylar neck or base fractures at least 5 years ago. The second aim was to compare masticatory performance and masticatory ability between patients with a history of condylar fractures and healthy subjects.
In this cross-sectional study, long-term outcomes of masticatory functioning were given after closed treatment for unilateral mandibular condylar fractures of at least 5 years ago. Further masticatory performance and ability in patients with a history of unilateral condylar fractures were compared with a group of healthy subjects.

Chapter 5 - Oral functioning after open versus closed treatment

The aim of this study was to compare open treatment with closed treatment for unilateral condylar mandibular neck and base fractures in a controlled clinical trial by objective functional outcomes and patient reported outcomes (PROs) measured at six weeks and six months follow-up. Additionally, a comparison of objective functional outcomes and PROs was made within six weeks and six months follow-up of the open and closed treatment groups.
In this two-centre controlled clinical trial, open treatment and closed treatment are compared for unilateral condylar mandibular neck or base fractures measured at six weeks and six months follow-up. Masticatory functioning is measured by objective functional outcomes in terms of the MAT and mandibular active range of motion, and PROs in terms of the MFIQ and the visual analogue scale (VAS) for pain. Additionally, a comparison is made within both groups between six weeks and six months follow-up.

Chapter 6 - Anatomical position of the condyle after open versus closed treatment

The first aim was to analyse and compare the final position of the initially fractured mandibular condyle following open and closed treatment of unilateral fractures. The second aim was to evaluate the association between the final position of the affected

condyle and mandibular functioning and pain. In addition, this study aimed to classify and compare the morphology of the condyle following open and closed treatment over time.
In this two-centre controlled clinical trial, the position of the mandibular condyle on cone beam CT-scans following open and closed treatment are analysed and compared. Thereby an evaluation was done to investigate if there is an association between the anatomical position of the mandibular condyle after treatment and masticatory functioning.

1

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CHAPTER 2

Articular soft tissue injuries associated with mandibular condyle fractures and the effects on oral function: a systematic review

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ABSTRACT

The majority of studies debating the optimisation of treatment for condylar mandibular fractures focus on the bony aspect first. However, fractures of the mandibular condyle may go together with soft tissue injury of the temporomandibular joint. An electronic literature search for this topic was undertaken. Assessment of quality was carried out using the Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies. Sixteen articles were included in this review. The reviewed literature showed that intracapsular fractures and dislocated condylar fractures result in more severe injuries. Serious injury to the disc and capsule of the temporomandibular joint is a contributing factor towards development of complications after closed treatment. The results of this review give an overview of the published studies focusing on articular soft tissue injuries caused by condylar mandibular fractures. Additionally, an overview of the MRI settings used to detect these injuries is provided. Until now the relation between soft tissue injuries and type of condylar trauma and their influence on clinical outcome has been insufficiently investigated. Before considering reduction of soft tissues next to reduction of the fracture, more research is needed into the impact of soft tissue injuries on oral functioning, in which a uniform classification is used.

INTRODUCTION

Treatment of condylar mandibular fractures remains a subject of discussion. In recent literature, to operate or not to operate is the ongoing question for debate.[1] Although it is known that condylar fractures result in trauma of the bony and articular soft tissue, the majority of studies in the literature focus on the bony aspect only, and the role of articular soft tissue injury is often overlooked.[1,2] The structures of the temporomandibular joint (TMJ) are intimately related to the mandibular bone, both anatomically and physiologically.[3–5] Alterations in the position, shape and form of the TMJ structures may interrupt the function of this integrated mechanism, apart from the bony injury. Because of this intimate relation, knowledge of the effect of condylar mandibular fractures on the structures of the TMJ could support treatment decision-making. The frequency and kind of TMJ injuries depend significantly on fracture localisation, level of energy at the bone, and extrusion rate.[6] Most soft tissue injuries of the TMJ described in the literature are disc displacement, disc disruption, hemarthrosis and capsular injury.[7] Undiagnosed or untreated intra-articular trauma or condylar fractures may cause long-term complications such as chronic pain, a clicking joint, limitation of function, ankylosis and osteoarthritic changes because of contact between the residual condyle and the fossa.[2,7,8]

In a trauma setting, computed tomography (CT) or conventional orthopantomogram (OPG) imaging remains the standard for radiologic evaluation of facial fractures. However, these examinations are optimal for viewing skeletal and dental tissues, whereas magnetic resonance imaging (MRI) is the standard for viewing soft tissues in medical fields.[9] MRI is nowadays considered a reliable diagnostic test for objective and non-invasive imaging of the TMJ and its injuries.[6] MRI can identify capsular injury, disc displacement, disc disruption and retrodiscal tissue injury.[6] However, the use of MRI for examination of the TMJ in an acute setting is discussed because of its cost, availability and insufficient direct contribution to initial treatment.[9]

For all that, when a better understanding of TMJ changes is achieved, a shift of opinion in the management of condylar injuries may be considered. Perhaps reduction of the bony fragments becomes only one aspect of the management of these injuries, and more attention will be given to soft tissue repair to achieve a better clinical outcome.

Therefore, this systematic review was conducted to provide an overview of the published studies focusing on articular soft tissue injuries as a result of mandibular condylar fractures and used MRI settings. The primary aim was to appoint what kind of soft tissue injuries appear after mandibular condylar fractures. The secondary aim was to look into the influence of soft tissue injuries on oral functioning in adults and if there is a relation between soft tissue injuries and oral functions. The third aim was to get insight in the used MRI-settings to visualise the damaged tissues for future use in research and clinical use.

METHODS

PROTOCOL AND REGISTRATION

This systematic review was registered in the PROSPERO international prospective register of systematic reviews (registration number CRD42017068913) and was conducted in accordance with the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

ELIGIBILITY CRITERIA

Studies focusing on soft tissue injuries, disc displacement, disc tear, disc perforation, hemarthrosis, lateral pterygoid muscle injury and retrodiscal injury after bilateral or unilateral condylar mandibular fractures in adults and detection of these soft tissue injuries by MRI before treatment were eligible for inclusion. Studies were excluded by the following criteria: (1) written in a language other than English, Dutch or German, (2) case reports, reviews, comments or abstracts, and (3) animal and/or cadaver studies.

INFORMATION SOURCES

Literature searches to identify studies were performed in the electronic databases PubMed [1966–2018], Embase [1966–2018] and Cochrane [1898–2018]. The electronic search was supplemented by snowballing of full articles retrieved. The search was conducted on July 3rd 2018. Key words used in the search strategy were: “mandibular condyle”, “mandibular fracture”, “soft tissue injury”, “temporomandibular disc injury”, “disc displacement”, “disc tear”, “disc perforation”, “hemarthrosis”, “lateral pterygoid muscle injury”, “retrodiscal injury” and “magnetic resonance imaging”. In PubMed, a combination of MeSH terms and title/abstract searches was used. The search strategy for Embase and Cochrane required adaptation from the PubMed search strategy (see Appendix 1).

STUDY RECORDS

After removal of duplicates, all titles and abstracts were screened by two authors (FMW and AJR). Afterwards, full-text articles were obtained, and relevant articles were included. If the full text was not available online, the author was contacted. The reference list of these reports was manually searched for additional citations. In case of a conflict, a third author (CMS) was consulted. Agreement was reached in all cases.

STUDY DATA

Two authors (FMW and CMS) extracted data on study design, study size, characteristics of study patients (age, sex, follow-up time), characteristics of the condylar trauma (affected side(s), classification), characteristics of the soft tissue injury (type of injury, extent of the injury, detection of the injury) and clinical outcome (see Table 1). Additionally, information about the technology and MRI setting used was collected only for those articles that reported these settings (see Table 2).

QUALITY ASSESSMENT

Quality assessment of included studies was done by authors FMW and CMS using the National Institutes of Health Quality assessment tool for Observational Cohort and Cross-Sectional Studies[10] (QAT-OCCSS; National Institutes of Health, 2014; see also Table 3). QAT-OCCSS is a 14-item quality appraisal tool that classifies study quality on the basis of methodological and reporting parameters. These parameters include the clarity of the study's research objectives, a participation rate of more than 50%, uniform inclusion and exclusion criteria, sample size justification, exposure of interest measured before outcome, sufficient time frame between exposure and outcome, examination of different levels of exposure in relation to outcome, defined and evenly applied exposure methods, exposure assessed more than once over time, defined and consistently applied outcome measure, blinding of assessors, loss of follow-up less than 20%, and key potential confounding variables measured and adjusted statistically for impact between exposure and outcome. Raters were instructed to indicate whether each of the quality indicators were present (i.e. "yes" or "no") in the included study, with a greater number of yeses indicative of a higher-quality study.

Two authors (FMW and CMS) independently completed the appraisal tool for each study and classified study quality according to appraisal guidelines. Finally, the total score was calculated as the amount of yeses over the amount of questions that applied. A quality indicator did not take part in the quality score if it was "not applicable" (NA). As QAT-OCCSS does not have strict guidance for determining the overall quality rating of observational cohort and cross-sectional studies, the overall study quality was rated for each study by FMW and CMS as poor, fair or good. This was not only based on the overall (percentage) score, but also on the risk of bias for each question which was answered with "no". This ultimately meant that a study was rated "poor" when the overall score was 40% or lower, "fair" when between 40% and 80%, and "good" when 80% or higher.

RESULTS

LITERATURE SEARCH

The selection process for the included studies is summarised in Fig. 1. The search and selection process were displayed according to the PRISMA 2009 flow diagram.[28] The search strategy resulted in 560 unique publications with one additional article retrieved from reference tracking. Unfortunately, none of the authors contacted responded to our request for full text. In total, 44 articles were selected based on title and abstract for full-text screening. Based on the full text of these articles, 28 articles were excluded, mainly because they were not about imaging of soft tissue injuries right after trauma. Finally, 16 studies were included for this review.[4,8,11–24] This included two articles focusing on soft tissue reduction during open treatment[12,15], two articles focusing on internal fixation for intracapsular condyle fracture[16,21], one article on outcome of functional management related to soft tissue injury[23], and the other 11 articles focusing on imaging of soft tissue injuries after condylar fracture.[4,8,24,11,13,14,17–20,22] All studies included were in English. Eight studies were cross-sectional[4,11,13,14,18–20,24], four were prospective cohort studies[16,17,22,23], and four were retrospective cohort studies.[8,12,15,21]

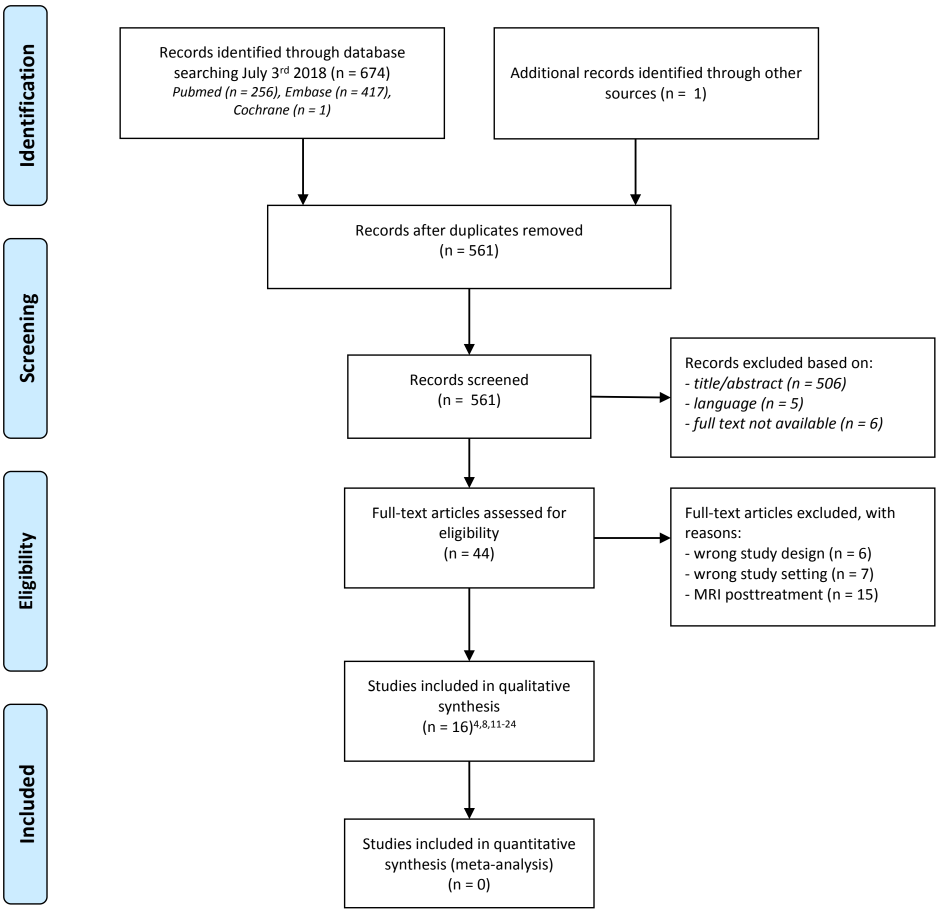

Figure 1. Flowchart of search and selection according to PRISMA 2009 flow diagram[28]

GENERAL STUDY CHARACTERISTICS

The general characteristics of the 16 included studies are listed in Table 1. The selected studies were conducted in seven different countries (China = 7[11,12,14–16,21,24], India = 2[17,23], Austria = 2 [18,19], Japan = 2[4,13], South Korea = 1[20], Egypt = 1[22], Ukraine = 1[8]). The publication dates of the included studies spanned two decades, with the earliest published in 1996[4] and the most recent published in 2018.[16] Approximately 94% (n = 15) of the included articles were published since 2004[8,11,20–24,12–19], with eight (50%) published within the last 5 years.[8,11,14–16,20,22,23]
The total number of patients included in all studies was 907. The number included varied from 10[4] to 160 patients[14], with a mean of 57 patients per study.
Most studies did not mention or did not have a follow-up visit[4,11,13,14,17–20,24], while two studies had a 5-year follow-up visit with imaging of the soft tissue by MRI.[12,22]

CONDYLAR FRACTURES

The number of condylar fractures included in each study varied from 12[4] to 222 [14] with a mean of 72 fractures per study, and a total sum of 1144 condylar fractures. A wide variety of classification systems was used (see also Table 1). Four studies used the ABCM-classification of intracapsular condylar fractures (ICFs) described by He and Yang.[11,12,14,21] One used the classification of Neff.[15] Three studies used classification according to Spiessl and Schroll[17–19], and two of them further classified depending on the severity of injury as grade I, II or III.[17,19] Lindahl's classification was used in one study.[20] One study used MacLennan's classification.[13] One study did not specify the type of condylar fracture; however, groups of condylar fracture with or without other mandibular fractures were made.[22] In two studies, no further specification of the condylar fracture was made[4,8], and in one study a distinction was made between high and low condylar fractures.[23] One study divided the condylar fractures into two groups: fractures with dislocation and fractures without dislocation.[24] One study proposed its own classification for ICFs.[16]
Three studies reported unilateral condylar fractures only[8,16,23], while the rest had a mixed patient group with both unilateral and bilateral condylar fractures. Treatment of the condylar fracture was mentioned in ten studies.[4,12–17,21–23] Overall three different treatment modalities were mentioned; open reduction and internal fixation (ORIF) of the fracture, ORIF combined with reduction of one or more articular soft tissues and closed treatment with intermaxillary fixation.

SOFT TISSUE INJURY

Soft tissue injuries were diagnosed in all studies by MRI. Two studies reported also soft tissue injuries identified during surgical reduction.[12,15] All studies had pre-treatment MRI, since this was an inclusion criterion for this review. In six studies, additional posttreatment MRI was done.[4,14–16,22,23]

Table 1. Characteristics of included studies considering study design, subjects, condylar fractures, soft tissue injuries and clinical outcome.

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries		Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
CAI ET AL. (2018)[23]	Retrospective cohort study	34 (13)	35 (16-76)	48 Surgical 48 MRI	48	Neffs classification of ICF's 7 type A 35 type B 6 type M	*Surgical (48):* 48 DDISP	*MRI (48):* 48 DDISP/ CAPT/ RDTT/ JE	Pre- and post-treatment	ORIF + disc reduction	40 normal disc position 4 anterior DDISP 3 condylar morphologic abnormalities	2 malocclusion 3 facial nerve injury 7 MO limitation (<2.6cm) 5 MO deviation 4 TMJ discomfort 5 joint noise
CHEN ET AL. (2010)[20]	Retrospective cohort study	129 (39)	32 (4-80)	164 Surgical 42 MRI	164	He & Yang's classification of ICF's: 88 type A 45 type B 9 type C 22 type M	*Surgical (164):* 4 DDISR 160 DDISP 119 RDTT 87 CAPT	*MRI (42):* 0 DDISR 41 DDISP 29 RDTT 22 CAPT	*Surgical:* per-treatment *MRI:* pre- and posttreatment	ORIF + open functional treatment	40 normal disc position 1 anterior DDISP 1 posterior DDISP	1 week follow-up (129 patients): 15 malocclusion 43 facial nerve injury 1-5 y follow-up (45 patients): 1 fibrous ankylosis 5 MO limitation (<2,5cm) 3 condyle resorption 3 facial nerve injury 2 TMJ click 7 MO deviation 1 malocclusion mean MO pre-treatment: 1.6cm (0.1-3.5cm) mean MO posttreatment: 3.3cm (1.5-5.3cm)
DWIVEDI ET AL. (2012)[11]	Prospective cohort study	15 (3)	22 (5-45)	MRI	17	Spiessl & Schroll's classification: 0 grade I (no CF) 12 grade II (type I, II, III) 5 grade III (type IV, V, VI) (2 High CF 15 Low CF)	8 HEM 8 DDISP 2 CAPT		Pre-treatment	IMF (CT)	NA	NM

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
EMSHOFF ET AL. (2007)[12]	Cross-sectional study	11 (6)	46 ± 21 (11-75)	MRI	17	Spiessl & Schroll's classification: 6 type V 11 type VI	17 HEM 1 DDISR 13 CAPT 12 RDTT 0 DAV	Pre-treatment	NM	NA	NM
GERHARD ET AL. (2007)[13]	Cross-sectional study	19 (9)	42 (11-75)	MRI	27	Spiessl &Schroll's classification: 11 grade I (no CF) 13 grade III (type I, II, III) 14 grade III (type IV, V, VI) (7 Unilateral CF 10 Bilateral CF 2 No fracture)	22 HEM 7 DDISP 17 CAPT	Pre-treatment	NM	NA	NM
HE ET AL. (2010)[15]	Retrospective cohort study	151 (42)	31	61 MRI	204	He & Yang's classification of ICF's: 110 type A 60 type B 9 type C 25 type M, 4 No displacement	58 DDISP (of 61 TMJs)	MRI pre-treatment, (n=43 patients, n=61 ICFs)	ORIF + disc reduction	NA	2 months - 5 y follow-up (35 patients): 0 malocclusion 3 facial nerve injury 1 TMJ clicking 4 condyle resorption MMO: 35.89mm

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
KIM ET AL. (2016)[14]	Cross-sectional study	34 (NM)	29	MRI	47	Lindahl's classification: 18 Dislocation 10 Displacement 15 No displacement 2 Lat.displacement 2 Chip fracture 21 Contralat. TMJs	 →18 DDISL →8 DDISL →7 DDISL →2 DDISL →1 DDISL →10 DDISL	Pre-treatment	NM	NA	NM
NABIL (2016)[16]	Prospective cohort study	100 (0)	(17-35)	MRI	100	Grouped: 20 group 1: UCF 20 group 2: UCF + MF ipsi 20 group 3: UCF + MF contra 20 group 4: MF without CF 20 group 5: BCF	Group 1: 12 DDISP, 10 JE Group 2: 5 DDISP Group 3: 16 DDISP, 4 JE, 5 DDISP on other TMJ Group 4: 3 DDISP, 2 JE on other TMJ Group 5: 20 DDISP, 15 JE and 20 DDISP and 15 JE on other TMJ	Pre-treatment, Posttreatment and +5y	IMF (CT)	Group 1: 14 DDISP Group 2: 2 DDISP Group 3: 10 DDISP, 7 DDISP other TMJ Group 4: 2 DDISP, 2 DDISP other TMJ Group 5: 20 DDISP, 20 DDISP other TMJ	Tenderness (n): posttreatment – 5 y follow-up 10 FS, NFS NM – 8 FS, 4 NFS (group 1) 9 FS, 5 NFS – 10 FS, 6 NFS (group 2) 6 FS, 4 NFS – 9 FS, 6 NFS (group 3) 3 FS, 2 NFS – 6 FS, 4 NFS (group 4) 20 FS, NFS NM – 8 FS, NFS NM (group 5) MO deviation (n): posttreatment – 5 y follow-up 4 – 6 (group 1) 3 – 4 (group 2) 2 – 3 (group 3) 0 – 1 (group 4) NM – NM (group 5)

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
											TMJ clicking (n): posttreatment – 5 y follow-up 2 – 2 FS, 5 NFS (group 1) NM – 4 FS, 7 NFS (group 2) NM – 3 FS, 5 NFS, 2 bilateral (group 3) NM – 2 FS, 5 NFS, 1 bilateral (group 4) NM – 5 FS, 7 bilateral (group 5) 2 limited MO (group 2) 3 anterior open bite (group 5) 4 limited jaw ROM (group 5)
POHRANYCHNA ET AL. (2017)[8]	Retrospective cohort study	22 (0)	(18-25)	MRI	22	CF, not specified	20 HEM 15 DDISL 12 DDEF 8 Dadhesion 3 DPERF 15 tension of ligaments 6 breaking of ligaments 5 damage joint surface	Pre-treatment	NM	NA	NM

2

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
TAKAHASHI ET AL. (2004)[21]	Cross-sectional study	15 (4)	36 (17-71)	MRI	18	MacLennan's classification with modifications: 6 type I 0 type II 5 type III 2 type IV 5 type V Grouped by location: 5 CHF 6 upper CNF 2 lower CNF 5 SCF	7 DDISL 11 JE	Pre-treatment	IMF (CT) or ORIF	NA	NM
TAKAKU ET AL. (1996)[4]	Cross-sectional study	10 (3)	30 (7-45)	MRI	12	CF + SCF	12 DDISP 11 CAPT 0 DDISR 0 Disc Tear 8 RDTT 8 JE 12 Swelling	Pre- and post-treatment	ORIF	NM	NM
TRIPATHI ET AL. (2015)[17]	Prospective cohort study	54 (13)	30 (17-45)	MRI	54	14 High CF 40 Low CF	42 HEM 37 DDISP 12 CAPT 5 DPERF	Pre-treatment	IMF (CT)	NA	5 grade I (HEM): normal ROM + MO, 0 joint noise + pain 20 grade II (HEM + DDISP): 10 ↓ROM, 10 ↓MO, 7 joint noise + pain 12 grade III (HEM + DDISP + CAPT): 8 ↓ROM, 8 ↓MO 5 grade IV (DPERF + grade I/II/III): 5 ↓ROM, 5 joint noise

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
WANG ET AL. (2009)[18]	Cross-sectional study	80 (30)	31 (5-69)	MRI	118	108 CF's with dislocation 10 CF's without dislocation	108 DDISP 11 DDEF 10 DPERF/DAV 103 Abnormal signal intensities of retrodiscal tissue 101 JE 103 Abnormal inferoposterior attachments of discs 45 Abnormal superoposterior attachments of discs 101 Abnormal joint capsules	Pre-treatment	NM	NA	NM
YING ET AL. (2018)[24]	Prospective cohort study	55 (19)	37 (18-55)	MRI	55	Ying's new classification for ICF's 7 A (no loss of height, no DDISP) 17 B (DDISP without loss of height) 31 C (loss of height +/- DDISP)	DDISP: 0 type A 17 type B 31 type C	55 Pre- and 48 posttreatment	IMF (CT in A) ORIF (in B + C)	48 normal disc position	0 malocclusion 1 pain 9 facial nerve injury
YU ET AL. (2013)[19]	Cross-sectional study	18 (7)	30 (17-66)	MRI	19	ICF classification: 4 type A 14 type B 0 type C 1 type M	16 DDISP 9 CAPT 16 RDTT 19 JE 16 HEM	Pre-treatment	NM	NA	NM

2

Table 1. Continued

Study	Design	Number of patients (Females)	Age in years (Range)	Detection of soft tissue injuries related to condylar mandibular fracture	N: CF	Kind of fractures	Soft tissue injuries	Time of detection of soft tissue injury by MRI	Treatment of the condylar fracture	Posttreatment MRI findings of soft tissue	Clinical Outcomes
ZHENG ET AL. (2016)[22]	Cross-sectional study	160 (48)	34 (8-52)	MRI	222	He & Yang's classification of ICF's: 75 type A 49 type B 11 type C 25 type M 40 CNF 22 SCF	178 DDISP	222 pre- and 32 posttreatment	ICF: ORIF + disc reduction CNF: ORIF or ORIF + disc reduction SCF: ORIF or ORIF + disc reduction	26 excellent disc position 2 good disc position 4 poor disc position	NM

HEM = hemarthrosis; DDISP = disc displacement; DDISR = disc disruption; DDISL = disc dislocation; DPERF = disc perforation; DDEF = disc deformation; CAPT = capsular tear; JE = joint effusion; RDTT = retrodiscal tissue tear; DAV= disc avulsion; TMJ = temporomandibular joint; Lat. = lateral; CF = condylar mandibular fracture; ICF = intracapsular condylar fracture; ECF = extracapsular condylar fracture; CHF = condylar head fracture; CNF = condylar neck fracture; SCF = subcondylar fracture; UCF= unilateral condylar fracture; BCF= bilateral condylar fracture; MF= mandibular fracture; F= female; y = years; ROM = range of motion; MO = mouth opening; MMO = maximal mouth opening; FS = fractured site; NFS = non fractured site; CT = closed treatment; IMF = intermaxillary fixation; ORIF = open reduction and internal fixation; NA= not applicable; NM = not mentioned;
Grade I = HEM, Grade II = HEM + DDISP, Grade III = HEM + DDISP + CAPT, Grade IV = DPERF + (HEM +/- DDISP +/- CAPT)

Not all studies focused on the same types of soft tissue injuries. One study mentioned that all ICF sides had soft tissue changes such as disc displacement, capsular tears, retrodiscal tissue tears and joint effusion, but did not mention specific numbers.[15]

Disc displacement and dislocation

Eleven studies with a total of 727 fractured condyles reported disc displacement.[4,11,24,12,14,16,17,19,21–23] This disc displacement was detected with MRI in 591 TMJs (81%). Two studies reported the surgical detection of disc displacement.[12,15] In addition, one study reported eight cases of disc displacement in non-fractured TMJ sides.[22] Three studies mentioned disc dislocation measured by MRI.[8,13,20]

Injury to the disc

A wide variety of definitions for injury to the disc was used: disc perforation, disc avulsion[8,23,24], disc deformation[8], disc disruption and disc tear.[4,12,18] Three studies with a total of 71 fractured condyles reported one case of disc disruption detected with MRI.[4,12,18] One study reported the surgical detection of disc disruption in four of the 164 fractured condyles.[12] Disc tear was discussed in one article, and was not detected in 12 joints.[4] The absence of disc avulsion was mentioned in one study.[18] Disc avulsion or disc perforation was mentioned in one study and was detected in 10 of the 108 fractured sites.[24] Disc perforation was mentioned in 14%[8] and in 9%[23] of cases.

Capsular injury

Capsular tear was reported in seven studies, with a total of 86 capsular tears detected by MRI in 188 fractures sites (46%).[4,11,12,17–19,23]
Retrodiscal tissue tear was diagnosed by MRI in four studies.[4,11,12,18] In one study, it was surgically detected in 119 of the 164 fractured sites (73%) and detected by MRI in 29 of the 42 sites (69%).[12] In the other studies, it was detected in 67%[4], 71%[18] and 84%[11] of the fractured sites.
Disc deformity (9%), abnormal signal intensities of retrodiscal tissue (87%), abnormal inferoposterior (87%) or superoposterior (38%) attachments of discs, and abnormal joint capsules (86%) were discussed in one study with 118 condylar fractures.[24]

Hemarthrosis and joint effusion

Five studies discussed hemarthrosis [11,17–19,23] and five joint effusion.[4,11,13,22,24] The presence of hemarthrosis in total was 78%, with variation from 47%[17] to 100%.[18] The presence of joint effusion in total was 59%, with variation from 24%[22] to 100%.[11] One study reported both hemarthrosis and joint effusion.[11] In this study, joint effusion was detected in all fractured sites, and hemarthrosis was detected in 16 of the 19 fractured sites.

Classification of soft tissue injuries

One study further classified articular soft tissue injuries from grade I to IV.[23] with grade

I: hemarthrosis only (5 of 54 patients), grade II: hemarthrosis and disc displacement (20 patients), grade III: hemarthrosis, disc displacement and capsular tear (12 patients), and grade IV: disc perforation in association with grade I, II or III (5 patients). Another study proposed a classification based on both bony and soft tissue injury, with type A: no loss of mandibular height or disc displacement, type B: no loss of mandibular height with disc displacement, and type C: reduction of mandibular height with or without disc displacement.[16]

Posttreatment MRI findings of soft tissue

In Table 1 MRI findings of the six studies who performed a posttreatment MRI are listed. In one study, however, these findings were not mentioned.[4] Four of the remaining five studies performed ORIF with or without reduction of the disc.[12,14–16] In the majority of these, the discs were seen in normal position. One study used closed treatment with IMF only.[22] In this study the position of most discs remained displaced after treatment.

LINK BETWEEN CONDYLAR FRACTURE AND SOFT TISSUE INJURY

A link between the severity of condylar injury and damage to the soft tissue was found in seven studies.[4,13,14,17–19,24] In one study, significant differences were found in the number of displaced discs between ICFs on the one hand and those of the condylar neck and subcondylar region on the other ($p < 0.001$)[14] One study reported a significant relation between the degree of condylar injury and the MRI finding of hemarthrosis, but there was no significant correlation with capsular tear detected by MRI.[17] Another study reported good diagnostic agreement between the degree of condylar injury and the MRI findings of capsular tear and hemarthrosis; however, no significant relationship was found for disc displacement detected by MRI.[19] In one study, hemarthrosis was found in all condylar fractures classified as type V and VI according to Spiessl and Schroll.[18] In one study, the relation between the position of the condylar fracture and MRI findings of joint effusion was statistically significant.[13] Another study mentioned 97.2% disc displacement in the group of condylar fractures with dislocation compared to 30% disc displacement in the group of condylar fractures without dislocation ($p < 0.01$).[24] In this study, abnormal retrodiscal tissue was significantly more present in the group of condylar fractures with dislocation compared to the group of condylar fractures without dislocation. One study mentioned 100% disc displacement when the fractured condylar process was dislocated.[4]

CLINICAL OUTCOMES

Six studies discussed the clinical outcome.[12,15,16,21–23] One study reported tenderness over the TMJ, deviation of the mandible and clicking over the TMJ in the follow-up period of 5 years.[22]

Five studies reported functional outcome by maximal mouth opening (mean range of 3.32–4.2 cm).[12,15,16,21,23] Three of these studies also reported joint noise, range of movement and mouth opening, and pain during movement.[15,16,23] The other two studies also discussed posttreatment complications in the long-term follow-up period: fibrous ankyloses (0.8%[12]), mouth-opening limitation/restricted movement (3.9%[12]), condylar resorption that required plate removal (2.3%[12]–11.4%[15]), facial nerve injury (2.3%[12]–8.6%[15]), TMJ clicking (1.6%[12]–2.9%[15]), mouth opening with deviation (5.4%[12]), mouth opening with deviation due to discontinued growth of the condyle after fixation (36.8%), and malocclusion (0%[15]–0.8%[12]) were reported. A link between the grade of soft tissue injury and clinical outcome was found in only one study.[23] This study reported restricted movement and joint noise in 100% of patients with a grade IV soft tissue injury, in 75% of patients with a grade III injury, in 50% of patients with a grade II injury, and no complications after 14 days in patients with a grade I injury. All these patients were treated with intermaxillary fixation. There was no statistical analysis done in this study.

MRI SETTINGS

In two studies, MRI planes alone are mentioned.[8,14] Specific MRI settings were described in 10 studies.[4,11,13,17–20,22–24] These settings are presented in Table 2. In eight studies, a 1.5-Tesla MRI-scan was used[4,11,13,18–20,22,24]; in two studies, this was not discussed.[17,23] In all 10 studies, a coil was placed over the TMJ. All 10 studies mentioned which planes and which sequences were obtained.

QUALITY ASSESSMENT

The methodological quality of all studies was assessed and is presented in Table 3. Overall, the methodological quality was fair. The reviewers (FMW and CMS) came to an agreement on all quality assessments. Total quality scores ranged from 18%[4] to 82%[14], with an average quality rating of 52.8%. Three studies were of poor quality[4,12,21], one of good quality[14] and 11 of fair quality. With respect to specific QAT-OCCSS items, 12 studies had clearly articulated a research question or objective (criterion 1)[8,12,23,24,13–15,17–20,22], all of the studies clearly specified their study population (criterion 2)[4,8,19–24,11–18] and 69% of the included studies adequately described their sample inclusion and exclusion criteria (criterion 4).[11,14,24,15–20,22,23] A participation rate could not be determined for 69% of the included studies (criterion 3)[4,8,23,13,15–20,22], and one study reported a participation rate of less than 50%.[12] None of the included studies provided justification for their sample size, nor a power analysis (criterion 5). In only six studies was the exposure variable of interest measured prior to the soft tissue injury (criterion 6).[8,14–16,22,23] For cross-sectional studies, this is not possible according to the manual of the QAT-OCCSS.

In six studies there was a sufficient timeframe (criterion 7).[8,14–16,22,23] Thirteen studies reported different levels of exposure as related to the outcome (criterion 8) of which in twelve studies the exposure measures were clearly defined, valid, reliable, and implemented consistently across all study participants (criterion 9).[11,12,21,23,13–20] Since diagnosis of the condylar fracture was done logically only once, the indicator "was the exposure(s) assessed more than once over time?" was not applicable for all (criterion 10). In fifteen studies the outcome measures were clearly defined, valid, reliable, and implemented consistently across all study participants (criterion 11).[4,8,19–21,23,24,11–18] In only one study the outcome assessors were blinded to the exposure status of participants (criterion).[16] Two studies reported a clear loss to follow-up after baseline of 20% or less (criterion 13).[15,22] In none of the studies were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s) (criterion 14).

Table 2. MRI-settings

MRI-setting:	Vendor	Field strength	TMJ coil used?	Mouth positions	Planes	Matrix	Field of view	Repetition time	Echo time	Slice thickness	3D	Other settings
DWIVEDI ET AL (2012)[11]	NM	NM	Y	open and closed	S, C	256x256	15x15 cm	800 ms	28 ms	5 mm	Y	Imaging time: 6.8 min
EMSHOFF ET AL (2007)[12]	Siemens	1.5T	Y	closed	PC, PS	252x256	14.5 cm	TSE-PD seq: 2800 ms	15 ms	3 mm	Y	Flip Angle in DESS-3D seq: 25° Inversion time in TIRM seq: 150 ms
								TIRM seq: 4000 ms	30 ms	3 mm		
								DESS-3D seq: 22 ms	7 ms	NM		
GERHARD ET AL (2007)[13]	Siemens	1.5T	Y	closed	PC, PS	252x256	14.5 cm	TSE-PD seq: 2800 ms	15 ms	3 mm	Y	Flip Angle in DESS-3D seq: 25° Inversion time in TIRM seq: 150 ms
								TIRM seq: 4000 ms	30 ms	3 mm		
								DESS-3D seq: 22 ms	7 ms	NM		
KIM ET AL (2016)[14]	Siemens	1.5T	Y	NM	A, S, C	224x256 240x256	150 cm	PWI: 2000 ms	15 ms	3 mm	NM	NM
								T2WI: 4000 ms	90 ms	3 mm		
NABIL (2016)[16]	Siemens	1.5T	Y	open and closed	S	NM	20 cm	660	15 ms	2 mm	NM	NM
POHRANYCHNA ET AL (2017)[8]	NM	NM	Y	NM	A, C, OC, S	NM	NM	NM	NM	1.5-2.5 mm	NM	NM
TAKAHASHI ET AL (2004)[21]	General Electric	1.5T	Y	open and closed	S, C	256x256	12 cm	T1WI: 500 ms	17 ms	3 mm	NM	NM
								T2WI: 3000 ms	92 ms			
								PWI: 2000 ms	23 ms			
TAKAKU ET AL (1996)[4]	Siemens	1.5T	Y	closed	S, C	256x256	NM	FISP-3D: 30 ms	12 ms	2 mm	Y	Acquisition: 5 times Imaging time: 10 min Flip Angle in FISP-3D seq: 40°

Table 2. Continued

MRI-SETTING:	Vendor	Field strength	TMJ coil used?	Mouth positions	Planes	Matrix	Field of view	Repetition time	Echo time	Slice thickness	3D	Other settings
TRIPATHI ET AL (2015)[17]	NM	NM	Y	NM	S	256x256	15x15 cm	800 ms	28 ms	5 mm	NM	Imaging time: 6.8 min
WANG ET AL (2009)[18]	General Electric	1.5T	Y	NM	OS, OC	320x192	10x10 cm	PAW-FSE: 1360-2000 ms	20-26 ms	1.5 mm	NM	
								T2WI (FSE): 3760-4300 ms	82-90 ms	2 mm		
YU ET AL (2013)[19]	General Electric	1.5T	Y	open and closed	OS, OC	256x160	14x14 cm	T1WI (FSE): 440 ms	13.4 ms	2 mm	NM	Flip Angle in GRE seq: 20°
								PDWI (FSE): 2700 ms	13.4 ms	2 mm		
								T2WI (GRE): 340 ms	15 ms	2 mm		

NM= not mentioned; Y= yes; T= Tesla; A= Axial; S= Sagittal; C= coronal; PS= parasagittal; PC= paracoronal; OS= Oblique Sagittal; OC= Oblique Coronal; seq= sequence; mm= millimeter; cm= centimeter; ms=millisecond; min= minutes; TSE-PD= turbo spin echo- proton density; TIRM= turbo inversion recovery magnitude; DESS-3D= double echo in steady state- 3 dimensional; FSE= fast spin echo; PAW= proton attenuation weighted; PWI= proton weighted images; PDWI= diffusion weighted images; FISP-3D= fast imaging with a steady procession sequence- 3 dimensional; GRE= gradient echo; T1WI= T1 weighted images; T2WI= T2 weighted images

Table 3. National Institutes of Health Quality assessment tool for Observational Cohort and Cross-Sectional Studies

CRITERIA	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	Quality Score	Quality (in%)	Overall Study Quality
CAI ET AL (2018)[23]	Y	Y	CD	Y	N	Y	Y	Y	Y	NA	Y	NA	Y	N	9/12	75	F
CHEN ET AL (2010)[20]	Y	Y	N	NM	N	N	N	Y	Y	NA	Y	N	N	N	5/13	38	P
DWIVEDI ET AL (2012)[11]	Y	Y	CD	Y	N	N	N	Y	Y	NA	Y	NA	NA	N	6/11	55	F
EMSHOFF ET AL (2007)[12]	Y	Y	CD	Y	N	N	N	Y	Y	NA	Y	NA	NA	N	6/11	55	F
GERHARD ET AL (2007)[13]	Y	Y	CD	Y	N	N	N	Y	Y	NA	Y	NA	NA	N	6/11	55	F
HE ET AL (2010)[15]	N	Y	Y	NM	N	N	N	Y	Y	NA	Y	N	N	N	5/13	38	P
KIM ET AL (2016)[14]	Y	Y	CD	Y	N	N	N	Y	Y	NA	Y	NA	NA	N	6/11	55	F
NABIL (2016)[16]	Y	Y	CD	Y	N	Y	Y	Y	N	NA	N	NA	Y	N	7/12	58	F
POHRANYYCHNA ET AL (2017)[8]	Y	Y	CD	NM	N	Y	Y	N	N	NA	Y	NA	N	N	5/12	42	F
TAKAHASHI ET AL (2004)[21]	Y	Y	CD	NM	N	N	N	Y	Y	NA	Y	NA	NA	N	5/11	45	F
TAKAKU ET AL (1996)[4]	N	Y	CD	NM	N	N	N	N	N	NA	Y	NA	NA	N	2/11	18	P
TRIPATHI ET AL (2015)[17]	Y	Y	CD	Y	N	Y	Y	Y	Y	NA	Y	N	N	N	8/13	62	F
WANG ET AL (2009)[18]	Y	Y	Y	Y	N	N	N	NA	N	NA	Y	NA	NA	N	5/10	50	F
YING ET AL (2018)[24]	N	Y	CD	Y	N	Y	Y	Y	Y	NA	Y	Y	N	N	8/13	62	F
YU ET AL (2013)[19]	N	Y	Y	Y	N	N	N	Y	Y	NA	Y	NA	NA	N	6/11	55	F
ZHENG ET AL (2016)[22]	Y	Y	Y	Y	N	Y	Y	Y	Y	NA	Y	NA	NA	N	9/11	82	G

1. Was the research question or objective in this paper clearly stated? **2.** Was the study population clearly specified and defined? **3.** Was the participation rate of eligible persons at least 50%? **4.** Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants? **5.** Was a sample size justification, power description, or variance and effect estimates provided? **6.** For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured? **7.** Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed? **8.** For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)? **9.** Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? **10.** Was the exposure(s) assessed more than once over time? **11.** Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? **12.** Were the outcome assessors blinded to the exposure status of participants? **13.** Was loss to follow-up after baseline 20% or less? **14.** Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?

N = no; Y = yes; CD = cannot determine; NA = not applicable; NM = not mentioned

P = poor quality (<40%); F = fair quality (40-80%); G =good quality (>80%)

2

DISCUSSION

Fractures of the mandibular condyle often go together with soft tissue injury of the TMJ. When a better understanding of these changes of the soft tissues in the TMJ is achieved, a shift of opinion in the management of condylar fractures may be considered. An overview of the published studies focusing on soft tissue injuries as a result of mandibular condylar fractures and their influence on oral functioning in adults is given in this review. Also, an overview is provided of the detection of soft tissue injuries.

SOFT TISSUE INJURIES AS A RESULT OF MANDIBULAR CONDYLAR FRACTURES

In the studies included in this review, many different types of soft tissue injury were discussed. An effect of condylar fractures on the adjacent soft tissue was found in this review, with evidence ranging widely from one poor-quality study (18%)[4] and eight fair-quality studies (42–62%, n = 8)[4,8,13–19,24] to one study of good quality (82%)[14].

Intracapsular fractures are more likely to cause disc displacement than subcondylar or condylar neck fractures.[14,16] Additionally, it is true that if the condylar fracture is dislocated, disc displacement is more often expected.[24] Besides mentioning this injury to the disc, no specific relation was reported between the type of fracture and the disc injury. Dislocated condylar fractures are more likely to result in more severe injuries of retrodiscal tissues than non-dislocated fractures.[24] Diagnostic agreement between capsular tear and both dislocated condylar fractures and dislocated condylar head fractures is of fair reliability.[19] Thereby, joint effusion is more likely to be present in head and upper neck fractures and condylar fractures with dislocation.[21] Hemarthrosis is more likely to be present in grade III condylar injury (i.e. condylar head and high and low condylar fractures with dislocation).[11,13]

A limitation is that, as there is logically no imaging done before trauma, we cannot be sure if a pathological finding is new or pre-existing. In one study the authors clarified how they differentiate acute traumatic disc displacement from chronic pre-existing disc displacement.[17] They examined the disc morphology and ancillary changes in the temporomandibular joint as over time a displaced disc is deformed to a biconvex or rounded disc.

INFLUENCE OF SOFT TISSUE INJURIES ON ORAL FUNCTIONING

An effect of soft tissue injuries due to condylar trauma on oral functioning was found in only one study included in this review.[23] The authors could relate clinical outcome directly to the degree of soft tissue injury. This study was of fair quality (62%) and no statistical analysis (and thus a significant correlation) substantiated this relation.[23] It suggests that serious injury to the disc and capsule of the TMJ is a major contributing factor towards the development of complications after closed treatment of condylar fractures, such as decreased mouth opening, restricted range of movement, joint noise and pain. The authors concluded that hemarthrosis alone plays a small role in the development of postoperative complications as long as early mobilisation of the joint is instituted. More severe soft tissue injury affects condylar translation and rotation due to greater shrinkage of the capsule. Unfortunately, in this study, no connection was made between the degree of soft tissue injury and classification of condylar fracture; therefore, no direct link could be made between the degree of condylar trauma and the clinical outcome.

A limitation is that no uniform classification was used when reporting condylar fractures, which makes it difficult to compare these studies with each other. Moreover, some studies did not use any classification system, so it remains unclear what kind of condylar fracture was studied or whether the claimed classification was used wrongly. Only one study used a classification for the grade of soft tissue injury.[23]

Although we can conclude that hemarthrosis and disc displacement are most commonly present in condylar fractures, unfortunately not all studies reported them.[12,14,18,20,21] In the majority of the studies, the definition of the type of soft tissue injury and how its diagnosis was made on MRI was not further specified.

The information on oral functioning is reported very heterogeneously. To get insight in oral functioning valid and reliable measurements of both objective measurements (*fi* maximum mouth opening, chewing ability) and patient reported outcomes should be used, however, none of the included studies reported systematically such outcomes. None of the studies mentioned a relation between subjective outcomes and soft tissue injury. This hampers to conclude what subjective consequences could be expected after condylar trauma with soft tissue damage. Furthermore, the clinical long-term follow-up on oral functioning was insufficient, only 3 studies reported a 5 year follow-up in only a small part of the initial population.[12,21,22] In the current studies it remains unclear if these objective outcomes are related to bone or articular soft tissue damage as these 3 studies all treated the fractures in a different way. None of the studies used control groups and it was impossible to compare these studies to each other.

MRI

MRI is effective in demonstrating TMJ soft tissue changes. However, the differences in MRI findings might be related to the diagnostic criteria references for soft tissue injuries on MRI. This could explain the differences in surgical findings of soft tissue injury. For fractures where the condyle is intact, it is acceptable to access the position of the disc based on the condyle, whereas it is harder when the condyle is displaced.[14] If the MRI planes cannot show the disc and stump simultaneously, retrodiscal tissue tear and lateral capsular tear will not be diagnosed and will be missed.[12] The differences in MRI finding may also be related to the different MRI settings that are used as seen in the overview, depicted in Table 2. Though it is accepted that for different vendors different naming in settings is used, we still see a variety of used settings, planes and positions. It would be preferable if research specific to these settings could clarify the best settings.

Several studies used MRI to investigate soft tissue injury in condylar trauma patients.[4,12,14,22]

Still, most of these studies investigated this injury after treatment of the fracture. Therefore, one cannot determine if the MRI findings are due to trauma or to treatment of the condylar fracture. One author reported that the posttreatment MRI scans showed a better anatomical reduction of the TMJ after surgical therapy compared to conservative treated patients. Although their study population was small, the functional recovery seems not to be dependent on complete anatomical restoration of the TMJ structures as can be achieved by functional open treatment.[3] An other study reported that open reduction of condylar fractures does not always lead to recapturing of the disc, seen on posttreatment MRI. They suggest that the disc has to be inspected during surgery. Simultaneous discal repositioning should be considered once the displaced disc is detected.[25]

TMJ effusion on MRI is also reported in TMJ sides with no signs of condylar injury. More data are necessary if TMJ effusion is to become generally accepted as a sign of hemarthrosis in patients with condylar injury. Further, one study found that trauma causes more delayed TMJ derangement on the non-fractured side than on the fractured side of the mandible in the follow-up MRI that was made.[22] A possible explanation for this is that direct trauma can cause condylar fractures that involve the structures of the TMJ, while the contralateral TMJ may be affected by indirect trauma. The TMJ receives less direct trauma when the mandible fractures than when the mandible remains intact, and presumably transmits the full force of the blow to the joint of the non-fractured side. Damage to the fractured condyle can also lead to derangement of the contralateral joint secondary to overloading, hypermobility, and disc displacement of the uninjured joint.[22] The question remains if it is conceivable that there would be an indication for performing a MRI in every case of condylar (head) fractures in the future. However this should be done pre- and posttreatment in research setting to find out what is a good indication for performing functional open treatment.

FUNCTIONAL OPEN TREATMENT

The key factor in failure of recapturing a displaced disc after trauma is the state of either the joint capsule or the disc. Both can be disrupted by trauma or can be damaged by surgical procedures. Overall, authors claim that anatomically correct reduction is of advantage for disc restoration. Repair and reconstruction of the joint's soft tissues is called functional open treatment and demonstrated good clinical outcomes on oral functioning in one study.[12] It means that reduction and fixation of the condylar segment and disc was done as well as repair of retrodiscal tissue, the lateral capsule and re-attachment of the posterior ligament to the disc. These are crucial steps to reduce posttreatment complications. Improvement of the soft tissues was confirmed by the follow-up MRI.[12] However, the disc was still anteriorly or posteriorly displaced in 5% of the TMJs after this intervention and complications due to the extra-oral approach such as weakness of the facial nerve are still existing. In literature successful cases without complications were reported of surgical reduction by extra-oral approach of the articular soft tissues in patients with chronic non-traumatic TMJ dislocations.[26,27]

Even if a correlation between soft and bony injury was reported, since there is still an ongoing discussion about the most favourable treatment for condylar fractures, it is hard to conclude if any outcome or complication is due to the treatment modality or to soft tissue injury. If complications such as ankyloses and limited range of motion of the mandibular condyle are the direct result of soft tissue injury, repair of the soft tissues might be a good indication for treatment.[7]

STRENGTHS AND LIMITATIONS OF THIS REVIEW

This review is strengthened by its methodology, conduction in accordance with the PRISMA guidelines and the use of quality assessment.

A limitation of this review is the overall quality of the studies included; most were of poor or fair methodologically quality. Only one study was of good quality. Overall statistical analysis is insufficiently performed, also, some studies only included a few study patients; therefore, the power and thereby conclusions overall could be questioned.

Another limitation of this review is the heterogeneity in reporting outcomes in the included studies. This limits the comparability of results and conclusions. Because of the general lack of statistical analysis and this wide variety on reported outcomes, the information provided from this review was insufficient to aggregate information to perform a meta-analysis.

As we limited our literature search for this review by use of database and publication language, selection bias might have occurred.

Since we did not make attempts to find unpublished studies (which are more likely to report negative findings), publication bias might have occurred.

FUTURE RESEARCH

In future research a prospective study design is needed.

Pre- and posttreatment registration of clinical and functional status will be required to determine the possibility of a prediction model for later functional deficits. Thereby, if it is clear which diagnosis of condylar fracture on a CT scan has a high a priori chance of having a certain soft tissue injury with impairing functional outcome, surgical reduction of soft tissue injury might be justified. It would also be preferable if research specific to MRI settings could clarify the best settings as we still see a variety of used settings.

Finally, we recommend the use of a classification for condylar fractures where there is at least a differentiation between condylar head, neck and base fractures and dislocated and non-dislocated fractures combined with a classification of soft tissue injury.

CONCLUSION

The results of this review give an overview of the reported soft tissue injuries caused by condylar fractures. Yet its influence on clinical outcome has been insufficiently investigated.

Before considering reduction of soft tissue injuries next to reduction of the fracture, more research is definitely needed. Future research should include a good clinical controlled study, with uniform condylar fracture classification (fi AOCMF), with a control group for treatment, with decent follow-up and report of objective and subjective outcomes and accurately description and classification of the soft tissue injuries. MRI is an efficient way to diagnose soft tissue injury of the TMJ in an acute setting.

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CHAPTER 3

Reproducibility and construct validity of the Utrecht Mixing Ability Test to obtain masticatory performance outcome in patients with condylar mandibular fractures

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ABSTRACT

OBJECTIVE

This study assessed the test-retest reproducibility of the Utrecht mixing ability test (MAT) and the construct validity of the MAT in relation to the Mandibular Function Impairment Questionnaire (MFIQ) in patients with mandibular condylar fractures.

MATERIAL AND METHODS

Twenty-six patients treated for a mandibular condylar fracture participated in this clinimetric study; all patients performed the MAT twice. Simultaneously the MFIQ was conducted. Test-retest reliability and construct validity were assessed using the intraclass correlation coefficient (ICC) and Spearman correlation, respectively.

RESULTS

The ICC of the MAT was 0.906 (95% CI: 0.801-0.957), which indicates an excellent reliability. A weak correlation of 0.386 (P = 0.052) between the first MAT and the overall outcome of the MFIQ was found. A significant moderate correlation of 0.401 (P = 0.042) was found between the retest of the MAT and the overall outcome of the MFIQ. One question on the MFIQ (about yawning) showed a moderate positive correlation of 0.569 (P = 0.002) and 0.416 (P = 0.034) for the MAT test and retest, respectively.

CONCLUSION

The MAT is an easy test to use in follow-up of patients. The test-retest reliability of this test is excellent in condylar trauma patients. As the validity of the MAT and the MFIQ could not be confirmed, the MFIQ may be an addition to patients' feedback about the rehabilitation process of their mandibular functioning.

INTRODUCTION

After a maxillofacial injury, patients frequently have problems with eating food (67%) and have to change their diet (55%) due to decreased masticatory functioning.[1] Mastication is a complex cooperation of different mechanical and chemical mechanisms. Mobility of the temporomandibular joint, facial musculature, bite and tongue force, sensory relations, occlusal units and saliva production all play a role in mastication.[2] The mandible is fractured in 36% to 54% of all patients with maxillofacial trauma.[3,4] In 36% to 44% of mandibular fractures, the mandibular condyle is involved.[3,4] Such a fracture can influence masticatory functioning due to anatomical change to the mandible or injury to the nerve or musculature.[5,6] However, the therapy received may influence mastication by complications due to open reduction and internal fixation, such as fistulas of the parotid gland and/or facial nerve damage or hardware problems. Similarly, ankyloses of the temporomandibular joint or limited mouth opening can occur due to long term immobilisation in the case of conservative treatment.[7] Thereby, malocclusion, limited range of motion of the mouth or chronic pain can disturb the mastication process.[8]

Masticatory performance is the objective efficiency of this mastication process, which can be measured by different methods (*fi* comminution or mixing ability methods).[9] The Utrecht Mixing Ability Test (MAT) with two-coloured wax was described as a reliable test for patients with cerebral palsy syndrome.[10] For patients with mandibular trauma, such as condylar fracture, the reproducibility and validity of this test has not yet been investigated.[2,9]

Masticatory ability is the subjective testing of the mastication process, which reflects the expectations of the patients and their quality of life by taking the psychological and emotional adjustment of the patient in their daily life into account. This can be an advantage over measurement of objective outcomes alone. Subjective efficiency of the mastication process is tested in various departments with several questionnaires, such as the Oral Health Impact Profile-14 questionnaire (OHIP-14)[11] and the Mandibular Function Impairment Questionnaire (MFIQ).[12,13] In recent studies, the MFIQ has been used to measure subjective masticatory ability in condylar trauma patients.[5,14]

It is important to the rehabilitation of the patient to get insight into mastication after mandibular injury by performing reliable and valid tests.[15] Therefore, the aim of this study is to determine, on the one hand, the test-retest reproducibility (reliability, measurement error, and agreement) of the MAT, and, on the other hand, the construct validity of the MAT in relation to the MFIQ in patients with mandibular condylar fractures. We hypothesise that the reproducibility of the MAT will be sufficient (ICC ≥0.7) and that the construct validity would be at least moderately correlated (≥ 0.60).

MATERIAL AND METHODS

SUBJECTS

Patients treated for a mandibular condylar fracture at the Department of Oral and Maxillofacial Surgery of the University Medical Centre Utrecht (UMCU), Amsterdam UMC, Vrije Universiteit Amsterdam and Onze Lieve Vrouwe Gasthuis (OLVG) Amsterdam between June 2017 and January 2019 were recruited for this study. Inclusion criteria were: 1) 18 years or older; 2) condylar base or neck fracture, with or without additional fracture locations of the mandible; 3) presence of disocclusion; and 4) dislocation of the fracture, caused by trauma. Exclusion criteria were: 1) additional mid-face fracture; 2) legal incapability; 3) inoperable conditions because of comorbidity; and 4) inability to understand the Dutch language. Sex and age were retrieved from clinical records.
All patients had to be stable on the interim period of measurements, and the test conditions and test instructions were kept similar for all subjects.

The study protocol was approved by the Ethics Committee of UMC Utrecht (NL59658.041.16). All subjects received a written explanation of the study, and informed consent was obtained from each subject before the start of the tests.

MASTICATORY PERFORMANCE

A comprehensive description of the Mixing Ability Test (MAT) as developed by the University Medical Centre Utrecht was published previously.[2,16,17] The MAT quantifies how well a patient is able to mix two layers of red and blue colour of a wax tablet by chewing a certain number of strokes, which are digitally analysed afterwards. The outcome variable is called the Mixing Ability Index (MAI) and ranges between 5 and 30, where a score of 5 means a fully mixed tablet and 30 an unused wax tablet. A lower MAI implies a better mixed tablet, hence a better masticatory performance.

The tablet consists of two 3-mm thick layers of coloured Plasticine modelling wax (non-toxic DIN EN-71, art. nos. crimson 52801 and blue 52809, Stockmar, Kalten Kirchen, Germany) with a diameter of 20mm. It is used at room temperature (20°C) and forms a compact bolus during chewing. Each subject was instructed to chew 15 times on the tablet.

A repetition of 15 times was chosen for this trauma group because the authors assume that this group has no problems with tongue mobility or dentition, in contrast to oncological patients, for whom this test was originally designed.[2] A ceiling in outcome will be received when chewing more strokes.[2] This procedure was repeated with a second wax tablet, with an appropriate time interval of 15 minutes minimum. Thereafter the chewed tablets were removed, flattened between foil to a thickness of 2.0mm and photographed on both sides using a high-quality scanner (Epson V750, Long Beach, CA, USA). The retrieved images were analysed and processed using Adobe Photoshop, CS3 extended (Adobe, San Jose, CA, USA), a commercially available program for image analysis. The MAI was obtained by measuring the intensity distributions of the red and blue colouring on the combined image on both sides of the flattened wax.

MANDIBULAR FUNCTION IMPAIRMENT QUESTIONNAIRE

The Mandibular Function Impairment Questionnaire (MFIQ) is designed to assess the masticatory ability, or, in other words, the patient's perception of mandibular function impairment. The MFIQ has been proven reliable in patients with painfully restricted temporomandibular joints by a moderate to good test-retest reliability (Spearman correlation of 0.69 to 0.96).[13]

The minimal amount of change to be detected is 14 units on a scale of 0 to 68,[13] where 0 indicates no mandibular function impairment and 68 a poor functional outcome. The MFIQ consists of 17 items. Each item is presented with a 5-point Likert scale, on which the patient can indicate how much difficulty was experienced while performing a particular mandibular movement or task (e.g. speech, daily activities, drinking, laughing, yawning, eating different types of food). The scores are: 0 = no difficulty, 1 = a little difficulty, 2 = quite a bit of difficulty, 3 = much difficulty, 4 = very difficult or impossible without help.

STATISTICAL ANALYSIS

Reproducibility of the test-retest

The test-retest reproducibility is divided into reliability and agreement parameters. Reliability (the proportion of the total variance in the measurements that is due to 'true' differences among patients) of the MAT was calculated with an intraclass correlation coefficient (ICC) with corresponding 95% confident intervals, based on a mean-rating (k = 2), absolute agreement, two-way random-effects model, single measures (ICC 2.1). This is calculated as: $(MS_R - MS_E) / (MS_R + (k - 1)MS_E + (k/n)(MS_C - MS_E))$, with MS_R = mean square for rows; MS_E = mean square for error; MS_C = mean square for columns; k = number of raters/measurements. Cut-off points for the ICC were chosen as < 0.5 = poor, 0.5 to 0.75 = moderate, 0.75 to 0.90 = good, > 0.90 = excellent reliability.[18] A threshold of 0.75 for the ICC was taken as an acceptable level of test-retest reliability.[18]

The measurement error consists of the systematic and random error of a patient's score, which is not attributed to true changes in the construct of disability. Agreement was assessed by calculating the Standard Error of Measurements (SEM) of the MAT. The SEM is a measure of how much measured test scores are spread around a 'true' score. This is calculated from the ICC as $SEM_{agreement} = SD * \sqrt{(1 - ICC)}$, with SD meaning 'standard deviation of the differences of the MAT'. The $SEM_{agreement}$ was additionally used to calculate the smallest detectable change values at the individual level (SDC_{ind}), using the equation $1.96 \times \sqrt{2} \times$

$SEM_{agreement}$, to yield 95% confidence that the observed change was real and not attributable to the measurement error. Limits of agreement (LoA) estimate the interval at which a proportion of the differences between measurements is positioned. These were calculated as *upper LoA = mean + 1.96 * SD* and *lower LoA = mean - 1.96 * SD*. The Bland-Altman plot was constructed to provide a visual representation of the presence of systematic errors. The Bland-Altman plot was based around three variables: the mean systematic difference between test and retest scores and the upper and lower limits of agreement, which span 95% of observations, assuming that the values for the difference between test and retest scores are distributed normally. These variables were integrated into a scatter plot where the difference between test and retest values was put on the Y-axis, and the average of the test and retest values was put on the X-axis.[18,19]

Construct validity

Construct validity was determined by hypothesis testing using Spearman's correlation. It was hypothesised that mastication assessed by the MAT and MFIQ (per item and summary score) would be at least moderately correlated (≥ 0.60). Cut-off points for the validity were chosen as: 0.00 to 0.19 = very weak, 0.20 to 0.39 = weak, 0.40 to 0.59 = moderate, 0.60 to 0.79 = strong, and 0.80 to 1.00 = very strong.[20]

A *P*-value of less than 0.05 was considered statistically significant. A Spearman's correlation was run to determine the relationship between the MAT and the outcomes of the MFIQ. All analyses were performed using SPSS version 25 (IBM Corporation, Armonk, NY, USA).

RESULTS

Twenty-six patients were included in this study and are depicted in Table 1. Eighteen patients (69%) were male, and the mean age was 41 years with a range of 18 to 69. Twenty-two subjects underwent the mixing ability test and retest six weeks after treatment for condylar fracture, and the remaining four subjects underwent the test and retest after six months.

REPRODUCIBILITY OF THE TEST-RETEST

The MAI of the test had a mean of 19.44 (SD: 3.23). The MAI of the retest had a mean of 19.37 (SD: 3.02). In this condylar trauma patient group, the ICC of the MAT was 0.906 (95% CI: 0.801–0.957), which means an excellent reliability. The results of the SD, SEM, SDC, and a Bland-Altman plot with corresponding LoA can be found in Table 2 and Figure 1. Systemic bias was visually assessed by Bland-Altman. It showed a consistent variability across the graph.

Table 1. Participants' characteristics and outcomes

	Total patient group n=26
Sex	
- Male, n (%)	18 (69)
- Female, n (%)	8 (31)
Age (years), mean (Range)	41 (18–69)
Fracture type	
- Condylar neck fracture, n (%)	7 (27)
- Condylar base fracture, n (%)	19 (73)
Hospital	
- UMC Utrecht, n (%)	15 (58)
- Amsterdam UMC, VUmc, n (%)	1 (4)
- OLVG, n (%)	10 (38)
Treatment of the fracture	
- Operative, n (%)	16 (62)
- Conservative (MMF), n (%)	10 (38)
Timing of Test-retest	
- 6 weeks post treatment, n (%)	22 (85)
- 6 months post treatment, n (%)	4 (15)

Amsterdam UMC, VUmc: Amsterdam University Medical Centra, Vrije Universiteit Medical centre; MMF: Maxillomandibular Fixation; OLVG: Onze Lieve Vrouwe Gasthuis, Amsterdam; UMC Utrecht: University Medical Centre Utrecht

Table 2. Test-retest reproducibility

Results	
MAI	
- Test, mean (SD)	19.44 (3.23)
- Retest, mean (SD)	19.37 (3.02)
Difference Test-Retest, mean (SD)	0.07 (1.38)
ICC, (95% CI)	0.906 (0.801–0.957)
$SEM_{agreement}$	0.43
SDC	1.19
95% LoA	-2.632 to 2.778

CI: confidence interval; ICC: intraclass correlation coefficient; LoA: limits of agreement; MAI: mixing ability index; SD: standard deviation; SDC: smallest detectable change; $SEM_{agreement}$: standard error of measurement.

CONSTRUCT VALIDITY

At the first measurement moment, there was a weak positive correlation of 0.386 between the MAT and MFIQ, which was not significant (P = 0.052). A significant moderate correlation of 0.401 (P = 0.042) was found between the overall outcome of the MFIQ and the retest of the MAT. One question on the MFIQ (about yawning) showed a moderate positive correlation of 0.569 (P = 0.002) and 0.416 (P = 0.034) for the MAT test and retest, respectively (see also Table 3).

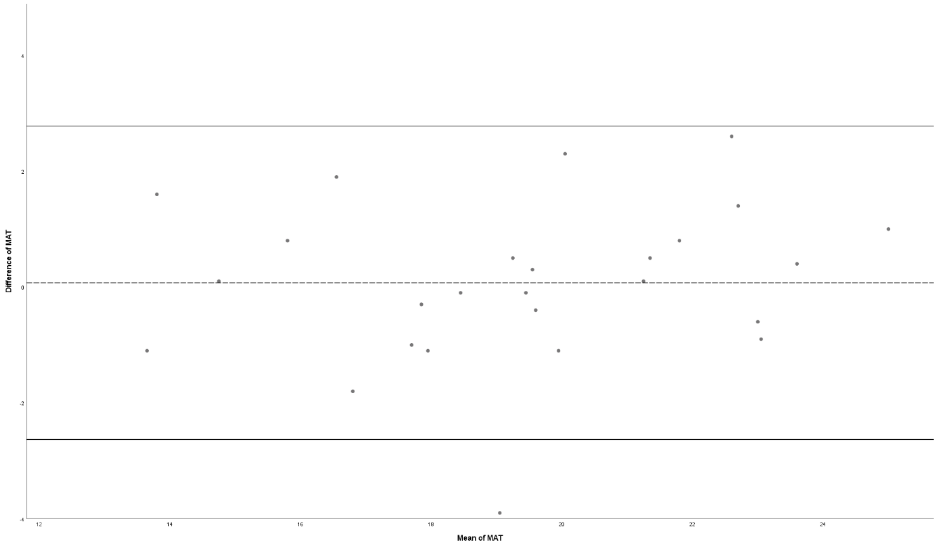

Figure 1. Bland-Altman plot for the test-retest reproducibility of the Mixing Ability Test.
The dashed line represents the mean difference, and the solid lines represent the 95% limits of agreement. MAT: Mixing Ability Test

Table 3 . Correlation MAT and MFIQ

MFIQ Question	Question topic	r-1 Test	*P*-value	r-2 Retest	*P*-value
1	Social activities	-0.022	0.916	0.103	0.617
2	Speaking	0.023	0.913	0.130	0.526
3	Biting	0.354	0.076	0.425	0.030
4	Hard food	0.338	0.092	0.299	0.138
5	Soft food	0.119	0.562	0.234	0.250
6	Daily activities	0.301	0.135	0.432	0.027*
7	Drinking	0.003	0.988	0.226	0.267
8	Laughing	0.169	0.409	0.320	0.111
9	Chewy food	0.314	0.119	0.278	0.170
10	Yawning	0.569	0.002**	0.416	0.034*
11	Kissing	0.244	0.230	0.172	0.401
12	Hard cookies	0.237	0.244	0.228	0.263
13	Meat	0.299	0.138	0.234	0.250
14	Raw carrot	0.381	0.055	0.314	0.118
15	Baguette	0.286	0.156	0.252	0.214
16	Nuts	0.267	0.187	0.254	0.211
17	Whole apple	0.191	0.375	0.125	0.542
Total MFIQ outcome		0.386	0.052	0.401	0.042*

*Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed).
MAT: Mixing Ability Test; MFIQ: Mandibular Function Impairment Questionnaire.

DISCUSSION

This study focused on the test-retest reproducibility (reliability, measurement error and agreement) and construct validity of the MAT in patients with mandibular condylar fractures. We found an excellent reliability of the Utrecht Mixing Ability Test in patients with a condylar fracture of the mandible. The SEM is 0.43, which is very small considering the range of outcome possibilities of the MAT. The SDC for the MAT in this group of condylar trauma patients is 1.19. This means that the MAI of an individual would have to change by at least 1.19 points before the observed change can be considered a true change in the masticatory performance of a subject and not potentially the result of measurement error. The limits of agreement are clinically interpreted as narrow. The Bland-Altman analysis visually showed that 95% of all data lies between the upper and lower LoA, with a consistent variability. These findings are acceptable.

As hypothesised, the ICC of 0.903 indicated an excellent test-retest reliability in patients with condylar fractures. In comparison, the ICC of the same MAT in children with cerebral palsy and typical development is 0.69.[10]

The hypothesis that the outcome of the MAT and MFIQ are at least moderately correlated, could not be confirmed since the weak positive correlation (r = 0.39) of the first test was not convincingly significant (*P* = 0.052). There was a moderate correlation of the retest with the MFIQ (r = 0.40) that was significant (*P* = 0.042). This weak-moderate correlation could possibly be explained by the fact that the MFIQ reflects the subjective masticatory ability and the MAT the objective masticatory performance. The MFIQ also comprehends questions about other aspects of the mandible whereas the MAT reflects the outcome of the complex masticatory process of oral muscle movements and coordination.

Nonetheless, in a normal follow-up situation the patient will only undergo the MAT once, the test in this study, with a mean of 19.44 (Range 13.1–25.5, SD 3.23). The retest had a mean of 19.37 (Range 13.0–24.5, SD 3.02) which was a bit better and more consistent. This could be an explanation for the small difference in significance of the correlation between the MFIQ with the test and the MFIQ with the retest. In a cross-sectional study they also found a significant but weak positive correlation between MAT and MFIQ in patients with condylar fractures (r = 0.25 with *P* = 0.033).[5]

Mandibular condylar fractures often go along with disc displacement of the temporomandibular joint.[15] Disruption in the anatomy of this joint interferes with its physiology and therefore affects the maximum mouth opening. This could be an explanation for the positive significant correlation between the question about yawning and the MAT, since yawning requires a large mouth opening movement. This is consistent with findings in another study with patients treated for oral cancer, where the authors concluded that MMO significantly contributed to the MAI.[17]

The authors expected the retest to generate a better outcome than the first test for two reasons. The first reason was that when a patient had just finished treatment of the condylar fracture, and the first thing the patient was allowed to chew on was the MAT tablet, the patient's chewing performance might be limited by fear (of *f.i.* pain), also known as kinesiophobia. Our second idea involved the presence of a learning curve in the method of chewing the wax tablet. As seen in Table 1, this difference in outcome is limited to a minimum. This minimal difference could be explained by possible fatigue of the masticatory muscles when taking the retest, despite the set time between taking the retest.

STRENGTHS AND LIMITATIONS

All results were written down according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) to ensure methodological quality.[21] The data of this study were collected with a prospective design. All data were collected by the same author (FMW). The MATs were evaluated by the same observer (CMS).

In general, this study was conducted with a fair sample size, with two different follow-up periods. The participants came from three different hospitals, resulting in a heterogeneous sample. One limitation of this study is that measurements on inter-rater reliability are missing. An additional measurement was judged to be too time-consuming for participants. In a usual care or research setting, most evaluative measurements would be performed by the same person.
As the subjects in this study were patients with condylar trauma, we have to be careful to generalise these results to general oral and maxillofacial trauma patients, and, in particular, all mandibular traumas.

FUTURE RESEARCH

As the treatment modality of patients with condylar trauma is still subject to debate, investigations like the MAT and MFIQ could help determine whether open surgery is preferable to conservative treatment, or vice versa. Based on the results of this study, we expect the outcome of the MAT to be of excellent reliability, and therefore reliable conclusions can be made.

CONCLUSION

The test-retest reliability of the MAT is excellent in condylar trauma patients and may be used in follow-up in prospective studies. As the validity of the MAT and the MFIQ is not convincing, the MFIQ could be an addition to patient feedback about the rehabilitation process of their mandibular functioning.

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CHAPTER 4

Long-term masticatory performance and ability following closed treatment for unilateral mandibular condylar neck or base fractures: a cross-sectional study

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ABSTRACT

PURPOSE

The aim of this study was to find explanatory variables for objective and patient-reported long-term masticatory functioning in patients treated with maxillomandibular fixation for unilateral condylar neck or base fractures. These outcomes were compared to healthy control subjects.

METHODS

Patients treated between 1996 and 2013 were enrolled in the study. Objective measurements included the mixing ability test (MAT) for masticatory performance, and range of motion of the mandible. Patient-reported measurements included the mandibular function impairment questionnaire (MFIQ) for masticatory ability, and the visual analogue scale for pain. Healthy subjects were recruited between October 2018 and January 2019, and performed the MAT and MFIQ.

RESULTS

Twenty-one patients and 30 healthy subjects were included. The average follow-up period was 11.67 years. In adjusted regression analysis, the amount of occlusal units (OU) was associated with the MAT (P = 0.020; R^2=0.253) and MFIQ (P = 0.001, R^2=0.454). The MAT outcome was similar in both groups when correcting for OU (P = 0.001; R^2=0.201). The MFIQ was inferior in the patient group (P = 0.001).

CONCLUSION

Long-term masticatory performance was similar in patients with a history of condylar neck or base fracture and healthy subjects, however, masticatory ability was inferior in patients compared to healthy subjects.

INTRODUCTION

The condyle is one of the most common sites of mandibular fracture, accounting for between 16% and 43% of fractures.[1] Traditionally, the management of mandibular condylar fractures involves closed treatment, where occlusion is corrected by maxillomandibular fixation (MMF) with either wires or elastics. Although this procedure is often preferred over open reduction with internal fixation (ORIF), the management of condylar fractures remains a subject of ongoing debate.[2,3] The primary goal in condylar fracture treatment is the restoration of occlusion. The secondary goals are to optimise patient outcome, oral functioning and masticatory problems, in particular, which are frequently observed following maxillofacial injury.[4,5] Rehabilitation of masticatory deficits after condylar trauma can be measured through masticatory performance and masticatory ability.[6–8] One of the main factors in determining masticatory performance are the number of occluding units (OU). This in combination with bite force could explain 70% of the variance in masticatory performance.[9] Masticatory performance can be objectively measured with the mixing ability test (MAT), which assesses the comminution of a bolus over a standard number of chewing cycles.[6–8] Masticatory ability can also be subjectively measured through patients' own perception of mastication, assessed using questionnaires such as the mandibular function impairment questionnaire (MFIQ).[6–8]

To the best of our knowledge, no studies in the literature have focussed on masticatory performance, assessed by MAT, and masticatory ability, evaluated by MFIQ, in patients following condylar fracture with a follow-up of at least 5 years. These long-term results are clinically valuable, as they can guide treatment decision-making and determine appropriate follow-up periods in this population.[4,10] The first aim was to find explanatory demographic and clinical variables for masticatory performance and ability in patients who received closed treatment for unilateral condylar neck or base fractures at least 5 years ago. The second aim was to compare masticatory performance and masticatory ability between patients with a history of condylar fractures and healthy subjects.

MATERIALS AND METHODS

PATIENTS AND HEALTHY SUBJECTS

Patients with unilateral fractures of the condylar neck or base who received closed treatment with MMF at the Department of Oral and Maxillofacial Surgery of the University Medical Centre Utrecht (UMCU) between January 1996 and December 2013 were enrolled in the study. The condylar fractures were classified in neck or base fractures according to the AOCMF classification system published in 2014.[11] The exclusion criteria were as follows: 1) younger than 18 years of age at the time of trauma, 2) unable to understand and/or read

Dutch, 3) presence of a bilateral condylar fracture or additional fracture of the midface, 4) reported intellectual disability or a history of psychiatric disorder(s), and 5) presence of condylar head fractures according to the AOCMF classification system for condylar process fractures.[11] This study followed the Declaration of Helsinki on medical protocol and ethics, and the Ethics Committee of the UMCU approved the study protocol (NL600.70.041.17). All patients who met the inclusion criteria were invited by letter to participate in a one-time visit to the outpatient clinic. If patients did not respond within 3 months, a follow-up letter was sent. All participants signed an informed consent form.

Data collection and reporting were based on the STROBE Statement checklist for cross-sectional studies.[12] The following demographic data were collected: gender, current age, age at the time of trauma, cause of trauma, diagnosis, other mandibular fractures, type of MMF received (guiding elastics or wires), total duration of treatment, and complications classified according to the Clavien-Dindo classification (CDC).[13] The following data were collected: active range of motion (AROM) of the mandible, including active maximum mouth opening (MMO), laterotrusion and protrusion; symptoms (clicking, pain, crepitation; yes or no) of the temporomandibular joint (TMJ); occlusion (stable occlusion, patient-reported malocclusion, objectively measured malocclusion); and OU. The number of OU were assessed as the functional units of the patients natural dentition in the premolar and molar region (range 0-12), where an occluding pair of premolars counts for one, and an occluding pair of molars counts for two. Additionally, pain at rest was assessed through a visual analogue scale (VAS). The mixing ability test (MAT) was performed to measure masticatory performance. Masticatory ability was evaluated through the mandibular function impairment questionnaire (MFIQ).

Healthy subjects were recruited between October 2018 and January 2019. The exclusion criteria were as follows: 1) younger than 18 years of age, 2) unable to apprehend and/or read Dutch, 3) functional disorders of the head and neck region, 4) reported intellectual disabilities or a history of psychiatric disorder(s), and 5) history of facial trauma. The Ethics Committee of the UMCU approved the study protocol (18-701/C). All healthy subjects were randomly asked to participate when they visited our outpatient clinic as a companion of a patient. All healthy subjects signed an informed consent form. In addition to performing the MAT and completing the MFIQ, participants' gender, age and number of OU were also noted.

MASTICATORY PERFORMANCE

A comprehensive description of the MAT has been published previously.[7,14,15] The MAT enables the quantification of masticatory performance by assessing the patient's ability to mix two wax layers of different colours (red and blue). The outcome variable of the MAT is the mixing ability index (MAI), where a MAI of 5 indicates mostly sufficient masticatory performance and a MAI of 30 indicates mostly insufficient masticatory performance. The test-retest reliability of the MAT is excellent (ICC = 0.906, 95% CI [0.801–0.957]) in condylar trauma patients.[16] The tablet consists of two 3-mm thick layers of coloured Plasticine modelling wax (non-toxic DIN EN-71, art. nos. crimson 52801 and blue 52809; Stockmar, Kalten Kirchen, Germany) with a diameter of 20 mm. It is used at room temperature (20°C) and forms a compact bolus during chewing. Subjects were instructed to chew on the tablet 15 times as if it were chewing gum. The chewed tablet was subsequently flattened to a thickness of 2.0 mm and photographed on both sides using a high-quality scanner (V750; Epson, Long Beach, CA, USA). The digitalised images were analysed and processed using a commercially available program for image analysis (Adobe Photoshop, CS3 extended; Adobe, San Jose, CA, USA). The MAI was obtained by measuring the intensity distribution of the red and blue colours on the combined image on both sides of the flattened wax.

MASTICATORY ABILITY

The MFIQ was designed to assess masticatory ability. The MFIQ has proven to be reliable in patients with painfully restricted TMJs (Spearman correlation of 0.69 to 0.96).[17] The questionnaire consists of 17 items, comprising questions on speech, laughing, yawning and eating. Each item was answered using a 5-point Likert scale: 0, no difficulty; 1, a little difficulty; 2, quite a bit of difficulty; 3, a lot of difficulty; 4, very difficult or impossible without help. The total score ranges from 0 to 68, where 0 indicates no impairment of mandibular function and 68 indicates severely impaired mandibular function. The total outcome of the MFIQ was analysed as a continuous variable.[17]

PAIN

To quantify pain, the validated VAS was used.[18,19] Patients indicated their pain experience at rest at the time of examination by choosing a position on the 100-mm horizontal line, where 0 mm indicates no pain and 100 mm is the worst pain.

ORAL ACTIVE RANGE OF MOTION

Maximum mouth opening (MMO) was measured twice intraorally as the distance between both maxillary and mandibular central incisors in the closed and maximal open positions. The greatest measured distance of overbite was added to the highest value of the two maximum mouth opening positions. Laterotrusion was measured as the distance between the midline of the central incisors of the maxilla and mandible. The value of the starting position in occlusion was added to or subtracted from the highest value of two measurements in maximum laterotrusion to each side. Protrusion was measured as the difference in distance between the labial side of the central incisors of the maxilla and mandible in occlusion and the highest value of two measurements in maximum forward protrusion.

STATISTICAL ANALYSIS

Categorical data is presented as frequency and percentages, whereas continuous data is expressed as the mean ± standard deviation (SD) and ordinal data as median ±interquartile range (IQR). For continuous data, normality was assessed using the Shapiro-Wilk test, as this is considered the most powerful test for data with non-normal distributions.[20] A linear regression analysis with MAI as well as MFIQ as the dependent outcome was constructed to assess the effect of characteristics in patients. We considered several potential associated factors: including gender, age, follow-up time, CDC, MMO, laterotrusion to ipsilateral side, laterotrusion to contralateral side, protrusion, TMJ symptoms, VAS_{pain} and number of OU. Thereafter a linear regression analysis with MAI as well as MFIQ as the dependent outcome was constructed to assess the effect of characteristics in both patients and healthy subjects. We considered several potential associated factors: including gender, age, number of OU, and patient/healthy group (meaning if the subject was a patient or healthy subject). We performed unadjusted (i.e. for each variable separately) and adjusted linear regression analyses. Results were reported as regression coefficients with 95% CI and *P*-value. Data were analysed using SPSS version 25 (IBM Corporation, Armonk, NY, USA). *P*-values of 0.05 or less were considered statistically significant.

RESULTS

PATIENTS AND HEALTHY SUBJECTS

Ninety-five patients were identified based on the inclusion and exclusion criteria specified in the study protocol. Of these patients, only 82 were approached, as address information was unavailable for 13 cases. Forty-five responded, of which 23 expressed no interest in participating in this study. Upon further inquiry, one patient did not meet the inclusion criteria. In total, 21 patients with unilateral condylar neck (N=9) or base (N=12) fractures provided informed consent and were included in the study. The mean follow-up time was 11.67 (SD 4.89; range 5.11–22.30) years. Patient demographics and study outcomes are presented in Table 1. Several patients presented with secondary mandibular fractures. Of these patients, 12 received ORIF for fractures of the corpus and three for fractures of the mandibular angle. The mean duration of treatment was 7 weeks until discharge of the out-patient clinic. Maximum two weeks of the treatment were with wires or tight elastics, followed by guiding elastics until the patient reached maximal occlusion. In total, five patients presented complications according to the Clavien-Dindo classification: three patients required physiotherapy because of a limited range of motion after their initial treatment (grade I), and two patients reported altered occlusion that did not need any therapy (grade I). MAI and MFIQ outcomes are depicted in Table 2. Thirty healthy subjects were included in the study for comparison with the patient group. The subject characteristics, MAI and MFIQ outcome are also presented in Table 2.

Table 1. Demographics and study outcomes of included patients (n = 21)

Demographics		
Gender, *n (%)*		
Male	16	76.2
Female	5	23.8
Age, *mean (SD)*	47.43	15.97
Age at trauma, *mean (SD)*	35.76	13.55
Follow-up time, *mean (SD)*	11.67	4.89
Cause of trauma, *n (%)*		
Traffic	5	23.8
Bike	5	23.8
Violence	3	14.3
Fall	6	28.6
Sports	0	0
Other	2	9.5
Diagnose (AOCMF), *n (%)*		
Condylar Neck fracture	9	42.9
Condylar Base fracture	12	57.1
Other Mandibular Fractures, *n (%)*		
No	6	28.6
Yes	15	71.4
Type of MMF, *n (%)*		
Elastics	8	38.1
Wires followed by guiding elastics	13	61.9
Total duration of treatment in weeks, *mean (SD)*	7.0	2.5
Clavien-Dindo classification for complications		
Grade I	5	23.8
Grade II	0	0
Grade III a+b	0	0
Grade IV a+b	0	0
Grade V	0	0
No complications	16	76.2
Study outcomes		
MMO, *mean (SD)*	47.69	7.80
Laterotrusion, *mean (SD)*		
To ipsilateral side	10.33	4.08
To contralateral side	11.17	4.02
Protrusion, *mean (SD)*	8.33	3.24
TMJ Symptoms, *n (%)*		
No	12	57.1
Yes	9	42.9
Occlusion, *n (%)*		
Stable	21	100
Patient-reported or objective malocclusion	0	0
Dentition status, *n (%)*		
Natural dentition	17	81
Partial denture	3	14
Maxillary denture, mandibular natural dentition	1	1
VAS for pain, *mean (SD)*	2.05	4.07

AOCMF: Classification system for condylar process fractures; MMF: Maxillomandibular Fixation; MMO: Maximum Mouth Opening;; SD: Standard Deviation; TMJ: Temporomandibular Joint; VAS: Visual Analogue Scale

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Table 2. Subject characteristics, MAI and MFIQ outcomes

		Patient group n = 21		Healthy subjects n = 30	
		Mean (SD)	*Median (IQR)*	*Mean (SD)*	*Median (IQR)*
Gender, *n (%)*					
	Male	16 (76.2)		19 (63.3)	
	Female	5 (23.8)		11 (36.7)	
Age		47.43 (15.97)		34.20 (14.26)	
OU		9.52 (4.46)		11.9 (1.00)	
MAI		18.80 (2.27)		17.42 (1.76)	
MFIQ outcome		4.29 (6.22)		0.47 (1.14)	
1.	Social activities	0.00 (0.00)	0 (0)	0.00 (0.00)	0 (0)
2.	Speaking	0.05 (0.22)	0 (0)	0.03 (0.18)	0 (0)
3.	Biting	0.67 (0.86)	0 (1)	0.03 (0.18)	0 (0)
4.	Eating hard food	0.38 (0.81)	0 (1)	0.07 (0.25)	0 (0)
5.	Eating soft food	0.19 (0.87)	0 (0)	0.00 (0.00)	0 (0)
6.	Daily activities	0.10 (0.30)	0 (1)	0.00 (0.00)	0 (0)
7.	Drinking	0.05 (0.22)	0 (0)	0.00 (0.00)	0 (0)
8.	Laughing	0.14 (0.48)	0 (0)	0.03 (0.18)	0 (0)
9.	Chewing resistant food	0.38 (0.67)	0 (1)	0.07 (0.25)	0 (0)
10.	Yawning	0.19 (0.40)	0 (0)	0.07 (0.25)	0 (0)
11.	Kissing	0.05 (0.22)	0 (0)	0.00 (0.00)	0 (0)
12.	Eating hard cookies	0.24 (0.63)	0 (0)	0.00 (0.00)	0 (0)
13.	Eating meat	0.24 (0.70)	0 (0)	0.03 (0.18)	0 (0)
14.	Eating raw carrot	0.38 (0.67)	0 (1)	0.03 (0.18)	0 (0)
15.	Eating French bread	0.19 (0.40)	0 (0)	0.07 (0.25)	0 (0)
16.	Eating peanuts	0.38 (0.67)	0 (1)	0.00 (0.00)	0 (0)
17.	Eating whole apple	0.67 (0.97)	0 (1)	0.03 (0.18)	0 (0)

MAI: Mixing Ability Index; MFIQ: Mandibular Function Impairment Questionnaire; OU: Occlusal Units; SD: Standard Deviation; ‡ Mann-Whitney U test; † Independent Sample T-test; ¥ Chi square test; * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

MASTICATION AND ASSOCIATED FACTORS IN PATIENTS

For the patient group, linear regression analyses are shown in Table 3 and 4. In unadjusted linear regression analysis the MAI was associated with the number of OU ($P = 0.020$). In the adjusted model, the number of OU remained significant ($R^2 = 0.253$, Table 3). In unadjusted linear regression analysis the MFIQ score was associated with gender ($P = 0.039$), VAS_{pain} ($P = 0.001$) and with OU ($P = 0.030$). In the adjusted model, the VAS_{pain} remained significant ($R^2 = 0.454$, Table 4).

MASTICATION AND ASSOCIATED FACTORS IN BOTH PATIENTS AND HEALTHY SUBJECTS

In unadjusted linear regression analysis for patients and healthy subjects, the variables age ($P = 0.013$), number of OU ($P = 0.001$), MFIQ ($P = 0.028$) and patient/healthy group ($P = 0.019$; meaning if subject was a patient or healthy subject) were associated with MAI (Table 5). The adjusted model showed that number of OU was associated with MAI ($R^2 = 0.201$). In unadjusted linear regression analysis for MFIQ, the variables age ($P = 0.023$), number of

OU (*P* = 0.000), MAI (*P* = 0.028) and patient/healthy group (*P* = 0.002) were of significant influence (Table 6). The adjusted model showed that number of OU and patient/healthy group remained explanatory variables for MFIQ (R^2 = 0.343).

Table 3. Adjusted and unadjusted linear regression models for MAI in patients

Variable	Unadjusted ModelRegression coefficients (95% CI)	*P*-value	Adjusted Model Regression coefficients (95% CI)	*P*-value
Gender	-0.125 (-2.621 – 2.371)	0.918		
Age (years)	-0.021 (-0.047 – 0.088)	0.529		
Follow-up time	0.055 (-0.167 – 0.276)	0.661		
CDC	-1.884 (-4.211 – 0.443)	0.107		
MMO	-0.120 (-0.247 – 0.007)	0.063		
Ipsilateral laterotrusion	-0.136 (-0.396 – 0.123)	0.284		
Contralateral laterotrusion	-0.158 (-0.418 – 0.102)	0.217		
Protrusion	-0.181 (-0.506 – 0.144)	0.257		
TMJ symptoms	0.378 (-1.763 – 2.512)	0.716		
VAS_{pain}	0.144 (-0.125 – 0.412)	0.275		
OU	-0.256 (-0.467 – -0.045)	0.020*	0.256 (-0.467 – -0.045)	0.020*
MFIQ	0.082 (-0.088 – 0.253)	0.326		
R^2			0.253	

CDC: Clavien-Dindo Classification; CI: Confidence interval; MAI: Mixing Ability Index; MFIQ: Mandibular Function Impairment Questionnaire; MMO: Maximum Mouth Opening; OU: Occlusal Units; TMJ: Temporomandibular Joint; VAS: Visual Analogue Scale; * $P < 0.05$

Table 4. Adjusted and unadjusted linear regression models for MFIQ in patients

Variable	Unadjusted Model Regression coefficients (95% CI)	*P*-value	Adjusted Model Regression coefficients (95% CI)	*P*-value
Gender	6.450 (0.345 – 12.555)	0.039*		
Age (years)	0.075 (-0.108 – 0.259)	0.401		
Follow-up time	0.497 (-0.065 – 1.059)	0.080		
CDC	2.250 (-4.510 – 9.010)	0.494		
MMO	0.028 (-0.355 – 0.411)	0.881		
Ipsilateral laterotrusion	-0.417 (-1.122 – 0.288)	0.231		
Contralateral laterotrusion	-0.343 (-1.067 – 0.381)	0.334		
Protrusion	0.723 (-0.130 – 1.577)	0.092		
TMJ symptoms	-3.417 (-9.075 – 2.242)	0.222		
VAS_{pain}	1.056 (0.483 – 1.630)	0.001**	1.056 (0.483 – 1.630)	0.001**
OU	-0.660 (-1.251 – -0.069)	0.030*		
MAI	0.618 (-0.665 – 1.901)	0.326		
R^2			0.454	

CDC: Clavien-Dindo Classification; CI: Confidence interval; MAI: Mixing Ability Index; MFIQ: Mandibular Function Impairment Questionnaire; MMO: Maximum Mouth Opening; OU: Occlusal Units; TMJ: Temporomandibular Joint; VAS: Visual Analogue Scale; * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

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Table 5. Adjusted and unadjusted linear regression models for MAI in patients and healthy subjects

Variable	Unadjusted Model Regression coefficients (95% CI)	*P*-value	Adjusted Model Regression coefficients (95% CI)	*P*-value
Gender	0.718 (-0.537 – 1.974)	0.256		
Age (years)	0.044 (0.010 – 0.079)	0.013*		
OU	-0.296 (-0.465 – -0.126)	0.001**	-0.296 (-0.465 - -0.126)	0.001**
MFIQ	0.144 (0.016 – 0.271)	0.028*		
Patient/healthy group	-1.372 (-2.505 – -0.239)	0.019*		
R^2			0.201	

CI: Confidence interval; MAI: Mixing Ability Index; MFIQ: Mandibular Function Impairment Questionnaire; OU: Occlusal Units; * $P < 0.05$; ** $P < 0.01$

Table 6. Adjusted and unadjusted linear regression models for MFIQ in patients and healthy subjects

Variable	Unadjusted Model Regression coefficients (95% CI)	*P*-value	Adjusted Model Regression coefficients (95% CI)	*P*-value
Gender	1.582 (-1.108 – 4.273)	0.243		
Age (years)	0.087 (0.013 – 0.162)	0.023*		
OU	-0.752 (-1.096 – -0.408)	0.000***	-0.612 (-0.971 - -0.253)	0.001**
MAI	0.661 (0.075 – 1.247)	0.028*		
Patient/healthy group	-3.819 (-6.146 – 1.492)	0.002**	-2.364 (-4.639 - -0.090)	0.042*
R^2			0.343	

CI: Confidence interval; MAI: Mixing Ability Index; MFIQ: Mandibular Function Impairment Questionnaire; OU: Occlusal Units; * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$

DISCUSSION

This study assessed long-term explanatory demographic and clinical variables for masticatory performance and masticatory ability in patients who received closed treatment for unilateral condylar neck or base fractures. The patient group was examined 11.7 years on average after initial treatment. We also compared patients' masticatory performance and ability with healthy subjects.

MASTICATION AND ASSOCIATED FACTORS IN PATIENTS

In patients with a history of unilateral condylar neck or base fractures, we found that the number of OU explained 25% of the masticatory performance, as R^2 was 0.253. Further, patient-reported pain and dental status significantly influenced masticatory ability, as measured by the MFIQ, where patient-reported pain explained 45% of the masticatory ability as R^2 was 0.454. These findings are consistent with a prospective clinical study of 114 patients with unilateral (73%) and bilateral (27%) condylar fractures who received MMF treatment.[4] Similar to our findings, the mean MFIQ outcome and the mean VAS_{pain} were 3.4 (SD 7.3) and 2.3 (SD 9.3), respectively, with a follow-up period of one year.[4] This indicates that there is negligible additional gain in patients' perception of functional recovery after one year, which suggests that patients' perception of rehabilitation reaches a plateau.[4]

However, a prospective clinical study from 2006, with a follow-up period of 6 months, found poorer scores on the MFIQ (mean 10.5, SD 12.1).[21] Although this is a worse outcome than our long-term result, the standard deviation was large and the follow-up period was short. Comparison with our results suggests that a 6-month follow-up period is too short, and improvement of masticatory ability after this period could be expected.
When comparing the mastication results from our patient group to those in the literature, similar results were reported in a cross-sectional study without a specified follow-up period in 48 patients with unilateral condylar fracture who received closed treatment.[10] In this study, both the MAT and MFIQ were performed (mean 18.4, SD 2.3; mean 4.96, SD 1.3, respectively), and a significant correlation was found ($r = 0.250$, $P = 0.033$).[10] In this study, only the distinction between dentulous and edentulous patients was made, therefore comparison to our results is difficult. In our patient group, the MAI and MFIQ did not remain a significant explanatory factor towards each other in adjusted analysis. This means that objective functionality does not necessarily correspond to patient-reported outcomes.[21] Therefore, objective and patient-reported measurements of functioning are complementary, and both results should be considered when deciding on the treatment that best meets the needs of the patient.[22,23]

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The association between the number of OU and the MAI indicates the necessity of natural dentition with a sufficient amount of OU (> 4) for an optimal masticatory performance. Therefore preservation and restoration of dentition and occlusal units are of great value in terms of masticatory performance and rehabilitation.[24]

Mastication and associated factors in both patients and healthy subjects

In this study, we found that the patient group had similar MAI outcomes compared to the healthy subjects when correcting for its explanatory variable OU as patient/healthy group did not remained an explanatory variable in the adjusted analysis. We found that OU was the influencing factor towards MAI for 20.1%, as R^2 was 0.201. This is consistent with the literature where, as is known, dental state is one of the key determinants of masticatory performance.[9] In a recent study published in 2021, increasing number of OU significantly shortened the chewing time and therefore would increase the mixing ability.[25] This is consistent with the findings of a systematic review published in 2015, where the effects of removable dentures compensated for reduced masticatory performance in the order of 50%.[24] This could mean that a chewing cycle for the MAT of 15 strokes was insufficient for the denture wearers in our patient group to achieve the same outcome as people with natural dentition.[7] Our findings of masticatory performance when corrected for dentition status are therefore consistent with similar studies, which reported that mastication is equivalent to healthy subjects after 1 year of follow-up.[26,27] Further, we found that the patient group had inferior masticatory ability, measured by the MFIQ, compared to healthy subjects as patient/healthy group remained an explanatory variable in adjusted analysis.

To the best of our knowledge, this is the first long-term study to use reliable methods to measure both masticatory performance and ability in the same patient group after MMF for unilateral condylar neck or base fractures. Throughout the study, there was strict compliance to the protocol. Demographic information of subjects who did not respond to the invitation to participate could not be compared to those evaluated at follow-up. Furthermore, despite approaching a large amount of subjects, only 51 participants were included in the study. This may influence the interpretation of our results.

Insufficient anatomical reduction of fractures after closed treatment could provide a functionally acceptable result for patients.[28,29] Objectively measured oral functioning and patient-reported oral functioning can be complementary for treatment selection, even if they are not identical. Therefore these measures should be combined in future research.[22] When anatomical measurements of the mandibular condyle are considered, it is possible to determine whether higher MAI or MFIQ outcomes are related to worse anatomical positioning after recovery. Prospective comparative studies are necessary to determine whether the treatment should remain focussed on objective outcomes or shift towards patient-reported outcomes to achieve the best results.

CONCLUSIONS

In patients with a history of unilateral mandibular condylar neck or base fractures who received closed treatment the number of OU are an explanatory factor for long-term masticatory performance and patient-reported pain was an explanatory factor for masticatory ability. Long term masticatory performance was similar in the patient group and healthy subjects, however, masticatory ability was inferior in the patient group. OU was of significant influence for both masticatory performance and masticatory ability.

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CHAPTER 5

Oral functioning after open versus closed treatment of unilateral condylar neck or base fractures: a two-centre controlled clinical trial

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ABSTRACT

BACKGROUND

Oral functioning and rehabilitation in patients after condylar trauma can be measured by objective functional outcomes and patient-reported outcomes. The similarities or differences between these outcomes may contribute to the decision if open treatment (OT) or closed treatment (CT) will obtain the most advantageous results.

OBJECTIVES

The aim of this study was to compare OT versus CT for unilateral condylar mandibular neck or base fractures in a two-centre controlled clinical trial by objective functional outcomes and patient-reported outcomes measured at six weeks and six months follow-up. Additionally, these outcomes were compared within each group.

METHODS

Patients were enrolled between January 2017 and November 2019. In one centre patients received OT by extra-oral open reduction and internal fixation. In another centre patients received CT by maxillomandibular fixation. Objective measurements included the mixing ability test (MAT) and mandibular active range of motion (ROM). Patient-reported outcomes included the mandibular function impairment questionnaire (MFIQ) and visual analogue scale (VAS) for pain. Independent t-tests and Mann-Whitney U tests were used to determine differences between the treatment groups at six weeks and six months follow-up. Paired t-tests and Wilcoxon Signed Rank tests were used to determine differences within each group.

RESULTS

Thirty-three patients were enrolled. No differences were found between the groups treated with OT or CT for MAT, ROM, MFIQ and VAS. Both groups showed functional improvement.

CONCLUSION

Good objective functional outcomes and patient-reported outcomes were achieved with both OT and CT in patients with unilateral condylar mandibular neck or base fractures.

BACKGROUND

The main options of management of unilateral mandibular condylar fractures are surgical open treatment (OT) with or without internal fixation techniques or closed treatment (CT) by maxillomandibular fixation (MMF). These modalities of treatment have their (contra) indications and (dis)advantages. In the literature, many studies were conducted comparing OT with CT. Of five systematic reviews, four concluded that OT of unilateral mandibular extra-capsular condylar fractures provides better subjective and objective clinical and functional outcomes in comparison to CT, especially with regard to occlusion, maximum interincisal opening (MIO) and laterotrusion.[1–4] However, one systematic review conducted in 2020 concluded that both treatment modalities provide comparable MIO and protrusion, whereas CT was superior for laterotrusion.[5] Despite all efforts by researchers and clinicians to indicate criteria for the optimal management of mandibular condylar fractures, many oral and maxillofacial surgeons find themselves in doubt when diagnosing one.[6] Independently from the chosen therapy, the aim of any treatment is first to restore oral function and aesthetics, and second, to reduce pain and complications. The restoration of oral functioning usually involves the re-establishment of the pre-traumatic relationship of the fractured segments, the occlusion and the maxillofacial symmetry. Nevertheless, decreased oral functioning is a frequent problem after maxillofacial injury.[7]

Masticatory performance and masticatory ability are two ways of measuring oral functioning in patients after condylar trauma.[8,9] Masticatory performance is defined as the objective efficiency of the mastication process, which can be measured by the ability to comminute or mix test food.[9] The Utrecht Mixing Ability Test (MAT) is a test with excellent reliability for patients with history of condylar trauma.[10]

Masticatory ability is a patient-reported outcome (PRO) of the mastication process. It reflects the expectations and quality of life of the patients. The Mandibular Function Impairment Questionnaire (MFIQ) is a PRO that specifically measures masticatory ability in condylar trauma patients.

To the best of our knowledge, there are no prospective controlled clinical studies that compare OT and CT by both objective functional outcomes, including the MAT, and PROs, including the MFIQ.[11] Since objective functional outcomes and PROs do not necessarily correspond with each other, it is important to consider both.[10,12–15] The similarities and differences between these outcomes may contribute to the discussion of which type of therapy will obtain the most advantageous results, both from a patient and an objective point of view. Therefore, the aim of this study was to compare OT with CT for unilateral condylar mandibular neck and base fractures in a controlled clinical trial (CCT) by objective functional outcomes and PROs measured at six weeks and six months follow-up. Additionally, a comparison of objective functional outcomes and PROs was made within six weeks and six months follow-up of the OT and CT groups.

MATERIALS AND METHODS

PATIENTS

Between January 2017 and November 2019, patients with unilateral neck or base fractures of the mandibular condyle were asked to participate in this two-centre CCT at University Medical Centre Utrecht (UMCU) and OLVG in the Netherlands. Inclusion criteria included: 1) age 18 years or older, 2) unilateral condylar mandibular fracture (neck and/or base according to the AOCMF classification system[16]) with displacement and with or without other fractures of the mandible, and 3) objective malocclusion. Patients could not participate if there was: 1) a contraindication for general anaesthesia, 2) mid-face fractures, 3) insufficient reading and writing skills of the Dutch language, 4) legally incapability, 5) a psychiatric disorder, or 6) pregnancy. The patients received usual care according to hospital protocol. This implies that patients at the UMCU received OT (OT-group) by extra-oral open reduction and internal fixation (ORIF) of the fracture by pre-auricular or retromandibular approach, depending on the level of the fracture. This was combined with bone screws with loose elastic guiding for two weeks postoperatively, so that mobilisation was possible and immediately encouraged. Patients treated at OLVG received CT (CT-group) by MMF with bone screws with tight elastic internal fixation for two weeks, followed by guiding elastics for four weeks.

This study was conducted according to the principles of the Declaration of Helsinki 2013 and the Medical Research Involving Humans Subjects Act (WMO). The research protocol was approved by the Medical Ethics Committee of the UMCU (NL59658.041.16). Written informed consent was obtained from all participants.

DATA COLLECTION

All consecutive patients were treated within seven days after trauma. Age, gender, diagnosis, other fractures, cause of trauma, malocclusion, occluding units (OU), if the patient had a denture yes/no, visual analogue scale for pain (VAS_{pain}) before treatment and timing of intervention were collected. The number of OU were assessed as the functional units of the patients natural dentition in the premolar and molar region (range 0-12), where an occluding pair of premolars counts for one, and an occluding pair of molars counts for two.[17]

Both patient groups were measured before treatment, and at six weeks and six months after the start of the treatment. Objective functional outcomes were obtained using the MAT and clinical examination by means of active range of motion (AROM) of the mandible. PROs were obtained through the MFIQ and VAS_{pain}. Furthermore, the duration of treatment, complications of treatment, objective- and patient-reported occlusion were noted.

OBJECTIVE FUNCTIONAL OUTCOMES

Masticatory performance

A comprehensive description of the MAT was previously published.[8,18,19] The MAT enables the quantification of masticatory performance by assessing the patient’s ability to mix two wax layers of the colour red and blue. The outcome variable of the MAT is the Mixing Ability Index (MAI), which is defined as the ability to mix both colours within a set amount of 15 chewing strokes. A MAI-score of 5 represents a fully mixed tablet and implies a mostly sufficient masticatory performance, whereas a score of 30 represents an unmixed wax tablet, which indicates a mostly insufficient masticatory performance. The test-retest reliability of the MAT is excellent due to an intraclass coefficient correlation (ICC) of 0.906 in condylar trauma patients.[10] The tablet consists of two 3 mm thick layers of coloured Plasticine modelling wax (non-toxic DIN EN-71, art. nos. crimson 52801 and blue 52809, Stockmar, Kalten Kirchen, Germany) with a diameter of 20 mm. The wax is used at room temperature (20 °C) and forms a compact bolus during chewing. Subjects were instructed to chew 15 times on the tablet as if it was chewing gum. The chewed tablet was then removed and flattened between foil to a thickness of 2.0 mm and photographed on both sides using a high-quality scanner (Epson V750, Long Beach, CA, USA). The digitalised images were analysed and processed using a commercially available program for image analysis, Adobe Photoshop, CS3 extended (Adobe, San Jose, CA, USA). The MAI was obtained by measuring the intensity distributions of the red and blue colouring on the combined image on both sides of the flattened wax.

Active range of motion of the mandible

MIO was measured intraorally as the distance between the central incisors of the maxilla and mandible in closed and active maximal open positions, and this was measured twice. The greatest value of the measurements of the overbite was added to the highest value of the two maximum inter-incisal opening positions. This test has an excellent inter-observer, intra-observer, and test-retest reliability (ICC, 0.85–0.96) and the smallest detectable change is a difference of 6–9 mm.[20,21] Laterotrusion was measured as the distance between the midline of the central incisors of the maxilla and mandible. The value of the starting position in occlusion was added to or subtracted from the highest value of two measurements in maximum laterotrusion to each side. Laterotrusion showed good to excellent reliable results (ICC, 0.74–0.82).[21] Protrusion was measured as the distance between the labial side of the central incisors of maxilla and mandible in occlusion and the highest value of two measurements in maximum forward protrusion.

PATIENT-REPORTED OUTCOMES

Masticatory ability

The MFIQ is designed to assess masticatory ability and was previously published.[10,22] This questionnaire has been proven reliable in patients with painfully restricted temporomandibular joints by a moderate to good test-retest reliability with a Spearman correlation of 0.69–0.96.[22] The MFIQ consists of 17 items. Each item is scored using a five-point Likert scale on which patients can indicate the experienced level of difficulty while performing particular mandibular movements or tasks (e.g., speech, daily activities, drinking, laughing, yawning, eating different types of food). The scores are: 0 = no difficulty, 1 = a little

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difficulty, 2 = quite a bit of difficulty, 3 = much difficulty, 4 = very difficult or impossible without help. A total outcome ranging from 0–68 is possible, where 0 indicates no mandibular function impairment and 68 a poor functional outcome. The total score of the MFIQ is analysed as a continuous variable.[22]

Pain

To quantify pain experience, the validated VAS_{pain} was used, which consists of a 100 mm horizontal line.[23,24] Patients indicate pain experience by choosing a position on the line in which 0 mm indicates no pain and 100 mm indicates worst pain. The VAS_{pain} is a reliable tool to assess acute pain, with an ICC between 0.95–0.98. The test-retest reliability is good with a Spearman's rho of 0.71.[24]

SAMPLE SIZE

Based on a previous study (with $\alpha = 0.05$ and $1\text{-}\beta = 0.80$), the sample size was calculated at 18 patients in each group to detect differences for the MAT using an independent t-test (G*Power 3.1.9.2).[8,25]

STATISTICAL ANALYSIS

Descriptive statistics were used to describe patient characteristics and the distribution of outcomes. Nominal data is presented as number and percentage, ordinal data as median and interquartile range, and continuous data as mean and standard deviation (SD). Normal distribution of continuous data was tested with the Shapiro Wilk Test of Normality and equality of variances with Levene's test. To determine significant differences between the OT-group and CT-group, the independent t-test (continuous data), Mann-Whitney U test (ordinal and non-normal distributed continuous data), and chi-squared test (nominal data) were used. To determine significant differences between six weeks and six months within the OT-group and CT- group, the paired t-test (continuous data) and Wilcoxon Signed Rank test (ordinal and non-normal distributed continuous data) were used**.** Statistical significance was considered at a two-tailed significant level of $P < 0.05$. Statistical analyses were performed using SPSS IBM version 25.0 (IBM Corporation, Armonk, NY, USA).[26]

RESULTS

Of the 39 patients who met our criteria, four patients did not wish to participate in this two-centre CCT. Initially 35 patients were included, and there was one drop-out in each group before any study measurements were conducted; therefore, these patients were excluded from the analysis. Of the 33 participating patients, 17 (51.5%) were included in the OT-group, of which in 12 cases, a pre-auricular approach was used, and in five cases, a retromandibular approach was used. In 14 cases Rhombic 3D Condylar Fracture Plates by KLS Martin were used for fixation and in 3 cases a 2.0 plate by KLS Martin was used. Sixteen (48.5%) patients were included in the CT-group and received MMF (Fig. 1). At six months, there were two patients lost to follow-up in the OT-group and five in the CT-group. The reasons for lost follow-up in two patients were due to personal reasons, in two other patients contact was lost, and three additional patients could not be measured at six months due to the coronavirus disease 2019 (COVID-19) pandemic.

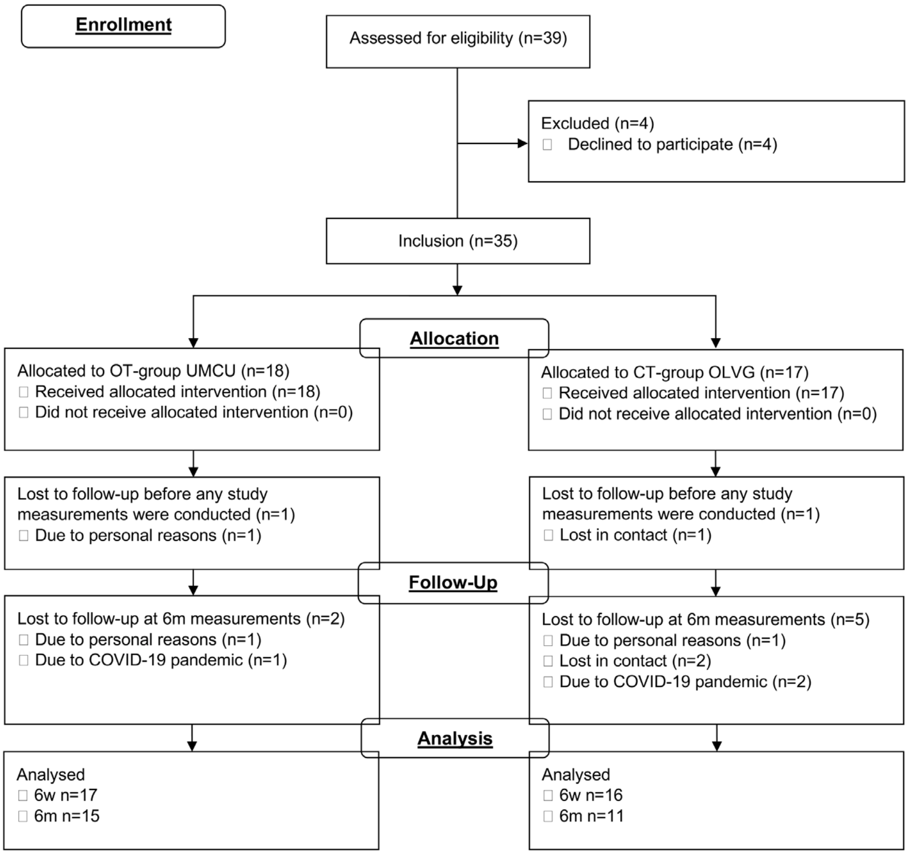

Figure 1. Flow diagram of enrolment

There were no significant differences between the OT-group and CT-group for age, gender, diagnosis, other fractures of the mandible, cause of trauma, objective malocclusion, OU, VAS_{pain} before treatment and time between trauma and treatment (Table 1).

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Table 1. Baseline characteristics OT-group and CT-group

	OT-group (N=17)	CT-group (N=16)	*P-value*
Age (years), *mean (SD)*	42.2 (16.6)	34.3 (13.3)	0.142†
Gender, *n (%)*			0.554ˣ
Male	10 (58.8)	11 (68.8)	
Female	7 (41.2)	5 (31.3)	
Diagnosis, *n (%)*			0.806ˣ
Condylar neck fracture	7 (41.2)	6 (37.5)	
Condylar base fracture	10 (58.8)	10 (62.5)	
Other mandibular fractures, *n (%)*			0.857ˣ
Yes	9 (52.9)	9 (56.3)	
No	8 (47.1)	7 (43.8)	
Cause of trauma, *n (%)*			0.462ˣ
Traffic	3 (17.7)	5 (31.3)	
Violence	4 (23.5)	1 (6.3)	
Fall	5 (29.4)	7 (43.8)	
Sports	2 (11.8)	2 (12.5)	
Other	3 (17.7)	1 (6.3)	
Malocclusion before treatment, *n (%)*			
Yes	17 (100)	16 (100)	
No	0 (0)	0 (0)	
OU, *mean (SD)*	11.3 (1.0)	11.4 (1.1)	0.818†
Denture, *n (%)*			
Yes	0 (0)	0 (0)	
No	17 (100)	16 (100)	
VAS_{pain} before treatment, *mean (SD)*	39.9 (18.1)	34.7 (22.9)	0.621‡
Time between trauma and treatment, days, *mean (SD)*	1.9 (1.6)	1.6 (0.8)	0.491†

CT: closed treatment; OT: open treatment; OU: Occluding Units; SD: standard deviation; VAS_{pain}: visual analogue scale for pain; ˣChi square test; † Independent Sample T-test; ‡ Mann-Whitney U test;

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No physiotherapy was applied in both groups during the 6 months follow-up of this study. The following complications were reported in the OT-group at six weeks: swelling (n = 3; 18%), sialocele (n = 1; 6%), abnormal healing of the scar (n = 1; 6%), weakness of the facial nerve with full recovery within six months (n = 1; 6%), and injury of the dental root after bone screw placement (n = 1; 6%). At six months, a noted complication was hypertrophic scarring in one case (6%). No plate fractures occurred. There were no complications in 11 patients (65%).

In the CT-group (n = 16), complications reported at six weeks included: infections of bone screws (n = 2; 13%) and replacement of bone screws (n = 2; 13%). At six months, no complications were noted. There were no complications in 10 patients (63%).

Four patients (24%) reported malocclusion in the OT-group at six weeks and one patient (6%) at six months. In the CT-group, patients reported malocclusion in five cases (31%) at six weeks and in two cases (13%) at six months. All malocclusions were confirmed clinically. No interventions were made to modify the occlusion.

Comparisons between the OT-group and CT-group showed no statistically significant differences for the MAT, MIO, protrusion, laterotrusion, MFIQ outcomes and VAS_{pain} at six weeks or at six months of follow up (Table 2).

In follow-up, both the OT-group and CT-group showed over time better outcomes for masticatory performance as measured by the MAT (P = 0.003 and 0.000, respectively), MIO (P = 0.000 and 0.009, respectively), protrusion (P = 0.020 and 0.007, respectively), laterotrusion (P = 0.004 and 0.001, respectively) and masticatory ability measured by the MFIQ (P = 0.001 and 0.000, respectively) (Table 2). In contrast, within the CT-group, between six weeks and six months follow-up for VAS_{pain} no significant improvement was found (P = 0.097).

Table 2. Comparison within six weeks and six months for the OT-group and CT-group and comparison between the OT-group and CT-group at six weeks and six months

	OT-group					CT-group					OT vs. CT	OT vs. CT
	6 weeks (N=17)		6 months (N=15)		6 weeks vs 6 months	6 weeks (N=16)		6 months (N=11)		6 weeks vs 6 months	6 weeks	6 months
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	*P-value*	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	*P-value*	*P-value*	*P-value*
MAI	20.3 (3.0)	20.0 (18.0)	17.9 (2.3)	17.4 (16.0)	0.003° **	19.7 (2.9)	20.0 (17.5)	17.9 (2.2)	17.2 (16.1)	0.000° ***	0.616†	0.965†
MIO, *mm*	30.4 (8.7)	29.5 (24.8)	44.8 (8.7)	45.0 (36.6)	0.000° ***	32.5 (10.9)	31.8 (27.6)	42.1 (8.0)	42.0 (36.0)	0.009° **	0.552†	0.432†
Protrusion, *mm*	4.8 (3.0)	5.5 (1.6)	6.8 (3.4)	7.3 (3.5)	0.020° *	4.3 (3.0)	3.8 (2.0)	7.3 (3.4)	7.0 (4.0)	0.007^{w} **	0.682†	0.747‡
Laterotrusion, *mm*	13.2 (5.8)	14.0 (9.3)	21.1 (6.7)	23.0 (17.0)	0.004° **	13.0 (6.5)	11.5 (7.5)	19.8 (4.8)	19.0 (17.0)	0.001° **	0.923†	0.604†
VAS_{pain}	16.4 (19.4)	10 (2.25)	3.3 (5.3)	1 (0)	0.009^{w} **	6.8 (8.8)	3 (0.25)	1.5 (2.7)	0 (0)	0.097^{w}	0.115‡	0.275‡
MFIQ	29.4 (12.3)	33.0 (17.0)	10.9 (10.0)	10.5 (1.5)	0.001° **	30.1 (14.3)	29.0 (17.0)	6.2 (4.2)	7.0 (2.0)	0.000° ***	0.892†	0.198†
1. Social activities		1 (1)		0 (1)	0.236^{w}		1 (1)		0 (0)	0.023^{w} *	0.418‡	0.031‡ *
2. Speaking		0 (1)		0 (1)	0.763^{w}		0 (1)		0 (0.3)	0.157^{w}	0.634‡	0.327‡
3. Biting		3 (3)		1 (1.5)	0.007^{w} **		2 (2.8)		1 (1)	0.005^{w} **	0.470‡	0.450‡
4. Eating hard food		3 (2)		1 (0.75)	0.004^{w} **		3 (3)		0.5 (1)	0.004^{w} **	0.496‡	0.133‡
5. Eating soft food		0 (1)		0 (0)	0.763^{w}		0.5 (1)		0 (0)	0.011^{w} *	0.519‡	0.154‡
6. Daily activities		1 (0)		0 (0)	0.013^{w} *		0.5 (1)		0 (0.25)	0.096^{w}	0.193‡	1.000‡
7. Drinking		0 (0)		0 (0)	0.414^{w}		0 (0)		0 (0)	0.317^{w}	0.324‡	0.812‡
8. Laughing		1 (0)		0 (1)	0.102^{w}		1 (1)		0 (0)	0.033^{w} *	0.748‡	0.132‡
9. Chewing resistant food		3 (2)		1 (1)	0.002^{w} **		2 (3)		1 (1)	0.005^{w} **	0.820‡	0.709‡
10. Yawning		1 (1)		0.5 (0.5)	0.020^{w} *		1.5 (1)		0 (1)	0.006^{w} **	0.916‡	0.221‡
11. Kissing		1 (1)		0 (0.75)	0.058^{w}		1.5 (2.75)		0 (0)	0.010^{w} *	0.210‡	0.319‡
12. Eating hard cookies		3 (3)		0.5 (1)	0.009^{w} **		3 (1.75)		1 (1)	0.004^{w} **	0.542‡	0.765‡
13. Eating meat		3 (2)		0 (1)	0.001^{w} **		2 (2)		0 (1)	0.004^{w} **	0.178‡	0.591‡
14. Eating raw carrot		2 (3)		1 (1)	0.006^{w} **		3 (2.75)		1 (1)	0.004^{w} **	0.579‡	1.000‡
15. Eating French bread		2 (2)		1 (1)	0.003^{w} **		2 (2)		0.5 (1)	0.005^{w} **	0.808‡	0.557‡
16. Eating peanuts		3 (3)		0 (1)	0.003^{w} **		3 (2)		0 (0.25)	0.004^{w} **	0.935‡	0.205‡
17. Eating whole apple		3 (2)		1 (2)	0.003^{w} **		4 (2)		1 (1)	0.004^{w} **	0.460‡	0.692‡

† Independent Sample T-test; ‡ Mann-Whitney U test; ^{w} Wilcoxon Signed Rank Test; ° Paired T-test; * P<0.05, ** P<0.001, *** P<0.000; CT: closed treatment; IQR: interquartile range; MAT: mixing ability test; MAI; mixing ability index; MFIQ: mandibular function impairment questionnaire; MIO: maximal interincisal opening; OT: open treatment; SD: standard deviation; VAS_{pain}: visual analogue scale for pain

DISCUSSION

This two-centre CCT compared OT with CT of unilateral condylar mandibular neck and base fractures with follow-up periods of six weeks and six months. No differences between the OT-group and CT-group were found in terms of objective functional outcomes, measured by the MAT, MIO, protrusion and laterotrusion, and PROs, measured by VAS_{pain} and the MFIQ. Additionally, within six weeks and six months follow-up of the OT-group and CT-group, significant differences were found showing a functional improvement on both objective functional outcomes and PROs.

A cross-sectional study published in 2018 comparing OT and CT in 58 patients with a follow-up of more than one year.[27] In this study, no differences were found for the MAT and MIO between the OT-group (n = 10) and CT-group (n = 48). This is consistent with our objective functional outcomes. Furthermore, the authors found better patient self-perceived mandibular function, as measured by the MFIQ, in the CT-group, compared to the OT-group, which is in contrast to our findings.[27] This study is the only study in literature that also used the MAT and the MFIQ.
Five RCTs found significant better objective functional outcomes in terms of MIO and laterotrusion in the OT-group compared to the CT-group.[28–32] This is in contrast to our study and two other RCTs where no differences were found for MIO and laterotrusion.[33,34] For protrusion, four RCTs found significant better results in the OT-group[29–32], which is in contrast to our findings and two other RCTs, as no differences were found for protrusion.[33,34] In terms of PROs, two RCTs found better patient self-perceived mandibular function, as measured by the MFIQ in the OT-group, meaning a greater functional impairment in the CT-group.[30,32] This is in contrast to our finding, as no significant differences were found. Moreover, five RCTs found lower VAS_{pain} scores in the OT-group compared to the CT-group.[28–32] This is in contrast to two other RCTs and our findings, as we did not find any differences.[33,34]

STRENGTHS AND LIMITATIONS

To the best of our knowledge, this was the first CCT that uses the reliable methods, the MAT and MFIQ, to measure both masticatory performance and masticatory ability in the comparison of OT and CT for unilateral condylar neck and base fractures. The AOCMF classification system was used for diagnosis. Because this study was conducted in two different hospitals with different treatment protocols for these fractures, the risk of inclusion bias was limited. Trauma patients are less likely to participate if a study is randomised, mainly due to personal preference for one form of treatment and the dislike of the idea of randomisation, therefore we chose a CCT studydesign.[35] Throughout the study, there was strict compliance to our study protocol. Thereby, the relatively small number of subjects in this study and missing data at six months are a possible source of bias. Despite all efforts

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to obtain the sample size that was calculated beforehand, the patient range was lower than expected and we decided to discontinue the inclusion, due to the COVID-19 pandemic.

CLINICAL RELEVANCE AND FUTURE RESEARCH

Since our study found no differences in masticatory performance and masticatory ability between OT and CT, we recommend management with the treatment that the surgeon is most experienced with, so the least complications could be expected.

In previous studies, it has been suggested that ORIF results in a better anatomical reduction, faster rehabilitation of mandibular function, quicker return to normal diet, better oral hygiene and on average, a shorter follow-up than MMF.[30,36,37] The results of three RCTs were in favour of operative treatment; however, no objective functional masticatory performance test and no PROs were performed.[28,29,34]

Operative treatment is invasive, which may cause postoperative complications, and general anaesthesia is required.[38] However, in our study, these complications were rare. The incidence of facial nerve injury after OT ranged from 0 to 21% in literature and was temporary in most patients, which is in accordance with the finding (6%) of our study.[3,31,32,39] CT by MMF has the advantage of not requiring general anaesthesia and, therefore, no risk of anaesthetic complications.[39,40] Healthcare costs for OT are higher, which favours CT.

In this study, no distinction was made between the degree of displacement of the fracture for treatment choice. Although there is consensus for OT in cases with more than 45 degrees of fracture displacement, it would be interesting to further differentiate between groups with different degrees of displacement in future research.[30]

CONCLUSION

There was no difference in masticatory performance and masticatory ability in patients with unilateral mandibular condyle neck and base fractures treated with open or closed treatment. Differences within six weeks and six months showed functional improvement for both treatment groups.

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CHAPTER 6

Anatomical position of the mandibular condyle after open versus closed treatment of unilateral fractures: a three-dimensional analysis

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ABSTRACT

This study aimed to compare open and closed treatment for unilateral mandibular condyle neck and base fractures by final three-dimensional (3D) condylar position at six months follow-up. 3D position was associated with mandibular functioning and pain.

Twenty-one patients received open (n=11) or closed (n=10) treatment. 3D positions were assessed on cone-beam computed tomography scans. Volume differences, root mean square, translations, and rotations were obtained related to the pursued anatomical position and compared between treatment groups by the Mann-Whitney U test. The 3D position parameters were associated with the maximum interincisal opening (MIO), mixing ability test (MAT), Mandibular Function Impairment Questionnaire (MFIQ), and pain based on Spearman correlation coefficients (r_s).

Translation in the medial-lateral direction was smaller after open treatment (*P*=0.014). 3D position was not associated with the MAT; however, worse position was associated with a smaller MIO. A larger pitch rotation was associated with a worse MFIQ (r_s=0.499, *P*=0.025). Volume reduction of the affected condyle was associated with more pain (r_s=-0.503, *P*=0.020).

In conclusion, after unilateral condylar fractures, worse 3D position is associated with a smaller mouth opening and worse patient-reported outcomes. This is independent of the chosen treatment, despite a better anatomical reduction after open treatment.

INTRODUCTION

The best treatment strategy for unilateral mandibular condylar fractures remains controversial. The main treatment options are surgical open reduction with internal fixation or maxillomandibular fixation without surgery. Both treatment strategies primarily aim to restore mandibular functioning and esthetics.[1] Besides, the reduction of pain and complications is pursued. The restoration of mandibular functioning usually comprises the recovery of the anatomical relationship of the fracture segments and dental occlusion.[2]

Thereby, the question arises if the anatomical relationship of the condylar fracture segments differs after open or closed treatment. It is expected that the anatomical relationship would be better after open treatment since an anatomical reduction of the fractured condyle is possible.[3,4] However, fixation of the condyle in a non-anatomical position could lead to degenerative joint changes.[5] On the other hand, closed treatment is often associated with a potential for ankylosis and internal derangement of the temporomandibular joint.[6,7]

The anatomical relationship after treatment can be indicated by the position and morphology of the affected condyle compared to the contralateral healthy condyle. Conventionally, panoramic radiographs have been preferred for diagnosis and follow-up after trauma. However, the 3-dimensional (3D) position of the fractured condylar segment cannot be evaluated on panoramic films. Computed tomography (CT) is a well-established imaging modality with the ability to assess the post-treatment healing pattern of condylar fractures.[8]

The anatomical position and healing morphology of fractured condyles affect mandibular functioning and pain.[8] Mandibular functioning has already been compared between open and closed treatment, presenting conflicting results.[9,10] Objective functional outcomes involve the maximum mouth opening and masticatory performance, and a patient-reported outcome (PRO) of mandibular functioning is the masticatory ability. Besides, ambiguous results are reported for comparison of open and closed treatment by experienced pain.[4,9] Therefore, it is important to know to what extent the anatomical position of the affected condyle is associated with mandibular functioning and pain.

To the best of our knowledge, there are no clinical studies that compare the 3D position and morphology of unilateral fractured mandibular condyles after open and closed treatment and relate these findings with both objective functional outcomes and PROs.[11] Objectifying differences or similarities in anatomy, and studying its association with mandibular functioning and pain might be helpful in the ongoing dilemma of treatment decision making. Therefore, the first aim was to analyse and compare the final position of the initially fractured mandibular condyle following open and closed treatment of unilateral fractures. The second aim was to evaluate the association between the final position of the affected condyle and mandibular functioning and pain. In addition, this study aimed to classify and compare the morphology of the condyle following open and closed treatment over time.

MATERIALS AND METHODS

PATIENTS

Between January 2017 and November 2019, consecutive patients with unilateral neck or base fractures of the mandibular condyle were asked to participate in this prospective two-centre controlled clinical trial (CCT) at University Medical Centre Utrecht (UMCU) and OLVG in the Netherlands. Patients who participated had to be diagnosed with a unilateral neck or base fracture of the mandibular condyle, according to the Arbeitsgemeinschaft für Osteosynthesefragen craniomaxillofacial (AOCMF) classification based on the level of the fracture[12], with objective malocclusion. Patients had to be aged 18 years or older. Patients were excluded in case of 1) predictable asymmetry of the condyles, 2) a contraindication for general anesthesia, 3) mid-face fractures, 4) insufficient reading or writing skills of the Dutch language, 5) legal incapability, 6) a psychiatric disorder, or 7) pregnancy.

Patients were treated according to the hospital protocols. Patients at UMCU received open treatment, including extra-oral open reduction and internal fixation of the fracture by a pre-auricular or retromandibular approach. This was combined with bone screws with loose elastic guiding for two weeks postoperatively. Guiding elastics stimulated an optimal occlusion while patients are able to move their mandible. The directions of elastics, the number of elastics and their strength were changed based on occlusion and deviation of the mandible by the progression of the rehabilitation. Patients at OLVG received closed treatment by maxillomandibular fixation with bone screws with tight elastic fixation for two weeks, followed by guiding elastics for four weeks.

This study was conducted according to the principles of the Declaration of Helsinki 2013 and the Medical Research Involving Humans Subjects Act (WMO). The research protocol was approved by the Ethics Committees of the UMCU (NL59658.041.16). Written informed consent was obtained from all participants.

DATA COLLECTION

Age, gender, other mandibular fractures, trauma to treatment interval and occluding units (OU) were prospectively collected. The number of OU were assessed as the functional units of the patients natural dentition in the premolar and molar region (range 0-12), where an occluding pair of premolars counts for one, and an occluding pair of molars counts for two. All patients received a CT or cone-beam computed tomography (CBCT) scan before treatment, and within two weeks and six months after the start of the treatment. These scans were used to assess the final position and classify the morphology of the affected condyle. Besides, mandibular functioning and pain were evaluated six months after the start of the treatment.

CT SCANS

All patients received a CT scan on which the condylar fracture was diagnosed. A second CT scan was made to evaluate the direct effect of the treatment within two weeks after treatment. This scan was preferably a CBCT scan, however, a CT scan was made if a patient was unstable. A follow-up CBCT scan was retrieved to evaluate the final situation of the affected condyle six months after the start of the treatment. These CBCT scans were captured with the i-CAT 17-19™ (Imaging Sciences International LLC, Hatfield, PA, USA), VGi EVO (NewTom, Imola, Italy), and Pax Zenith 3D systems (VATECH, Hwaseong-si, South Korea). Voxel size was set 0.3 or 0.4 mm, independent of the CBCT system, and field of view was set to capture the whole mandible including both condyles. The follow-up CBCT scans were used for the 3D analysis of the final position of the affected condyle to evaluate if the anatomical position was achieved.

DATA PROCESSING OF CBCT SCANS

Segmentation

Digital Imaging and Communications in Medicine (DICOM) data from follow-up CBCT scans were imported into Mimics (Version 24.0, Materialise, Leuven, Belgium) for semi-automatic segmentation of the mandible. At first, a reduced scatter filter was applied to reduce metal artifacts. Next, bone tissue was segmented by thresholding based on grayscale levels (Fig. 1a). Manual post-processing of the segmentation mask was necessary to achieve accurate bone representation of the condyle. Manual segmentation was performed on a few slices and subsequently auto-interpolated between these slices. Surgical plates and screws were manually excluded (Fig. 1b-c). Subsequently, the segmentation mask was transformed into a 3D object using interpolation to acquire continuity between voxels (Fig. 1d). Finally, the object was smoothed by manual fine-tuning of irregularities and automatic global smoothing (Fig. 1e).

Registration

3D objects of the mandible were further processed in 3-Matic (version 16.0, Materialise, Leuven, Belgium) to enable the comparison of the 3D positions of the affected condyle to the contralateral healthy condyle. At first, the 3D object was duplicated and mirrored over the sagittal midplane, resulting in two objects: 1) the original mandible focusing on the healthy condyle, and 2) the mirrored mandible concentrating on the affected condyle. The mirrored mandible was automatically globally aligned with the original mandible (Fig. 2a-b). Next, regions for refined registration were selected on both objects. This was achieved by manual annotation of landmarks, which were used for the automatic creation of planes that defined the borders of the selected region. The following landmarks were selected: the lowest point of the sigmoid notch (Sn) of both mandibular sides, gonion (Go) of both mandibular sides, and the most posterior point of the healthy condylar head (Co). The posterior ramus plane was defined as the plane through both Go-landmarks and the Co-landmark. Perpendicular to this posterior ramus plane and through both Sn-landmarks, the sigmoid notch plane was defined. The sigmoid notch plane marked the superior border of the region for registration. The anterior border was set by the parallel ramus plane, which was the plane parallel to the posterior ramus plane through the Sn-landmark of the side of interest. The inferior and posterior borders of the region for registration followed the edge of the mandible (Fig. 2c). Based on these selected regions, the mirrored mandible object was registered to the original mandible object with the iterative closest point (ICP) algorithm (Fig. 2d). This resulted in a refined overlay of affected and healthy sides of the mandible, enabling the comparison of the 3D positions of the affected and healthy condyles (Fig. 2e).

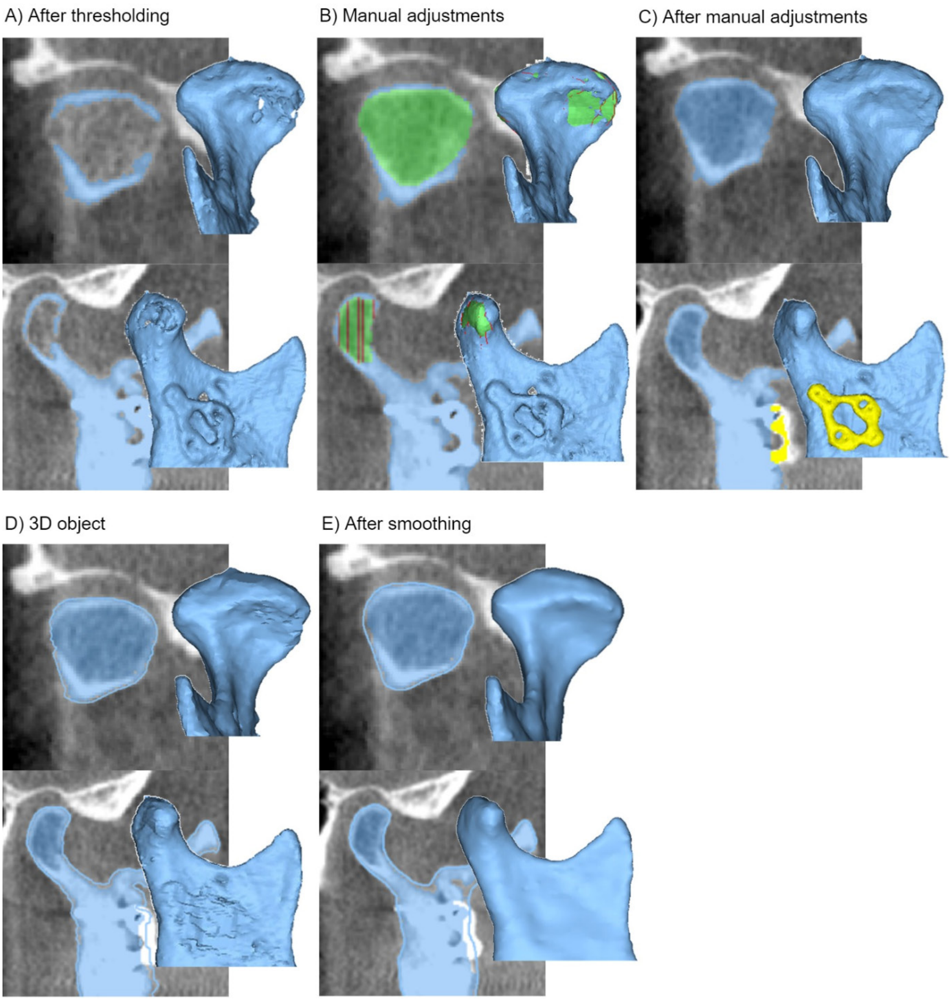

Figure 1. Semi-automatic segmentation of the mandible. A. mask after thresholding; B. manual correction (red) with automatic interpolation (green); C. mask after manual corrections, also excluding surgical plates screws (yellow); D. conversion of the mask to 3D object; E. 3D object after semi-automatic smoothing.

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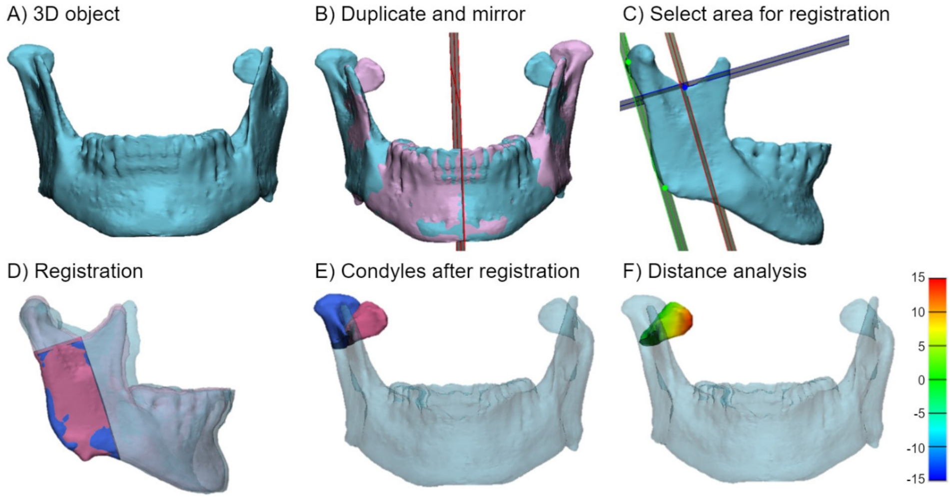

Figure 2. Registration of affected mandibular condyle to contralateral healthy condyle. A. initial 3D object with the affected condyle at the left side; B. duplicated object (pink) of initial object (blue), mirrored over midplane; C. posterior ramus plane (green), sigmoid notch plane (blue), and parallel ramus plane (red) defining the selected area for registration; D. registration of mirrored and initial objects based on selected areas; E. position of affected condyle related to the healthy condyle after registration; F. colormap presenting distance (mm) between condyles.

3D position

To compare both condyles, the (absolute) volume difference, root mean square (RMS) of the distances, translation, and rotation were determined. The inferior border of both condyles was defined by the sigmoid notch plane. The volume difference was determined by subtracting the volume of the healthy condyle from the volume of the affected condyle in 3-Matic. Absolute volume differences were also calculated, to indicate the overall differences between both condyles. Next, the signed Euclidean distance was calculated from the affected condyle to the closest point of the healthy condyle in 3-Matic (Fig. 2f). The RMS of these distances was calculated by first squaring the distances, then taking the mean, and finally neutralising the squaring by taking the square root. The RMS provided information about the extent of differences between the 3D positions of both condyles.

Analysis of the 3D position of the affected condyle in comparison to the healthy condyle was elaborated in 3DMedX® (Version 1.2.24.0, 3D Lab RadboudUMC, Nijmegen, The Netherlands). The positions of both condyles after the refined registration were set as the initial positions. Next, the affected and healthy condyles were aligned utilising the ICP algorithm based on the condylar heads. The performed transformation was saved and the translations and rotations of the affected condyle were extracted. The translations presented the displacement of the affected condyle compared to the healthy condyle in medial-lateral, anterior-posterior, and inferior-superior directions. The rotations demonstrated the pitch,

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roll, and yaw of the affected condyle with the condyle object origin as the center of rotation. Pitch, roll, and yaw were the rotations around the medial-lateral, anterior-posterior, and inferior-superior axis, respectively. Translations and rotations were presented in absolute values. Moreover, the total 3D Euclidean distance was calculated by taking the square root of the sum of the squared translations in each of the three directions. Besides, the sum of the rotations was calculated as an estimate of the total rotation.

Reliability

The reliability of the data processing was evaluated for the segmentation and registration steps.

Good to excellent inter- and intraobserver reliability has already been reported for semi-automatic segmentation of mandibular condyles on CBCT scans.[13–15] To verify the reliability of the segmentation of condyles treated for unilateral fracture, segmentation was performed twice by the same observer with an interval of one month and once by another observer for a sample of the included patients (three randomly selected patients from each group). The Dice similarity coefficient (DSC) was determined between segmentations of the affected condyle, healthy condyle, and mandible without dental area. The DSC statistically measures the similarity based on the spatial overlap[16]. The DSC was calculated by dividing two times the volume of the overlap between two segmentations by the total volume of these segmentations. The DSC could have values between 0 and 1, with 0 indicating no overlap and 1 presenting complete overlap between objects. Good overlap occurs when DSC > 0.70.[16] The DSC for interobserver segmentations was > 0.92 for the affected condyle, > 0.94 for the unaffected condyle, and > 0.96 for the mandible without dental area for all six patients. The DSC for intraobserver segmentations was > 0.95, > 0.94, and > 0.97 for the affected condyle, unaffected condyle, and mandible without dental area, respectively. These good DSC values indicate that the method of segmentation was reliable.

To assess the inter- and intraobserver reliability of the semi-automatic registration, the registration was performed twice by the same observer with an interval of one month and once by another observer with the same segmented 3D objects for all included patients. Intraclass correlation coefficients (ICCs) were calculated between the condylar volumes, volume differences, and RMS of the distances. A two-way random model with an absolute agreement was applied. ICC(2,2) and ICC(2,1) were applied for inter- and intraobserver reliability respectively. ICCs were interpreted as poor (< 0.50), moderate (0.50 – 0.75), good (0.76 – 0.90), and excellent (> 0.90) reliability.[17] The inter- and intraobserver registrations resulted in ICCs > 0.99 with *P*-values of 0.000 for condylar volume, volume differences, and RMS of the distances, presenting excellent reliability of the registration method.

MANDIBULAR FUNCTIONING AND PAIN

Mandibular functioning and pain were evaluated during the assessment six months after the start of treatment. Functioning was objectively assessed by the maximum mouth opening and masticatory performance. Besides, the masticatory ability and pain were evaluated as PROs. These mandibular functioning and pain scores were associated with the 3D position of the affected condyle regardless of the performed treatment modality.

Objective functional outcomes

The maximum mouth opening was measured by the maximum interincisal opening (MIO). The MIO was measured intraorally as the distance between the central incisors of the maxilla and mandible in closed and active maximal open positions. Excellent reliability (ICC = 0.88 -0.98) was reported for the MIO.[18](Rauch et al., 2018)

The masticatory performance was evaluated by the Utrecht Mixing Ability Test (MAT). A comprehensive description of the MAT was previously published.[19–21] The MAT assesses the patient's ability to mix two wax layers of the colors red and blue. The outcome of the MAT is the Mixing Ability Index (MAI), which evaluates the ability to mix both colors in 15 chewing strokes. The MAI is obtained by measuring the intensity distribution of the red and blue colors in digital photographs of both sides of the wax after flattening. The MAI ranges from 5 to 30, with 5 presenting a fully mixed wax tablet and 30 an unmixed tablet. The better the mixing, the better the masticatory performance. Excellent test-retest reliability (ICC = 0.91) was reported for the MAT in condylar trauma patients.[22]

Patient-reported outcomes

The masticatory ability was assessed by the Mandibular Function Impairment Questionnaire (MFIQ), which is a reliable instrument for measuring a patient's perception of mandibular functioning.[22–24] This questionnaire consists of 17 items. Each item is scored using a five-point Likert scale on which patient indicate their experienced level of difficulty while performing mandibular movements or tasks. The total outcome ranged from 0 to 68, with 0 presenting no mandibular function impairment and 68 a poor functional outcome.

The patient's experienced pain was scored by a visual analog scale (VAS_{pain}). This VAS_{pain} consists of a 100 mm horizontal line on which the patient chooses a position, with 0 mm indicating no pain and 100 the worst imaginable pain. The VAS_{pain} was reported reliable to assess acute pain.[25]

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MORPHOLOGY

The morphology of the affected condyle was classified according to the AOCMF classification based on all three (CB)CT scans of each patient. This classification evaluated, fracture level, fragmentation, sideward displacement, and angulation of the condylar fracture. Fragmentation was classified as none (0), minor (1), or major (2) depending on the number of fragments and structural integrity of the condylar process. Six months after the start of the treatment, the condylar fractures were ossified, meaning that there was no fragmentation. Sideward displacement was classified as none (0), partial (1), or full (2) independent of the direction of displacement. Angulation was classified as <5° (0), 5 – 45°

(1), or >45° in any direction.[12] The affected condyles were classified by two observers until consensus was achieved. Additionally, classifications were compared between consecutive scans and categorised as improved, unchanged, or deteriorated.

STATISTICAL ANALYSIS

Descriptive statistics were used to describe patient characteristics. Normal distributed continuous data were presented as means and standard deviations, ordinal and non-normal distributed continuous data as medians and interquartile ranges (IQRs), and nominal as frequencies. Normal distribution was assessed visually and evaluated with the Shapiro-Wilk test and the z-values of skewness and kurtosis. To determine significant differences between the open and closed treatment groups the independent t-test was applied for normally distributed continuous data, Mann-Whitney U test for ordinal and non-normally distributed continuous data, and chi-square test or Fisher's exact test for nominal data. The Pearson's (r; normally distributed continuous data) or Spearman's correlation coefficient (r_s; non-normally distributed continuous data) was obtained to correlate the 3D position of the affected condyle with mandibular functioning and pain scores for the patients of both groups together. Absolute values of correlations were interpreted as weak (< 0.35), moderate (0.35 – 0.67), high (0.68 – 0.89), and very high (≥ 0.90).[26] *P*-values below 0.05 were considered statistically significant. All statistical analyses were performed using SPSS software (version 27, IBM, NY, USA).

RESULTS

Of the 33 participating patients included in this CCT, 12 were excluded for this study. These patients were excluded because of having a ramus fracture with dislocation or fragmentation (n=2), absence of the follow-up scan (n=6), incomplete capture of condyles at the follow-up scan (n=3), or major movement artifact at the follow-up scan (n=1). Eleven patients were included in the open treatment group and 10 in the closed treatment group. There were no significant differences between the open and closed treatment groups for age, gender, fractured side, fractured region, other mandibular fractures, occluding units, and mandibular functioning and pain scores as depicted in Table 1. No physiotherapy was applied in both groups during the 6 months follow-up of this study.

3D POSITION

The (absolute) volume differences, RMS of the distances, translations in anterior-posterior and inferior-superior directions, total 3D distance, and rotations did not significantly differ between the open and closed treatment groups at six months follow-up. Only the translation in the medial-lateral direction significantly differed between both treatment groups, presenting less translation after open treatment (Table 2).

Table 1. Characteristics of the patients receiving open or closed treatment. Data are presented as median (interquartile range) or frequency.

Characteristic	Open treatment group (n=11)	Closed treatment group (n=10)	*P*-value
Age, y	51 (25 – 54)	29 (25 – 32)	.204[b]
Gender			.183[a]
Male	5	8	
Female	6	2	
Fractured side			.361[a]
Left	6	8	
Right	5	2	
Fractured region			.670[a]
Neck	4	5	
Base	7	5	
Other mandibular fractures			.601[a]
No	6	4	
Paramedian contralateral	1	4	
Corpus contralateral	1	1	
Angulus contralateral	2	1	
Multiple regions contralateral	1	0	
Trauma to treatment interval, d	1 (1 – 3)	2 (1 – 2)	.798[b]
OU	12 (10-12)	12 (12-12)	.171[b]
Treatment to follow-up scan interval, m	5.9 (5.7 – 6.4)	6.2 (5.5 – 6.7)	.673[b]
MAI at follow-up	17.4 (16.4 – 19.4)	16.9 (16.1 – 18.4)	.217[b]
MIO at follow-up, mm	46.0 (35.0 – 52.0)	44.0 (38.3 – 53.6)	.944[b]
MFIQ at follow-up	13.0 (0.0 – 18.0)	5.0 (0.5 – 8.5)	.156[b]
VAS_{pain} at follow-up	1.0 (0.0 – 5.0)	0.0 (0.0 – 2.3)	.332[b]

[a]Fisher's exact test, [b]Mann-Whitney U test
d: days; m: months; MAI: mixing ability index; MFIQ: mandibular function impairment questionnaire; MIO: maximum interincisal opening; mm: millimeter; OU: Occluding Units; VAS_{pain}: visual analog scale for pain; y: years.

Table 2. Parameters presenting 3D position of the affected condyle of the patients receiving open or closed treatment at six months follow-up. Data are presented as median (interquartile range).

Parameter		Open treatment group (n=11)	Closed treatment group (n=10)	*P*-value
Volume difference, mm^3		64.4 (-185 – 234)	-220 (-294 – 124)	.260
Absolute volume difference, mm^3		185 (118 – 315)	241 (160 – 461)	.481
RMS of the distances		2.0 (1.4 – 3.5)	4.6 (2.5 – 6.4)	.078
Absolute translation, mm	Medial-lateral direction	0.3 (0.1 – 2.9)	4.1 (1.3 – 6.4)	.014*
	Anterior-posterior direction	1.3 (0.7 – 4.4)	3.9 (1.5 – 7.9)	.205
	Inferior-superior direction	1.3 (0.8 – 2.3)	2.1 (0.9 – 7.0)	.573
	Total 3D distance	2.5 (2.0 – 6.5)	8.0 (3.3 – 12.2)	.139
Absolute rotation, °	Pitch	8.0 (7.0 – 19.8)	9.1 (3.3 – 30.6)	.622
	Roll	7.0 (2.5 – 16.3)	12.0 (5.3 – 28.7)	.260
	Yaw	10.3 (2.0 – 17.5)	21.2 (2.3 – 34.3)	.159
	Sum of rotation	27.8 (21.1 – 47.7)	51.2 (36.2 – 71.1)	.057

Statistical analyses are performed by the Mann-Whitney U test; *: $p < 0.05$.
3D: three dimensional; mm: millimeter; mm^3: cubic millimeter.

3D POSITION VERSUS MANDIBULAR FUNCTIONING AND PAIN

Weak to moderate correlations were found between the 3D position and mandibular functioning and pain for the patients of open and closed treatment groups together (Table 3). The MIO demonstrated significant correlations with the RMS (r_s = -0.569), absolute volume difference (r_s = -0.460), translation in the anterior-posterior direction (r_s = -0.441), and total 3D distance demonstrated (r_s = -0.574). There were no significant correlations found between any of the parameters describing the 3D position and the MAI. The pitch rotation was significantly correlated with the MFIQ (r_s = 0.499). The volume difference presented a significant correlation with VAS_{pain} (r_s = -0.503).

Table 3. Spearman correlation coefficients between 3D position of the affected condyle and mandibular functioning and pain scores of the patients in open and closed treatment groups together at six months follow-up.

Spearman correlation coefficient			MAI	MIO	MFIQ	VAS_{pain}
Parameters 3D position	Volume difference		.085	.405	-.099	-.503*
	Absolute volume difference		-.123	-.460*	-.144	.257
	RMS of the distances		.011	-.569**	.069	-.010
	Absolute translation	Medial-lateral direction	-.054	-.351	-.111	-.012
		Anterior-posterior direction	-.130	-.441*	.285	.175
		Inferior-superior direction	.174	-.113	.191	-.133
		Total 3D distance	-.018	-.574**	.205	.089
	Absolute rotation	Pitch	.194	-.286	.499*	.050
		Roll	.049	-.363	.073	.154
		Yaw	.304	.035	-.284	-.159
		Sum of rotation	.212	-.398	.035	-.018

*: $P < 0.05$; **: $P < 0.01$.
MAI: mixing ability index; MFIQ: mandibular function impairment questionnaire; MIO: maximum interincisal opening; RMS: root mean square; VAS_{pain}: visual analog scale for pain.

6

MORPHOLOGY

The AOCMF classification of the morphology of the affected condyles on the pre-treatment, post-treatment, and follow-up (CB)CT scans revealed no significant differences between the open and closed treatment groups (Table 4). There was a significant difference in the comparison of the pre- and post-treatment classification between both treatment groups. The classification was for more patients improved within the open treatment group compared to the closed treatment group. There was no significant difference in the comparison of the post-treatment and follow-up classification.

Table 4. Morphology of mandibular condyle after fracture presented by the AOCMF fracture classification[12] for the patients receiving open or closed treatment based on (cone beam) computed tomography scans captured pre-treatment, post-treatment, and at six months follow-up.
Data are presented as median (interquartile range) for ordinal data with frequencies for each category, and as frequency for nominal data.

AOCMF classification of affected condyle		Open treatment group (n=11)	Closed treatment group (n=10)[c]	*P*-value
Pre-treatment	Fragmentation	0 (0 – 1)	0 (0 – 0.25)	.254[b]
	None	6	8	
	Minor	3	1	
	Major	2	1	
	Sideward displacement	2 (1 – 2)	1.5 (0 – 2)	.193[b]
	None	1	4	
	Partial	2	1	
	Full	8	5	
	Angulation	1 (1 – 1)	1 (0 – 1.25)	.490[b]
	< 5°	1	3	
	5 - 45°	8	5	
	> 45°	2	2	
Post-treatment	Fragmentation	0 (0 – 0)	0 (0 – 0.50)	.392[b]
	None	10	7	
	Minor	1	1	
	Major	0	1	
	Sideward displacement	0 (0 – 1)	2 (0 – 2)	.097[b]
	None	8	4	
	Partial	2	0	
	Full	1	5	
	Angulation	0 (0 – 1)	1 (0 – 1.5)	.301[b]
	< 5°	6	3	
	5 - 45°	4	4	
	> 45°	1	2	
Follow-up	Fragmentation	0 (0 – 0)	0 (0 – 0)	1.000[b]
	None	11	10	
	Minor	0	0	
	Major	0	0	
	Sideward displacement	0 (0 – 0)	0 (0 – 2)	.118[b]
	None	10	6	
	Partial	0	1	
	Full	1	3	
	Angulation	1 (0 – 1)	1 (0 – 1.25)	.397[b]
	< 5°	5	3	
	5 - 45°	5	5	
	> 45°	1	2	
Post-treatment versus pre-treatment				.002[a]*
Improved		9	1	
Unchanged		1	7	
Deteriorated		1	1	
Follow-up versus post-treatment				.642[a]
Improved		3	2	
Unchanged		6	7	
Deteriorated		2	0	

[a]Fisher's exact test, [b]Mann-Whitney U test; *: $P < 0.05$; [c]: n = 9 for post treatment classification for closed treatment group.

DISCUSSION

The choice of open or closed treatment for unilateral fractures of the mandibular condyle remains controversial. This study compared open and closed treatment by the final 3D position of the affected condyle. The translation in the medial-lateral direction was the only parameter presenting the 3D position that significantly differed between both treatment groups, demonstrating less translation of the affected condyle compared to the pursued anatomical position after open treatment. Associating the 3D position of the affected condyle with mandibular functioning and pain presented only weak to moderate correlations for the patients of open and closed treatment groups together. The AOCMF classification of the morphology of the affected condyles on the pre-treatment, post-treatment, and follow-up (CB) CT scans revealed no significant differences between the open and closed treatment groups.

3D POSITION AND MORPHOLOGY

Open treatment allows anatomical reduction. Thereby minimal differences between the affected and healthy condyles were expected immediately after treatment. A prospective cohort study revealed mean displacements of the affected condyle compared to the healthy condyle of 0.8° and 1.9° for coronal and sagittal displacements, respectively, immediately after open treatment, indicating a good anatomical reduction.[27] A randomised controlled trial (RCT) demonstrated a significant decrease in the angulation of the fractured condyle and shortening of the ascending ramus in the open treatment group from pre-operative to immediately postoperative, which was not so in the closed treatment group.[4] Similar results were found in our study, which demonstrated that 9 of the 11 patients had an improved morphology of the affected condyle immediately after open treatment. This was significantly different from the results for the patients after closed treatment. Most patients had an unchanged morphology immediately after the start of closed treatment.

However, postsurgical changes are known to occur. A prospective cohort study revealed that between 10% and 20% of the condyles had changes in positions of more than 10° between measurements immediately after surgery and six months follow-up.[27] That study presented mean displacements of the affected condyle compared to the healthy condyle were 4.0° and 3.1° for coronal and sagittal displacement, respectively, at six months follow-up. Our study presented that the morphology of the affected condyle deteriorated for 2 of the 11 patients between the post-treatment and six months follow-up measurements after open treatment. One of these patients had a poor result of the open treatment, with the affected condyle placed in a non-anatomical position during surgery, and the morphology deteriorating during the post-operative course. None of the patients in the closed treatment group had a deteriorated morphology of the affected condyle between post-treatment and follow-up measurements. Nonetheless, the morphology of the affected condyle did not significantly differ between open and closed treatment groups at six months follow-up.

The final position of the affected condyle was evaluated in more detail in earlier studies based on two-dimensional orthopantomograms and radiographs in Towne's view. A retrospective study demonstrated no statistically significant relationship between the method of treatment and coronal and sagittal displacement and loss of ramus height at six months follow-up.[28] However, two other studies presented significantly less angulation of the affected condyle and shortening of the ascending ramus after open treatment compared to closed treatment at follow-up.[4,29]

Our study showed that the final 3D position of the affected condyle was significantly more translated in medial-lateral direction compared to the healthy condyle after closed treatment than after open treatment. However, the other parameters presenting the 3D position did not significantly differ between groups (Table 2). For parameters presenting *P*-values between 0.1 and 0.9, there is certainly no reason to suspect that these are different between open and closed treatment groups.[30] The RMS of the distances and sum of rotation had *P*-values of 0.078 and 0.057, respectively. These values were larger than the designated threshold of significance for this study, but differences between open and closed treatment groups cannot be eliminated. The median values showed smaller RMS of the distances, (absolute) volume differences, translations, and rotations for treated condyles after open treatment compared to closed treatment. This suggests that the 3D position of the treated condyle might be more symmetric to the contralateral condyle after open treatment compared to closed treatment, implying a better anatomical result after treatment.

3D POSITION VERSUS MANDIBULAR FUNCTIONING AND PAIN

The best association was found between the total 3D distance and MIO with r_s= -0.574, indicating that the larger the translation of the affected condyle in any direction, the smaller the mouth opening. The second best association was found between the RMS of the distances and MIO with r_s= -0.569, meaning the larger the distance (either positive or negative) between the healthy and mirrored and transformed affected condyles, the smaller the mouth opening. Other significant associations with the MIO were found for the translation in the anterior-posterior direction and the absolute volume difference, also presenting moderate negative correlations. Thus, a worse position of the affected condyle is moderately correlated with lower MIO.

None of the parameters presenting the 3D position of the affected condyle were significantly associated with the MAI, suggesting that the objective efficiency of the masticatory process is not affected by the 3D position of the affected condyle. The MAI of both treatment groups in our study equals the MAI of healthy subjects, presenting a good clinical outcome.[20] Mastication does not only depend on the condylar position, but also on muscles, ligaments, and occlusal units. Musculature, skeleton, and dentition adapt for a favourable outcome after condylar fracture. Earlier research demonstrated that restoring the condyle after fracture to its

initial position does little to alter changes in chewing patterns.[31] This supports our finding that the 3D position of the condyle is not significantly associated with the MAI.
The association between the patient's experience and the 3D position of the affected condyle was restricted. The MFIQ presented only a significant correlation with pitch rotation with r_s = 0.499 at six months follow-up. The larger the rotation of the condyle to anterior or posterior, the higher the MFIQ score, which means a poorer experience of mandibular functioning.

The experienced pain only correlated significantly with the volume difference between affected and healthy condyles with r_s = -0.503. This negative correlation presents that negative volume differences are associated with higher VAS_{pain} and positive volume differences with lower VAS_{pain}. Negative volume differences occurred when the volume of the affected condyle was less than the volume of the healthy condyle, for instance, due to relapse. Thus, a poorer position of the condyle is associated with more pain at six months follow-up. Positive volume differences could have occurred due to remodelling of the treated side. This suggests that a remodelled bone does not necessarily lead to pain.

No other studies were identified that associated the 3D position of condyles with mandibular functioning or pain in patients after a unilateral fracture. Earlier studies associated the position of the condyle in the fossa with other functional outcomes than evaluated in our study for patients with non-traumatic oral- maxillofacial pain or healthy subjects.[32,33]

STRENGTHS AND LIMITATIONS

To the best of our knowledge, this was the first study that compared the position of the affected condyle between patients after open and closed treatment based on 3D analysis, and the first study that associated this 3D position with mandibular functioning and pain. Although a larger number of study patients would be interesting, this study indicate new information. The data processing of CBCT scans was extensively documented which allows reproduction for future research. The data processing was automated as much as possible to eliminate operator errors and facilitate a less time-consuming workflow. The applied methods of segmentation and registration were proven to be reliable.
The affected condyle was compared to the healthy contralateral condyle. Anatomical variations in position and morphology between healthy contralateral condyles were not considered in the analysis. The anatomical variation depends on the growth pattern, as evaluated in a cross-sectional study.[34] That study presented that condyles in non-traumatic patients with normal occlusion showed no significant asymmetry for the diameter of the condyle and the position of the condyle in the fossa. Significant differences were reported for the position of both condyles related to the mid-sagittal plane. Our study registered the condyles at the ascending ramus, so the comparison of the condyles was not performed related to the mid-sagittal plane. Thereby, it is expected that the anatomical variation in position and morphology of condyles would not have significantly affected the results.

The RMS of the distances between affected and healthy condyles was retrieved from closest point calculations. This closest point did not automatically correspond to the same anatomical location, especially in large deviations between the object surfaces. Correspondent point calculations use shape analysis to map the distance between correspondent anatomical points.[35] The use of correspondent point calculations for comparing affected and healthy condyles could be investigated. It may lead to more accurate results, but in-depth knowledge is required to make use of this technique, which makes it difficult for the wider medical community.

This study was performed in two different hospitals with different standard treatment protocols for unilateral condyle fractures, which limits the risk of inclusion bias. This CCT remains less strong than an RCT; however, trauma patients are less likely to participate in a randomised study, mainly because of personal preference for one form of treatment and the dislike of the idea of randomisation.[36]

RECOMMENDATIONS

This study gives insight into the final position of affected condyles after open or closed treatment, but this should be interpreted with caution because of the small sample size. More research is necessary to underline the differences or similarities in condylar anatomy between open and closed treatment.

None of the 3D position parameters that significantly correlated with mandibular functioning or pain scores significantly differed between open and closed treatment groups. The 3D position parameters that were significantly associated with mandibular functioning seem to be of no significant influence on the choice of treatment.
Thereby, it may be preferable to avoid surgery and concomitant complications.[37] Besides, closed treatment avoids operating room time, more expensive equipment, a longer general anesthesia time, hospitalisation, and sickness leave cost.[1010] However, closed treatment requires more patient commitment since more visits to the outpatient clinic may be necessary. Open treatment is preferable in specific patients, but future research is necessary to reveal for which patients which treatment is indicated.[38]

In conclusion, open treatment of unilateral condylar fractures results in a better fracture reduction than closed treatment, considering the significantly lower translation in the medial-lateral direction of the affected condyle compared to the pursued anatomical position at six months follow-up. The final position of the affected condyle is not associated with masticatory performance; however, a worse position is associated with a smaller mouth opening. A worse pitch rotation of the affected condyle is associated with a worse patient-reported masticatory ability. Besides, patients who have a volume reduction of the affected condyle report more pain.

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CHAPTER 7

General discussion and summary

GENERAL DISCUSSION AND SUMMARY

This thesis addresses mandibular condylar neck and base fractures and present the functional and anatomical outcomes of open and closed treatment.
Condylar fractures of the mandible have a major influence on functioning of the mandible by disturbance of the anatomy of the bone itself and the surrounding soft tissues. Functioning of the mandible is normally a well-coordinated interplay of all anatomical structures: bone, muscles, ligaments, articular discs of the temporomandibular joint (TMJ), nerves, and blood vessels. Minor disturbance in this interplay will challenge both the physician and the patient in recovery to acceptable functional outcomes of the mandible. This path to recovery can be observed from an objective point of view, measuring masticatory performance with objective and repeatable tests, and from a patient's point of view, measuring masticatory ability by questionnaires and outcomes reported by the patient (PROMs). Focusing on both points of view is of importance regarding factors that play an important role in masticatory functioning. When focusing on treatment methods, however, literature is inconclusive. There is still an ongoing discussion whether to perform surgery, or not.

> *Chapter 2: The primary aim was to appoint what kind of soft tissue injuries appear after mandibular condylar fractures. The secondary aim was to investigate the influence of soft tissue injuries on oral functioning in adults and if there is a relation between soft tissue injuries and oral functions. The third aim was to get insight into the used MRI settings to visualise the damaged tissues for future use in research and clinical use.*

There are five levels of evidence, assigned to studies based on the methodological quality of their design, and applicability to patient care, level 1 being the highest level of evidence. In **chapter 2** we reached level 2 evidence with a systematic overview of existing literature describing the different soft tissue injuries after mandibular condylar fractures and its influence on masticatory functioning. Sixteen studies, with a total number of 907 patients were included for analysis. Intracapsular fractures and dislocated condylar fractures result in more severe injuries like disc displacement.[1–3] Serious injury to the disc and capsule of the TMJ is a contributing factor towards development of complications, such as decreased mouth opening, restricted range of movement, joint noise and pain. As long as early mobilisation of the joint is instituted, hemarthrosis disappears soon and therefore plays a small role in the development of postoperative ankylosis.[4] It is hard to conclude if functional outcome or complication are due to the treatment modality or to the soft tissue injury. If complications regarding mandibular functioning are the direct result of soft tissue injury, repair and reconstruction of the soft tissue of the TMJ (functional open treatment) might be indicated.[5,6] For now, evidence is insufficient and functional open treatment is therefore not conducted in acute setting. In the UMCU , a conservative attitude is adopted and in case of persisting complaints, secondary reconstruction is indicated. Regarding to MRI, a wide variety of used settings, planes and positions is used in research, due to different vendors and different naming in settings, which makes it hard to compare different studies. Ideally MRI should be done pre- and posttreatment in research setting to investigate indications for performing functional open treatment. However, clinical use of MRI in acute setting is time-consuming, often unavailable and therefore hard to perform in multi-trauma patients which are the majority of patients in a level I trauma centre like UMC Utrecht..

The Utrecht Mixing Ability Test (MAT) is an objective test to measure masticatory functioning and is developed for patients treated for oral cancer.[7,8] This test was not validated for condylar trauma patients specifically.

> Chapter 3: *The aim of this study is to determine, on the one hand, the test-retest reproducibility (reliability, measurement error and agreement) of the mixing ability test (MAT), and, on the other hand, the construct validity of the MAT in relation to the mandibular functioning impairment questionnaire (MFIQ) in patients with mandibular condylar fractures. We hypothesise that the reproducibility of the MAT will be sufficient (ICC ≥ 0.7) and that the construct validity would be at least moderately correlated (≥ 0.60).*

In **chapter 3** the reliability, measurement error, agreement, and construct validity of the MAT was investigated in patients treated for condylar mandibular fractures. To investigate the construct validity, the MAT was tested for convergent association with the mandibular function impairment questionnaire (MFIQ). In total, 26 patients were included in this study, and all underwent a test and retest. An excellent test-retest reliability of the MAT in patients with a condylar fracture was found (ICC = 0.906, 95% CI: 0.801-0.957). The hypothesis that the construct validity of the MAT would at least be moderate, could not be confirmed since the weak positive correlation (r = 0.39, P = 0.052) of the first test taken and the MFIQ was not convincingly significant. However, there was a moderate correlation of the retest of the MAT with the MFIQ (r = 0.40, P = 0.042). This weak-moderate correlation could be explained by the fact that the MFIQ reflects the subjective masticatory ability and comprehends questions about multiple aspects of the mandible, whereas the MAT reflects the objective complex masticatory movements and coordination. Therefore, combining measurements of objective- and subjective functioning are complementary to each other, should strengthen each other and lead to treatment in a way that meets the needs of patients.[9–13]

> Chapter 4: *The first aim was to find explanatory demographic and clinical variables for masticatory performance and ability in patients who received closed treatment for unilateral condylar neck or base fractures at least 5 years ago. The second aim was to compare masticatory performance and*

masticatory ability between patients with a history of condylar fractures and healthy subjects.

In a cross-sectional study conducted in **chapter 4**, masticatory functioning outcomes for patients treated with closed treatment for unilateral mandibular condylar neck or base fractures were investigated and further compared with a group of healthy subjects. The study population contained 21 patients and 30 healthy subjects. The patient group was examined 11.7 years on average after initial treatment. The MAI and MFIQ are not a significant explanatory factor towards each other, confirming our previous findings that objective and patient-reported measurements of masticatory functioning are complementary.[13] The number of occluding units was an explanatory variable for masticatory performance (R^2 = 0.253). This indicates the necessity of natural dentition with a sufficient number of occluding units for optimal masticatory performance. Preservation and restoration of occlusal units are therefore of great value in terms of masticatory performance and rehabilitation.[14] Explanatory variable for masticatory ability was pain (R^2 = 0.454). Outcomes of MFIQ and pain in this study were similar to findings in literature with a follow-up of only one year, suggesting that patients' perception of rehabilitation reaches a plateau after one year already.[15] Moreover, in the cross-sectional study, patients with a history of condylar fracture had a similar masticatory performance compared to the healthy subjects meaning mastication is comparable after one year of follow-up.[16,17]

These findings revealed a good clinical outcome in the long-term obtained with closed treatment. However, in literature there are still two camps of oral and maxillofacial surgeons: those who advocate closed treatment with maxillomandibular fixation and those who advocate open treatment with reduction and internal fixation. Though a lot of research has already been conducted on this subject of debate, it is striking that the majority of these studies focus on objective clinical outcomes measures or anatomical position of the condyle alone. A few studies combined these outcomes regarding masticatory functioning, in particular in combination with PROMs. Yet, as mentioned before, these outcomes are complementary. Besides, decreased masticatory functioning is frequently reported by the patient after maxillofacial trauma, which is important since the whole medical field is shifting from the patient as a passive receiver, towards a more and more patient-centred approach.[18] Therefore, in **chapter 5 and 6** a two-centre controlled clinical trial was obtained in which open and closed treatment were compared. This prospective study evaluated patients with unilateral condylar neck or base fractures at six weeks and six months follow-up.

Chapter 5: The aim of this study was to compare open treatment with closed treatment for unilateral condylar mandibular neck and base fractures in a controlled clinical trial by objective functional outcomes and patient reported outcomes (PROs) measured at six weeks and six months follow-up. Additionally, a comparison of objective functional outcomes and PROs was

> *made within six weeks and six months follow-up of the open and closed treatment groups.*

In **chapter 5** the focus is on masticatory functioning. Masticatory functioning was measured by objective functional outcomes (masticatory performance) and PROMs (masticatory ability). In total, 33 patients were included for analysis. No statistically significant differences between the open treatment and closed treatment groups were found for objective functional outcomes, measured by the MAT, maximum interincisal opening (MIO), protrusion and laterotrusion, and for PROMs, measured by the MFIQ and VAS_{pain} at six weeks and at six months of follow up. Meaning that when oral and maxillofacial surgeons are familiar and experienced with the treatment of choice, no differences could be expected in outcome. Treatment decision making must therefore be based on considerations such as health care-specific factors (such as costs, availability of surgeon or facilities) and patient-specific factors (such as general health, compliance or preference).

> *Chapter 6: The first aim was to analyse and compare the final position of the initially fractured mandibular condyle following open and closed treatment of unilateral fractures. The second aim was to evaluate the association between the final position of the affected condyle and mandibular functioning and pain. In addition, this study aimed to classify and compare the morphology of the condyle following open and closed treatment over time.*

In **chapter 6** the focus is on anatomical position of the fractured mandibular condyle. The position of the condyle on (conebeam) CT-scans following open and closed treatment were analysed and compared. Thereby an evaluation was done to investigate if there is an association between the degree of anatomical reduction of the mandibular condyle and masticatory functioning. In total 21 patients were included in this paper. The position of the condyle was associated with the MIO, MAT, MFIQ, and pain. These associations were weak. Open treatment results in a better fracture reduction than closed treatment at six months follow-up. The final position of the affected condyle is not associated with masticatory performance; however, a worse position of the condyle is associated with a smaller mouth opening. Besides, patients who have a volume reduction of the affected condyle report more pain.

Based on the results of chapter 6 in which anatomical, functional and PROMs are combined the clinician should be able to make a choice between open and closed treatment for condylar neck and base fractures. In favour for open reduction are anterior or posterior rotation of the condyle (pitch) as MFIQ revealed worse results if the condyle remained in the dislocated position. Besides that, MIO is slightly restricted if the condyle remained in larger translated position in all directions. A strong plea in favour of closed treatment is that MAT does not demonstrate a difference between open and closed treatment. So functionally both type of treatment is interchangeable. A third recommendation to the clinician was not investigated but is stated here. In multi trauma cases in level I trauma centres especially with concomitant midfacial and mandibular fractures, all three dimensions of the viscerocranium may be lost. In these cases, open reduction and internal fixation of condylar base and neck fractures may be helpful in restoring the anatomical dimensions of the face. Finally, indication for open reduction with internal fixation of a condylar base fracture exists in case of bilateral condylar fractures. In these cases restoration of mandibular height is achieved. This recommendation, however, is outside the scope of this thesis.

GENERAL LIMITATIONS

All research comes with limitations. Especially, conducting a surgical randomised controlled trial (RCT) (which is still considered reaching the highest level of evidence) for trauma patients is proven to be a major challenge, hence foreseeing difficulties is difficult.[19] Trauma patients are less likely to participate if a study is randomised, mainly because of personal preference for one form of treatment and in general, the dislike of the idea of randomisation.[19] Furthermore, trauma patients are somehow less compliant to research follow-up than for instance patients treated for oral cancer.[20] Therefore in **chapter 5 and 6**, we have chosen a controlled clinical trial (CCT) study design, which is lower in evidence ranking than an RCT, however, in our opinion more likely to succeed.

Originally, a third centre participated in this study with an endoscopically assisted reduction and internal fixation technique. Unfortunately, inclusion of eligible patients in this medical centre was difficult due to logistic reasons and the patients that were willing to participate, were somehow incompliant from the start. Therefore, we had to decide to stop inclusion in this centre. Additionally, inclusion rate in other centres was a challenge. Nevertheless, due to continuous attention for this research in both centres and close contact with the participating patients, we have full confidence that our sample size was the best achievable. Another hesitancy of ours before, was the heterogeneity in study population between a level 1 trauma centre (UMC Utrecht) and a level 2 trauma centre (OLVG). To our best knowledge and interpretation of our results, this doubt turned out to be unfounded.

For the cross-sectional study in **chapter 4**, the inclusion-rate and achievement of the sample size was problematic as well. Though not further investigated, this could possibly be explained by patient-related factors such as travel-issues, age, time for participation, socio-economic status or embarrassment for their mechanism of injury.[19,20]

Another difficulty in interpretation of the overall literature to compare our research results with, is the heterogeneity in reporting outcomes and the lack of use of a uniform classification system. Most studies focus on objective outcomes and only few report subjective PROMs, which makes comparison and translation into clinical relevance hard.

CONCLUSIONS OF THIS THESIS

- There is a need for uniform reporting in research papers of condylar fractures of the mandible by use of the AOCMF classification system (**Chapters 2, 4, 5 and 6**).
- The role of soft tissue injuries and the possibility to perform open functional treatment is insufficiently investigated (**Chapter 2**).
- The Mixing Ability Test is an easy, objective test of excellent reliability to measure masticatory performance in patients with condylar fractures of the mandible (**Chapter 3**).
- Patients treated for condylar fractures of the mandible by closed treatment by maxillomandibular fixation reach the same objective masticatory performance as healthy subjects after one year (**Chapter 4**).
- Patients' perception of rehabilitation after closed treatment by maxillomandibular fixation reaches a plateau after one year and remains inferior to healthy subjects (**Chapter 4**).
- Combining measurements of objective- and subjective functioning are complementary to each other and is necessary in research towards patient-centred medicine (**Chapters 3, 4 and 5**).
- Open treatment by extra-oral open reduction and internal fixation, and closed treatment by maxillomandibular fixation for unilateral condylar neck and base fractures have the same outcomes in objective functional outcome measures (MAT and range of motion) and in patient reported outcomes (MFIQ and VAS_{pain}) after 6 weeks and 6 months follow-up (**Chapter 5**).
- Open treatment of unilateral condylar fractures results in a better fracture reduction than closed treatment (**Chapter 6**).
- The final position of the affected condyle is not associated with masticatory performance; however, a worse position of the condyle is associated with a smaller mouth opening. Patients with pitch rotation in anterior or posterior direction of the affected condyle have worse MFIQ outcomes and patients with a volume reduction report more pain (**Chapter 6**).

FUTURE RESEARCH

From now on, all research in general should include objectively measured outcomes and PROMs to move towards patient-centred medicine, as objective good results do not necessarily have to be translated into patients' satisfaction, and vice versa. Thereby, use of a uniform classification, such as the AOCMF classification for mandibular condylar fractures is necessary for documentation and further differentiation between groups with different degrees of displacement. Before considering functional open treatment, in terms of reduction of soft tissues, next to open treatment of the fracture, more research is needed into the impact of soft tissue injuries on masticatory functioning.

To determine the sample size that should be required for a future study, we computed the required sample size using G*power given α = .05, power = 0.8 (1-beta), and the expected effect size for two independent means (matched pairs) with this study's MAI score outcomes at six weeks.[21,22] The mean MAI score was 20.3 (±3.0) for the open treatment group and 19.7 (±2.9) for the closed treatment group. Therefore, the required sample size is estimated at 762 subjects (381 per group). Given the number of potential subjects per centre of around 25 patients, per year, we estimate that 32 centres are needed to achieve the required inclusion in 2 years.

To conclude, based on this thesis, in order to achieve best masticatory functioning after condylar neck or base fractures of the mandible, recommendation can be made that the oral and maxillofacial surgeon uses the type of treatment that he or she is most experienced with. Complications risk, comorbidity, patient commitment and healthcare costs should be considered.

Lastly, if we compare our knowledge, treatment and perspective of condylar fractures with the old Egyptians, we have come a long way. For todays' treatment it is time to cross our t's and dot our i's and personalise it in a way that patientcare deserves.

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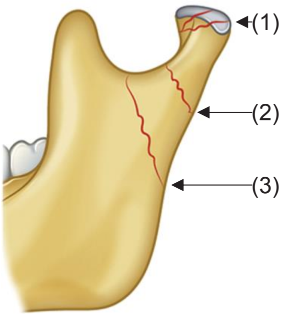
CHAPTER 8

Nederlandse samenvatting
List of publications
Dankwoord
Curriculum Vitae

NEDERLANDSE SAMENVATTING

Dit proefschrift beschrijft de functionele en anatomische resultaten van twee behandel mogelijkheden van colllum mandibulae fracturen, namelijk de conservatieve- en operatieve behandeling. De conservatieve behandeling bestaat uit het verbinden van de boven- en onderkaak met strakke elastieken (maxillomandibulaire fixatie) om zo naar een goede occlusie te sturen. De operatieve behandeling bestaat uit een snede door de huid (extra-orale benadering), waarbij de botbreuk wordt opgezocht, in de juiste positie wordt geplaatst en wordt gefixeerd met een plaatje en schroeven.



Figuur 1. Deel van de onderkaak met, weergegeven door de rode lijnen, een (1) intracapsulaire fractuur, (2) een hoge collumfractuur, en (3) een lage collumfractuur.

Collumfracturen hebben een grote invloed op het functioneren van de onderkaak door verstoring van de anatomie; enerzijds door de breuk in het bot en anderzijds door beschadiging van de omliggende zachte weefsels. Het bewegen van de onderkaak is normaal gesproken een goed gecoördineerd samenspel van alle anatomische structuren: bot, spieren, ligamenten, het temporomandibulaire gewricht (TMG), zenuwen en bloedvaten. Kleine verstoringen in dit samenspel kunnen het herstel voor de patiënt bemoeilijken. Herstel van de functie kan worden bekeken vanuit een objectief oogpunt, waarbij de kauwfunctie wordt gemeten met objectieve testen, en vanuit het oogpunt van de patiënt, waarbij functie wordt gemeten met behulp van door de patiënt gerapporteerde uitkomsten (PROs). Aandacht voor zowel objectieve uitkomsten als PROs na de behandeling van collumfracturen is van belang wanneer we willen onderzoeken welke factoren een belangrijke rol spelen bij de functie. In de kaakchirurgische literatuur is nog geen consensus welke behandeling, conservatief of operatief, het beste resultaat geeft voor de patiënt. De uitgevoerde studies in dit proefschrift zullen zich daarom op deze punten focussen.

Er zijn vijf niveaus van wetenschappelijk bewijs die worden toegekend aan studies op basis van de methodologische kwaliteit van de studieopzet en toepasbaarheid in de patiëntenzorg, waarbij niveau 1 het hoogste niveau van wetenschappelijk bewijs is. In **hoofdstuk 2** bereikten wij niveau 2 met een systematische review van bestaande literatuur waarin de verschillende weke delen letsels en de invloed hiervan op de kauwfunctie na collumfracturen worden beschreven. Zestien studies, met totaal 907 patiënten, werden geïncludeerd in dit review. Uit deze review kwamen als belangrijkste punten naar voren dat intracapsulaire fracturen en verplaatste collumfracturen resulteren in ernstiger letsel van de weke delen van het TMG.[1-3] Ernstig letsel van de meniscus en het gewrichtskapsel van het TMG geven meer complicaties, zoals een verminderde mondopening, een beperking in de beweging van de onderkaak, gewrichtsgeluiden en pijn. Wanneer vroeg wordt gestart met mobilisatie van het gewricht zal er minder stijfheid en vergroeiingen binnen het gewricht optreden.[4] Het is moeilijk te concluderen of belemmering in functie of een complicatie te wijten zijn aan het type behandeling van de collumfractuur of aan het letsel aan de weke delen. Als complicaties met betrekking tot de kauwfunctie het directe gevolg zijn van weke delen letsel, zou herstel en reconstructie van de weke delen van het TMG (functionele open behandeling) geïndiceerd kunnen zijn.[5,6] Vooralsnog is hiervoor onvoldoende bewijs. MRI is de beste manier om de weke delen letsels te diagnosticeren. In een ideale situatie zou er vóór en na de behandeling van de fractuur een MRI gemaakt moeten worden om verder te kunnen onderzoeken of herstel en reconstructie van de weke delen zinvol is. Het uitvoeren van een MRI op de spoedeisende hulp is echter tijdrovend, vaak niet beschikbaar en daarbij ook moeilijk uit te voeren wanneer het om patiënten met nog andere (grote) letsels gaat.

De Utrecht Mixing Ability Test (MAT) is een objectieve test om de kauwfunctie te meten en werd initieel ontwikkeld voor oncologie patiënten die worden behandeld voor kanker van de het hoofd-hals gebied.[7,8] Bij de MAT wordt de mate van menging van een rode en blauwe kleur op een wastablet gemeten waar patienten een aantal keer op moeten kauwen. Deze test is nog niet specifiek gevalideerd voor patiënten met collumfracturen.
In **hoofdstuk 3** werden de betrouwbaarheid, meetfout, meetovereenkomst en construct validiteit van de MAT onderzocht bij patiënten die behandeld werden voor collumfracturen. Om de constructvaliditeit te onderzoeken werd getest of de MAT geassocieerd was met een patiënt gerapporteerde uitkomstmaat; de mandibulaire functiebeperkingsvragenlijst (MFIQ). In totaal werden 26 patiënten geïncludeerd in dit onderzoek en allen ondergingen twee maal (test en hertest) de MAT. Er werd een excellente test-hertest betrouwbaarheid van de MAT bij patiënten met een collumfractuur gevonden (ICC = 0,906; 95% CI: 0,801-0,957). De hypothese dat de uitkomst van de MAT en de MFIQ gecorreleerd zijn, kon niet worden bevestigd, aangezien de zwakke positieve correlatie ($r = 0{,}39$; $P = 0{,}052$) van de eerst afgenomen test niet overtuigend significant was. Er was een matige correlatie van de hertest van de MAT met de MFIQ ($r = 0{,}40$; $P = 0{,}042$). Deze matige correlatie kan worden verklaard door het feit dat de MFIQ de kauwfunctie weergeeft die de patiënt zelf ervaart en vragen bevat over meerdere aspecten van de onderkaak, terwijl de MAT de objectieve

kauwfunctie weergeeft. Daarom zijn gecombineerde metingen van objectieve- en patiënt gerapporteerde uitkomsten complementair aan elkaar, versterken ze elkaar en leiden zo uiteindelijk tot een behandeling die aansluit bij de behoeften van patiënten.[9-13]
In een cross-sectionele studie in **hoofdstuk 4** werd de kauwfunctie onderzocht bij patiënten die gemiddeld 11,7 jaar geleden een conservatieve behandeling voor enkelzijdige collumfracturen hadden ondergaan. Vervolgens werd de kauwfunctie vergeleken met een groep gezonde proefpersonen. De onderzoekspopulatie bestond uit 21 patiënten en 30 gezonde proefpersonen. De MAT en de MFIQ vragenlijst bleken geen verklarende factor ten opzichte van elkaar te zijn, wat onze eerdere bevindingen bevestigt dat objectieve uitkomsten en PROs complementair zijn.[13] Het aantal occlusale eenheden dat een patiënt heeft, was een verklarende variabele voor de kauwfunctie (R^2 = 0,253). Het behoud en herstel van occlusale eenheden zijn daarom van grote waarde voor de kauwfunctie en rehabilitatie.[14] De verklarende variabele voor de kauwfunctie was pijn (R^2 = 0,454). Uitkomsten van de MFIQ en pijn in deze studie waren vergelijkbaar met bevindingen in de literatuur met een follow-up van slechts één jaar, wat suggereert dat de mate van revalidatie na een conservatief behandelde collumfractuur al na één jaar een plateau bereikt.[15] Bovendien was er geen significant verschil in kauwfunctie tussen patiënten met een voorgeschiedenis van collumfracturen en gezonde proefpersonen. Hieruit kan geconcludeerd worden dat de kauwfunctie één jaar na behandeling van een collumfractuur vergelijkbaar is met de kauwfunctie van gezonde personen.[16,17]

De bevindingen in hoofdstuk 4 toonden een goed klinisch resultaat op de lange termijn met de conservatieve behandeling. Hoewel er al veel onderzoek is gedaan naar conservatieve versus operatieve behandeling van collumfracturen, valt op dat de meerderheid van de studies zich alleen richt op objectieve uitkomstmaten of anatomische (eind)positie van het collum. Weinig studies combineren zowel objectieve uitkomsten als PROs. Toch zijn deze uitkomsten, zoals eerder beschreven, complementair en belangrijk en dragen deze bij aan de verschuiving in de medische zorg waarbij de individuele patiënt meer centraal komt te staan. Daarom werd een controlled clinical trial in twee centra verricht waarin de conservatieve en operatieve behandelingen werden vergeleken. Dit werd beschreven in **hoofdstuk 5 en 6**. Deze prospectieve studie evalueerde patiënten met een unilaterale lage of hoge collumfractuur zes weken en zes maanden na de behandeling.
In **hoofdstuk 5** ligt de nadruk op de functie. Kauwfunctie werd gemeten aan de hand van objectieve uitkomstmaten van het kauwstelsel, en PROs. In totaal werden 33 patiënten geïncludeerd in deze studie. Er werden geen statistisch significante verschillen gevonden tussen de conservatieve en operatieve behandelgroep voor de objectieve functionele uitkomsten kauwfunctie, gemeten door de MAT, maximale mond opening, protrusie en laterotrusie, en voor PROs, gemeten met de MFIQ en pijnscore zes weken en zes maanden na de fractuurbehandeling. Dit betekent dat wanneer de chirurg vertrouwd en ervaren is met de gekozen behandeling, er geen verschillen in uitkomst te verwachten zijn. De

besluitvorming over de behandeling moet derhalve gebaseerd zijn op overwegingen zoals zorgspecifieke factoren zoals kosten, beschikbaarheid van chirurg of faciliteiten, en patiëntspecifieke factoren zoals algemene gezondheid, therapietrouwheid of voorkeur.

In **hoofdstuk 6** staat de anatomische positie van het gefractureerde collum centraal. De positie van het collum op (conebeam) CT-scans na conservatieve en operatieve behandeling werd geanalyseerd en vergeleken. Daarbij werd onderzocht of er een verband bestaat tussen de mate van anatomische stand van het collum en de functie. In totaal werden 21 patiënten geïncludeerd in deze studie. De positie van het collum blijkt een zwakke associatie te hebben met zowel objectieve- als door patiënt gerapporteerde kauwfunctie; de maximale mondopening, MAT, MFIQ en pijn. De operatieve behandeling resulteerde in een betere stand van het collum dan de conservatieve behandeling gemeten na zes maanden. De uiteindelijke positie van het collum bleek niet geassocieerd met de kauwfunctie te zijn. Een slechtere positie van het collum was wel geassocieerd met een kleinere mondopening. Bovendien rapporteerden patiënten met een volumereductie van het aangetaste collum meer pijn.
Op basis van de resultaten van **hoofdstuk 6**, waarin de anatomische stand, objectieve uitkomsten en PROs worden gecombineerd, moet de clinicus een keuze kunnen maken tussen conservatieve en operatieve behandeling. Rotatie van het collum naar anterieur of posterieur is een reden om te kiezen voor een operatieve behandeling, aangezien de MFIQ slechtere resultaten liet zien wanneer het collum in een verplaatste positie bleef staan. Daarnaast is de maximale mondopening licht beperkt als het collum in een grotere afwijkende positie in alle richtingen stond. Deze gevonden associaties waren zwak. Een sterk pleidooi voor conservatieve behandeling is dat er geen verschil gevonden is voor de kauwfunctie tussen de conservatieve en operatieve behandeling. Dus functioneel zijn beide typen behandeling evenwaardig.

CONCLUSIES VAN DIT PROEFSCHRIFT

- Er is behoefte aan uniforme rapportage in onderzoeksliteratuur van collumfracturen van de onderkaak door gebruik te maken van het AOCMF-classificatiesysteem (Hoofdstuk 2, 4, 5 en 6).
- De rol van weke delen letsels en de mogelijkheid om een open functionele behandeling uit te voeren is onvoldoende onderzocht (Hoofdstuk 2).
- De Mixing Ability Test is een eenvoudige, objectieve test met een uitstekende betrouwbaarheid om de kauwfunctie te meten bij patiënten met collumfracturen van de onderkaak (Hoofdstuk 3).
- Patiënten behandeld voor collumfracturen van de onderkaak door conservatieve behandeling met maxillomandibulaire fixatie bereiken na een jaar dezelfde objectieve kauwfunctie als gezonde proefpersonen (Hoofdstuk 4).
- De patiënt gerapporteerde uitkomsten na conservatieve behandeling door

maxillomandibulaire fixatie bereiken ook na een jaar een plateau maar blijven inferieur aan gezonde proefpersonen (Hoofdstuk 4).

- Het combineren van objectieve metingen en patiënt gerapporteerde uitkomstmaten zijn complementair aan elkaar en is noodzakelijk in patiëntgerichte geneeskunde en gerelateerd wetenschappelijk onderzoek (Hoofdstuk 3, 4 en 5).
- Operatieve behandeling door extra-orale benadering met interne fixatie, en conservatieve behandeling door maxillomandibulaire fixatie voor enkelzijdige collumfracturen hebben dezelfde uitkomsten in objectieve functionele uitkomstmaten (kauwfunctie en bewegingen van de onderkaak) en in patiënt gerapporteerde uitkomsten (MFIQ en pijnscore) na 6 weken en 6 maanden follow-up (Hoofdstuk 5).
- Operatieve behandeling van enkelzijdige collum fracturen resulteert in een betere anatomische stand van de fractuur dan conservatieve behandeling. (hoofdstuk 6)
- De uiteindelijke positie van het aangetaste collum is niet geassocieerd met de kauwfunctie; een slechtere positie van het collum is echter wel geassocieerd met een kleinere maximale mondopening. Patiënten met rotatie in anterieure of posterieure richting van het aangetaste collum hebben slechtere MFIQ-uitkomsten en patiënten met een volumereductie van het aangetaste collum rapporteren meer pijn (Hoofdstuk 6).

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CURRICULUM VITAE

Florine Monique Weinberg was born on May 3rd of 1989 in Breda, the Netherlands. She completed grammar school in 2007 at Stedelijk Gymnasium in Breda. After a gap-year, studying Biomedical sciences, she started to study medicine at the Catholic University of Leuven, Belgium, in 2008. During these medical studies interest in maxillofacial (reconstructive) surgery grew as a result of a one-year internship in plastic and reconstructive surgery.
In 2015, she graduated from medical school with distinction and started working as a surgical resident (ANIOS) at the Albert Schweitzer Hospital in Dordrecht. At that time, the first discussions were held with both the VU medical centre and the University Medical Centre Utrecht about a forthcoming set-up of Oral and Maxillofacial research. In May 2016 she started as a PhD-student at the Department of Oral and Maxillofacial Surgery at the University Medical Centre Utrecht, VU medical centre (now Amsterdam University Medical Centres) and OLVG under supervision of prof. dr. A.J.W.P. Rosenberg, prof. dr. T. Forouzanfar and dr. C.M. Speksnijder. Between 2019 and 2021, this PhD-study was combined with the study dentistry (TOVA) at the Radboud University Nijmegen. In January 2022, she started her residency at the Department of Oral and Maxillofacial Surgery at the University Medical Centre Utrecht.
Florine is married to Joost, and they live together in Breda as proud parents of their daughters Pien (2019) and Kate (2022).

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