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Gnathodynamic analyses of function of the masticatory system using several tests of oral-motor function were examined in a sample of controls, and two groups of patients treated for fractures of the mandibular condyle. Patients treated with open reduction and internal fixation of their fracture had less impairment of oral-motor function than those treated with closed reduction. Among patients treated non-surgically, deviation of the mandible towards the side of fracture was noted during opening of the mouth.

These results indicate that masticatory function can be normalized early postsurgery by open reduction and internal fixation of their fracture.

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INTRODUCTION

The topic of condylar injury in adults has generated more discussion and controversy than any other in the field of maxillofacial trauma. It is an extremely important subject because such injuries are common; fractures of the condyle account for between 25% and 35% of all mandibular fractures in reported series.[23,75,79,92] Further, complications of trauma to the temporomandibular joint (TMJ) are far-reaching in their effects and not always immediately apparent. Disturbance of occlusal function, deviation of the mandible, internal derangements of the TMJ, and ankylosis of the joint with resultant inability to move the jaw are all sequelae of this injury. These problems are discussed below after a brief discussion of how condylar fractures are treated, and the biomechanics of jaw function following fracture of the condyle.

Treatment of Condylar Fractures

Unlike the non-surgical approach to condylar fractures in *children*, for which there is a great consensus of opinion, the treatment of condylar fractures in *adults* is still a highly debated theme. The broad range of treatment advocated for these individuals is best demonstrated in the statement by Malkin, Kresberg and Mandel:[63] "Concerning the treatment of condylar fractures, it seems that the battle will rage forever between the extremists who urge nonoperative treatment in practically every case and the other extremists who advocate open reduction in almost every case." The dichotomy between those surgeons who favor non-surgical and those who favor surgical treatment of adult condylar fractures is largely the result of two main factors. First, non-surgical treatment gives satisfactory results in the majority of cases. Second, there are no large series of patients reported in the literature who have been followed after surgical treatment since management of condylar fractures has historically been with non-surgical means. A review of the findings and associated problems with each of these methods of treatment highlights our lack of knowledge in this area.

Non-Surgical Treatment. Although non-surgical treatment is the most common method by which fractures of the mandibular condyle are treated, there is no unanimity of opinion regarding the most appropriate means by which this is accomplished. The most commonly-used method of non-surgical management involves a period of maxillomandibular fixation (MMF) followed by occlusal "guidance". Variables in this treatment are the duration of MMF and the method of occlusal guidance. While these may seem to be of little significance, they belie theories which may or may not have any underlying value.

The duration of MMF varies considerably from those who advocate "until the fracture heals", usually 6 weeks in adults,[15,26,27,43,81,109] to those who advocate a few to several days to overcome the discomfort from the traumatic edema in the muscles and/or TMJ.[3,5,41,50,78,107] Those individuals who believe that MMF should be continued until the fragments unite accept a non-reduced position following the injury. Further, they feel movement prior to healing will result in a fibrous union of the fragments. Those who advocate little or no MMF also believe that the position of the fragments is irrelevant, but that healing of the fragments will occur even in the face of active jaw movements. Their reason for mobilizing the jaw early is to "train" the muscles. In both circumstances, the formation of a "new" articulation, even if a pseudoarthrosis, is the goal of management.

The mode of occlusal "guidance" or physiotherapy also varies among surgeons. Most commonly, orthodontic elastics are used to apply force between the upper and lower dentition to "guide" the mandible into the proper relationship with the maxilla. These are usually continued until the patient can repeatedly close the mandible into the proper interocclusal relationship with the maxilla. However, the actual mechanism by which occlusal "guidance" maintains this objective is not clear. It may be a training of the musculature, i.e., establishing a new motor habit following loss of one or both temporomandibular (TM) articulations.

Further, it has been demonstrated that adaptations such as intrusion of the molars and extrusion of the incisors occur following condylar fracture, especially when interocclusal elastics are used (see below).

Surgical Treatment. Over the years, several authors have advocated surgical treatment for select condylar fractures. Their reasons are intuitively logical, arguing that since reduction and immobilization of the fracture is the goal in the treatment of every other skeletal fracture, the mandibular condyle should be no exception. These authors feel that the reason surgical treatment of condylar fractures is not practiced more commonly is because of the difficult access that surgery of the mandibular condyle presents, with the inherent anatomical hazards (i.e. VII nerve). However, most of these same authors reserve surgical treatment to condylar fractures which are displaced or dislocated, where a loss of vertical ramus support results.[12,15,18,33,47,48,51,59,62,67,68,72,80-83,95,96,101,102]

The goal of surgical treatment is to reduce the fracture, i.e. re-align the fragments to prevent the loss of vertical dimension occurring with fracture and dislocation. Another goal is prevention of postsurgical displacement of the fractured condyle by applying fixation devices (i.e. bone plates). Following surgical intervention, depending upon the rigidity of the fixation device(s), periods of MMF may be instituted and postsurgical physiotherapy with interocclusal elastics frequently used.

Biomechanics of Condylar Support

Current theoretical analysis and experimental measurements in animals indicate that forces normally are transmitted through the condylar processes during mastication and isometric biting.[4,11,32,36,38,40] Earlier studies suggesting that no forces are transmitted through the temporomandibular joint have been shown to contain serious faults.[35,38] These condylar forces serve in part to support and maintain vertical position of the masticatory apparatus during mastication and biting. The exact magnitude of these forces are currently unknown, but current theory suggests that during incisor biting both condyles will normally be loaded equally and that during unilateral biting and chewing the working side (ipsilateral) condyle will normally be less heavily loaded than the balancing side (contralateral) condyle.

The masticatory system is inherently highly adaptable and these normal patterns of loading could be modified by altering muscle activity patterns during biting and chewing.[30,98] Theoretically, loads on the working side condyle could be reduced or eliminated, although there is no evidence that this occurs in normal individuals.[98] However, it seems likely that individuals with damaged temporomandibular joints will adapt their muscle activity patterns in ways that will reduce load on the damaged joints. In addition, neuromuscular adaptation should be required to generate normal occlusal forces following damage to the temporomandibular joints. One purpose of this study is to investigate how muscle activity patterns adapt to altered biomechanical conditions following damage to the temporomandibular joints with and without surgical intervention.

Compensatory Mechanisms Occurring After Condylar Fracture

Condylar fractures with displacement or dislocation result in a loss of skeletal support to the mandible, i.e., the effective length of the mandible on the side of fracture is reduced. This is why bilateral fractures tend to produce anterior open-bites and unilateral fractures produce deviation toward the fractured side. Those surgeons who advocate open reduction of displaced or dislocated condylar fractures feel that re-establishment of mandibular length and ramus height obviates the need for most of the compensatory mechanisms discussed below. While this seems intuitively obvious and *may* be true, there are no studies of functional adaptation to surgical treatment of condylar fractures.

With *non-surgical* treatment, adaptations occur which help compensate for this loss of vertical ramus support and allow, in most instances and with physiotherapy, the maintenance of a proper occlusal relationship. These can be broken down into adaptations within the neuromusculature, the skeletal tissues, and the dentition.

Neuromuscular Adaptations. Following condylar fracture, neuromuscular adaptations may occur which allow establishment of a proper occlusal relationship. However, the nature and extent of these adaptations are very poorly understood. Biomechanical theory[10,17,18,20,30,37-39,85,86,99] predicts that loss of support from one condyle should produce several neuromuscular adaptations to shift forces away from the damaged or missing joint: 1) Chewing might be confined to the same side as the fracture since as the working side condyle it would theoretically be less loaded than the balancing side joint. 2) Muscles on the non-fracture side would be theoretically expected to increase their activity levels relative to those on the fracture side in order to further reduce the load on the damaged condyle. However, there is a functional cost to these first two adaptations. Theoretically, reduction of the load on one condyle (without reducing occlusal force) must be compensated by increased load on the opposite condyle. Therefore, it is possible that decreased loading of the non-functional condyle might, over the long term, produce degenerative changes in the healthy condyle. 3) Reduction of occlusal force, particularly during incisor bites, would reduce the magnitude of forces on both condyles.[37,38] 4) Alterations of muscle activity, for example a relative increase in posterior temporalis activity, could theoretically shift the total muscle force closer to the position of the bite. This adaptation could reduce or, for molar bites, even eliminate loads on both condyles.[73,74,84,88,93,103,104] However, this adaptation would also reduce occlusal force. It is therefore probable that if this mechanism is used, it is only a short-term adaptation, used until a new TM articulation has been re-established by the adaptations discussed below. Currently there is little experimental evidence to indicate how the neuromuscular system adapts to loss of condylar support in the ways predicted by biomechanical theory. No studies to date have looked for reduced occlusal force or altered muscle activity patterns in subjects in which condylar displacement is not reduced. Although unilateral chewing following condylar fracture is well known[26,27,71,91] it is not clear whether this results from reduced ability to translate or an attempt by the masticatory apparatus to reduce joint forces. If neuromuscular adaptations occur following condylar fractures which allow maintenance of a normal occlusal relationship, they have not been identified or quantified.

Skeletal Adaptations. With displacement, dislocation or even condylectomy, a complex series of changes occur within the TMJ which have the potential of producing a new mandibular condyle. Lindahl and Hollender[55] called this process condylar "restitution", and it has been demonstrated by dozens of investigators in both animals[9,34,45,57,66,77,87,100] and humans.[7,28,55,58] This is the same response that orthopedic functional appliances rely upon to treat skeletodental malocclusions.[64] Of note, however, is that this response is maturation-dependent. Skeletally *im*mature individuals regenerate condyles very rapidly following fracture dislocation. On the other hand, skeletally mature individuals (adults) have a more limited ability, and instead of "restitution" of a new condyle, a "functional" remodelling is the rule.[55] The remodelled condyle functions as a TM articulation allowing hinging motion but does not appear "normal" in most instances. Further, re-establishment of the lost vertical ramus height does not occur in these cases. Instead, the remodelled condyle articulates anteromedially against the articular eminence and/or skull base. The mandibular fossa slowly fills in with osseous tissue and becomes shallow. Thus, the skeletal adaptations which occur following fracture in the adult consist less of condylar regeneration, which occurs in the young and is the most advantageous skeletal adaptation possible, but of remodelling and the formation of a new articulation along the eminence, with some permanent loss of vertical dimension and mandibular length.[29]

Dental Adaptations. With loss of posterior vertical dimension of the ramus from fracture, the only manner in which a normal occlusal relationship can be maintained is if the musculature brings the mandible into occlusion irrespective of a TM articulation, or if the teeth have adapted by extrusion/intrusion. For instance, after a bilateral condylar fracture in an adult, loss of posterior vertical dimension results in an anterior open-bite until "training of the musculature" by interocclusal elastics allows re-establishment of the normal occlusal relationship. Whether the muscles are actually being "trained" has not been demonstrated, although we know from clinical experience that patients can usually obtain a normal occlusal relationship within a few days following institution of interocclusal elastics when they are used. Later, however, it seems probable that a new TM articulation is re-established by the skeletal adaptations noted above. Since a loss of posterior vertical dimension is a permanent finding in adults, the only way a normal occlusal relationship can then exist is for the anterior teeth to extrude and the posterior teeth to intrude. Götz *et al.*[29] found that this response occurs routinely when non-surgical treatment of condylar fractures is instituted. The mandibular plane was shown to become more steep in every case, reflecting the shortening of the ramus from condylar fracture. Thus, the interocclusal "training" elastics may initially help develop a neuromuscular adaptation, but in time, a new articulation is established by shortening of the ramus until the condylar stump either heals to the displaced condylar head or re-establishes a new articulation somewhere along the cranial base. For the occlusion to be maintained, the dentition must adapt, and the elastic therapy probably facilitates this response.

Masticatory Function Following Condylar Fractures

A potential problem when non-surgical means are used to achieve a correct occlusal relationship in the face of loss of posterior vertical dimension resulting from the fracture is an over-stressing of the contralateral, uninjured TMJ. Several investigators have noted that patients who have pain and/or dysfunction of one TMJ preferentially chew on that side, i.e. unilaterally masticate.[26,27,71,91] Since the mandibular condyle frequently loses it's ability to translate following fracture, patients tend to chew on this side, allowing translation on the opposite, uninjured joint for the development of masticatory force. Hylander[38] has experimentally demonstrated that the contralateral (balancing) joint undergoes more compression across its surface during the power stroke of mastication than does the side of the bolus (working side). It is probable that unilaterally masticating on the side of injury helps to "protect" the injured joint by subjecting it to less compressive force during mastication. It is not surprising that patients who sustain unilateral condylar fracture frequently develop pain and dysfunction in the opposite joint up to years later.[1,26,27,53,54,59,76,89,90]

Further, it is becoming increasingly apparent that injuries to the TMJ result in late pain and dysfunction in the injured joint.[18,21,28,52,65] These investigators feel that injuries in the TMJ hasten the development of degenerative joint disease and may produce internal derangements. Curphey[18] states that *all* cases of fracture dislocation will result in painful symptoms. Because of this, he feels it essential to surgically return the condyle to the fossa.

Despite the common occurrence of condylar fractures, there is little scientific data to suggest that any of the instituted treatments are effective in normalizing function of the masticatory apparatus. "Success" of treatment has never been defined. Most investigators feel that successful treatment of condylar fractures includes the ability to obtain a pre-traumatic occlusal relationship and good range of mandibular motion (usually >40 mm).[2,3,5,6,14,16,49,60-63] However, the percentage of "successfully-treated" cases reported in large series using these *minimal* criteria is only somewhere around 85%. Of interest is the finding that all *large* studies of patients treated for condylar fractures have been those where treatment was non-surgical. Conceivably, surgical treatment may improve results since it has been demonstrated that closed-treatment of displaced articular fractures in other joints is complicated by both early dysfunctions and late arthritic changes which may occur 10 to 50 years later.[22] Unfortunately, we do not know if surgical treatment of condylar fractures may fare any better than non-surgical treatment since reports are not available in the literature.

There have been a few studies which have tried to more thoroughly evaluate oral-motor function and masticatory/TMJ dysfunction in patients treated non-surgically for condylar fractures. Most of these have used maximal mouth opening, mandibular deviation, TMJ crepitus, TMJ radiographs and subjective reports by the patients to determine treatment outcomes. Generally, the results are not encouraging.

Summarizing the literature with respect to function/dysfunction following non-surgical treatment of condylar fracture, the following conclusions can be reached:

1) Signs and symptoms of dysfunction occur in 12%[52] to 85%[44] of cases depending upon the study and the testing modalities used for assessment.
2) Dysfunction is much more common when fractures are sustained in skeletally mature individuals (adults) than when sustained in the young.[19,28,56]
3) Signs and symptoms of dysfunction are more frequently when there is no contact between the condylar head and the fossa following fracture (i.e. displaced and dislocated fractures).[15,19,26-28,42,52,53,56,59,89,90,95,96]
4) TMJ dysfunction occurs in both the injured joint and in the contralateral, uninjured joint.[26,27,44,52,53,56,59,89,90]
5) Displaced/dislocated condylar fractures result in an increased distance between the intercuspal and retruded condylar positions, the significance of which is unknown.[19,42,56,69]
6) Most studies of mandibular function to date have not used methodology nor techniques which are sensitive indicators of masticatory function.
7) Details of neuromuscular adaptation remain unresolved.
8) The functional capabilities of patients following *surgical* treatment of condylar injuries is unknown.

The purpose of this investigation is to expand our knowledge concerning oral-motor function following surgical and non-surgical treatment of fractures of the mandibular condyle in adults. Six tests of oral-motor function are being examined in all subjects in order to develop a more complete picture of function in patients who sustain fractures of the mandibular condyle.

Two *general* hypotheses are being tested:

1) Patients treated with open reduction and internal fixation of condylar fractures will have less impaired oral-motor function than those treated non-surgically.
2) Among patients treated non-surgically, oral-motor function will be more impaired in those with significant condylar displacement (or dislocation) than those with minimal displacement or no displacement.

Six *specific* questions are being addressed in this research to test the above hypotheses. The questions concern parameters of oral-motor function which are tested in all patients:

1) Are resting levels of adductor muscle activity elevated? Resting levels are used as a baseline for comparison with muscle activity during function. Activity levels elevated beyond those found in controls may indicate pain or other aspects of muscle dysfunction.
2) Are there reductions in the maximum range of motion, and if so, are the limitations due to pain, muscle limitations, or restrictions within the soft tissues?
3) Are limitations in range of motion or changes in muscle activity patterns present

during mastication? Significant deviation from patterns seen in controls would indicate that limiting factors are affecting masticatory function.

4) Are there reductions in maximal occlusal force generation or reduction of muscle efficiency at submaximal occlusal forces?
5) Are changes in muscle activity patterns reflecting attempts to protect the affected joint from loading? Differences in activity patterns from those of controls may indicate redistribution of the two joint forces.
6) Are muscle activity patterns altered by occlusal guidance with post-fracture interarch elastics to compensate for loss of condylar support.

Evaluating patients with condylar fracture who are treated non-surgically provide insight into the biology of adaptations which occur in the masticatory system to this traumatic insult. Comparison of the functional and anatomical results of the two most common forms of treatment for condylar fracture provide information about the efficacy of our therapies.

BODY

Methods

1. Patient Selection

This investigation is a non-randomized clinical trial of two treatments of condylar fracture. Patients admitted to the Parkland Memorial Hospital with fractures of the mandibular condyle are asked to participate in this study. The proposed treatments and analytical procedures are explained. Patients who meet the inclusion criteria (below) and who consent to participate in the randomized portion of the study are asked to sign an IRB-approved voluntary consent form.

Criteria for inclusion of a subject into this investigation are: 1) age--18 years or greater; 2) isolated injuries of the mandible where one or both condyles have been fractured (high intracapsular fractures are excluded--these are impossible to treat with open reduction and fixation); 3) medical condition--American Society of Anesthesia (ASA) Classification I or II (no major medical problems); 4) state of dentition--partial edentulism permitted as long as bicuspid occlusion present and bilaterally symmetrical; 5) no pretraumatic history of TMJ/MPD (myofascial pain & dysfunction); 6) no gross pre-traumatic skeletal malrelationship of the jaws and associated malocclusion; 7) patient consents to participate. We prefer to use skeletally mature individuals since the controversy over treatment regimens surrounds these patients. Further, it is in these patients that most reports of post-traumatic masticatory dysfunction are found. Bilaterally symmetrical occlusion is important since if a unilateral pattern of mastication is noted post-fracture, an occlusal cause can be eliminated. Other fractures of the mandible are permitted in both treatment groups. However, for subjects in the *surgical* group, inclusion depends upon the rigid internal stabilization of the other fractures with bone plates and screws, permitting immediate, active mandibular function (no MMF). The patients' systemic health must permit general anesthesia and surgery. A detailed history of the patient to establish eligibility is obtained using the *Patient History* form (see Appendix).

2. Treatment Groups

The risks and benefits of each treatment as we now perceive them are discussed with patients who sustain condylar fractures by the principal investigator. An attempt is made to standardize the discussions. Patients select one of two treatment groups: 1) Surgery, and 2) Non-surgery.

Surgery Group. Patients in the surgery group have arch-bars placed on the maxillary and mandibular dentition. All mobile fractures of the mandible are rigidly stabilized using internal bone plate and screw fixation. This allows immediate use of the mandible following surgery. The surgical approach varies considerably depending upon the anatomical location of the fracture(s).

Non-surgery Group. Patients in the non-surgical group undergo application of arch-bars and 6 weeks of MMF. Other fractures of the mandible which require open reduction to reposition and/or control fragments have open reduction of these other fractures. However, the fractured mandibular condyle does not undergo surgical repositioning and/or stabilization. Six weeks of MMF is adequate time for other fractures of the mandible to become stable.

Post-fracture Physiotherapy. Patients in both groups are instructed in the same physiotherapy protocol. However, patients in the *surgery* group are able to have these exercises instituted immediately after surgery whereas those in the non-surgery group begin exercises at 6 weeks post-surgery, when MMF is released. The protocol is that routinely used in our hospital at the present time and consists of the following:

1) Occlusal Guidance--Any patient unable to easily repeat their normal occlusal relationship are placed in elastics (rubber bands). This usually consists of one or two elastics

between the maxillary and mandibular arch-bars placed bilaterally in the cuspid/bicuspid region. Frequently, they must be positioned such that they impart an anterior vector to the mandible. The elastics assist in obtaining the normal occlusal relationship. They are *not* meant to provide MMF--mandibular mobility is desired. Therefore the lightest forces which help restore the patient's occlusal relationship are used. The elastics are worn 24 hours a day for six days. The patient may remove them to eat and brush the teeth, but they are replaced immediately.

The elastics are withdrawn 24 hours prior to being seen for the appointment one week following surgery in the *surgery* group, or one week following release of MMF in the *non-surgery* group. If the patient can obtain a normal occlusal relationship at the one week visit, the elastics are omitted. If the occlusion is still difficult to obtain, the elastics are maintained. The patient is weaned off the elastics by switching from 24-hour wear to wearing them only at night. This may take several weeks of wearing, especially in the non-surgery group. The arch-bars are maintained at least two weeks beyond the time when elastics are no longer necessary.

2) Functional Exercises. Four exercises are prescribed for the patient--maximal mouth opening, right and left lateral excursions, and protrusive excursions. The post-fracture functional exercises are goal-oriented. Each week, the patient is given a new goal which is based upon the previous recording of their progress. For instance, on release of MMF in the *non-surgery* group or the day following surgery in the *surgery* group, a patient may open 15-20mm between the incisors and have very limited lateral and protrusive excursions. An increase in 5mm of interincisal dimension is added each week to that value until a minimum of 40mm is achieved. If the patient has difficulty achieving their goal for interincisal opening, the use of wooden tongue-blades wedged between the terminal molars is instituted by the patient several times during the day until the goal is met. They are encouraged to try and maintain their mandible in the midline when they open or protrude the mandible, however, this goal is not routinely achieved in unilateral fractures which are displaced/dislocated. For lateral and protrusive excursions, an additional 2mm per week is added until lateral excursions are greater than 10mm and protrusive greater than 12mm. Patients are not released from active treatment until these goals are met.

3. Methods of Data Acquisition

Clinical assessments of function take place at least four times during the study. Both groups undergo complete recording sessions (described below) at 8, 12, 24 and 48 weeks following institution of treatment. Radiographs, while obtained prior to and immediately after surgery, are also be obtained at these times. Attempts are made to obtain 2- and 3-year follow-up visits in all patients in addition to the above times.

A. Radiographic Analysis

Panoramic Radiography. Panoramic radiographs are obtained on all patients prior to treatment, immediately after surgery, and at each evaluation period using a single radiographic machine. The purpose of this film is for assessment of the dentitional state of the individual, as a scout for other fractures, etc. No quantification or assessment are performed from these films.

Cephalometric Radiography. Posteroanterior (PA) cephalometric radiographs are obtained for each subject immediately after surgery and at each evaluation period using a single radiographic machine (Quint Sectograph) with a standardized source-object distance (60"). Each radiograph are traced onto acetate and digitized using a cephalometric model which includes 24 dental and skeletal landmarks. A computer program (Ceph-Master, Trilobyte Inc., Northville, MI) calculates linear, angular, and ratio measurements among the 24 points. Analysis of this information allows assessment of morphological differences among the patients and determine if skeletal changes occur following treatment.

Linear Tomography. Each subject receives a sagittal linear tomographic examination of both TMJs prior to treatment, immediately after surgery, and at each evaluation period. This is performed using a Quint Sectograph which allows standardized films to be repeated due the incorporation of a head positioner (cephalostat). The sagittal images are taken perpendicular in the sagittal plane using the cephalostat with the patient positioned as if a lateral cephalogram were being taken. No "correction" to the mediolateral axis of the mandibular condyle are performed since the axis of the condyles are at different positions in each patient following fracture and during treatment. Sufficient 3mm cuts are obtained to completely image the condyle, from lateral to medial poles in the sagittal images and from anterior to posterior in the coronal images in the closed-mouth position. Mid-condylar sagittal cuts are also obtained in a maximum gape position of the mandible to evaluate condylar mobility.

The tomograms are traced onto acetate for three purposes. First, classification of the fracture according to Lindahl[54] is performed. This system classifies condylar fractures by the following means: 1) Fracture level--condylar head, condylar neck, subcondylar. 2) Dislocation of the fragments at the level of the fracture in both coronal and sagittal planes for condylar neck and subcondylar fractures--The angulation which the condylar segment makes with the ramus in the coronal plane is calculated using a protractor. The presence and direction of overlapping of the condylar and ramal segments are quantified in millimeters, i.e. medial override; lateral override; angulation without override; fissure, etc. Similar measures are calculated in the sagittal views using a line drawn between the posterior border of the ramus and the long axis of the condylar fragment. Fractures are categorized into those with less than 20° of angulation, 21-45°, and >45°. 3) Position of the condylar head with respect to articular fossa)--no to slight displacement, moderate displacement, severe displacement (dislocation--condyle no longer in contact with fossa).

This information is tabulated to determine how similar the two treatment groups are prior to treatment. Second, sequential observations of morphological alteration are possible (qualitative) by superimposing tracings on stable cranial base structures. In this manner, it is possible to evaluate how condylar remodelling correlates with changes in subjective and functional parameters over time for both the injured and the non-fractured condyle. Third, assessment as to the magnitude of condylar translation from the closed- to open-mouth radiograph is quantified by direct measurements between the mid-condylar points in the closed-mouth and maximal gape tomograms (after superimposing on cranial base structures).

B. Clinical Analysis of Function

Subjective assessment of function. Questioning the patient at the follow-up appointments to determine the patient's assessment of function is performed using a standardized questionnaire (see Appendix). The subjective assessment of function consists of five categories: 1) presence of pain, 2) presence of joint noise, 3) perceptible change in occlusion, 4) limitations in range of mandibular motion, and 5) limitations in diet. Patients are scored as being positive or negative for these criteria. This data are used to determine how patients' symptoms change over time, differ between patient groups, and correlat ith objective measures of function.

Gnathodynamic assessment of function. A quantifiable assessment of function is obtained using simultaneous recordings of electromyography (EMG), three-dimensional movements of the mandible, and voluntary bite-force recordings. The methods of obtaining the functional data are described below:

1) Measurement of Mandibular Motion. In all experiments measuring mandibular motion the subject is seated upright and relaxed in a comfortable wooden chair with Frankfort horizontal parallel to the floor. A special magnet is attached to the gingiva at the base of the central incisors with a removable adhesive and a magnetic sensor array (Sirognathograph, Siemens Corp.) is placed on the head so that the jaw magnet is located at its center. The magnet's

position, to the nearest 0.1 mm, is recorded around three orthogonal axes in real time and can be monitored on a computer screen (IBM AT) following each functional test. The amount of motion is displayed either as motion in two planes (Sagittal and Frontal) or as deviation of three traces (Vertical, Lateral, and Anteroposterior), with time (Sweep Mode). In the display of motion in two planes, maximal and average numerical values for motion along the three axes are displayed automatically on the computer screen. In the sweep mode, muscle deviation in three directions and jaw muscle activity levels are recorded simultaneously during each motion. Portions of each tracing of jaw position can be measured using a keyboard controlled cursor, and the values can be correlated with the electromyographic information from the jaw muscles.

Two types of movement are recorded: 1) Voluntary Maximum Excursions and 2) Movement during mastication of a constant bolus.

1) For voluntary maximum excursions, the patient is asked to voluntarily move their mandible to its maximum open position, then with the teeth in contact, to produce the maximum left and right deviations and protrusion. Each movement is repeated five times and the following measurements are recorded to the nearest 0.1 mm: During opening, a) Maximum interincisal distance, b) Maximum vertical excursion, c) Maximum protrusion; and with the teeth in contact: d) Maximum left excursion, e) Maximum right excursion, f) Maximum protrusion. Comparison is made with voluntary ranges of motion in controls to indicate abnormal ranges of voluntary motion.

2) The patient is given a standardized constant bolus (Gummi-Bears, HARIBO, GMBH & Co., Bonn, West Germany) and asked to chew naturally for 10 cycles while jaw position and muscle activity patterns are recorded. The test is then repeated with a fresh bolus for an additional 10 cycles. Maximum and average excursion in the vertical, lateral, and anteroposterior directions are recorded and compared to the maximum voluntary ranges of motion, and excursions during mastication in controls.

<u>2) Measurement of Muscle Activity</u>. Electrode sites are scrubbed with alcohol and pairs of pregelled disposable silver/silver chloride electrodes (Electrotrace, Huntington Beach, CA) are placed over the superficial masseter, anterior temporalis, posterior temporalis, and suprahyoid muscles bilaterally. Signals from the eight muscles are amplified using a set of eight differential amplifiers (Bio-pak, Bio-Research Associates, Milwaukee,WI) with a band pass of 40-1000 Hz and are digitized in real time at a sampling rate of 1.2 KHz per channel using Bio-pak software. Digitized signals from all channels are monitored on the computer screen immediately following each test. Comparison of recording levels is adjusted using a common 0.5mV, 600 Hz calibration signal. Maximum voltage (in μV) and the integrated EMG values (in μVmsec) for each trace are also automatically displayed. Levels of muscle activity are recorded as average integrated EMG (IEMG) over a two second interval. Muscle activity is measured 1) during resting in centric occlusion, 2) during rest while biting on the bite force transducer (see below) at various tooth positions, 3) while producing various levels of occlusal force at various tooth positions, and 4) during mastication.

1) Baseline muscle activity levels are recorded for a one-second period while the subject is relaxed in centric occlusion, producing no mandibular motion or occlusal force. These baseline levels are examined for evidence of hyperactivity and to determine amounts of activity increase during function.

2) Second, muscle activity levels at each of the 9 tooth positions listed above are recorded before (postural activity) and during generation of occlusal force. Postural muscle activity levels prior to force generation indicate baseline activity required to maintain the mandible at each occlusal position. The same occlusal force is maintained at each position at approximately 50% of the subject's maximum incisor bite force while the average integrated EMG values for each of the eight jaw muscles is recorded. The pattern of muscle activity levels

associated with each tooth position at each stage of treatment are compared among themselves and with patterns seen in controls.

3) The bite force transducer (at a height of 10mm) is placed between the patient's teeth at the central incisor and right and left molar positions. Muscle activity is then recorded during isometric bites at approximately 25%, 50%, 75%, and 100% of the maximum occlusal force at each position. At each bite force level the average integrated EMG values are recorded. Their rate of increase with increasing occlusal force is calculated. This test determines the rate at which each muscle increases activity with increasing occlusal force.

4. Patterns of muscle activity associated with the four phases of mastication of a constant bolus (Slow open, Fast open, Fast close, and Power stroke) are compared with those seen in controls and at each time interval. Average frequency and variance of the masticatory cycles are calculated.

3) Measurement of Occlusal Force. Occlusal force is measured using a specially designed unidirectional transducer capable of measuring force between a single pair of upper and lower teeth. During isometric bites the specified occlusal force is maintained for three seconds. Control of occlusal force during isometric bites is maintained by displaying force output on a large scale voltmeter visible to the patient. Force values during each test are entered via the keyboard to be stored with the corresponding motion and electromyographic data.

4. Methods of Data Analysis

The major question which is asked concerning the data collected in these studies is: 1) Do the subjective and functional evaluations differ significantly among the two condylar fracture patient groups and controls? The methods of data analysis follow:

Cephalometric Analysis

Posteroanterior Cephalograms. The digitized radiographs are used to determine if changes occur in the cant of the occlusal plane and the bi-gonial plane. A repeated measures analysis of variance with multiple comparisons are used to both determine the significance of changes from one interval to the next within each treatment group and to identify differences between the two patient groups over time. A significant result would indicate that the curves are not parallel and therefore the two groups behaved differently.

Tomographic Analysis

The main purpose of analyzing these radiographs is to determine how similar are the two patient groups. The fracture level, dislocation, and position of the condylar head is individually be subjected to a multivariate analysis of variance to determine if the two groups were significantly different. Should significant difference between groups be found, all the following subjective and functional variables would be subjected to an analysis of co-variance, with the significantly different variables in fracture type/position as the co-variate.

A second use of the tomograms is to determine the significance of differences in condylar translation between the two patient groups. Tomograms allows direct measurement of condylar translation which is not possible with the Sironathograph, which offers only indirect evidence. Measurement of condylar translation is determined by the difference in position of the mid-condylar point from the closed-mouth to the open-gape sagittal tomogram. The measures for each patient are included as a measure of mandibular motion with the other parameters of mandibular function generated by the gnathodyamic analysis for correlations (see below).

Subjective Analysis

Each of the five questions on the questionnaire are scored as even positive or negative based upon the answer given by the patient. The patient may therefore have a score of 1 to 5. A repeated measures analysis of variance on ranks are used to determine the significance of changes from one interval to the next within each treatment group and to identify differences between the two patient groups over time. A significant result would indicate that the curves are not parallel and therefore the two groups behaved differently.

Gnathodynamic Analysis

For each of the measurements of range of motion (from the Sironathograph) and condylar translation measured from tomograms (see above), descriptive statistics are generated to check for normal distribution and record mean values for each patient group at each time interval. A repeated measures analysis of variance with repeated measures are used to determine the significance of changes from one interval to the next within each treatment group and to identify differences among controls and the two patient groups. A significant result would indicate that the curves are not parallel and therefore the groups behaved differently. (Since no control data is available on condylar translation, a comparison between only the two patient groups are performed for this variable).

Mean values for resting and postural levels of IEMG muscle activity of the eight jaw muscles are analyzed in the same way as the jaw motion data.

Muscle activity during biting at different tooth positions are normalized for bite force and at each time interval. Mean values of muscle activity for the fracture and non-fracture sides separately are compared between treatment groups at each time interval. Analysis of the data proceeds in the same manner as described above for mandibular motion.

The relationship between muscle activity and occlusal force is analyzed using regression analysis. The slopes of these regressions for the fracture and non-fracture sides are compared between treatment groups at each time interval for significant differences using multifactorial analysis of variance.

If and only if significant differences are found in any of the variables between the patient groups, then correlations among the variables are tested.

Progress to Date

Beginning in February 1991, we began to enroll patients in the study. We have had no adverse effects from any of our data collection methods.

Subjects

Controls. Because our former studies found significant differences in functional parameters between the sexes, the data must be analyzed separately for males and females. Further, it was necessary to obtain sufficient control subjects for comparison to our patients. We began recruitment of control subjects at the onset of the grant and have now completed three examinations on 52 controls (26 male and 26 females). In order to test for changes over time, we took two additional measurement sets on each control subject.

Patients. As of 11-15-93, we have enrolled 89 patients with condyle fractures into this study. As might be expected from previous studies on facial fractures, there is a preponderance of male subjects, only 15 are female. As also expected, the vast majority are unilateral condyle fractures (n=74), only fifteen are bilateral condyle fractures. Of the 74 unilateral fractures, 46 had closed treatment and 28 open reduction. Although we would have liked to enroll more patients, our projection on available sample was fairly good.

Comparison Between the two Patient Groups. The overall score of fracture severity -- based upon the level of the fracture, the amount of dislocation, and position of the proximal fragment -- was 1.892 $\pm$ 1.868 for the closed reduction group, and 1.960 $\pm$ 1.695 for the open reduction group. There was no significant difference in severity of fractures between the two groups prior to treatment.

The major problem we have had with our patient population is compliance with recall.

Even with the financial incentive for returning, we have suffered a high rate of attrition. To date, we have performed the 8-week examination on all 89 patients, the 6-month examination on 40 patients, the 1-year examination on 31 patients, and a 2-year examination on 19 patients. We have instituted various recall programs, but the main problem is the socioeconomic condition of most patients who sustain facial fractures. Many have no phone numbers, are vagrants, and few have permanent addresses. We carefully counsel the patients on their initial visit and attempt to obtain useful information on their whereabouts and relatives. However, significant problems with recall remain.

Results

For purposes of this mid-term report, we have concentrated on analysis of only some of the functional parameters due the enormous amount of work involved in analysis of data such as EMG. To make meaningful comparisons between the open and closed reduction groups, we have attempted to compare similar subjects. Therefore, this analysis does not include females or patients with bilateral condyle fractures. The results below are for male patients who sustained unilateral condyle fractures unless otherwise stated. Of the 54 subjects, 36 had closed treatment and 18 had open treatment of their fracture. The analysis is limited to the first recording session, at 8 weeks post-injury, because longitudinal comparisons are not yet complete.

Question 1: Are resting levels of adductor muscle activity levels elevated in condylar fracture patients? Although the data to answer this question have been collected, it was not analyzed for this preliminary report.

Question 2: Are there reductions in maximum range of motion in both treatment groups? Is this reduction less in the open reduction group?

Our results indicate that both patient groups differ significantly from controls in several measures but from one another only in the amount of lateral deviation during maximal opening (Table 1). Those patients treated without surgery showed significant deviation toward the side of fracture. This suggests that the fractured condyle does not translate as well as the contralateral condyle. Those patients treated open showed more symmetrical mandibular motion on opening, indicating that their fractured condyle translated as well to their contralateral condyle. Both groups showed similar reductions in interincisal opening, excursion away from the fracture side, and protrusion. These changes appear to be independent of the type of treatment.

TABLE 1
Range of Maximum Voluntary Motion

Motion (mm)	Controls Mean s.d. min max	Closed Redn Mean s.d. min max	Open Redn Mean s.d. min max	Sig
Interincisal Dimension (vertical opening)	48.1 6.3 35.7 57.0	36.8 9.7 18.3 54.6	37.6 8.8 22.8 53.3	*** ###
Deviation on Opening (+ = toward side of fx; - = away from side of fx)	3.0 5.5 -7.7 10.0	5.5 5.9 -6.3 20.8	-1.5 6.0 -11.9 9.0	*** @@
Excursion Away from Fracture Side	12.6 3.1 6.9 21	8.1 2.4 0.6 16.7	8.4 3.7 0.0 13.8	
Excursion Toward Fracture Side	11.0 3.9 0.0 18.8	10.3 2.9 3.8 15.0	9.6 3.2 1.5 15.0	
Protrusive Excursion	10.7 3.2 4.8 17.5	7.0 2.8 2.3 14.0	7.0 2.3 2.7 12.1	*** ###

* = diff betw controls and closed reduction group (* = 0.05, ** = 0.01, *** = 0.001 level of confidence)

\# = diff betw controls and open reduction group (# = 0.05, ## = 0.01, ### = 0.001 level of confidence)

@ = difference between closed and open reduction groups (@ = 0.05, @@ = 0.01, @@@ = 0.001 level of confidence)

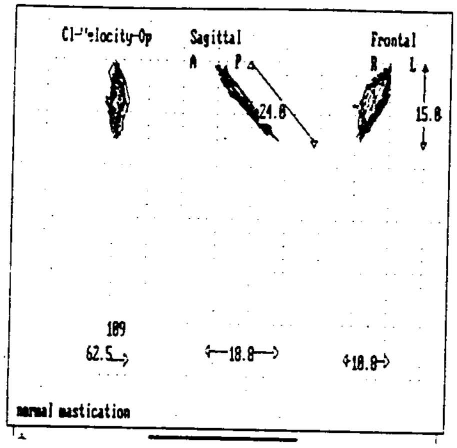
Question 3: Are there limitations in range of motion or changes in muscle activity patterns during mastication?

The ranges of motion during mastication were nearly equivalent in both patient groups to those of controls (Table 2). These preliminary results suggest that both methods of treatment return patients to normal ranges of opening and posterior excursion within 6 to 8 weeks following fracture. However, the apparent similarities among the groups and controls for the lateral excursion measure is misleading. This measure includes total excursion from right to left, not the extent of excursion from the midline. As shown in the figure below, control subjects and those with open reduction tend to have masticatory excursion centered around the midline. In contrast, the closed reduction subjects often have excursion limited to only one side. Quantification of this difference will be done for future reports.

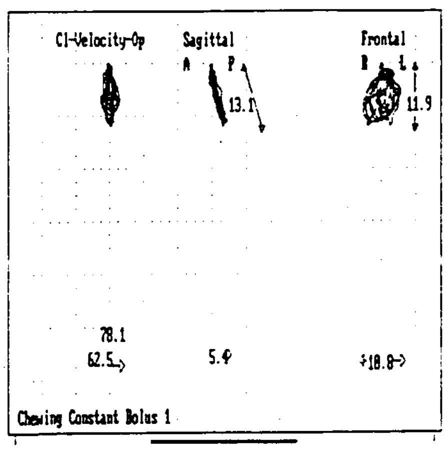
Data to determine changes in muscle activity patterns during mastication has been collected but has not yet been analyzed.

TABLE 2
Range of Motion During Mastication

	Controls	**Closed Reduction**	**Open Reduction**
Interincisal Opening	20.654±3.905 14.0-30.9	19.91±5.578 10.2-34.1	21.368±6.894 13.1-40.6
Lateral Excursion	14.981±3.958 7.9-21.9	12.734±3.750 5.6-21.9	11.245±3.606 6.70-20.0
Posterior Excursion	8.665±3.162 4.4-17.5	9.398±3.407 3.3-18.8	9.527±4.367 3.5-22.5



Tracing of patient treated by closed reduction of right condyle fracture--Note deviation to the right side when viewed in the frontal plane



Tracing of patient treated by open reduction--Note symmetrical pattern of mastication when viewed in the frontal plane

Question 4: Are there reductions in maximal occlusal force generation or reduction of muscle efficiency at submaximal occlusal forces.

The ability to generate occlusal force was determined while biting at the incisors and first molars bilaterally. Statistical comparison between the two groups was made using ANOVA. These preliminary results indicate that at 8 weeks post-treatment, there is no significant difference in the two treatment groups' ability to generate occlusal force (Table 3). However, both groups have significant decreases in molar bite force when compared to controls. These preliminary results suggest that the method of treatment has little effect on ability to generate occlusal force.

Table 3
Maximum Isometric Bite Forces

Bite Position	**Controls** Mean (Kp) s.d. min max	**Closed Redn** Mean (Kp) s.d. min max	**Open Redn** Mean (Kp) s.d. min max	Sig
Incisor	16.4 7.9 7.5 40.0	8.4 5.1 1.0 20.0	9.7 8.9 1.0 30.0	** #
Ipsilat Molar	48.7 12.8 23.0 80.0	29.3 18.1 6.0 100.0	29.4 17.2 5.0 60.0	*** ##
Contralat Molar	50.0 14.4 25.0 80.0	29.4 14.1 9.0 90.0	28.0 18.2 3.0 60.0	*** ###

* = diff betw controls and closed reduction group (* = 0.05, ** = 0.01, *** = 0.001 level of confidence)
# = diff betw controls and open reduction group (# = 0.05, ## = 0.01, ### = 0.001 level of confidence)
@ = difference between closed and open reduction groups (@ = 0.05, @@ = 0.01, @@@ = 0.001 level of confidence)

Data to determine the level of muscle efficiencies has been collected but not yet analyzed.

Question 5: Are there changes in muscle activity patterns related to protecting the fractured joint from loading?

The electromyographic activity in the anterior temporalis, posterior temporalis and masseter muscles was recorded during isometric incisor bites are reported in Table 4. Because of the many combinations of right and left muscle activities, bite positions, and bite force levels, we only are showing the results of the *incisor* bites at the patient's maximum bite force level. However, statistical analysis of all bite positions, all muscles, and bite forces was performed and is briefly described below.

Table 4
EMG During Incisor Bites

Muscle	**Controls** Mean (mV) s.d. min max	**Closed Redn** Mean (mV) s.d. min max	**Open Redn** Mean (mV) s.d. min max	**Sig**
Fx Side Anterior Temporalis	32.3 17.7 6.0 66.0	25.7 17.1 5.1 71.1	29.7 18.4 9.4 63.4	
Non-Fx Side Anterior Temporalis	32.1 19.2 11.1 78.0	26.4 19.0 6.0 66.2	34.0 28.2 6.9 109.0	
Fx Side Posterior Temporalis	29.0 22.8 6.0 82.6	21.1 10.5 6.0 44.5	22.5 25.8 6.0 109.0	
Non-Fx Side Posterior Temporalis	23.9 24.2 6.0 108.0	46.1 114.67 6.0 579.0	20.7 18.8 6.4 82.6	
Fx Side Masseter	63.9 35.4 22.0 143.0	36.6 25.0 6.0 114.0	38.2 37.6 6.4 151.0	** #
Non-Fx Side Masseter	66.7 29.4 28.0 137.0	37.6 26.8 6.0 97.9	35.0 43.9 6.0 186.0	** ##

* = diff betw controls and closed reduction group (* = 0.05, ** = 0.01, *** = 0.001 level of confidence)
# = diff betw controls and open reduction group (# = 0.05, ## = 0.01, ### = 0.001 level of confidence)
@ = difference between closed and open reduction groups (@ = 0.05, @@ = 0.01, @@@ = 0.001

When compared to controls, patients in both groups tended to have lower levels of activity during isometric bites, reflecting their lower levels of occlusal force. This was most evident for the masseter muscle in which patients had almost a 50% reduction in activity levels. Similar patterns were seen at the other bite positions.

There was no consistent indication that working/balancing ratios were altered during isometric bites in either group of fracture patients. Such a shift would indicate attempts to prevent loading of the fractured joint. Perhaps joint loads are minimized by reducing occlusal forces. These preliminary results suggest that muscle activity patterns during isometric bites are not affected by the method of treatment. However, due to the high variance inherent in EMG measurements, larger sample sizes are needed to rule out subtle differences between the two patient groups.

Question 6: Are muscle activity patterns altered to compensate for loss of condylar support.

Data to determine whether muscle activity patterns during mastication and voluntary maximum excursions has been collected and remains to be analyzed.

4. Summary of Results and Relevance

The major preliminary findings of this investigation are that the patients treated by closed reduction have a significantly deviation toward the side of the fracture when opening the mouth. This was not only different from controls, but from patients treated by open reduction. This indicates that the fractured condyle does not translate well when treated without surgical repositioning and stabilization. The long term effects of this could not be assessed in this preliminary examination, nor could it be determined whether or not this finding will be present in the patients followed up for a longer period of time. We suspect that the deviation toward the side of the fracture will be permanent, as other studies have shown. Whether or not this aberrant pattern of motion will lead to degenerative joint disease in either the fractured or contralateral TMJ is not known.

What has never been shown in past studies is the ability of open reduction and internal fixation of the fractured condyle to provide normal mandibular mobility. We are very pleased with this finding, and have been gratified by the ability of patients treated by open reduction to produce normal mandibular excursion as little as four weeks postsurgery. We have found that this group of patients required less careful follow-up than the closed reduction group because the proper use of elastic traction between the upper and lower teeth for control of the occlusion has been unnecessary in the open reduction patients. Reduction and fixation of their fracture condyle has provided these patients with their pre-traumatic occlusion--no postsurgical elastic guidance of the occlusion was used in any patient.

There are many reasons why we didn't find significant differences in bite force and EMG between the open and closed reduction groups. Analysis of data from our control subjects indicated that the ability to generate bite force and muscle efficiency are gender-dependent. Therefore, it is not possible to lump male and female patients. This limited the number of patients for analysis, most notably in the open reduction treatment group. If we could have included female subjects, our sample size would have been larger. However, Another probable confounding factor is the amount of displacement of the condyle. From a cursory review of individual patients, we believe that patients with greater amounts of displacement treated by closed reduction have much more asymmetric patterns of EMG activity. This is probably a compensation by the central nervous system to take loads off the fractured joint. However, in the open reduction patients, this pattern is much less evident. We are anxious to examine this difference further when our sample size allows us to stratify subjects by the amount of displacement of their fracture.

A number of questions remain for which data has been collected but not yet analyzed: 1) Subjective evaluations of pain, joint noise, motion and diet, 2) Resting EMG levels, 3) Muscle activity patterns during maximum voluntary excursion, 4) Muscle activity patterns during mastication, 5) Timing of masticatory cycles and their phases, and 6) Muscle efficiency levels. Analysis of this data will determine further variables in which, at 6-8 weeks after fracture, the treatment groups differ, both from controls and from each other. We will also correlate these objective findings with the patients' subjective self-evaluations. In addition, this data, and that to be collected over the next two years, will help us understand long term adaptation in these patients and how these changes relate to the patients perception of well-being.

CONCLUSIONS

The results of this investigation show that there are clear differences between patients with condyle fractures treated by closed or open reduction. Further, patients in both groups, at least at 6-8 weeks postsurgery, differ in many variables from controls. The results of this preliminary analysis of some of our data indicate that there may be sound indications for treating patients with open reduction. Not only is the postsurgical management simplified, but the occlusal and functional results are more normal, even early in the postoperative time period.

We feel that the best manner in which we can clarify the above findings, and possibly show more differences between the treatment groups, is to enroll many more patients in the study and to obtaining compliance with postsurgical examinations so longitudinal changes can be assessed.

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