AN ANALYSIS OF THE STABILITY OF CRANIOFACIAL FRACTURE FIXATION USING A MANDIBULAR MODEL

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Man's face is his most distinguishing physical characteristic. It is at once the key to his identity and his primary means of communicating both thought and emotion. Acknowledging these important functions of the face, modern society has come to place a premium on its preservation.

R. C. Schultz 1970.

Schultz RC. *Facial Injuries.* Chicago, Illinois: Year book medical publishers, 1970.

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Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

The Relationship Between Fracture Severity and Rate of Complications in Miniplate Osteosynthesis of Mandibular Fractures.

The British Journal of Plastic Surgery 1994; 47:310-311.

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

Patterns of Mandibular Fractures in Adelaide, South Australia.

The Australian and New Zealand Journal of Surgery 1994; 64:307-311.

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

A Comparative Study of Miniplates Used in the Treatment of Mandibular Fractures.

Plastic and Reconstructive Surgery

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ABSTRACT

This thesis aims to investigate the differences in mechanical properties of major miniplating systems used for non compression miniplate osteosynthesis of mandibular fractures, and to determine whether these properties influence treatment outcome. The study was conducted in three parts. Six of the major miniplate systems currently used at the Royal Adelaide Hospital were subjected to bending tests at the University of Adelaide Engineering Department to quantify the relative stiffness of each plate. A wide variation in the mechanical properties of the individual plating systems was identified. In addition the properties of the materials, their biocompatibilty and CT compatibility are discussed. In the second part of the study, patients with recent mandibular fractures were treated using internal fixation with miniplates that were the least stiff as identified earlier. These patients then had a load applied across the fracture, and cephalometric radiographs were taken to detect any deformation of the fracture. No deformation was detected a tolerable loads, suggesting that the pain response protected these patients from a bite force which would deform the malleable miniplates. In the third part of the study, a prospective sample of patients presenting with mandibular fractures was analysed. These patients were treated with a variety of the miniplating systems. The results of treatment as a whole were compared to identify any direct benefit consequent on the miniplate selected. Whilst significant differences in stiffness existed between the plating systems and the cost of the miniplates, no significant differences in treatment outcome were identified between the non-compression miniplates employed. As no observable benefits have been identified by choice of miniplate, selection should be based on surgical preference, biocompatibility, CT compatibility, and unit cost. Due to the variations in materials, design, properties, CT compatibility and unit costs, it is important not to regard all miniplates as equal and interchangeable.

This work contains no material which has been accepted for the award of any other degree or diploma in any university of other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by any other person, except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the University Library, being made available for loan and photocopying.

Timothy JC Edwards
30th August 1995

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INTRODUCTION

The treatment of facial fractures during the first seventy years of this century was dominated first by the external fixation devices and later by the internal wire suspension methods devised by Adams in 1942. Mandibular fractures were principally managed by intermaxillary fixation or occasionally by interfragmentary wiring. However the treatment of facial fractures was revolutionised by Luhr in 1968 who published his work on the treatment of mandibular fractures using a compression plate and screw system. This work was closely followed by others including Michelet(1973), Champy(1976), and Spiessl(1976) who further developed the techniques of internal miniplate fixation of facial fractures.

The use of miniplate osteosynthesis as the treatment of choice in the treatment of facial fractures (and also for osteosynthesis of surgical osteotomies used in craniofacial surgery) is now accepted in most centres in the world. Currently there are four major commercially available plating systems; Luhr, Champy, AO/ASIF Group, and Würzburg. Recently an Adelaide company Aus Systems has developed its own miniplate design which is now being marketed in Australia and Asia.

In 1990 as Associate Registrar in the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital I saw a large number of patients who had sustained facial fractures. Whilst non compression miniplate osteosynthesis was the treatment of choice for the majority of these fractures, it became apparent that there was a plethora of commercially available miniplating systems exhibiting various design features, and that these were essentially used interchangeably.

Research to gauge the effectiveness of the various plating systems has mainly centred around clinical impressions of post-operative results and complications of a particular plating system being used in a particular institution. There has been little work carried out to compare the various plating systems available. In addition, few authors have investigated the stability of the fracture fixation achieved in vivo, beyond the assumption that a satisfactory post-operative result infers stable fracture fixation during the healing process, because hitherto accurate radiological measuring devices have not been available.

As the miniplates used in fixation of facial fractures have been refined, there has been a shift towards use of materials such as Vitallium and titanium, due to their apparent biocompatibility. In addition, different grades of titanium have been introduced which are more ductile and malleable, and therefore more "user friendly" as they can be moulded to the contours of the facial skeleton. As the miniplates are usually expected to remain in situ for the rest of the patients life, manufacturers have also tended towards thinner smaller miniplates to reduce the incidence of removal of the plates due to cosmetic contouring deformities.

With this in mind, the specific aims of this study were; firstly to compare scientifically the engineering properties of miniplates commonly used in fracture treatment; secondly to measure the stability of fracture fixation achieved in vivo; and thirdly in a clinical setting to compare the in vivo performances of the same miniplates to identify which of these properties influence treatment outcome. The final objective was to investigate the unit cost of each miniplate system.

Mandibular fractures were selected for study as they are the most common fracture of the facial skeleton, the mandible is subjected to the greatest muscular forces in the facial skeleton, and the post operative result is most accessible to objective analysis. Although I originally planned to also investigate the stability of midface fractures this was not practical for a number of reasons. Unlike the common fracture patterns that are encountered in relation to the mandible, midface fracture patterns are complex, and large numbers of similar fractures are not often seen. However the major difficulty lies in the post operative evaluation which would require computerised tomograhic scanning in order to asses the stability of fixation. As this is not routinely required for clinical post operative evaluation, it would have necessitated an unjustifiable investigation. For this reason the mandibular fractures were chosen for study, as the results of treatment can be assessed through occlusal studies and plain radiology. Nevertheless many of the conclusions will be shown to apply to the whole spectrum of craniofacial fracture fixation, as the miniplates referred to in this study are used throughout the craniofacial skeleton. For this reason the role of miniplates in the discussion will not be confined to mandibular fractures and reference will repeatedly be made to their use in other fracture sites.

Analysis of the engineering properties of the miniplates was carried out at the Department of Materials Engineering of the University of Adelaide. Using an Instron 1026 three point tensile testing machine, the stiffness of the individual plates was calculated. In addition, with the aid of the product guides and literature review, the biocompatibility and CT scan compatibility, and cost of the individual miniplate systems were compared.

For the second part of the study, the least stiff (most ductile) of the miniplates was selected for an in vivo analysis using cephalometric radiology. A group of patients who had recently plated mandibular angle fractures had biplanar cephalometry performed with and without a 10 Newton load applied across the fracture. This load was designed to simulate a non chew diet. This investigation aimed to show whether there was any detectable shift at the fracture site under these conditions.

The final part of the study was a three year prospective study of patients with mandibular fractures presenting to the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital. This trial was designed to identify any differences in treatment outcome related to the selection of miniplate. Patients were randomly treated with a variety of miniplates and the results of treatment analysed to identify any differences in treatment outcome consequent on the selection of miniplate.

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CHAPTER 1

THE OPERATIVE FIXATION OF FACIAL FRACTURES:

EVOLUTION AND CURRENT CONCEPTS

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1.1 INTRODUCTION

Traumatic injuries to the face have the potential to devastate both the form and the function of man's most distinguishing characteristic. For thousands of years men and women have sought to heal these injuries and to reconstruct the face to its previous state. From humble beginnings, the management of facial injuries has become a highly sophisticated specialty in its own right. This chapter will trace the history, the evolution, the science, and the controversies of the modern fixation of craniofacial fractures.

1.2 HISTORICAL PERSPECTIVE

Fractures of the craniofacial skeleton are common, and have been since time immemorial. The head has been a target in war and in sport, and has been susceptible to injury in road traffic accidents. With 'progress' the severity of these injuries has increased, for example the replacement of the club and spear by the bullet and shell, or the horse and carriage by the car and the motor cycle. The vulnerability of the head to injury has resulted in the development of full face helmets from antiquity to the present day. Greek soldiers wore helmets with cheek guards prior to 700 BC (Gurdjian 1973, Snodgrass 1967), but adopted full face helmets from 700BC, as do motor cyclists and amateur boxers to this very day. Early historical writings describe some of these injuries, and also the methods by which men and women attempted to heal them. Epigraphy of the Edwin Smith papyrus, which was written in hieroglyphs in the middle of the sixteenth century B.C. shows that clinical descriptions of the craniofacial fractures formed the basis of management decisions in ancient Egypt (Breasted 1930). One method of treatment was an attempt at external fixation using firm bandages soaked in oils in an attempt to mould the face. The treatment of fractures of the nose and dislocations of the mandible is also discussed, as is wound closure by adhesive tapes, and the use of topical ointment for wounds which was shown by Manjo (1991) to be effective against staphylococci and coliform bacteria.

By far the most important of the early physicians working with facial fractures was Hippocrates. Hippocrates was born on the island of Kos in 460 BC (Gahhos 1984) , the son and pupil of the physician Heraclides. Hippocrates is credited as being the first to cast superstition and magic aside and develop scientific principles based on observation (de Moulin 1974). The management of facial fractures described by Hippocrates formed the basis of management for over 2000 years after his death. Many of these writings are to be found in the treatises 'On wounds in the head and on joints' (Hippocrates, transl Witherinton 1927), perhaps written by Hippocrates himself but probably written later. For example the Hippocratic texts describe the treatment of mandibular fractures using interdental gold wiring to produce intermaxillary fixation. This was supplemented by external splints using leather glued to the skin and tied behind the head. Hippocrates was careful to warn against bandaging of fractures of the jaws as this "tends to turn the fragments inwards at the lesion rather than bring them back to their natural position".

The teachings of Hippocrates were brought to the Roman empire and collected by Aulus Cornelius Celsus in AD 30. Celsus described the use of interdental horse hair ligatures to stabilise mandibular fractures, and also recognised the importance of a soft diet until union had occurred (Celsus 1938). Galen (AD 129-199) the physician to the emperor Marcus Aurelius and physician to the gladiators of Pergamon would undoubtably been experienced in the field of facial trauma. Yet despite his enormously important studies in anatomy and pathophysiology, and his experience in craniofacial trauma, his writings add nothing to those of Hippocrates (Galen, transl Siegel 1976).

The dark ages which followed the collapse of the Roman empire saw little progress in Western Europe until the birth of the renaissance. Nevertheless Arab scholars continued to write on the subject, based again on the work of Hippocrates which was brought to the East by Paul of Aegina after the fall of Alexandrina in AD 643 (Hoffmann-Axthelm 1982).

The late fifteenth and sixteenth century saw the renaissance and with it renewed interest in the advancement of medicine and surgery. The works of Galen and Celsus were revisited, with Galen published in latin in 1490, and Celsus reprinted in 1478 (Simpson and David 1995). One of the central figures of this time was Ambrose Paré (1510-1590) who was surgeon to four French kings. He became experienced in (amongst other things) facial injuries during his military service. However whilst he described the management of facial injuries in great detail and also wrote about wound care and suturing techniques, his management of mandibular and nasal fractures was essentially the Hippocratic method.

Despite the occasional use of reconstructive techniques during the renaissance, such as Tagliacozzi's pedicled flap for nasal reconstruction (Tagliacozzi 1597), facial reconstruction was principally the domain of the maxillofacial prosthodontist. One of the earliest records of maxillofacial prostheses being used in this way was by Tycho Brahe (1546 - 1601) the Danish scientist and astronomer whose nose was amputated during a duel at the age of twenty (Lee 1972). Using a wax mould of the missing part of his nose he made a cast of gold or copper and glued this to his face. Ring (1991) also records an example of the ingenuity of the early prosthodontists by describing a prosthesis made for a soldier who lost his entire lower jaw to a cannon ball in 1806 during the Napoleonic wars. A silver chin was fashioned that contained a small compartment for a sponge to soak up the saliva, thereby restoring the contour of the face and saving the patient from constant dribbling. Figure 1.1 shows an example of an early prosthetic nose.

The constant supply of casualties from battles around the world assured the maxillofacial prosthodontists of a regular client base. The development of plastic surgery as an effective alternative and adjuvant treatment with the use of prosthetics to treat traumatic injuries of the face was not facilitated when in 1788 the Faculty of Medicine in Paris forbade plastic surgery of the face in any circumstances as the Church considered these operations as meddling in God's domain (Wolfe and Berkowitz 1989).

The nineteenth century brought the first real innovations in mandibular fracture management since the time of Hippocrates. Surgeons began to experiment with external fixation devices that were essentially metal splits around the dental arch, fixed externally to a wooden frame (Hoffmann-Axthelm 1982). These devices were cumbersome and often caused intolerable pressure points which resulted in their use for only short periods at a time. Numerous modifications were designed, but it was the mandibular splints designed by Gunning in 1861 which became a practical solution. After reducing the fracture he would apply a vulcanised rubber splint preformed by dental impressions, and anchored by screws to the molar teeth. Gilmer (1887) then showed how a mandibular fracture could be treated by intermaxillary fixation.

The development of anaesthesia in 1846 combined with Lister's work on infection were to facilitate the next phase of fracture management, that of internal fixation. The nineteenth century saw some important advances in facial skeletal surgery, which were later to aide in the development of similar techniques for the treatment of facial fractures. In 1849 Hullihen described an anterior segmental mandibular osteotomy, and in 1867 Cheever removed a maxillary antral tumor via a hemi-maxillary osteotomy in order to preserve the maxilla, the operation now regarded as the first hemi-Le Fort I osteotomy ever performed. These procedures began to introduce surgeons to the approaches to the facial skeleton, and hence were the forerunners to the development of the techniques of open reduction and internal fixation.

The next major step to be taken was by Réne Le Fort (1869 - 1951) , whose work in anatomical pathology forms the basis of the classification of facial fractures to this day. Le Fort was a French surgeon who experimented on thirty-five cadavers. He inflicted trauma on the faces with blows to the head using clubs, kicks to the head, or by hurling decapitated heads against the edge of the autopsy table (Tessier 1972, Patterson 1991). He then removed the flesh and described in detail the resultant fractures (Figure 1.2). In 1901 Le Fort published the results in an article entitled "Étude experimentale sur les fractures de la mâchoire superiure". Paul Tessier (1972), the founder of modern craniofacial surgery, described Le Fort's work as "a masterpiece" which had directly led to the development of many surgical procedures, for example the Le Fort II and Le Fort III osteotomies.

Le Fort provided a framework for the classification of common fracture patterns, stimulating thought and discussion regarding facial fracture patterns. The Le Fort fracture lines remain relevant to the present day in the planning of craniofacial osteotomies. However the increasing sophistication of radiologic imaging has rendered the classification too crude for the majority of facial fractures.

During the latter half of the nineteenth century surgeons such as Thomas (1867), Hannsman(1886), and Lane(1895) began to experiment with operative methods of treatment of facial fractures. However, it was not until the outbreak of World War I and the ensuing numbers of casualties with facial fractures that flowed from all aspects of wartime, that the treatment of facial fractures began to attract concerted and world-wide attention.

In Great Britain, Sir Harold Gillies orchestrated the treatment of patients with facial fractures during World War I, and published his classic book on his experiences of treating wartime facial injuries in 1920 (Figure 1.3). The Queen's hospital was established in Kent in 1917 as a specialist unit for the treatment of maxillofacial injuries, and under the leadership of Gillies treated over 5000 cases during the first world war (Simpson and David 1995). Concurrently working around the world were Morestin and Martin in France, Cohn-Stock in Germany (a German Jew who fled Germany in 1939 and later worked in London), and Blair who was the chief consultant in maxillofacial surgery to the American Expeditionary Forces during World War I (Wolfe and Berkowitz 1989).

The innovations made during this time provided the impetus for the evolution of modern management of facial fractures.

1.3 EVOLUTION OF CURRENT TECHNIQUES

The current methods for the treatment of facial fractures have their roots in the last half of the nineteenth century. Thomas, writing in the Lancet in 1867, describes his approach to treatment of mandibular fractures. He would pass a drill through the mandible on each side of the fracture and then secure a silver wire around the fracture, tightening by twisting. The patient was forbidden to use the jaw and his fracture was found to be united after twenty eight days. This is one of the first reported treatments to avoid the use of intermaxillary fixation. In 1886 the Hamburg surgeon Hannsman introduced non compressive bone plating, and he was followed by Lane in Britain in 1895. Unfortunately for these early innovators (and for those that attempted the technique over the next fifty years) despite achieving rigid fixation failure was common. Luhr (1987) notes that these high failure rates have led to prejudices against plating systems that persist to this day. In retrospect it seems that these failures resulted from poor biocompatibility of the metallic plates employed (see page29).

In 1936 Blair et al. published an extensive review of the then popular approaches to various facial fractures. For occlusal fractures with no displacement they recommended rest and prohibiting chewing for three weeks. When displacement had occurred then intermaxillary fixation was the treatment of choice. Blair et al. were the first to advocate delays of seven to ten days prior to reducing impacted maxillary fractures, partly to lower the risk of infection, and partly as "this time might be profitably used to improve the general and local condition of the patient".

Downward displacement of the maxilla was treated with a Kingsley splint, an upper buccal splint elevated by means of bandages around the top of the head. For malar fractures the authors advocated the Gillies lift, the closed reduction technique described by Gillies et al (1927). Orbital floor fractures were treated by packing the maxillary antrum with iodoform soaked gauze. It is interesting to note that at no stage in this comprehensive article is bone plating mentioned, one would assume due to its fall from favour as alluded to earlier.

In 1942 Adams produced his landmark paper on the internal wiring fixation of facial fractures. Adams had been working for a number of years to achieve a simple treatment of facial fractures which afforded complete immobilisation. His early attempts centred around extraoral appliances such as plaster head caps. However, Adams noted that "these appliances are complicated, their preparation and application are time consuming, they are cumbersome and uncomfortable for the patient, and they require close watching and repeated adjustments on the part of the surgeon". Adams introduced the principle of open reduction and internal fixation by wiring the fractured parts to neighbouring unfractured bony structures. For example, in the case of a simple Le Fort I fracture Adams would fix the wire to the infraorbital ridge by means of a small skin incision. The wire was then passed over the anterior wall of the maxillary antrum, exiting over the second molar tooth. The fracture was reduced and the wire fixed to one or more teeth (Figure 1.4). If the maxillary fracture was associated with a zygomatic fracture, then the wires would be attached higher to the supraorbital rim just above the zygomatico-frontal suture line. Adams illustrated the success of his treatment with three case studies and concluded by stating the procedure was quick, simple, and required a minimum of equipment.

The revolutionary approach of Adams contrasts with the rather pessimistic tone of McIndoe one year earlier in 1941 who said that the treatment of middle third fractures was poorly understood, and frequently neglected, commonly resulting in hopeless consolidation of impacted fractures. McIndoe described in detail methods of disimpacting maxillary fractures using Ash's and Walshem's forceps. Fixation was achieved either intraorally with cap splints and intermaxillary fixation, or extraorally with plaster head cap, Kingsley type splint and extraoral fixation.

Melmed (1972) notes that following Adams' article, internal wiring suspension became the treatment of choice, with few authors advocating the use of the head cap. Rowe and Killey's book, 'Fractures of the Facial Skeleton' (First Edition 1955), which was the definitive text of the time, reinforced the use of internal wire fixation and internal wiring suspension in the treatment of facial fractures.

The form of a noſe artificially made, both alone by it ſelf, and alſo with the up-per-lip covered as it were with the hair of the beard,

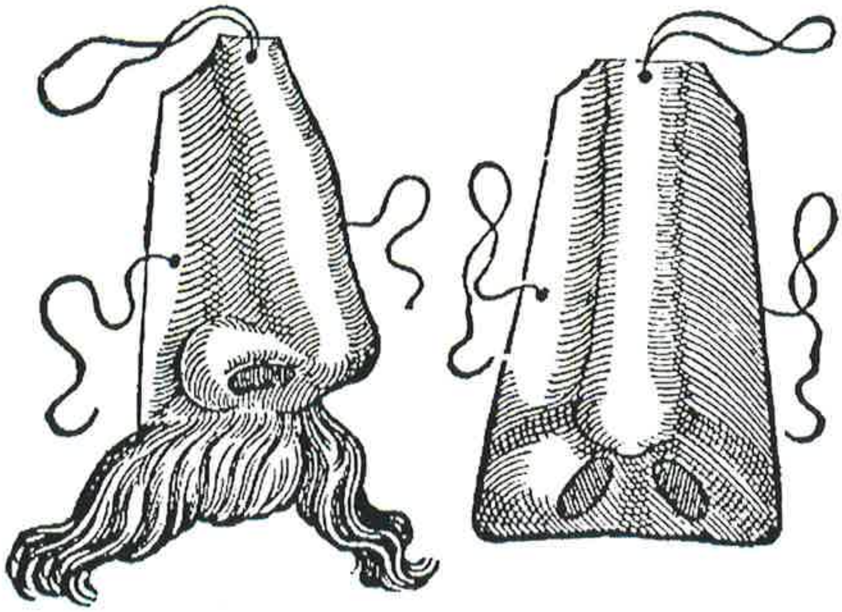

Figure 1.1 An example of a prosthetic nose. Made from gold or silver, the nose was glued in place.

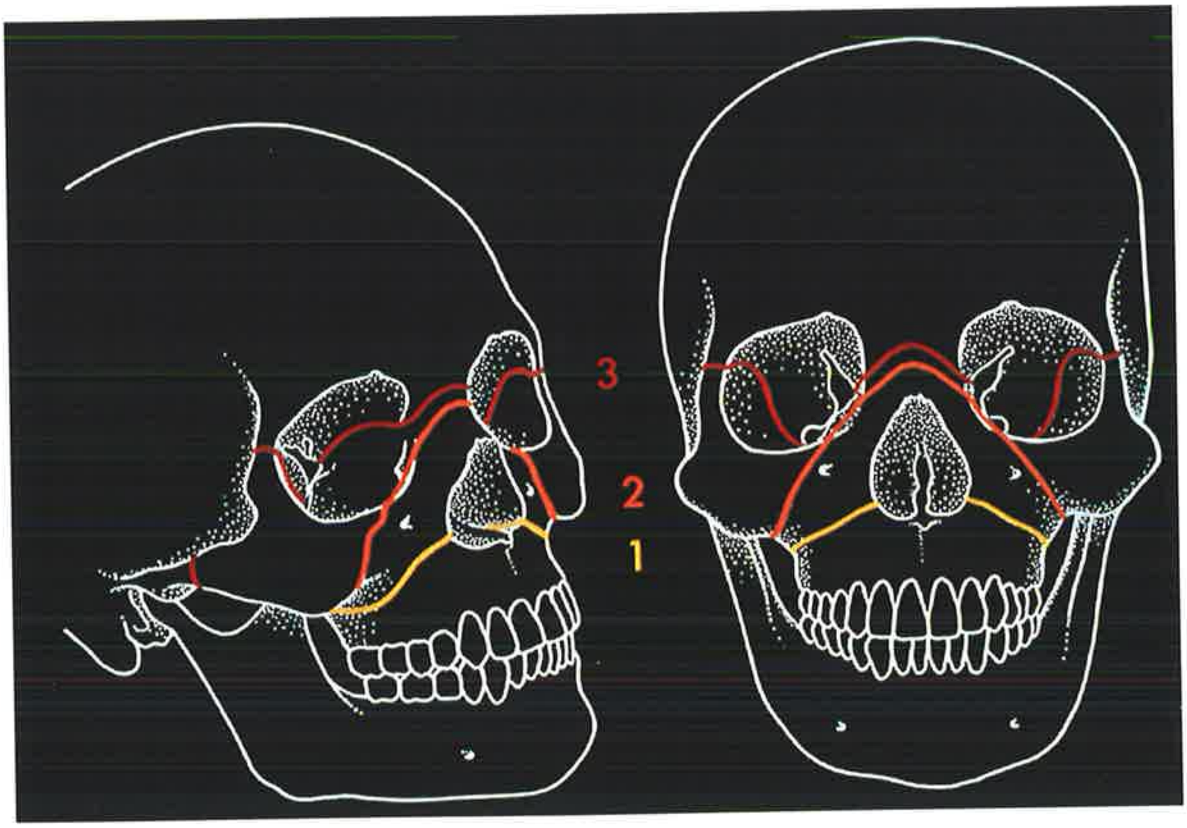

Figure 1.2 A schematic representation of the fracture lines described by Le Fort.

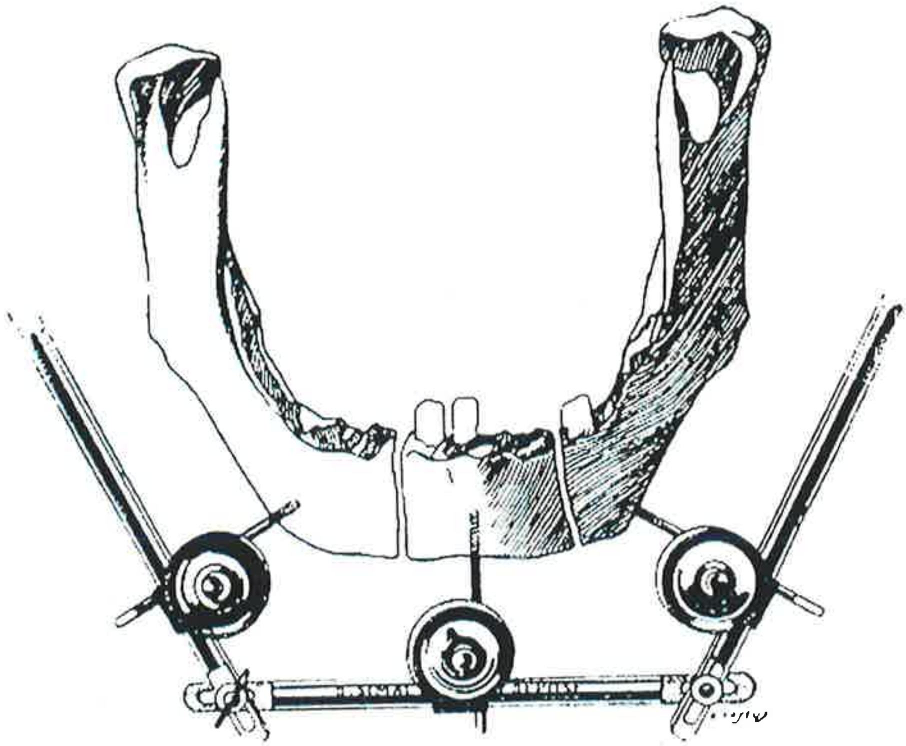

Figure 1.3 Early technique of external fixation of mandibular fractures.

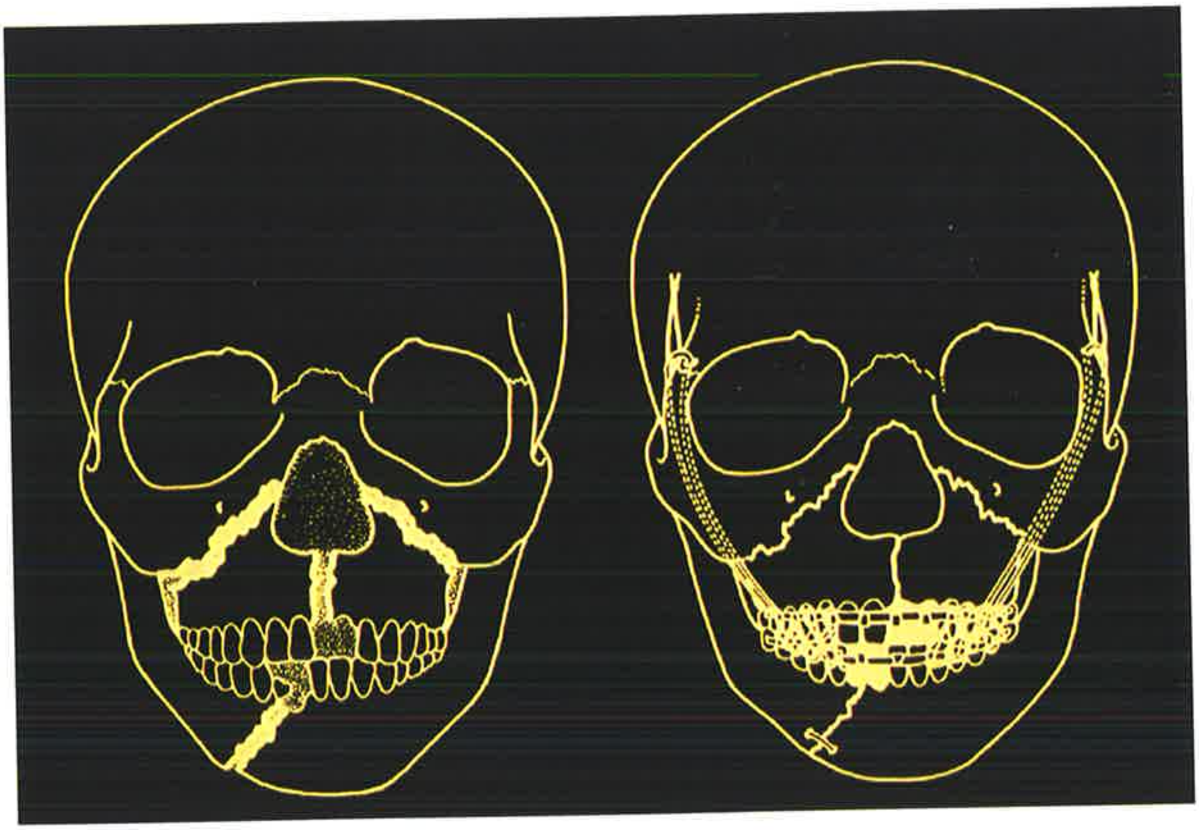

Figure 1.4 Internal wire suspension of maxillary fractures as described by Adams.

In the 1960's and 1970's, various external fixation devices were introduced. These were based on the technique perfected for treatment of cervical spine injuries (a head frame screwed into the skull to allow attachment of traction) and adapted for purposes relative to the facial bones (Rontal and Hohmann 1973). The new methods were modifications of the halo frame designed by Crawford(1943) during World War II (Figure 1.5), and the skeletal head frame designed by Flynn et al. in 1958. Modifications followed including the Mount Vernon head frame (Figure 1.6) (Dawson and Melmed 1971), the frame designed by Alexander et al.(1964) around two sets of Crutchfield tongs, the Royal Berkshire Hospital Halo frame of Mackenzie (1971), and the Levant frame, designed by a Melbourne dental surgeon as a simpler modification of the Mount Vernon box frame (Kellman and Schilli 1987), which became recognised in many quarters as the best frame available (Figure 1.7).

Despite renewed interest in external skeletal traction in the early 1970's, Rontal and Hohmann (1973) pointed out that for most facial fractures, stabilisation by internal wire fixation was possible and preferable. Only in cases of severe facial trauma should external fixation become necessary.

In some centres during the latter part of the 1970's there was a shift away from the internal wire suspension techniques towards internal wire fixation and, where necessary, external fixation instead of internal suspension (Kellman and Schilli 1987). This occurred due to the growing recognition that the upward and backward pull resulting from internal wire suspension often resulted in relapse of the fracture with mid-facial height reduction (Manson et al. 1980). Stoll et al. (1983) attempted to solve this problem by using the same principles and fixation points as described by Adams in 1942, but employing a maxillary stabiliser instead of using wires, this was a solid rod of stainless steel fixed at both ends (solid bone and fractured segments) by two screws. This system had the advantage that the fractured segment was then stabilised in both the vertical and sagittal planes, to eliminate the deleterious effects of the backward and upward pull of internal wire suspension.

The shift away from internal wire suspension was not universal however. Chasmar (1969) noted that midface fractures were not generally treated by external skeletal fixation in North America (as they were in the specialised maxillofacial units of Europe) as these specialised units did not exist in North America to any degree. Indeed, in a review of the treatment of midfacial fractures at Bellevue Hospital Center in New York from 1955 - 1976, external skeletal fixation was never employed (Kuepper and Harrigan 1977). Most maxillary fractures were treated by a combination of transosseous wiring and craniomaxillary fixation. These regional differences in fracture management techniques were to continue until the present day.

Internal wire fixation also began to be employed as a method of treating mandibular fractures, although this was usually restricted to cases where intermaxillary fixation was not adequate. Various techniques were employed, including interosseous wiring (Paul 1968), circumferential wiring (Kruger 1982), and zygomaticomaxillary wire suspension of the mandible (Kruger 1982).

Figure 1.5 The halo frame for external fixation of maxillary fractures.

Figure 1.6 External box frame applied for a mandibular fracture

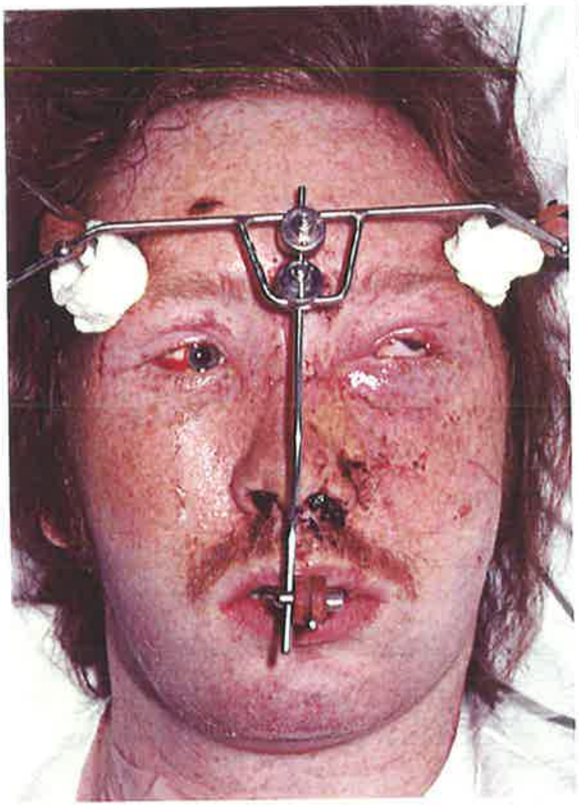

Figure 1.7 The Levant frame used for external fixation of a maxillary fracture

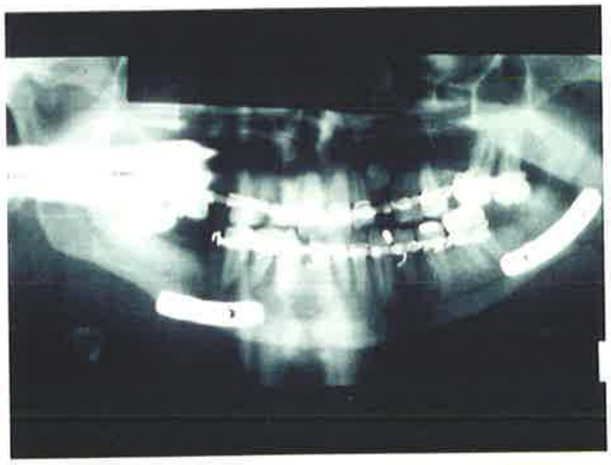

Figure 1.8 Internal fixation of a mandibular fracture using compression plates.

Figure 1.5-1.8

Figure 1.5

The halo frame for external fixation of maxillary fractures.

Figure 1.6

External box frame applied for a mandibular fracture

Figure 1.7

The Levant frame used for external fixation of a maxillary fracture

Figure 1.8

Internal fixation of a mandibular fracture using compression plates.

Whilst the debate about wire fixation and external skeletal fixation continued around the world, concurrent work in France and Germany was to revolutionise management of facial fractures and supersede the above modalities. It was Luhr in 1968 who first published his work on the use of the mandibular compression screw plate for the repair of mandibular fractures. His work was closely followed by others including Spiessl (1976), Michelet et al.(1973), and Champy et al. (1976). In essence the new techniques involved rigid fixation of the exposed fracture under direct vision, using a system of small plates bridging the fracture and fixed on either side by screws (Figure 1.8). Of course, rigid internal fixation of fractures was not new, dating back to Hannsman in 1886, it had merely fallen into disrepute due to unsatisfactory early results.

In 1947 Danis showed that rigid internal fixation with axial compression could promote bone healing, and these principles were later adopted by the AO/ASIF group (Arbeitsgemeinschaft fur Osteosynthesefragen/Swiss Association for the Study of Internal Fixation) (Müller et al. 1991). This group attempted to develop standard indications, operating techniques and equipment for internal fixation. One of their most important early contributions was in the area of metals research, investigating the most effective implant materials and the possible reactions to these implants in vivo. It has been speculated that one reason for the early failure of implants such as those used by Thomas (1867), Hannsman (1886), and Lane (1895) was the poor materials used which may have had inappropriate stiffness, incompatible metals leading to corrosion, and poor biocompatibility. The initial work of the AO/ASIF group centred on long bone fractures, and these principles were soon adopted and adapted to facial fractures.

There were two main schools of thought - those who believed that axial compression provided by the plating system produced superior results, including Luhr (1968) and Marsh (1989), and those who believed equally good results were achieved by rigid internal fixation with miniplates that did not produce axial compression, such as Worthington and Champy (1987) and Michelet et al.(1973). These viewpoints are discussed under miniplate technology (section 1.5).

Workers soon published results comparing the new treatment with the old. By 1973 Michelet et al. had already amassed and published a series of 400 cases of facial fractures and facial osteotomies treated using Vitallium miniplates. Although not directly comparing post operative results with results of treatment with wire systems, Michelet was sufficiently convinced of the benefits of his new miniplate system to conclude by strongly recommending the use of miniplates in all types of osseous maxillofacial surgery. It was Ewers and Harle (1985) who definitively illustrated the mechanical benefits of the plating systems. Using a combination of theoretical physics and photoelastic experiments they showed that metal wire systems could never guarantee three dimensional stability. In contrast the screw-plate system always resulted in a constant pressure situation. Controlled clinical trials also showed superior outcomes for patients treated with plating systems as opposed to those treated by intermaxillary fixation and wiring systems (Klotch and Gilliland 1987, Stoll and Schilli 1988).

Whilst Europe enthusiastically embraced this new technology, North America was to be far more sceptical. Kellman, the Director of Maxillofacial Trauma Surgery at the State University of New York stated as recently as 1987 that his initial attempts in the use of plating systems met with scepticism and criticism from his colleagues. He went on to encourage his colleagues to adopt these new European techniques. This scepticism, however, continues. Duckert (1991) writing on the management of middle third fractures states that the use of internal wire remains the treatment method of choice in most situations. He also advocates the continued use of internal wire suspension and external fracture fixation. According to Duckert, the benefits of these methods are that they are technically unchallenging and inexpensive, and because the stabilisation is non rigid, fractional anatomic adjustments occur throughout the period of fixation thereby allowing a more desirable functional result. In contrast to the views held by most writers in the field, Duckert asserts that rigid plate osteosynthesis is time consuming, expensive, and very unforgiving resulting in malocclusion unless realignment is absolutely precise.

1.4 HEALING OF FACIAL BONE FRACTURES

A thorough understanding of the mechanisms of bone healing is essential if rational methods are to be used to treat these fractures. Healing of long bones fractures has been extensively studied. However, histological evaluation of facial fracture repair in humans has received little attention (Thaller and Kawamoto 1990). Until recently the most commonly held theory was that many facial bones healed by a fibrous union, rather than by true bony union as in long bone fractures (Hepenstall 1982). This, according to Edwards and Kitchin (1937) was because it was assumed that maxillary fractures could not heal by osseous union due to the absence of periosteum in this region.

Long bone fracture healing is described in many orthopaedic and bone pathology texts, for example Apley's System of Orthopaedics and Fractures (1982). Fracture healing normally proceeds through an orderly sequence of events resulting in secondary (indirect) union. This occurs when the fracture is not fully immobilised, and is the most common form of fracture union. A typical description of this well known sequence of events is provided by Apley (1982).

1. Tissue destruction and haematoma formation.
At the point of fracture, vessels are torn and a haematoma forms around the fracture site. Bone adjacent to the fracture is devascularised and dies back for one to two millimetres.

2. Inflammation and cellular proliferation.
Eight hours after the fracture an acute inflammatory reaction occurs with proliferation of inflammatory cells. This inflammatory reaction bridges the fracture site. Collagen is laid down and cells capable of osteogenic and chondrogenic differentiation migrate in. At the same time, haematoma is absorbed.

3. Callus formation.

The proliferating cells are chondrogenic and osteogenic. These form a thick cellular mass which contains islands of bone and cartilage, this is the callus (or splint). The callus is then mineralised into immature woven bone and at this point the fracture unites.

4. Consolidation.

During this phase the woven bone is transformed into lamellar bone. At this point the bone is strong enough to carry loads.

5. Remodelling.

Remodelling will occur over the ensuing months to years as the bone slowly resumes its premorbid state.

In the situation where fractures are rigidly fixed and the fracture ends are closely opposed then healing may proceed by direct (primary) bone union. In direct union, osteoclasts appear at the fracture site and burrow into the bone debris, whilst osteoblasts lay down new bone directly across the fracture site. Thus in direct union there is no callus formation. Where the distance between the bone ends is less than 0.1mm contact healing is said to occur. New bone projects out across the fracture line establishing continuous Haversian systems across the fracture (Spiessl 1989). Where the distance between the bone ends is 0.1 - 1mm, this is too great to allow direct bridging of the gap by the Haversian systems. In this situation gap healing occurs, whereby granulation tissue forms in the fracture space, into which trabeculae of bone are laid down. These trabeculae are ultimately remodelled and converted into lamellar bone. Rahn (1987) notes that direct union of fractures is not necessarily better than indirect union, merely different. This view is not universally held, and the physiological difference between indirect and direct bone healing is fundamental to the debate over miniplate design [see section 1.4].

The process of healing of facial bone fractures has received less attention in the literature than that of long bone fracture healing. It has been suggested that facial bones may heal via a different sequence of events in line with their different process of embryological development (membranous ossification) as opposed to long bones (cartilaginous ossification) (Thaller and Kawamoto 1990).

Rever et al. (1991) studied healing of facial fractures in New Zealand White Rabbits. They inflicted zygomatic fractures on the rabbits using an osteotome, then killed the animals at two, four and eight weeks post fracture to enable histological evaluation of the fracture site. The histological sequence seen was as follows.

Week 2: There were necrotic bone fragments and osteoclasts at the fracture site. The defect was partially bridged by cartilaginous matrix. New woven bone was forming from the ends of the existing bone.

Week 4: A completely mineralised bony matrix now bridged the defect. The bony matrix was still in the form of woven bone.

Week 8: The fractures had been completely remodelled into lamellar bone.

Thus Rever et al. concluded that facial bone healing in the rabbit zygoma resembled indirect (secondary) endochondrial bone union, with no evidence of fibrous union taking place.

Thaller and Kawamoto (1990) concluded the issue by analysing biopsy specimens across healed facial fractures of human subjects. This study confirmed the occurrence of direct (primary) osseous union across the fracture site when the fracture segments were closely approximated. In regions where movement at the fracture site occurs, then healing will result by indirect (secondary) union. In fractures of the mandible healing commonly occurs by indirect union, this was shown using biopsies taken from healing mandibular fractures (Rowe and Killey 1955). In 1987 Luhr showed that rigid fixation of mandibular fractures resulted in direct (primary) bone union.

From these studies it is clear that not only do facial bones heal by a process of osseous union, but that the method of that union can be influenced by the proximity and stability of the fracture segments. The method of fracture management selected will therefore be influenced by the histological process of bone healing you wish to achieve. Those fixation methods which allow for a limited degree of interfragmentary motion will result in indirect bone healing, whilst absolute interfragmentary immobilisation will result in direct bony healing (Rahn 1987). These two fundamental principles form the basis of different internal fixation systems developed by Luhr (1968) and Champy (1976).

Complications of Fracture Healing

There are four principal complications of fracture healing, namely delayed union, non-union, mal-union, and infection (Apley 1982).

Delayed Union.
This refers simply to bony union taking longer than would normally be expected. It may be due to inadequate blood supply, infection, or incorrect splintage of the fracture. If the cause is not identified and rectified, then delayed union may progress to non-union.

Non-union.
This may result from the above causes, in addition to other factors such as too large a gap between the bone ends or interposition of soft tissues between the fracture.

Infection.
This is an important issue, as fractures involving the mandible and maxilla are often compound into the oral cavity. Fractures may often involve teeth in the fracture line,

and the dental hygiene and presence of dental caries will influence the incidence of infection.

Figure 1.11 The Luhr mandibular compression plating set produced by Howmedica (top) compared to the Aus System mono cortical miniplate set (bottom)

1.5 MINIPLATE TECHNOLOGY

Rigid Internal Fixation

The principle of rigid internal fixation of all types of fractures has been championed by the AO/ASIF group (Prein and Kellman 1987). By achieving rigid fixation, direct (primary) bone healing will result. According to Müller et al. (1991), the advantages of direct bone healing include early pain free movement, avoidance of intermaxillary fixation, safe airways without tracheostomies, and shorter periods in hospital and out of work. They found that the principle of interfragmentary compression provides the most rigid fixation possible. In addition, the incidence of infection has been shown by Becker (1979) and by Tu and Tenhulzen (1985) to be directly related to mobility of the bone fragments. Hence rigid immobilisation, as opposed to interfragmentary wiring which allows micromotion of the fracture ends, decreases the incidence of infection.

The concept of axial compression was first introduced by Danis in 1949, however his work centred around long bone fractures. The method used to produce compression in the facial skeleton involves the dynamic compression plate (DCP), designed by Allgöwer, Peren and Matter in 1970. The design of the plate ensures that as the screws are tightened and their heads contact the plate, the screw heads (and consequently the bone fragments) are forced together producing compression. Similar concepts were accepted practice in orthopaedic treatment of long bone fractures before these plates were adapted for use in facial bone fracture.

Rigid fixation of fractures cannot be achieved by wiring . Luhr (1987) also believes that the failure of simple bone plates used earlier this century was due to their inability to effect compression. The Luhr vitallium mandibular compression screw system is shown in Figure 1.11.

Luhr found his mandibular compression plates to be superior to all forms of wiring and simple bone plates. This was due, he claimed, to the following advantages;

1. Axial compression forces remain throughout the healing period of the fracture.
2. More rapid bone healing than with non-compression methods.
3. Direct bone healing as opposed to indirect bone healing.

Based on the success and principles of his mandibular compression system, Luhr (1990) has applied the same principles in the development of the mini-compression system for the treatment of middle third facial fractures.

Monocortical Miniplate Osteosynthesis

The views held by Luhr (1968) and the AO group (Müller 1991) are not universally shared. Worthington and Champy (1987) point out that compression is not necessary for the healing of maxillofacial fractures. They argue that it is illogical to apply a compression plate to an area where physiological stimulation of bone already exists. Monocortical miniplates were first designed by Michelet et al. (1973) and later refined by Champy et al. (1976,1978). The rationale for these plates followed work by Champy et al (1978) plotting lines of force through the mandibular body. It was found that in the normal state the alveolar side is under tension, whilst compressive forces act along the inferior border (Figure 1.12). Mandibular compression plates must be fixed using bicortical screws, and due to the position of the dentition and the inferior alveolar nerves, mandibular compression plates must be placed along the inferior border, that is in the suboptimal position (Figure 1.13). The placement of these plates along the inferior border is insufficient to prevent distraction at the alveolar side (Prein and Kellman 1987). Champy argued that a more logical approach would be to site the plate along the line where it can counteract distraction forces. He also felt that this would achieve the desired stabilisation of the fracture without being so rigid as to remove all physiological stimuli to bone healing.

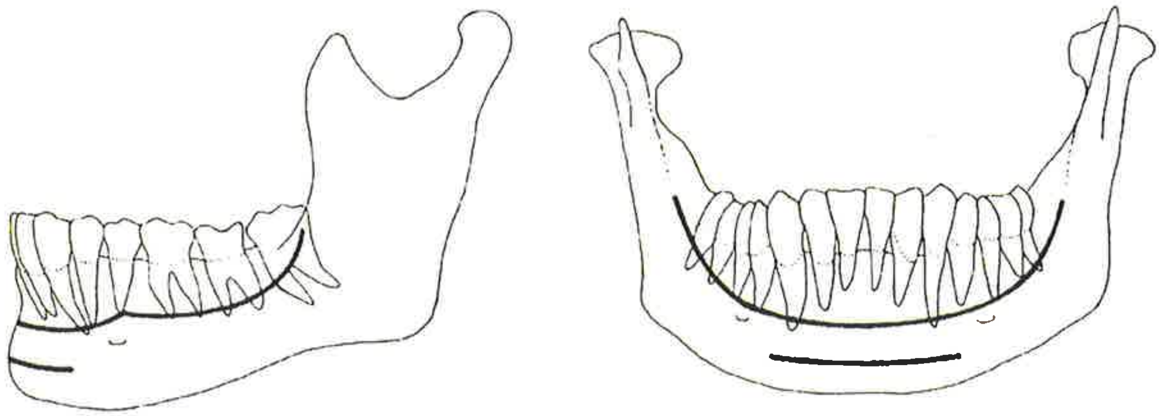

Figure 1.12 Champy's lines of tension

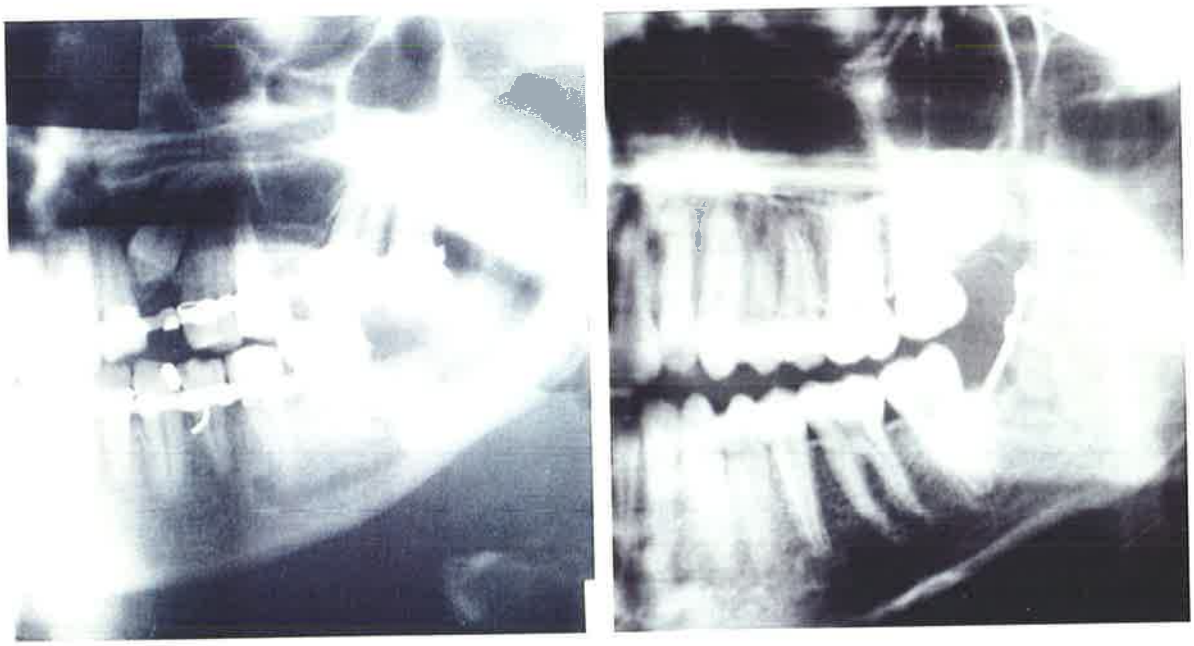

Figure 1.13 The different positioning of a lower border compression plate (left) and non compression monocortical miniplates along the tension lines of Champy

Ikemura et al. (1988) compared monocortical miniplates with dynamic compression plates on excised canine mandibles. They found that in simple fractures of the mandible, monocortical osteosynthesis provided rigid fixation. They concluded that rigidity of fixation does not depend chiefly on the compressive force but on the rigidity of the plate itself.

The rational behind the explanation of the tension/compression forces acting on the mandible dates back to Frye in 1942 who described fractures of the mandible as favourable or unfavourable depending on whether the assumed muscle forces acting on the mandible and across the fracture caused distraction or reduction. These views were confirmed by experimentation which compared the mandible to a two-dimensional cantilever beam model (Rudderman and Mullen 1992). These models consistently showed the forces acting on the mandible to be tension at the upper margin and compression at the lower margin, as confirmed by Champy et al. (1978) [see above]. However Rudderman and Mullen (1992) have shown the results of these experiments to be incorrect by the use of more sophisticated models of analysis. This was achieved using full three dimensional finite element analysis (FEA) models. These models include points of attachments of the masticatory muscles, the direction of these forces, and the behaviour of the tempero-mandibular joints. By analysing the forces under these conditions it has been shown that the pattern of forces is not nearly as simple as was earlier thought. Zones of tension and compression vary depending on the location of the force being applied. Importantly, the compression forces may in some circumstances act on the upper margin with tension forces on the lower margin (ie the opposite to that found by the earlier models). In addition, these models have shown that there may be a reversal of the distribution of forces contralateral to the bite load (Rudderman and Mullen 1992). This new information has the potential to change markedly the protocols of placement of miniplates across fracture lines (see section 4.2).

Miniplate Materials

Different materials are and have been in use for the manufacture of plating systems. The original plates used by Champy were stainless steel, whereas Michelet and Luhr opted for vitallium, an alloy of cobalt, chromium and molybdenum (see section 2.4). Recently manufacturers such as Synthes (AO plates), Aus Systems and Liebinger (Würzburg) have turned to titanium. Titanium and Vitallium were found to be superior to stainless steel as they are non corrosive (Müller 1991). The AO/ASIF group states that titanium is the best material as it is the most biologically inert, and therefore has the least chance of producing any low grade immunological response. No allergic reactions to titanium have been reported (Hobar 1992). Vitallium has been extensively used since 1936 without any significant side effects being reported (Orthopaedic Knowledge Update I 1984). The biocompatibility of titanium is attributed to the immediate formation of stable oxides on exposure to air which result in a tough ceramic coating of the implant (Ellender 1991). Although titanium is non-corrosive under physiological conditions, it may undergo surface alteration due to the action of free radicals released in areas of acute inflammation by polymorphonuclear leucocytes. There has been little research into the long term effects that these changes may have.

Titanium also holds a significant advantage over stainless steel due to its relative radiolucency (Simpson 1965) as it is does not produce scattered interference over computed tomographic (CT) scans, yet the titanium plates can still be imaged on three-dimensional CT reformats (Marsh 1989). This may be important in the post operative evaluation of a patient with miniplates in situ, especially if further surgery becomes necessary.

Titanium differs significantly from stainless steel and vitallium as it has a much lower modulus of elasticity. This makes the titanium plates more malleable and therefore easier to mould for surgery (Orthopaedic Knowledge Update II, 1987). Vitallium is reported by the manufacturers as having two to three times the tensile strength, fifty percent more yield strength, and two times the hardness of titanium and stainless steel (Hobar 1992).

Champy et al. (1976) advocated the removal of miniplates at three to four months post operatively, although he had no specific reason, and this became standard practise in some centres (Cawood 1985). Brown et al. (1989) challenged this practice by analysing the results of miniplates left in situ long term. They found that 18% of patients required removal of plates due to local complications, and no evidence that plates left in situ long term (3 - 5 years) would cause systemic complications. Thus they concluded that plates should only be removed if clinically indicated. This view has been supported by Jackson et al. (1986), and Beals and Munro (1987).

1.6 CURRENT MANAGEMENT

The clinician involved in the initial assessment of a patient with facial fractures must of course at all times concern himself with the well being of the whole patient. It must be remembered that maxillofacial injuries in isolation are rarely fatal (Gratten and Hobbs 1985). Zaccharides et al. (1982) reported on 6433 admissions over a ten year period to a Greek hospital. Of nine deaths only two were directly related to the maxillofacial trauma (0.03%). Thus the craniofacial evaluation should proceed only after a general examination of the patient has been undertaken to identify other injuries and to exclude or treat life threatening injuries. Of critical importance is the exclusion of injury to the cervical spine. A review of 2555 patients with facial fractures by Davidson and Birdsell (1989) found 1.3% to have a significant neck injury, whilst Lewis et al. (1985) found a 19.3% incidence of facial injury amongst 982 patients with cervical spine injuries.

In 1993 Lim described the associated injuries in 839 patients with facial fractures presenting to the Australian Craniofacial Unit at the Royal Adelaide Hospital. Of these patients, 11.3% sustained a significant injury in addition to their facial trauma. The majority of these were neurosurgical (5.4%) and limb (7.4%) trauma, however 8 patients (0.8%) sustained spinal injuries.

Management of facial fractures is based on a thorough history and examination. The management then involves investigations and treatment. Investigations may include various radiological techniques (plain radiography, cephalometric analysis, two-dimensional and three-dimensional computed tomography), and dental analysis with construction of occlusal models. Treatment will be based on a plan devised at a planning meeting involving the relevant members of the team who will individually and collectively review the patient and the investigations. Table 1 shows the specialists likely to be involved in the management of a complex facial fracture. At the Australian Craniofacial Unit the role of craniofacial surgeon is filled by a plastic and reconstructive surgeon, however in many centres this will vary, where for example an oral surgeon may fill the role. In the future, craniofacial surgery may stand alone as a discipline, training those with a suitable background in fellowships in craniofacial surgery (David and Brown 1995).

Table 1
Facial Fracture Team

Craniofacial Surgeon	**Photographer**
Neurosurgeon	**Radiologist**
Dentist	**ENT surgeon**
Opthalmologist	
Anaesthetist	
Social Worker	

Thus the facial injury must be managed in perspective with the other often more immediate and perhaps more life threatening injuries that the patient may have. Trott and David (1995) suggest that delaying surgery is beneficial as it allows stabilisation of the patient, proper multidisciplinary assessment, reduction of swelling from the initial injury, and a superior operative result. The essential principles of surgery involve wide surgical exposure of the fractures using the craniofacial approach, open reduction of the fracture, and internal fixation with the use of miniplating systems.

Current description of facial fractures relies on the artificial division of the face into thirds to facilitate description of the fractures on a regional basis.

Fractures of the Upper Third.

This involves fractures of the forehead, anterior cranial base, lateral and superior orbital margins.

1. Fractures of the Forehead and Anterior Cranial Base.

The aim of surgery should be a one stage surgical correction of the injuries to take place five to seven days post-injury (David and Moore 1990). Surgical exposure is through the bicoronal scalp flap. A frontal bone flap is then elevated. The fractures are then identified , reduced, and fixed with miniplates (Figure 1.14). In some cases where there are no expected forces across the fracture line, and where the miniplates may cause noticeable contouring deformity, microplates have been suggested as suitable for use due to their lower profile.

2. Frontal Sinus Fractures.

In the case of frontal sinus fractures, the treatment depends on the position and severity of the fracture in question. David and Moore (1990) state that undisplaced fractures of the anterior wall do not require operative intervention; however if these are displaced they should be explored in order to debride damaged nasal mucosa and reduce the fracture. Gross comminution of the posterior wall also requires surgical repair as it is commonly attended by dural injury.

3. Frontonasoethmoidal Fractures.

These fractures are difficult to treat, and primary or secondary augmentation of the nasal dorsum is often required.

4. Nasoethmoid-Orbital Fractures.

Markowitz et al. (1991) reviewed 1162 patients with nasoethmoid-orbital fractures. Important to note is that 80% of these patients suffered from some other associated facial fracture. They recommended that single fragment injuries be treated with junctional rigid internal fixation alone. More severe fractures will require an inferior and superior approach with junctional plate and screw fixation across the fracture complex. They also commented on the frequency with which nasal bone grafting was required; in their series 42% of nasoethmoid-orbital fractures were treated in this manner.

Fractures of the Middle Third.

The middle third of the face contains the orbits, zygomatic arches, the nose, the palate, and the maxilla.

1. Orbital fractures.

The orbit is often fractured as part of a pattern of maxillary and/or zygomatic fractures. However blunt trauma to the anterior aspect of the orbit may cause the unique fracture known as a blow-out fracture, whereby the pressure of the force is transmitted through the orbital contents resulting in a fracture of the floor or medial wall of the orbit (Schultz 1970). Herniation of orbital content may result in enopthalmos and diplopia which were originally described by Lang in 1889 (Wiess 1969). As the floor is the most fragile structure it is here that the blow-out fractures most commonly occur; however the fracture may involve the medial wall, the roof, or even the greater wing of the sphenoid (Figure 1.15). Fractures of the orbital floor may also occur in conjunction with fractures of the infraorbital rim, these are, by definition, not blow out fractures.

It has been generally accepted that surgical intervention is necessary to inspect and reconstruct the orbital floor (Büttow and Eggert 1984). The original approach was to enter the maxillary antrum via the Caldwell-Luc approach and then pack the antrum with iodoform soaked gauze. Later, reconstruction was attempted using various materials including cartilage, teflon, and silicone (Wiess 1969).

Figure 1.14 A patient with a naso-ethmoidal fracture as part of a Le Fort III complex fracture.

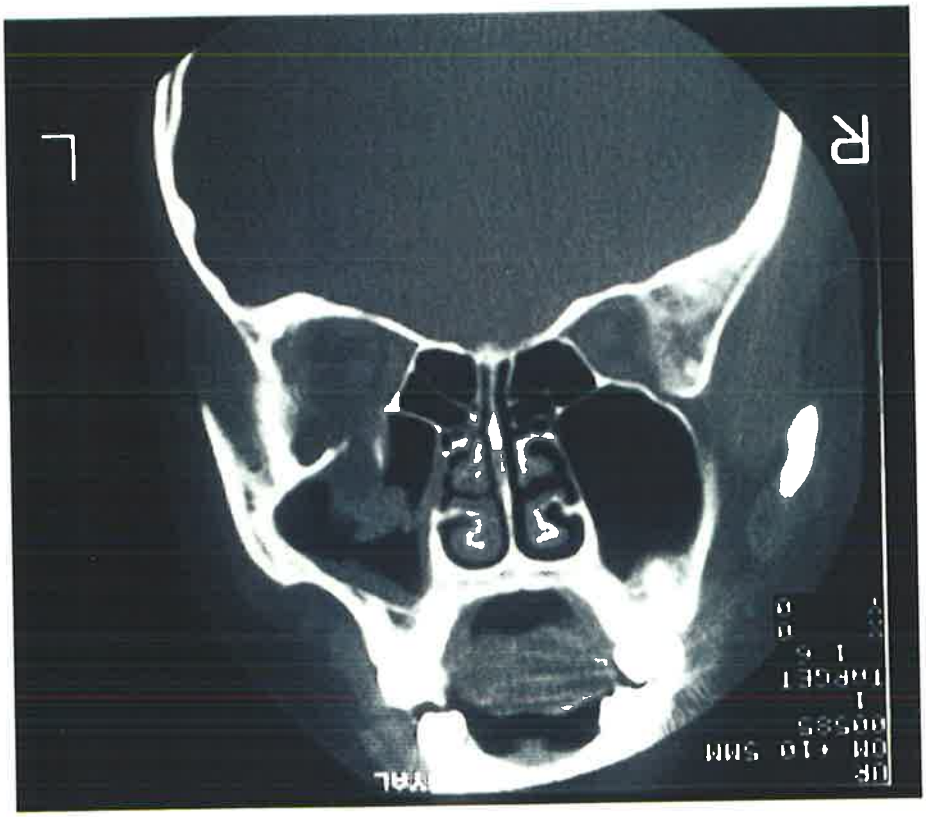

Figure 1.15 A coronal CT scan showing an orbital blow out fracture of the orbital floor.

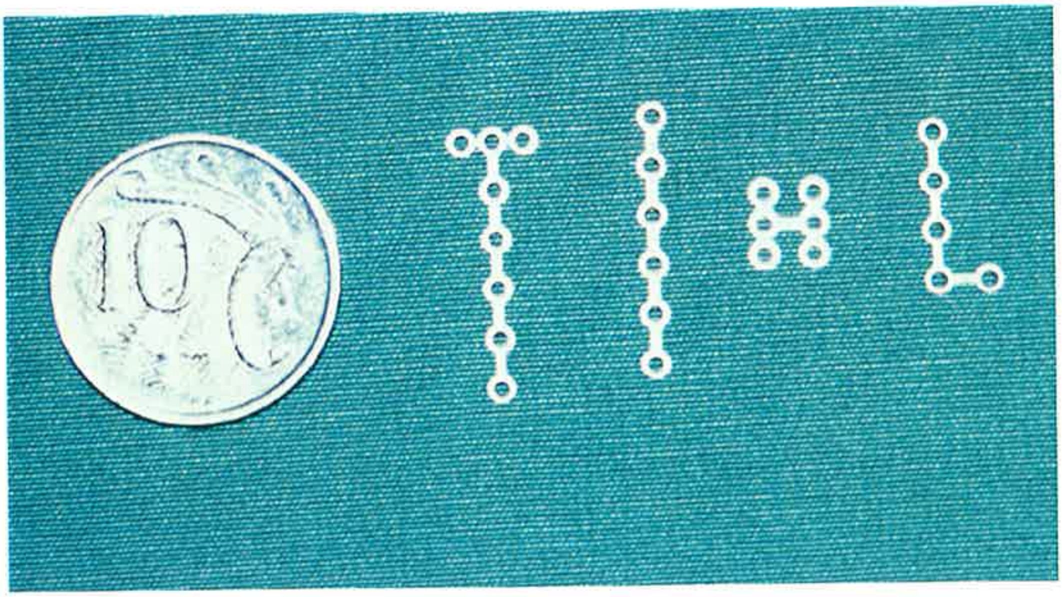

Figure 1.16 The smallest plates currently available are the microsystems, such as the Luhr microplates shown here.

Figure 1.17 An undisplaced mandibular fracture may be managed non-operatively with close follow up to detect any shift in the position of the fracture

Current therapy involves exploration of the orbital floor via a transconjunctival approach. This was first described by the Parisian surgeon Bourguet in 1920. After reduction of the orbital contents from the maxillary sinus the defect is repaired using bone graft, usually calvarial. Reconstruction of the orbital walls may be achieved with alloplastic materials such as Silastic sheeting, Marlex mesh, or Vitallium mesh. These have the obvious advantage of avoiding the need for a donor site. However the alloplastic materials are prone to infection and extrusion. For this reason Trott et al (1995) have recommended the use of autogenous bone graft for orbital reconstruction. This has been commonly used as simple onlay bone graft, however rigid fixation of the bone graft will result in a greater chance of survival (Rahn 1989), and this has been achieved with miniplates or more recently with microplates. Bartley and McCaffrey (1990) also advocate the use of autogenous material. They have experimented with cryoprecipitated fibrinogen (fibrin glue) in orbital surgery. This was used to repair a traumatic right orbital blow out fracture which had resulted in a traumatic naso-orbital fistula. A facia lata graft was fixed in place over the fistula with autologous fibrin glue.

2. Zygomatic Fractures.

Open reduction and internal fixation of zygomatic fractures are necessary to prevent facial disfigurement. Rinehart et al. (1989) investigated fixation of zygomatic fractures using cadaver heads with osteotomies cut to simulate zygomatic fractures. The fractures were fixed with wires or miniplates, after which static and oscillating loads were applied to the zygoma simulating the normal masticatory stresses applied by the masseter muscle on the zygoma. The results showed that neither single miniplate fixation at the zygomatico-frontal osteotomy, nor triple wire fixation at all three osteotomy sites, was sufficient to stabilise the zygoma against these simulated forces. Only double miniplate fixation at the zygomatico-frontal and zygomatico-maxillary osteotomies was successful in withstanding the simulated physiological masticatory forces. The authors suggest that this was due to the absolute three-dimensional stability afforded by two miniplates. The thin skin and subcutaneous tissue in this region means that miniplates are often palpable and may even produce noticeable contour deformities. For this reason lower profile plates have been suggested, for example Yaremchuk (1993) recommended that microplates be used at the infraorbital rim and the zygomaticofrontal suture (Figure 1.16).

3. Maxillary Fractures.

Maxillary fractures are best treated by rigid internal fixation after disimpaction of the fracture and restoration of the occclusion. The bones of the maxilla are extremely thin, nevertheless they are amenable to screwed miniplates. Ewers and Schilli (1977) proved in a tension-optical research project that even in areas of very thin compact bone metal plate osteosynthesis resulted in a ten times higher structural strength than wire osteosynthesis. There are four anterior vertical midface buttresses and these provide a guide to the reduction of the fracture and a site for miniplate fixation. Accurate moulding of miniplates to the three dimensional contours of these bones is important, so malleable miniplates are an advantage (Trott et al 1995).

Occlusal Fractures.

Occlusal fractures may result from middle third or lower third fractures. Facial fractures which disrupt the occlusion (either maxillary or mandibular) require careful analysis if satisfactory post-operative functional and aesthetic results are to be achieved. Trott and David (1995) recommend a standard preoperative preparation. In this, the examination by the craniofacial team dentist is of primary importance. After examining the occlusion, the dentist takes a set of dental moulds and arrange for dental models to be made. After careful study of the pre-morbid occlusion, the orthodontist cuts the models to restore the occlusion of the models to the pre-morbid state. Now armed with this model the orthodontist arranges for the manufacture of an intermaxillary wafer. This wafer will allow the teeth to be wired into their normal occlusion intraoperatively following reduction of the fracture. Reduction is the single most important factor in the treatment procedure. The first principle is to restore the dental occlusion in a correct relationship with the skull base. Once this is achieved the occlusal complex can be placed in the correct position to ensure alignment and soft tissue contouring of the face (Cook 1986). The patient is thus placed in intermaxillary fixation using the wafer to ensure correct occlusion. The fracture is then stabilised with screwed miniplates via an intraoral approach. The oral approach is preferred as it avoids incisions on the face, and also is associated with a lower rate of post-operative infection and osteomyelitis (Luhr 1987). Once the fracture is stable the intermaxillary fixation is released.

Fractures of the Lower Third.

This refers only to fractures of the mandible. Mandibular fractures are the second most common facial fracture, second only to nasal fractures (Cook 1986). Since mandibular fractures often disrupt the occlusion, many of the principles involved in their management have been discussed above under "Occlusal Fractures".

The basic management of mandibular fractures revolves around the occlusion. An undisplaced fracture not disrupting the occlusion may be managed without operative intervention by resting the jaw (possibly in intermaxillary fixation) and observing closely for any shift in the status quo (Figure 1.17). However if there is any displacement of the occlusion then open reduction and internal fixation are essential. The techniques of internal fixation of mandibular fractures will be discussed in chapter 4.

1.7 CONCLUSION

The management of facial fractures has seen revolutionary changes in the last fifty years and is now a highly sophisticated area of surgical practice. Treatment methods currently employed have been designed with reference to the histological processes involved in fracture healing and the biophysical properties of the fixation systems. It is important to note that the evolution of these techniques is an on going process and that many questions remain unanswered.

Although titanium has been acclaimed for use in clinical practice, little is known of any long term detrimental effects. The safety of this material has been assumed on a variety of evidence. This will be discussed in detail in Chapter 2. However bitter experience with other implant materials shows that absence of long term side effects should never be assumed. Development of absorbable miniplates is one option that has yet to gain wide acceptance, such as the nylon plates developed by Pistner et al. (1991). In 1989 Bos et al. successfully treated ten unstable zygomatic fractures with plates and screws made of bioabsorbable poly(l-lactide) plates. They found that these plates remained in place for a sufficient time to allow osteosynthesis to occur, and that bioabsorption was complete in approximately eighteen months.

The use of autologous materials should be encouraged where possible. For example, autologous bone graft used to reconstruct the traumatised orbital floor is preferable to silicon implants. Bartley and McCaffrey (1990) have experimented with cryoprecipitated fibrinogen (fibrin glue) in orbital surgery. With increased concern over the long term effects of permanent implants in the body I expect the development of autologous materials to receive increased attention.

The evaluation of the effectiveness of miniplate fixation has taken the form of two broad areas of research. The first involves clinical studies which broadly assess the results of treatment based on clinical evaluation in categories such as post operative occlusion, complication rates, re-operation rate etc (Klotch and Gilliland 1987, Schwimmer and Greenberg 1986, Stoll and Schilli 1988). The second category of research has involved in vitro, cadaver, and in vivo studies. These have calculated the stability afforded by miniplate fixation across osteotomies cut through facial bones or perspex models (Ewers and Harle 1985, Ikemura et al. 1988, Rinehart et al. 1989). Kroon et al. (1991) found that the fixation techniques commonly used were inadequate to stabilise an osteotomy across a perspex model. These studies have significant errors built in to them as a result of the method employed. They fail to appreciate the added stability afforded by the ragged ends of the fracture as opposed to the clean ends of an osteotomy. In addition, the in vitro methods must use basic uni-directional forces assumed to be acting across the osteotomy. These forces cannot take into account the complex multidirectional forces of facial musculature, both prime movers and synergists. In addition, these studies assume that movement at the fracture site in the experimental model is indicative of failure, despite there being no conclusive evidence to support this view. Whilst the proponents of dynamic compression plates such as Luhr (1968) and Marsh (1989) claim that best results are achieved by allowing no movement at the fracture site, and hence direct (primary) bone healing , Ikemura et al. (1988) proved that non compression plating was equally effective. Further evidence supporting this view is provided by the excellent results achieved by the time honoured techniques of external fixation of long bone fractures which allow limited movement at the fracture site (Apley 1982).

As miniplate technology has developed, a number of clinicians have chosen to use miniplate which are lighter, smaller, and more malleable titanium, such as those produced by Aus Systems. These plates are easier to use at the time of surgery as they can be moulded to the contours of the facial skeleton by hand or with light pliers. Recently, Luhr (1990) has taken this trend further with the development of microsystem plates for use in craniofacial surgery. These vitallium plates are non compression plates only 0.5 mm thick. Luhr suggests that the low plate-screw profile combined with the ductility of the alloy allows for easy contouring of the plates in regions not subjected to remarkable muscle actions.

As clinicians increasingly turn to the use of smaller plates with monocortical screws the stability provided by these devices will be closer to the critical load characteristics of the fractures. If movement does occur at the fracture site the load characteristics change and much greater stresses are placed on the plating systems (Rudderman and Mullen 1992). It therefore follows that studies must be done to determine the properties required of the plating system for each fracture site, so that the choice of miniplate can be tailored to the biomechanics of each particular fracture site.

In view of the ever increasing costs of health care, and the current trend to casemix type funding across Europe, North America, and Australia, the pressure on health budgets has probably never been greater. To this end the cost effectiveness of treatment has become an important evaluation indicator. One critic of the miniplate techniques is Duckert (1991) who states that in comparison to the internal or external suspension techniques, the individual plates and screws are expensive, as is the special instumentation required. This is far too narrow an analysis to make any reasonable conclusions regarding the cost effectiveness of a procedure. Thaller et al. (1990) compared cost effectiveness of miniplate fixation against intermaxillary fixation. Despite the initially higher costs associated with the hardware associated with miniplate techniques, the miniplates were shown to be cost effective as they resulted in reduced time in hospital, fewer outpatient visits, fewer complications, and a more rapid return to premorbid lifestyle.

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CHAPTER 2

COMPARISON OF THE BIOMECHANICAL PROPERTIES OF MINIPLATES

CONTENTS

2.1 INTRODUCTION

Since the introduction of miniplates for the treatment of mandibular fractures in the 1960's, there has been a rapid expansion in the number of miniplating systems commercially available. One only has to read the journals that commonly carry articles regarding cranio-maxillo-facial surgery to be acutely aware of the large number of products and manufacturers saturating the market. Whilst the debate between the proponents of compression and non-compression plating has been thoroughly investigated and reported, there has been little comparative work with regard to miniplates of apparently similar design and function. Manufacturers have sought to improve these products (and their market share) by varying the design, properties, profile and materials of the implants. This has resulted in a great deal of choice afforded to the clinician. However, despite the large number of obviously different systems, little comparative work has been published to date. In an endeavour to understand the clinical relevance of these specifications the present comparative study was undertaken to generate meaningful information to help surgeons to choose an optimal plating system for mandibular fracture management.

This chapter will investigate the important principles in miniplate design, and then compare the properties of the five major systems in use at the Royal Adelaide Hospital.

The ideal miniplate would exhibit a number of features. It would be;

- cost effective
- easy to mould to the contours of the facial skeleton
- sufficiently stiff to maintain rigid fixation, and strong enough to resist deformation across the plate during fracture healing
- completely biocompatible
- low in profile so as not to be palpable
- of composition so as not to produce scatter in CT scans
- not intrinsically responsible for producing complications

2.2 MATERIALS

Any comparison of the engineering properties of miniplates must take into consideration their metal composition. This is of particular importance as many of these plates are often left in situ indefinitely, so biologically inert metals are preferred. The three commonly used implant materials are stainless steel, Vitallium, and titanium. The choice of the implant material will influence the strength and stiffness of the implant, the biocompatibility of the implant, and the imaging properties of the implant, particularly with regard to CT investigations.

In choosing a plating system from the product information of the various manufacturers the clinician may be confounded by the terminology used. For example the hardness of the component metal may be expressed in a variety of units such as the Vickers hardness number (VHN) and the Rockwell scale (R_B and R_C). The tensile strength and elongation to fracture of the core metal are other parameters often quoted. Unfortunately these indicators do not take into account the structural performance of the individual plates, and hence do not provide the clinician with a simple guide to directly compare the plates. Table 2.1 details some of the information provided in the product information sheets provided by the manufacturers.

Table 2.1

	AUS SYSTEMS	LUHR	WÜRZBURG	CHAMPY
Material;	Pure titanium Grade 2	Vitallium	Titanium	Stainless Steel
Thickness	1.0mm	0.7mm	1.0mm	1.0mm
Tensile Strength	to yield 230 M Pascals to fracture 280 M Pascals	ultimate 2% yield strength 67 ksi	ultimate 2% yield strength 41 ksi	ultimate 2% yield strength 40 ksi
Elongation to fracture	52%			
Hardness	125 VHN	scale 25 R_C (=125 R_B)	68 R_B	81 R_B

This information often refers to tests carried out on the core metal, and the terminology used is not consistent. In addition the concepts used are not those with which clinicians are usually familiar. Finally, most of the manufacturers make no attempt to link the information they have provided with clinical trials that demonstrate the reasoning behind the miniplate design.

More than any other author, Luhr has performed extensive laboratory and clinical research into the maxillofacial plating systems that bear his name. A disadvantage of this research is that it is principally directed at the Luhr system, and rarely affords the reader with any comparative work. He does however remain convinced of the benefits of vitallium over other implant materials due to the much greater hardness and tensile strength of the alloy. Here through experiments at Howmedica research and development, Luhr shows that the Luhr vitallium alloy has 60% greater yield strength than pure titanium and 316L stainless steel, and 84% and 54% greater hardness than pure titanium and 316L stainless steel respectively. What this does not tell us is whether the extra strength and hardness are *necessary*, *beneficial*, or have *detrimental* effects. It is not simply enough to argue that if the plate is stronger for the same (or even lower profile) that it is intrinsically superior, as there are significant disadvantages in working with stiff and unyielding plating systems. Most clinically apparent intraoperatively is the difficulty in moulding these plates to the shape of the bony skeleton. If the compression plate is not accurately moulded to the contours of the bony skeleton, then when the screws are tightened to secure the plate, the fracture can actually be deformed (Figure 2.1).

2.3 BIOCOMPATIBILITY

Biocompatibility is defined as the interaction between biomaterials and the body (Williams 1986). Luhr (1985) expands on this definition and states that biocompatibility is "the state of affairs when a material exists within a physiological environment without either the material adversely affecting the body, or the environment of the body adversely and significantly affecting the material ".

Metallic implants have been used for internal and external fixation of bony fractures since the latter part of the 19th century. Early surgeons using these techniques were aware of the tissue reactions that occurred with the placement of these implants. Hansmann in 1886 realised the possibility of a reaction between the plate and screws and therefore incorporated the need for routine removal of implants into his surgical planning. In the early part of the 20th century various workers began to report the extensive tissue destruction that occurred when dissimilar metals were present in the same wound (Byrne 1973). However Venable et al (1937) were the first to demonstrate experimentally that the electrochemical reaction that occurs between metals causes soft tissue and bony destruction.

Consequent on these early studies has been continuing research to quantify the extent of tissue destruction resulting from a given electrochemical reaction, to develop new alloys of greater biocompatibility, and to investigate the systemic effects of metallic implants in situ.

Mechanism of corrosion

Corrosion refers to the electrochemical destruction of metal, and therefore requires a complete circuit for current to flow (Byrne et al 1973). For corrosion to occur, a flow of current must first occur, and this requires a potential difference to exist between anode and cathode.

This pathway consists of four components;

the anode

the electrolyte

the cathode

a metallic pathway between the anode and the cathode

All four components may exist when a metallic implant is placed in vivo. This is most obvious when dissimilar metals are placed in a wound as noted earlier, however it may occur even when apparently the same metal is used. This may be due to fragments of the screwdriver head of dissimilar metallic content being deposited in the wound, or it may be due to impurities in a single piece of metal thereby producing anodic and cathodic foci. Thus when using titanium plates it is essential to use titanium screws of identical composition, and titanium tipped screwdrivers should also be used (Simpson 1965) lest minute shavings of dissimilar metal be left near the implant and result in a corrosive reaction.

The mechanism of corrosion consists of four parts (French et al 1984, Rostoker et al 1974).

1. Depassivation

   this refers to destruction of the inert protective surface of the metal that prevents corrosion. Metals form this protective surface by oxidation. Thus when titanium is implanted a film of titanium dioxide forms over the metal thereby rendering it extremely resistant to corrosion. This has the potential to reform except in the presence of fretting.

2. Fretting

   the presence of continual motion which causes depassivation and also releases small fragments of the metal (wear particles). These wear particles are a particular problem in load bearing joint replacement and are perhaps less important in the relatively rigid environment of the facial fracture miniplate.

3. Galvanic cell component

this refers to the formation of a galvanic cell at crevice areas, especially screw plate interfaces. The 316L stainless steel used in many implants have been shown to be particularly vulnerable to crevice corrosion. Crevice corrosion occurs because the electrolyte (interstitial fluid) in a crevice becomes stagnant. The oxygen saturation falls allowing accumulating metallic chlorides to hydrolyse, and thus causes the pH in the crevice to fall (Cohen 1972).

4. Local environmental factors.

a fracture is associated with an inflammatory response, and the lower pH which results may facilitate corrosion (Moberg et al 1989). Varying temperature, oxygen tension, or electrolyte concentration may also influence the rate of corrosion (Rowe and Killey 1970, Byrne and Laskin 1973).

Tissue reaction to corrosion

Corrosion of metallic implants may result in loosening of the implant, pain, delayed or non-union, a sterile abscess, osteomyelitis, generalised dermatitis, or produce systemic effects that are less readily directly attributable to the implant (Byrne and Laskin 1973, Kubba et al 1981, Moberg et al 1989, Guyuron and Lasa 1992). Whilst voltages of 1-20 microamperes have been shown to stimulate bone growth (as seen with pisoelectric forces), voltages greater than 40 milivolts are sufficient to cause bone and soft tissue necrosis (Byrne 1973). This may be due to either the electrical stimulation of the tissues, or as a result of toxic irritation caused by metallic ions deposited in the tissues. Stainless steel often develops potentials in this range in vitro (Byrne and Laskin 1973)

Two types of tissue reaction have been observed. One is simply a chronic inflammatory reaction characterised by granuloma formation, macrophages, and necrotic areas (Coleman et al 1974). The second type of reaction is that of an allergic reaction to the metal ion.

Release of metal ions from implants.

That metal ions are released from implant materials is well established (Michel 1987, Lugowski et al 1991). Release of metal occurs in vivo from all alloys used in implants, including cobalt, chromium, nickel, molybdenum, aluminium, and titanium (Moberg et al 1991). Cobalt, chromium, nickel, molybdenum, and aluminium have all been shown to cause local tissue reactions as well as varying levels of cytotoxicity. In a study using seven monkeys of the Cercopithecus aethiops species, Moberg et al (1989) implanted Champy miniplates (stainless steel), Vitallium plates and titanium plates. They found that cobalt, chromium, nickel, molybdenum, aluminium, and titanium were all found in the soft and hard tissues near the implants.

In addition to the possibility of local reactions to metal implants, there is a theoretical risk of a carcinogenic response. Chromium and nickel have shown carcinogenicity in animal experiments, and one author has reported eleven cases of malignant tumors possibly related to metallic implants, most of which contained chromium (Altobelli 1992).

2.4 IMPLANT MATERIALS

The choice of implant material has become more critical in recent years. This is because plates are often left in situ indefinitely, unless complications ensue. Champy et al. (1976) advocated the removal of miniplates at three to four months post operatively, although he had no specific reason, and this became standard practise in some centres (Cawood 1985). Brown et al. (1989) challenged this practice by analysing the results of miniplates left in situ long term. They found that 18% of patients required removal of plates, and no evidence that plates left in situ during the period of the study (3 - 5 years) would cause systemic complications. Thus they concluded that plates should only be removed if clinically indicated. This view has been supported by Jackson et al. (1986), and Beals and Munro (1987).

Most of the concern regarding the implant materials centres around their biocompatibility. As stated earlier, an ideal state of biocompatibility exists when "a material exists within a physiological environment without either the material adversely and significantly affecting the body, or the environment of the body adversely and significantly affecting the material" (Luhr 1985). If the plates are to be left in situ indefinitely, then they must fulfil the requirements of biocompatibility. Whilst it is known that these plates cause a local tissue reaction, that reaction must be proven not to have any long term deleterious local or systemic effects.

Stainless Steel

The first miniplates were stainless steel, and the use of this implant material is still maintained by both the AO and the Champy systems. The metal used is known as 316L stainless steel and contains 62.5% iron, 17.6% chromium, 14.5% nickel, 2.8% molybdenum and minor amounts of other elements (Disegi 1992). However stainless steel has been shown to be susceptible to corrosion (Weinstein et al 1973, Sutow and Pollack 1981). Two important points should be made. First, this research centres on orothopaedic implants that are possibly subjected to greater stresses than the miniplates used in treating facial fractures. Continuous abrasion accelerates corrosion and may lead to the metallosis syndrome seen following orthpaedic joint replacement surgery. Secondly, will this corrosion result in long term negative effects on local or distant tissues.

As has already been discussed, stainless steel implants result in the release of metal ions including chromium, nickel, iron, and molybdenum into the surrounding tissues. Nickel is a strong hapten, causing contact dermatitis in 10 % of women and 2% of men (Schubert et al 1987). It has been proposed that an allergic reaction (delayed type hypersensitivity Type IV reaction) could cause loosening of the implant, pain, malunion, a sterile abscess, generalised dermatitis, or produce systemic effects that are less readily directly attributable to the implant (Kubba et al 1981, Moberg et al 1989, Guyuron and Lasa 1992). In a study of fifteen patients with mandibular fractures treated using stainless steel miniplate osteosynthesis, Torgersen et al (1993) tested the patient for a delayed type hypersensitivity reaction to nickel. They found that the presence of nickel at a concentration of than or equal to 5μg/ml was associated with toxic changes in the lymphocytes. However no significant link between lymphocyte transformation and complication rate was demonstrated. The incidence of nickel sensitivity in the general population is far greater than the incidence of clinical reactions in relation to stainless steel implants. It may well be the case that the slow release of haptens from the implant produces tolerance in most cases (Kubba 1981).

However since implant materials of greater biocompatibility are available it would seem prudent to use them. The Luhr system, which is widely used comprises vitallium which is a cobalt - chromium - molybdenum alloy. Titanium is also widely used, exclusively by Aus Systems and Würzburg, and in certain implants produced by the AO group.

Vitallium

Vitallium is an alloy of cobalt, chromium, and molybdenum comprising 60-61% cobalt, 28-29% chromium, 4.5-5% molybdenum, and 1.5-2% nickel (Ardary 1989). This alloy was first used in 1936 by Venable and Stuck (1947). It is highly biocompatible and has been used since that time with no evidence of harmful systemic reactions (Williams 1981, Orthopaedic Knowledge Update I 1984). Vitallium is resistant to corrosion due to the formation of a surface coat of chromium oxide (Cohen 1962) and can remain in the organism for an unlimited period of time (Venable and Stuck 1947). Although claimed to be corrosion resistant in comparison to other implants (in particular stainless steel), Cohen (1972) reported a case of failure of a vitallium Thornton plate and Smith-Petersen nail which they attributed to crevice corrosion. They proposed that the failure was due to the wrought vitallium component of the implant and not the cast vitallium component. Cast vitallium was shown to have similar mechanical properties and greater corrosion resistance than wrought vitallium.

Titanium

Recently manufacturers such as Synthes (AO plates), Aus Systems and Liebinger (Würzburg) have turned to titanium. Titanium and Vitallium were found to be superior to stainless steel as they are non corrosive (Müller 1991). The AO group states that titanium is the best material as it is the most biologically inert, and therefore has the least chance of producing any low grade immunological response. No allergic reactions to titanium have been reported (Hobar 1992). The biocompatibility of titanium is attributed to the immediate formation of stable oxides on exposure to air which result in a tough ceramic coating of the implant (Ellender 1991). This coating of titanium dioxide renders the implant very resistant to corrosion. The tissue around the implant may be found to contain the pigmented deposits of titanium dioxide, but there is no evidence to suggest that these are irritative or detrimental in any way (Rosenberg 1993). Although titanium is non-corrosive under physiological conditions, it may undergo surface alteration due to the action of free radicals released in areas of acute inflammation by polymorphonuclear leucocytes. There has been little research into the long term effects that these changes may have.

Titanium, element 22 on the periodic table, is principally produced from mineral sands such as rutile and ilemite. Australia supplies nearly half of the worlds rutile, producing approximately 240 000 tonnes per annum. Most manufacture of pure titanium occurs principally in Japan.

Titanium used in the manufacture of miniplates for surgical use includes Grade 1,2, and 3 titanium. These grades of titanium contain small quantities of nickel, carbon, hydrogen, iron, and oxygen. The composition of each grade is shown in Table 2.2.

Table 2.2

ELEMENT	GRADE 1	GRADE 2	GRADE 3
NITROGEN	0.03	0.03	0.05
CARBON	0.10	0.10	0.10
HYDROGEN	0.015	0.15	0.015
IRON	0.20	0.30	0.5
OXYGEN	0.18	0.25	0.4
RESIDUALS(tot)	0.4	0.4	0.4
TITANIUM	99.075	98.77	98.765

Rosenberg et al (1993) examined a series of thirty two patients who had either titanium or Champy (stainless steel) miniplates in situ, and examined the soft tissue and bone in following removal of the implants. Examination of the soft tissues showed microscopic metallosis in 71.8% of cases where titanium plates were removed, and in 65.3% where stainless steel was in situ. Analysis of the tissue from around the titanium miniplates showed only the presence of titanium dioxide between the collagen fibres.

No titanium dioxide was found in macrophages. In contrast the soft tissue around the stainless steel plates contained chromium, nickel, iron, and molybdenum. These particles were found to have been taken up by giant cells. They conclude that as the stainless steel plates release toxic materials they should be removed as a matter of routine. As to whether titanium plates should be removed the answer is unclear. However, as there is no convincing evidence of toxic effects of these plates, then there is no clear indication for the routine removal of titanium plates.

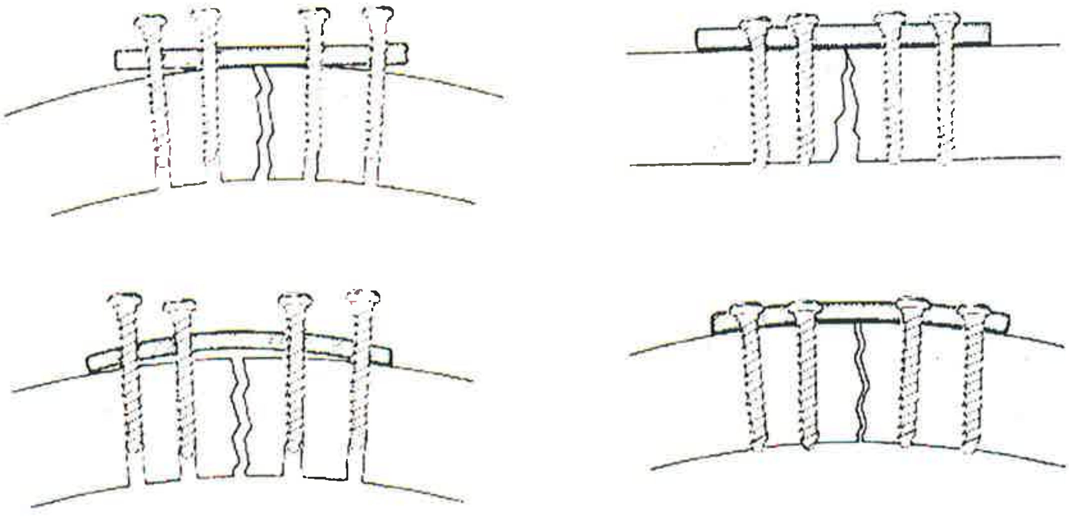

Figure 2.1 This diagram shows how a rigid plate that is not accurately moulded to the fracture (a) will deform the fracture. The plate must be accurately moulded (b) to avoid this when the screws are inset.

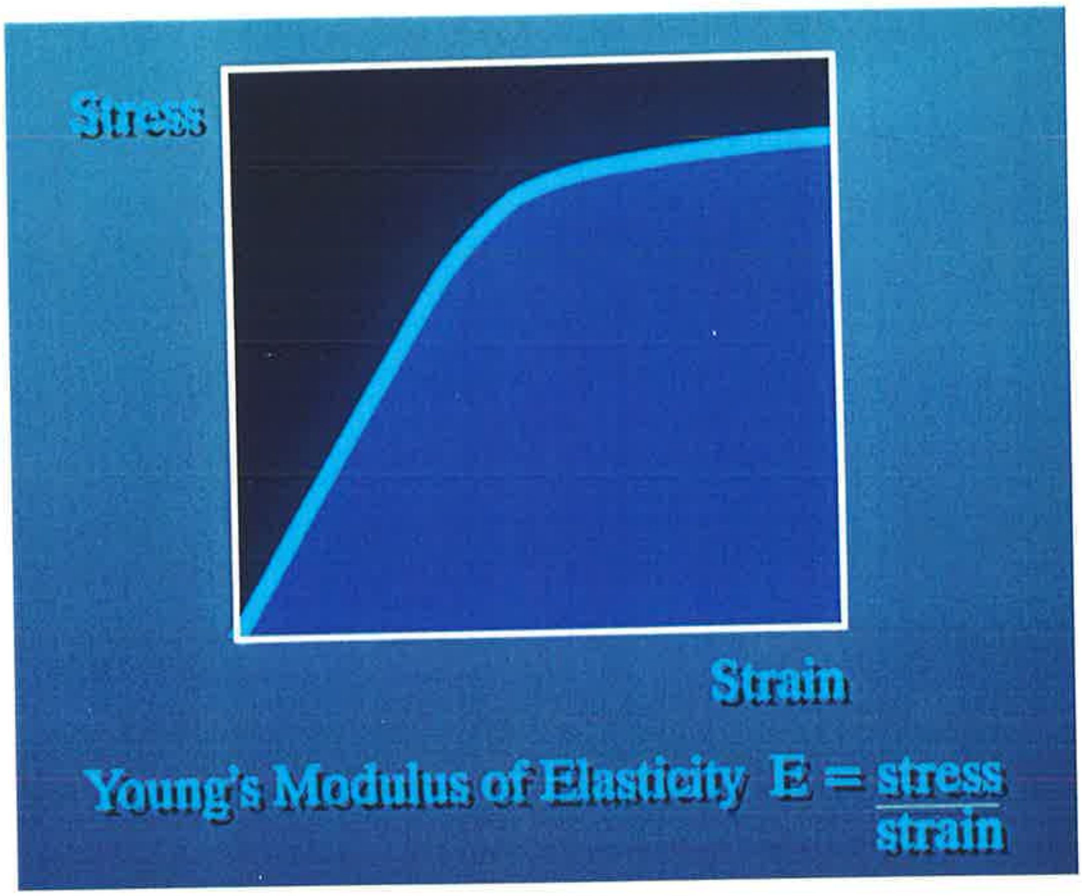

Figure 2.2 The stress strain curve

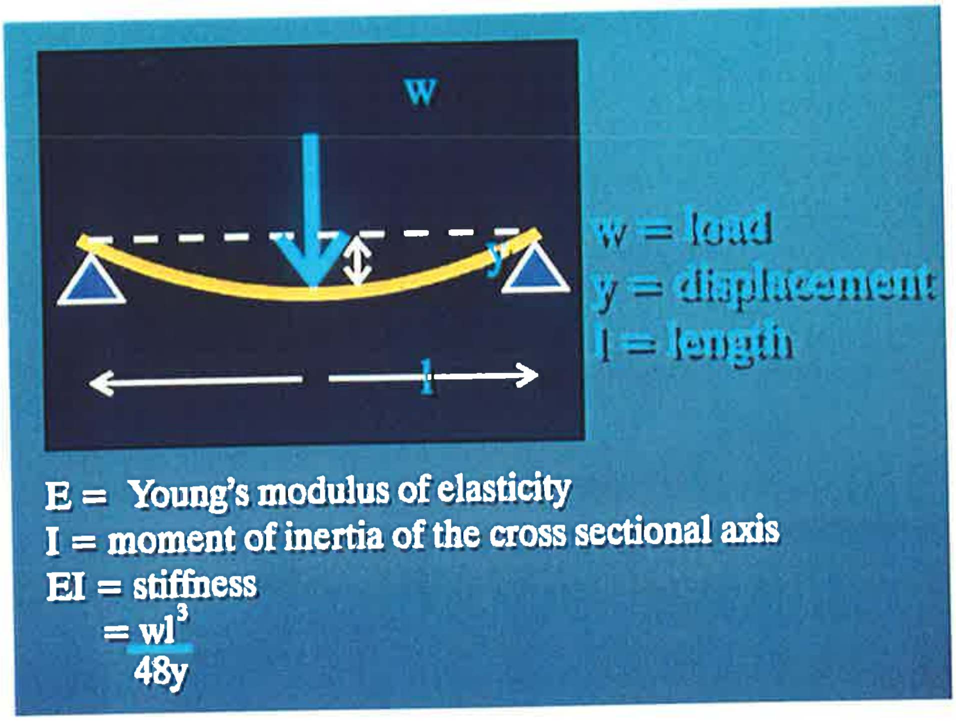

Figure 2.3 The method of calculating the stiffness of the plate

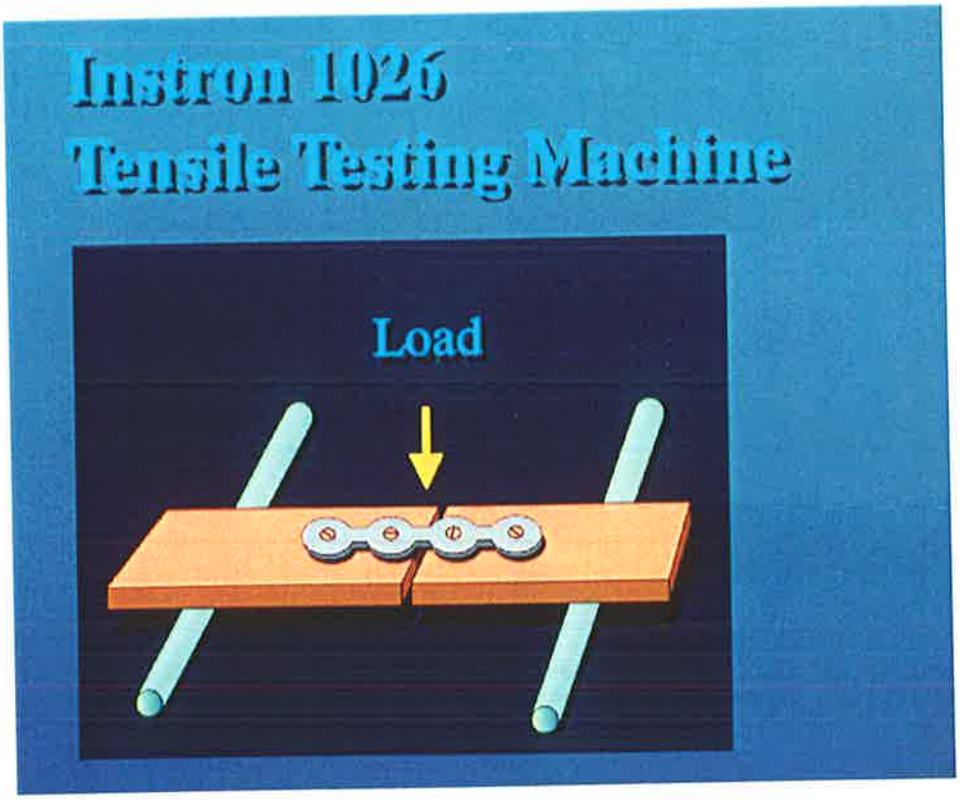

Figure 2.4 The testing rig designed to test the miniplate and screws as a functional unit

2.5 BIOMECHANICS OF IMPLANTS

Literature Review

The biomechanical properties of miniplates are of obvious importance in achieving stable fixation of a craniofacial fracture. Various biomechanical indices are often referred to in both the product literature and in scientific articles addressing a particular plating system. This has not yet reached as far as providing clinical comparison between different plating systems, and so there is no scientific basis on which to base the selection of one miniplating system over another. For example, although Luhr (1985) provides comparison of mechanical properties of the Luhr system with Würzburg, Champy, and AO systems, and concludes that as the Vitallium is a material of greater tensile strength, hardness and yield strength, then the vitallium plates are superior. This is based on the assumption that the greater the hardness of the implant, the more efficacious the miniplate must be. However the results are not correlated with any comparative clinical research and hence as a guide to plate selection they are virtually useless. This is not to infer that Luhr has not responsibly audited the performance of the Luhr plating systems, but to point out that the comparative analysis of the plating systems has yet to be fully investigated.

As a result of the lack of experimental data, clinicians are left to select plating systems based on inadequate information. Taking this one step further, the science of selection of the size and strength of plating system for various regions of the craniofacial skeleton has also been neglected, leaving clinicians to estimate the strength of plate that might be required for a specific area, eg a 'heavy plate' for a mandibular fracture due to the perceived forces applied across the mandible, or a 'small plate' to stabilise a nasoethmoid fracture due to the absence of large muscular forces applied across this fracture.

Recently some literature has appeared analysing the biomechanical properties of miniplates. Damron et al (1994) compared the biomechanical properties of Luhr vitallium minifragment plates, Synthes titanium minifragment plates, and Synthes stainless steel minifragment plates designed for craniofacial applications but in this study used for dorsal plate fixation of proximal phalangeal fractures. This study, while useful as a baseline of biomechanical comparative data, fails, to compare the in vivo performance of the plates to allow conclusions to be drawn as to whether the biomechanical differences between the plates are reflected in the clinical outcome.

Hegtvedt et al (1994) have compared the Luhr minisystem with the Luhr microsystem to provide a comparison of the biomechanical properties of each system. They showed that there is a significant difference in the force required to bend miniplates compared with microplates. They then review some of the expected forces that occur in vivo, and make some guarded conclusions about correlating the in vitro biomechanical properties with in vivo forces. For example, if a plate is shown to withstand a certain force in a biomechanical model, does this mean that the plate can withstand a similar occlusal force in vivo. The authors make it clear that clinical studies are needed to confirm such an assumption.

ORIGINAL RESEARCH:-

Biomechanical properties of miniplates.

The aim of this study was to produce a clinically relevant comparison of the different mechanical properties of the miniplates. Many different standards are used by the manufacturers to display the properties of their plates; however these rarely include comparisons with other plates, and differing standards are employed, making comparison by the clinician virtually impossible. In addition the figures quoted often refer to standards of the core metal used, rather than figures which directly relate to the actual miniplate.

The most important indicators to the clinician are

the stiffness of the miniplate

and

the force that is required to permanently deform the plate

If the clinician is armed with the answers to these two questioń, then he/she will be able to select a miniplate (taking into account the cost, biocompatibility, and CT compatibility of the plate) able to withstand the expected forces, yet still malleable enough to be shaped to the contours of the bone and hence 'operator friendly'.

2.6 MATERIALS AND METHODS

This study was conducted at the department of materials engineering at the University of Adelaide. Five miniplate systems were selected for investigation, these being the five systems commonly used at the Royal Adelaide Hospital, ie the Luhr, Würzburg, AO/ASIF, Medicon, and Aus Systems miniplates.

Mechanical Properties

When considering the mechanical properties of miniplates, the prime consideration should be their stiffness and strength in bending. As the aim of this study was to test the miniplates already in use, not to develop new miniplate design, it was possible to test each miniplate system and its screws as a functional unit: this is more relevant than tests performed on a standard piece of the alloy or metal.

When a load is applied across a material this is defined as stress, where

$$\text{stress} = \frac{\text{force}}{\text{area over which the force is applied}}$$

The deformation of an object in response to an applied load is known as strain, where

$$\text{strain} = \frac{\text{elongated length - original length}}{\text{original length}}$$

Stress versus strain behaviour may be represented graphically, and a curve that represents a continuous response of the material toward the imposed force is recorded (Fig 2.2). In the elastic section, the strain is reversible, that is to say that the metal returns to its original shape after the stress is removed. This is Hookes law;

Hookes law - for a linear elastic material, the strain increases in direct proportion to the applied stresses

The slope of the linear elastic section (denoted by E) is Young's modulus of elasticity.

$$E = \frac{\text{stress}}{\text{strain}}$$

Young's modulus of elasticity is a measure of the rigidity of the material, and is therefore a property of the material.

At a certain point, the deformation of the material ceases to be elastic (reversible) and becomes plastic (permanent). In the plastic region strain changes are no longer proportional to the applied stress. The point at which this occurs is known as the yield point, and is the most important value for design.

The critical property of the plate in vivo are those which resist the bending forces across a fracture line, that is the stiffness of the plate and its yield load.

If E = Young's modulus of elasticity

and I = the moment of inertia of the cross sectional axis at mid span

then E × I = the stiffness of the plate

E x I is found by the equation;

$$\text{Stiffness} = E.I = \frac{w.L^3}{48y}$$

where w = load

y = displacement

l = length

As the distance 'l' between the grips is known, and the load 'w' and the displacement 'y' are measured, thus EI can be calculated using the formula (Figure 2.3).

With this in mind, the specific aim of this study was to scientifically compare the engineering properties of miniplates commonly used in fracture treatment, and thereby to allow in a clinical setting a comparison of the in vivo performances of the same miniplates, in order to identify which of these properties influences treatment outcome.

The miniplates tested were those in use at the Royal Adelaide Hospital, and they represent some of the most popular plates in use around the world. These were;

AO miniplates

Aus Systems miniplates

Champy miniplates

Luhr mini compression plates

Medicon miniplates

Würzburg miniplates

These miniplates are constructed of different materials, and do not conform to any standard size, profile, or shape. However they are all used in the treatment of mandibular fractures, and this was the reason for comparing them.

In conjunction with the Department of Materials Engineering of The University of Adelaide, a testing rig was designed (Figure 2.4). A four hole miniplate was screwed into a brass template with two holes on each side, and a 0.25 mm gap to simulate a fracture. The screw holes were pre-tapped to accept the particular systems screws. This allowed each plating system to be tested as a functional unit, rather than testing individual screws independently. As the length l is the distance between the grips, then the equation gives the empirical value of stiffness for the composite structure (miniplate and brass plates). However in this model the brass plates were assumed to be infinitely stiff, thus only the deformation of the miniplating system could account for any deformation recorded. Obviously the distance between the grips is empirically chosen , and does not attempt to reflect the real case in vivo. This system was then placed in an Instron 1026 tensile testing machine, which is a three point bender exerting a known load on the simulated fracture line. Each plate was tested ten times and an average stiffness and yield point was established.

The Instron 1026 tensile testing machine was operated according to its operational protocol;

1. Selection of the load range required.
2. Calibration of the machine.
3. Insertion of the appropriate chart.
4. Selection of the cross head gears.
5. Set the grips to the requires separation.
6. Insert the specimen between the grips.
7. Press the up button to start the test.
8. Press the stop button when the test is complete.

Using our model, a load displacement curve replaces the stress strain curve. Young's modulus of elasticity multiplied by the moment of inertia of the plate gives the stiffness of the plate.

Each plate was tested ten times and an average stiffness and yield point was established.

2.7 RESULTS

The results of the engineering component of the study are shown in table 2.3, which lists both the yield points and the stiffness of each of the plates tested.

Table 2.3

	Yield Point (kg)	Stiffness (EI)
Aus Systems miniplates	1.12	2951.1
Champy miniplates	1.25	3699.1
Würzburg miniplates	1.25	5494.1
AO non comp[n] miniplates	1.8	2951.1
Medicon miniplates	2.2	4864.2
Luhr mini comp[n] plates	25	73981

2.8 DISCUSSION

As has been discussed earlier, miniplates vary in both their material composition and their design, and this has been well recognised. This study for the first time compares the differences in mechanical properties of the plating systems. The results of this study highlight that there are also many variables in the mechanical performance of the available miniplating systems which are used for the same indications in various treatment centres. Hence it is erroneous to consider them as interchangeable. It is also too simplistic to select a miniplate on the basis of one criterion. For example selection of a plate on the basis of stiffness alone ignores the other important variables such as biocompatibility, CT compatibility, cost etc.

Many of the desirable qualities of a miniplate have been discussed in this chapter. However the significance of the variation in mechanical properties can only be established when related to appropriate clinical trials. Whilst a plate that is easy to mould to the contours of he facial skeleton is important, what stiffness and yield point is required to achieve stabile fracture fixation for a given fracture? In chapter three I will examine the stability of mandibular fracture fixation using the "least strong" of the miniplates, namely the Aus Systems, and in chapter four I will compare the clinical results of treatment using the major plating systems.

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CHAPTER 3

IN VIVO ANALYSIS OF THE STABILITY OF MANDIBULAR FRACTURE FIXATION USING CEPHALOMETRIC RADIOGRAPHY

TABLE OF CONTENTS

3.1 INTRODUCTION

The clinician who wishes to select a miniplate suitable for fixation of a certain fracture needs to know the mechanical properties of the miniplate as discussed in chapter two, in addition he/she must also know the forces that are likely to be applied across the fracture line in vivo, and the direction of these forces.

Champy in 1976 was the first to consider this and used the amount of force and the direction of that force as a means for developing the rationale supporting the use of non compression miniplates rather than compression miniplates. Champy used an araldite mandibular model, and applied loads to the model and examined the effects of this under polarised light. Essentially he was able to demonstrate that in this model the mandible was subjected to tension forces at the upper border and to compression forces at the lower border. Thus by addressing the direction of forces acting across the mandible Champy was able to argue in favour of upper border plates to counteract the distracting forces, rather than the lower border compression plates that were in favour at the time. This was presented as the ideal osteosynthesis line. The presence of rotational forces at the anterior segment of the mandible, presumably due to the action of bilateral muscle groups on this area, was demonstrated and hence a combination of upper and lower border miniplates was recommended.

Champy (1976) then set about examining the forces acting on the mandible in vivo. He measured the maximum biting forces in young men with healthy teeth and his findings are listed below in Table 3.1.

Table 3.1

Region	Max^{m} Bite Force
Incisor region	290 N
Canine region	300 N
Premolar region	480 N
Molar region	660 N
Torsional forces anterior to canines	100 N

The results of Champy's theory on the direction of force acting across fracture lines was a critical factor in the shift towards monocortical non compression miniplates osteosynthesis, and influences the treatment of mandibular fractures to this day. In contrast the measurements of maximum bite force are not clinically relevant. This is due to a number of reasons. Firstly, during the healing phase of an occlusal fracture, no clinician expects a miniplate to resist the extreme forces of maximum bite force. Rather patients are placed on a strict non chew diet in order to avoid these forces. Thus the forces that must be respected include actions such as those associated with the opening and closing of the jaws, smiling, yawning, and "involuntary actions" during sleep.

Thus the challenge to enable a more scientific development of miniplate technology is to further refine knowledge related to the forces acting across a fracture line in vivo and the direction of those forces.

3.2 ASSESSMENT OF BITE FORCE

Measurement of bite force became possible when strain gauge instruments were developed in the 1950's (Anderson 1951). Gibbes et al (1980) took the important step of attempting to measure the bite force during chewing. They measured these occlusal forces using a sound transmission system. This has the advantage of avoiding the disturbance caused by intraoral insertion of a bite fork on which the subject bites, but is more technically demanding (Hagberg 1987). Gibbs et al (1980) showed that these forces were greatest in occlusal phase, second greatest in closing, and lowest in the opening phase of chewing. Thus the greatest forces occur during occlusion, when the jaw is motionless. The chewing forces were affected by the consistency of the food. Not surprisingly forces were greater for hard food (eg peanuts) than for soft food (eg cheese). Gibbs et al (1980) found maximal forces at occlusion of 356 Newtons when chewing peanuts, as compared to 229 Newtons when chewing soft cheese. Forces as high as 50 Newtons were measured during the opening phase of chewing.

Knowing the bending characteristics of the miniplates, and also having information regarding bite force and chewing occlusal forces, investigators have turned their attention to forces required to deform a miniplate in vivo. The technical and ethical difficulties of such a study make it difficult to perform in vivo, as any deformation would result in a mal-union hence requiring corrective surgery. In 1991 Kroon et al studied the effects of forces on mandibular fractures fixed with upper border non compression miniplates, using polyurethane mandibular models fixed to a transducer. However, they were unable to reach a conclusion about the amount of force that would be required to displace a fracture in vivo. The mandibular model, with an osteotomy cut to resemble a fracture, can never accurately simulate the clinical situation, as the reduced fracture has its own inherent stability providing some resistance to shearing and torsional forces, due to the jagged edges of the fracture, and the support of surrounding soft tissue attachments. This problem was also encountered by Rinehart et al (1989). They studied the adequacy of two point fixation of zygomatic fractures at the zygomaticofrontal and zygomaticomaxilliary sutures. The subjects were eight adult human cadaver heads with fractures simulated by saw osteotomy cuts through the zygomaticofrontal, zygomaticomaxilliary and zygomaticotemporal sutures. Again the usefulness of the conclusions of this study suffer from the inherent instability of the pseudofractures created.

With this in mind, the aims of this study were to examine the stability of fixation of mandibular fractures in a clinical model, using live subjects with recently treated mandibular fractures.

3.2 MATERIALS AND METHODS

This pilot study involved five male subjects with a recent fracture of the mandibular angle, treated by monocortical non compression Aus Systems miniplate osteosynthesis as described by Moore et al (1990). The Aus Systems plates were chosen for this study as they have the lowest stiffness and the lowest yield point as shown in chapter two (table 2.3). Hence it was felt that if any plates were to be deformed by a force applied across the fracture line, these would be the most susceptible. A proposal was submitted to Ethics Committees of both the Royal Adelaide Hospital and the Adelaide Children's Hospital (Appendix A) and approval to carry out the study was granted by these Committees (Appendix B). The five patients selected for the study were counselled as to the reasons for their involvement and they were provided with an information sheet (Appendix C) and asked to sign a consent form (Appendix D). The details of the five patients are listed in Table 3.2.

Table 3.2

Case	Age	Sex	Injury	Fracture
1	18	M	Assault	L angle, R parasymphyseal
2	20	M	Assault	R angle
3	22	M	Assault	Bilateral angle
4	32	M	Assault	R parasymphyseal, L subcondylar
5	30	M	Assault	R angle, L subcondylar

Each of the patients underwent standard open reduction and internal fixation of their mandibular fractures according to the protocols described in Chapter 4. Following the surgery they were transported on day one post operatively from the Royal Adelaide Hospital to the Adelaide Children's Hospital. The subjects were positioned as for biplanar cephalometric radiography, with their heads secured in a fixed position by means of a head frame. Initially, cephalometric radiographs were taken with the patient in resting occlusion. Following this a downward force of 10 Newtons was applied to the lower central incisors to simulate the small physiological forces that may be applied in the post operative phase. The application of this force was achieved simply by hanging a 1 kilogram weight from the central lower incisors via a small hook. This equates to a static force of 9.8 Newtons. The patient positioned his hands underneath the weight (but not touching it) and was instructed to lift the weight thereby releasing the force if he felt pain. The plan was to increase the force to 30 Newtons if the patients tolerated the force, ie approaching the relatively low force recorded during the opening phase of chewing Gibbs et al (1980). All of the subjects felt some discomfort, but all were able to tolerate the force for the time it took to take the second cephalometric radio graph. All five of the subjects felt that they would be unwilling to take any greater load on their central incisors.

All of the five patients went on to fracture healing without complications, and with satisfactory post operative occlusion.

The cephalometric radiographs were then analysed to compare without and with the 10 Newton load. This was achieved by plotting the known points and measuring these distances using a point plotting program.

3.4 RESULTS

Case 1

A	Width of angle fracture	-0.04mm
B	Length of upper border plate	-0.36mm
C	Top screw to angle fracture (anterior)	-0.43mm
D	Top screw to angle fracture (posterior)	-0.36mm
E	Upper parasymph. fracture to angle fracture	-0.46mm
F	Upper parasymph. fracture to angle fracture	-0.24mm

Case 2

A	Lower border angle fracture width	-0.35mm
B	Length of upper border plate	-0.36mm
C	Distance between upper border screws	-0.15mm
D	Top screw to angle fracture	-0.19mm
E	Bottom screw to angle fracture	-0.35mm
F	Incisor to angle fracture	+0.53mm

Case 3

A	lower border to angle fracture	-0.29mm
B	lower screw to angle fracture	-0.29mm
C	Upper screw to angle fracture	+0.43mm
D	Incisor to top screw	-1.05mm

Case 4

A	Length of condylar plate	+0.18mm
B	Incisor to parasymph plate	+0.62mm
C	Incisor to condylar plate	-3.28mm
D	Incisor to condylar screw	-2.94mm

Case 5

A	Angle plate to incisor	+1.91
B	Angle screw to incisor	+2.05
C	Condylar plate to incisor	-1.61
D	Condylar plate to incisor	-1.79

3.5 DISCUSSION

This pilot study has attempted to demonstrate the stability of mandibular fracture fixation in vivo when treated by the modified Champy technique as described by Moore et al 1990.

The results show that the three cases (1, 2, 3) showed no significant alteration in the fracture position under the 10 Newton force, within the error of the technique, which was plus or minus 1mm. Unfortunately the subjects in cases 4 and 5 were unable to close their mouth due to discomfort. Thus the preload cephalometric X-ray was taken with the teeth in occlusion, whilst that with the load applied was taken with the jaws apart. Hence cases 4 and 5 could not be considered as this technical error may have accounted for the measurement discrepancies observed..

Previous studies investigating stability of facial fracture fixation have relied on in vitro studies using models, or cadaver studies using fractures simulated by osteotomy. This pilot study is the first to outline a protocol for investigating stability of fixation in the clinical setting. However, to take this investigatory protocol to its logical conclusion, that is, to analyse a range of forces to determine those that will displace a stable fracture reduction, is ethically impossible. One possible alternative would be the use of fresh cadaver specimens with fractures produced by blunt trauma rather than by osteotomy cuts. These fractures could then be surgically reduced and plated, following which cephalometric analysis of the fracture under differing loads could be performed. Such a cadaver study would be technically demanding and expensive in terms of resources. In addition, contentious ethical considerations might arise. Nevertheless, without such detailed studies the critical load characteristics of particular fracture types, and therefore the minimum plating requirements, may never be accurately known.

Of significant interest from this small study is the fact that for the load investigated there was no movement at the fracture site demonstrated, and that this load was at the limit of what the patients thought they could tolerate. This is the first study that has attempted to demonstrate this in vivo. This suggests then that, at least in this early post operative time that the protective pain reflex is felt before permanent deformation of fracture fixation occurs in fractures fixed with the Aus Systems miniplates. I believe that this is the significant finding of this study, that patients had difficulty tolerating an incisor load that has not been shown to deform the fracture internal fixation either elastically or plastically, in fractures fixed with the least stiff miniplates (Aus Systems) as shown in chapter 2. This study also highlights the difficulty in assessing fracture stability in any other way than by assessing post operative results. Whilst the assessment of post operative results may be a satisfactory way of investigating currently used miniplates, it is not satisfactory for the assessment of new lighter, smaller, less stiff miniplates.

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CHAPTER 4

PROSPECTIVE CLINICAL ANALYSIS OF INTERNAL FIXATION OF MANDIBULAR FRACTURES USING MONO-CORTICAL NON-COMPRESSION MINIPLATES

CONTENTS

4.1 INTRODUCTION

In this chapter I aim to examine the internal fixation of mandibular fractures, with assessment based on clinical results. This is based on a three year prospective study of patients presenting to the Royal Adelaide Hospital with a facial fracture. The results of management of these fractures will be compared with those already published in the world literature.

The advantages of internal bone plate fixation over both intermaxillary fixation, interosseous fixation, and external skeletal fixation are recognised by the majority of workers in this field. The advantages included are many (Thaller et al 1990);

- rapid return to normal masticatory function. By eliminating the need for intermaxillary fixation, normal jaw function (aside from chewing) can begin as soon as practicable post operatively. This has additional benefits including less post operative weight loss, and a reduction in the time taken to return to normal activities (eg employment).

- elimination of the need for intermaxillary fixation (IMF). IMF is associated with a number of post operative dangers, importantly the airway restriction and the dangers of vomiting while fixed in IMF. Rix et al. (1991) note that IMF is also unsuitable for epileptics, alcohol and drug abusers, patients with chronic obstructive airways disease, and those whose health would be adversely affected by the decreased nutrition afforded by a liquid diet. The abolition of IMF also results in less weight loss during the healing phase.

- more rapid bone healing

• three dimensional stability of fixation which can not be achieved by interosseous wiring (Ewers and Harle 1985). Controlled clinical trials showed superior results for patients treated by miniplate osteosynthesis as opposed to those treated by intermaxillary fixation and wiring systems (Klotch and Gilliand 1987, Stoll and Schilli 1988).

• probable lowering of the post operative infection rate. A number of studies have now been published which suggest that the post operative infection rate is lower when miniplates are used to fix mandibular fractures (Moore et al. 1990, Cawood 1985, Ikemura et al. 1988). Concern regarding infection has centred around the foreign body effect of the implant. Koury (1992) reviewed the orthopaedic literature which shows that bony union can occur in the face of infection as long as immobilisation of the fractured segments is maintained.

• lower treatment costs due to a reduction of the number of outpatient visits required, shorter period of hospitalisation, and more rapid return to work.

However there is little if any consensus of opinion as to the most appropriate techniques that should be employed for a given situation. A large variety of techniques, materials, and treatment philosophies are currently in use. Some of these differences are minor, whilst others amount to major philosophical divisions. These differences of opinion were highlighted by Hardman and Boering (1989) who compared the treatment of facial fractures by oral and maxillofacial surgeons in the United Kingdom, The Netherlands, the United States of America, India and Hong Kong, by means of a questionnaire. This highlighted significant differences in many of the areas examined. For example, the Americans strongly favoured the extra-oral route to the mandible for bone plating, whereas the Dutch were much more likely to employ the intraoral approach. The British strongly favoured the use of Champy miniplates as did the Dutch, however the British seldom used compression plates. Compression plates were popular with the Dutch and the Americans.

There is an old surgical maxim that states that when multiple therapies are in use for the same condition, this usually mean that none of the treatments works particularly well. I do not believe that this applies to this situation. Much of the lack of consensus may well be explained by examining the clinicians working in this field. This reveals a number of barriers. Firstly, there is the language barrier, with a number of the leaders in this area publishing in the German and French literature, whilst others confine themselves to the English language literature. In addition, a greater number of specialties would appear to devote themselves to the treatment of facial fractures than is seen with any other disorder. Thus it is necessary to monitor literature relating to plastic and reconstructive surgery, craniofacial surgery, oral and maxillofacial surgery, dentistry, opthalmology, and otorhinolaryngology to name simply the major sources. The confusion does not end there however, as the specialty responsible for the treatment of facial fractures varies from city to city, country to country, and continent to continent. These language, cultural, and specialty differences amount to a communication barrier which, I suggest, plays a significant role in stalling the international effort to implement the most effective treatment regimes possible. This is not to say that standardisation of treatment is necessarily a desirable goal. However with such diversity of methods currently employed, it is conceivable to suggest that there is also a diversity of success being achieved.

4.2 ANALYSIS OF SURGICAL TECHNIQUES

As discussed in Chapter 1, a number of different techniques are currently in use in different centres around the world for the internal fixation of mandibular fractures. These can essentially be broken down into the lower border compression plate osteosynthesis, and the Champy technique of upper border miniplate osteosynthesis, and further broken down into individual variations on the above techniques.

Luhr Dynamic Compression miniplates

Luhr developed the compression plate for the treatment of mandibular fractures and reported on this in 1968. This system, known as the mandibular compression system, also operates by way of an eccentrically placed screw holes which forces the plate sideways as the screws are tightened, thus achieving compression. Self tapping screws have replaced the tapped screws that were originally used as they have been shown to be equally effective (Vangsness et al 1981). Luhr maintains the importance of conservative managements of mandibular fractures in the edentulous mandible using intermaxillary fixation (Luhr 1982). Under his criteria approximately 35% of all mandibular fractures are treated by compression osteosynthesis.

Luhr recommends an intraoral approach to the fracture site, however an extraoral approach may be necessary as the operative conditions dictate. The intraoral approach is to be preferred due to the lower incidence of osteomyelitis in cases where this route was employed (Luhr et al 1985). Once the fracture is identified and reduced, an appropriate compression plate is selected for application. Due to the rigidity of the plates a number of different shapes are produced to suit the various anatomical regions.

The AO/ASIF Method

The AO/ASIF method was pioneered by Spiessl (1976). Spiessl adopted the principles of the AO/ASIF group who advocated the dynamic compression plate. These plates follow the spherical gliding principle developed by Perren et al. (1969). Spiessl modified this by adding a tension band (either using an arch bar or a tension band plate). This modification enabled Spiessl to overcome the rotational forces at the alveolar (tension) side of the fracture (Schwimmer and Greenberg 1986).

An alternative to the dynamic compression plate is the extended dynamic compression plate (Schmoker et al. 1982, Levine 1982). This compression plate is modified to contain two outer screw holes in addition to the four (two on each side of the fracture) required to fix the fracture. The outer screw holes are designed with their slots perpendicular to the plate, so that as the screws tighten the plate forces compression at the upper border also, thereby eliminating the need for a tension band.

Iizuka and Lindqvist (1992) detailed their management using the AO/ASIF method. They routinely administer intravenous penicillin and metronidazole both pre and intraoperatively. At operation, occlusion is established with arch bars and intermaxillary fixation. Of 270 cases, 212 (78.5 %) were approached extraorally (Figure 4.1). In those cases where the extraoral approach was required, a nerve stimulator was employed to avoid damaging the facial nerve. Fractures were stabilised using a stainless steel compression plate, with or without employing a tension band plate.

Champy miniplates

The Champy technique for treatment of facial fractures was developed by Champy in 1976 (Champy et al. 1976, Champy and Lodde 1976), as a modification of the non compression monocortical miniplate osteosynthesis developed and described by Michelet et al. (1973). This technique was based on the development of the ideal osteosynthesis line, along which the miniplates should be placed. This line was plotted by observing the lines of tension that developed in an araldite mandibular model subjected to bending forces. Michelet et al (1973) and Champy (1986) found that tension occurred at the upper border and compression at the lower border . The monocortical miniplates were thus ideal for placement at the upper border in the tension zone. As stated earlier this theory has since been shown to be erroneous by Rudderman and Mullen (1992) who showed that zones of tension and compression may be reversed when forces are generated along the posterior teeth. However Champy's technique has shown excellent results (Gerlach et al. 1983) and the technique remains popular with many clinicians (Jackson et al. 1986).

The use of the Champy miniplates at the Cologne and Strasbourg hospitals increased rapidly following their introduction in 1976, and by 1982 81.2% of all mandibular fractures presenting to these hospitals were treated by this method (Pape et al 1983).

The technique as described by Champy et al (1986) involves the almost exclusive use of the intraoral approach except in certain circumstances such as when exposing the mandibular condyle. The fracture is reduced and the patient placed in IMF. The plate should then be bent into place to lie along the ideal osteosynthesis line, and the fracture fixed with at least two screws on each side of the fracture. Champy also believed that two plates were necessary around the symphysis to overcome the torsional forces peculiar to this region.

The Ellis Modification

Ellis noted the high complication rate peculiar to angle fractures, however he noted that although the AO/ASIF method gave a low rate of post operative infection, it carried with it other risks as described earlier (facial scars, damage to the facial nerve etc) (Ellis 1994). Mindful of the AO/ASIF recommendation for the application of two compression bone plates for angle fractures, Ellis suggested the use of an upper and lower border noncompression miniplate.

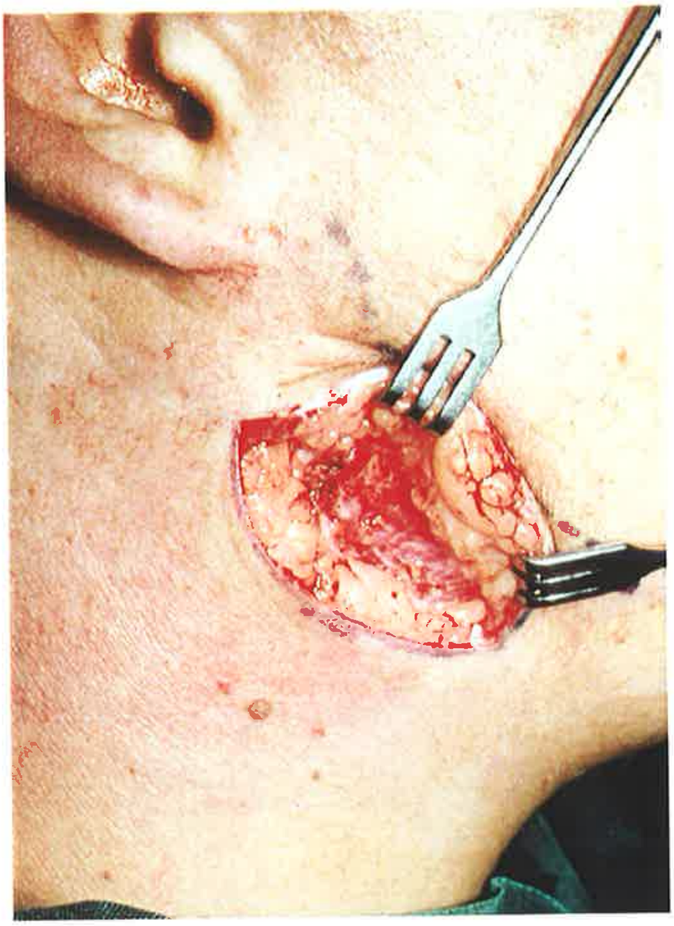


Figure 4.1 The incision used for an external approach to a mandibular angle fracture

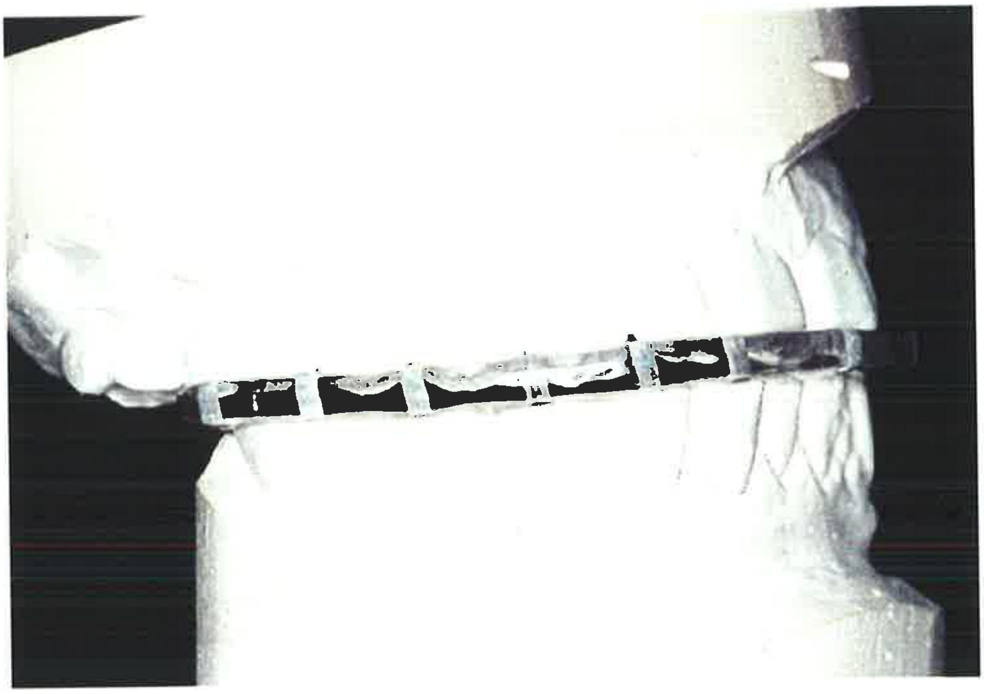


Figure 4.2 A set of dental models with an occlusal wafer in situ

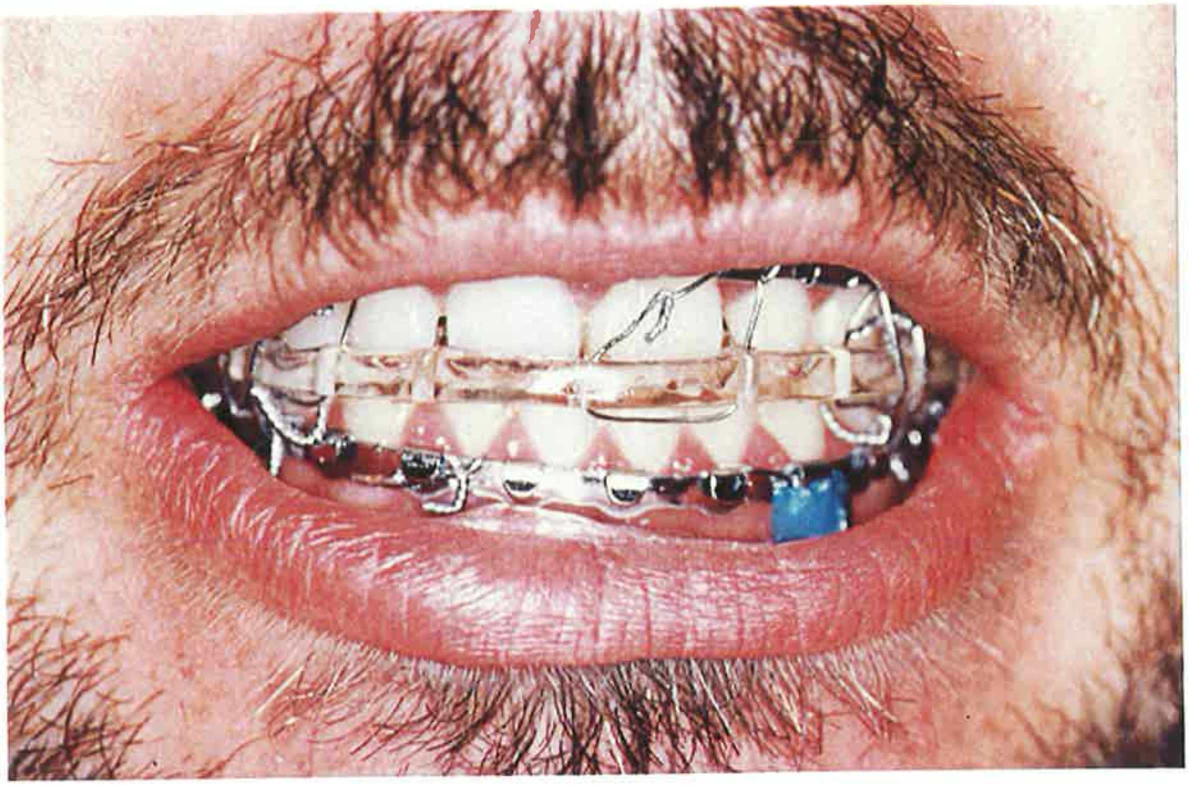


Figure 4.3 A patient in intermaxillary fixation with arch bars and an occlusal wafer

Figure 4.4 Application of a miniplate to the body of the mandible through an intraoral incision

Australian Craniofacial Unit

The Australian Craniofacial Unit utilises the Champy approach to the treatment of mandibular fractures, as described by Moore et al. (1990) and Trott et al (1995). This approach was based on the experimental work of Champy (1978) who showed that distraction forces operate at the upper border of the mandible, whilst compression forces operate at the lower border. Monocortical upper border non-compression miniplates are therefore used at the angle as a tension band to counteract the tensile forces and allow stable osteosynthesis. As discussed earlier, this theory has since been contradicted by Rudderman and Mullen (1992) who showed that zones of tension and compression may be reversed when forces are generated along the posterior teeth. Thus the original theory upon which this treatment modality was based has been challenged, however the method has been retained as the post operative results and complication rate are comparable with those reported around the world, and the method holds significant advantages over bicortical compression plate osteosynthesis (Moore 1990). As described by Champy et al. (1986), two plates are used around the symphysis to overcome the torsional forces in this region.

The advantages of monocortical miniplate osteosynthesis over bicortical compression plates are listed by Moore (1990). These include;

- compression often requires an extraoral approach, and the extra oral approach is technically more difficult. For example Ardary (1989) in a series of 102 patients treated with Luhr compression plates found it necessary to use the extraoral approach in 62 out of 102 cases (60.8%), whilst Iizuka and Lindqvist (1992) used the extraoral approach for 212 out of 270 patients (78.5%).
- bicortical plates risk damage to the inferior alveolar nerve.
- routine use of intraoral incisions with monocortical plates requires minimal dissection, avoids an external scar.

- risk of damage to the inferior alveolar and mandibular nerves using the monocortical plates is negligible.
- the technique is easily taught, and excellent results are achieved by junior registrars.
- in simple fractures of the mandible, monocortical osteosynthesis provides rigid fixation (Manson et al. 1985), and Ikemura et al. (1988) found no complications caused by inadequate stability of fixation.
- it is difficult to make compression plates adapt to the bony curvatures (Ikemura 1988).

Treatment of mandibular fractures at the Australian Craniofacial Unit is usually initiated by referral from the Accident and Emergency Department, or by transfer of patients from outlying country areas. Patients presenting with such injuries are often intoxicated and/or uncooperative. Medical Officers in the Accident and Emergency Department are encouraged to be judicious with their use of radiological examinations as these are frequently of poor quality in the uncooperative patient and will often have to be repeated. As the radiological confirmation of a fractured mandible will not change the initial management, it is preferable to delay this investigation until the next morning when better results should be achieved.

The radiological investigations preferred at the ACFU include an orthopantomogram and a mandibular series consisting of postero-anterior, lateral and Townes views. Some authors suggest that an OPG alone is sufficient for the diagnosis of a mandibular fracture, and that the mandibular series does not increase the diagnostic accuracy rate (Chayra et al. 1986, Moilanen 1982). However Reiner et al. (1989) presented cases where the OPG failed to demonstrate fractures of the mandible that were obvious on plain films from the mandibular series. This is because the OPG is essentially two lateral radiographs and hence a PA view is necessary. This has also been our experience, and additionally we have found the mandibular series useful as a guide to the degree of displacement of mandibular fractures which can not be assessed from the one view.

The policy of this unit is not geared towards early surgery as has been recommended by others (Rowe and Killey 1955); rather, surgery is scheduled for a convenient time, preferably within five to seven days of the injury. There is no evidence of any detrimental effects resulting from this delay (Press et al. 1983), and indeed substantial benefits can be expected, including resolution of post traumatic oedema, and thorough surgical planning. In the interim the patient is prepared for surgery. The patient is placed on a non-chew diet, and is counselled by the dietitian about his or her post operative dietary intake during the bone healing phase. During this time the patient is administered prophylactic antibiotics. We currently employ a regime of intravenous cephalothin and metronidazole. Investigations employed include radiology and a dental consultation. The radiology required involves a mandibular series and an orthopantomogram. Following this the patient is reviewed by the team dentist. The dentist as part of his examination will take a set of dental impressions to enable the manufacture of a full set of dental models (Figure 4.2). Using these models the dentist will establishes the patient's premorbid occlusion, and then cuts the models to demonstrate the adjustment necessary to restore this occlusion. From these models a dental wafer is prepared which will allow establishment of the premorbid occlusion intraoperatively once the fracture is reduced. Once all of the above are in place, a planning meeting is arranged at which time the surgeon and dentist will examine the radiology, the dental models, and the patient in order to plan the surgery. In many instances with appropriate home support this work up can be achieved as an outpatient (on oral antibiotics) thus allowing a cost saving related to inpatient bed cost.

The operation is always carried out under general anaesthesia. A nasal endotracheal tube is generally used, however an oral endotracheal tube may used if there is sufficient room for it to be wired behind the most posterior molar tooth without restricting the application of intermaxillary fixation (Edwards et al 1995). The facial skin and oral mucosa are prepared with a solution of full strength Betadine.

The operation commences with the application of arch bars, with the dental wafer fixed to the maxillary arch (Figure 4.3). The fracture is then exposed via an intraoral approach and debrided as required. Subsequently the fracture is reduced, and the patient is placed into intermaxillary fixation, with the dental wafer used to establish the correct occlusion. The fracture is then fixed with non compression monocortical miniplates via an intraoral approach (Figure 4.4). During the period of this study, the ACFU has used Luhr, Medicon, Würzburg, and Aus Systems miniplates interchangeably. However the use of malleable titanium miniplates such as the Aus System plates is preferred as they are sufficiently malleable to be accurately moulded to the contours of the mandible, and this allows final moulding as the plates are screwed into place as they do not show memory, unlike stiffer steel or Vitallium plates which deform the fracture rather than mould to it when they are screwed into place (Trott et al 1995)

Post operatively the patient is recommenced immediately on the non-chew diet, and is again counselled by the dietitian (in conjunction with the family if appropriate). Vitamisers are made available to patients if required to assist in the preparation of non-chew food. Post operative antibiotics are continued for 24 hours then ceased.

The patient is taken out of intermaxillary fixation at the end of the procedure, however the arch bars are left in situ. Trott et al (1995) state that if the patient does not settle into normal occlusion quickly then light elastic rubber bands attached to the arch bars can be used to assist this. I do not agree with this technique, as the fracture fixation is rigid, and therefore cannot be expected to change. Post operative swelling and masticatory muscle imbalance should settle in the absence of this elastic traction. In addition, the direction of pull against the traction directly reverses Champy's lines of distraction and compression. As the removal of the arch bars can cause considerable discomfort in an outpatient setting, the use of arch bar elastic traction should be tested in a scientific study and abandoned if no benefits are found.

Every attempt is made to follow these patients in the outpatient clinic, however they are notoriously non compliant with this instruction. Appointments are recommended at one week, six weeks, and three months post operatively. Further review is arranged as required.

4.3 MATERIALS AND METHOD

The patients included in this study included all patients with a facial fracture presenting to the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital during the three year period from 1/7/89 up to and including 30/6/92. Prior to this, members of the Department of Plastic and Reconstructive Surgery designed a form known as the 'Trauma Form' (see appendix E). This form remained with the patient's case notes for the duration of his/her inpatient and outpatient treatment and details of management were entered as they occurred, thereby eliminating the need for retrospective case note analysis. In particular, the operative description was completed by the surgeon who performed the surgery, and the outpatient details were entered at the time of the examination by the clinician conducting the outpatient examination. The content of the Trauma Form was intentionally comprehensive to allow as much information as possible to be collected.

Treatment of mandibular fractures was carried out as described in the protocol listed above under analysis of surgical techniques. During the period of this study, the ACFU has used Luhr, Medicon, Würzburg, and Aus Systems miniplates interchangeably. Unfortunately the selection was not randomised, however the three consultants along with registrars and fellows all used a variety of the systems. No surgeon exclusively used one system.

The Royal Adelaide Hospital is a major teaching hospital of 650 beds associated with the University of Adelaide, and is located centrally within the City of Adelaide. It is the major referral centre of South Australia for a number of surgical specialties. The Department of Plastic and Reconstructive Surgery is a large department offering general plastic surgery, craniofacial surgery, microsurgery, head and neck surgery, hand and upper limb surgery, and a specialised burns injury unit. The Royal Adelaide Hospital is the principal tertiary trauma referral centre. Thus it receives most of the major trauma from the country areas of South Australia, and also referral from two of the four metropolitan teaching hospitals that do not provide a maxillofacial service.

Other hospitals in Adelaide would therefore see smaller numbers of mandibular fractures presenting largely from their local area, and often not in association with major injuries which would necessitate transfer of those patients to the Royal Adelaide Hospital.

4.4 RESULTS

During the three year period of the study, 832 patients with facial fractures received treatment from the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital. Of these, 324 (38.9%) had sustained a fracture of the mandible.

The method of injury was recorded at the time of presentation to the Department of Accident and Emergency Medicine wherever possible. These were recorded under the categories as shown in Table 1.

Table 1

Method of Injury	**Total**	**Average age**
Assault	172	28.04
Road Traffic Accident	68	27.91
Sport	42	23.41
Industrial	4	38.0
Fall	26	42.66
Gunshot	4	29.5
Other	8	23.12
Total	**324**	**28.60**

The methods by which these injuries were sustained were further broken down within the categories listed above, and these details are shown below.

Road traffic accident

Motor vehicle	42
Motor cycle	12
Pedestrian	4
Pedal cycle	10

Sporting

Australian rules football	26
Soccer	2
Rugby	2
Horse riding	1
Cricket	4
Other	7

The overwhelming majority of persons sustaining mandibular fractures in Adelaide were males (table 2).

Table 2

	Male	**Female**
Mandibular fractures	260 (80%)	64 (20%)

Table 3

Method of Injury	**Male**	**% of males**	**Female**	**% of females**
Assault	143	55.0	29	45.3
Road Traffic Accident	51	19.6	17	26.6
Sport	40	15.3	2	3.1
Industrial	4	1.5	-	-
Fall	12	4.6	14	21.9
Gunshot	3	1.2	1	1.6
Other	7	2.7	1	1.6

There was a marked preponderance of males in most aetiological categories. The proportionate representation of males and females was relatively similar for road traffic accidents and assaults, however there was a preponderance of females sustaining mandibular fractures as a result of falls, whilst a much larger proportion of males sustained their fractures from sporting injuries (Table 3). (It is important to note that no attempt was made to separate out 'assaults' from 'accidents', any fracture occurring during sport was listed as a sporting injury. Undoubtably a significant proportion of these were malicious assaults.) Similarly the history was taken at face value for all aetiological factors, some of which, for example 'falls' in females may represent unreported assaults.

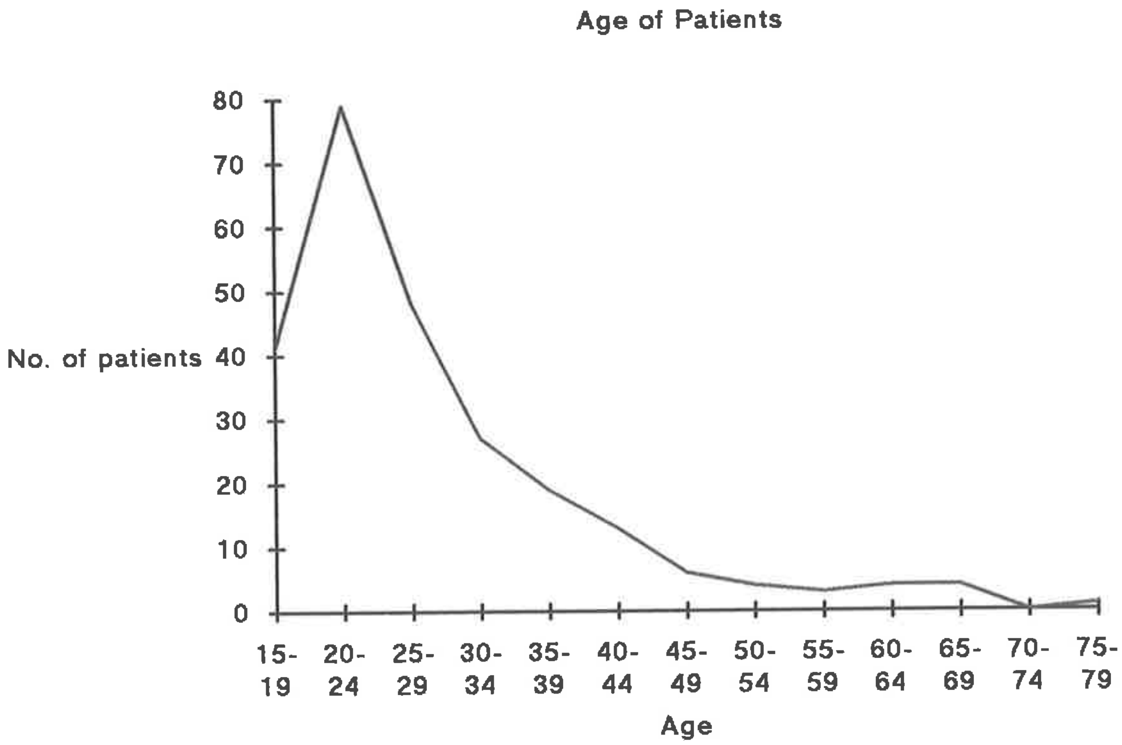
A significant proportion of the injuries (30%) showed alcohol consumption as a contributing factor to the injury. Alcohol was more likely to be associated with male persons sustaining mandibular fractures than female (table 4). Whilst 48.6% of male patients were under the influence of alcohol to some degree, only 23.1% of females were similarly affected. It is important to note that these figures only apply to alcohol consumption by the person sustaining the injury, unfortunately no figures are available regarding those also involved, such as the assailant, or the driver of cars involved in a road traffic accident.

Table 4

	Alcohol involved	**Alcohol not involved**
Male	85 (48.6)	175
Female	12 (23.1)	52
Total	**97 (29.9%)**	**227**

The average age of persons sustaining fractures of the mandible was 28.60 years. However, as seen from Figure 4.5, the graph is strongly skewed to the right, partially due to the fact that children less than the age of 15 are not included in this study as the Royal Adelaide Hospital functions as an adult institution. As the mean is strongly influenced by such a skewed distribution, the median gives a better indication of age distribution. In this case the median age was 25 years.

Figure 4.5



Anatomic Distribution of Fractures

The 324 patients in this study suffered 491 fractures of the mandible. In all, 46.9% of patients suffered fractures in two places, whilst 2.5% sustained fractures in three places. The majority (50.6%) sustained a single fracture. Table 5 presents the numerical distribution of fractures by location in the mandible. No distinction is made for left or right side.

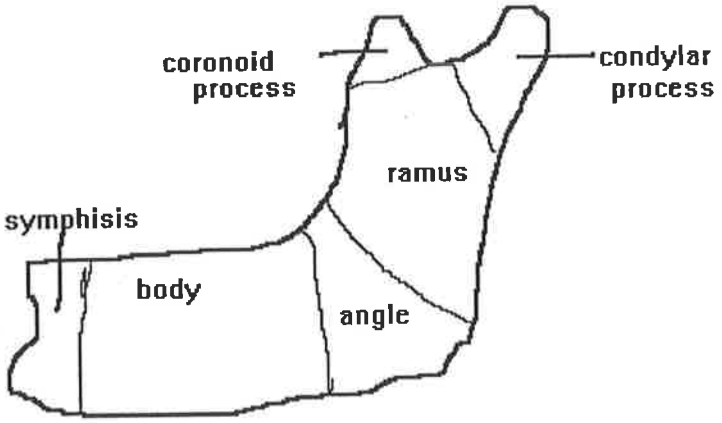


Table 5

Site	Number	Percentage
Condylar Fracture	99	20.2%
Coronoid process	1	0.2%
Ramus	15	3.05%
Angle	179	36.46%
Body	81	16.50%
Symphyseal	116	23.82%

In table 6 a detailed analysis of the actual pattern of fracturing seen in individual cases is presented is presented.

Table 6

SITE OF FRACTURE	N° OF CASES	PERCENTAGE
Condylar Head	4	1.23
Subcondylar	**36**	**11.11**
Angle	**78**	**24.07**
Bilateral angle	10	3.09
Parasymphyseal/symphyseal	**20**	**6.17**
Bilateral parasymphyseal	5	1.54
Ramus	3	0.93
Bilateral ramus	1	0.31
Body	**20**	**6.17**
Bilateral body	7	2.16
Parasymphyseal/angle	**40**	**12.35**
Parasymphyseal/body	3	0.93
Parasymphyseal/subcondylar	**30**	**9.26**
Parasymphyseal/ramus	5	1.54
Parasymphyseal/condylar head	3	0.93
Subcondylar/body	10	3.09
Subcondylar/angle	7	2.16
Condylar head/body	1	0.31
Ramus/body	3	0.93
Ramus/angle	1	0.31
Angle/body	**26**	**8.02**
Coronoid process/body	1	0.31
Subcondylar/body/symphyseal	1	0.31
Subcondylar/angle/body	2	0.62
Subcondylar/angle/symphyseal	5	1.54
Unknown	2	0.62

OPERATIVE RESULTS

A total of 324 patients with mandibular fractures presented during the three year period of the study, and of these 247 (76%) were treated by open reduction and internal fixation with miniplates. The miniplates used were the Aus Systems non-compression monocortical miniplates, the Würzburg non-compression monocortical miniplates, the Medicon non-compression monocortical miniplates, Luhr minicompression plates, used in a non compression fashion as described by Munro (1989), and Luhr compression plates.

The results of open reduction and internal fixation at the Australian Craniofacial Unit will be presented in two parts. Firstly the results as a whole will be tabled, and compared with those published in the international literature. In the second part the results of treatment will be examined to compare the different miniplates in use at the unit to identify any discrepancies in outcome related to the type of plates used.

Over the three year period of the study, the five plating systems have been used interchangeably, and the frequency of use is shown in table 7.

Table 7

MINIPLATE	NUMBER
Aus Systems	105
Würzburg	50
Medicon	11
Luhr non-compression	62
Luhr compression	19

The overall complication rate for all patients treated at the unit during the study was 15.8%, as shown in table 8. Note that the figures relate to complications per *patient*, not complications per fracture as is the case in many series. In addition, removal of plates has been classed as a complication as it is not the standard protocol of the unit. Many authors would not include plate removal as a complication as it is either routine in their unit, or is classed as a routine event rather than a complication.

Table 8

COMPLICATIONS	**N^{0}**	**%**
Plate fracture	2	0.8
Infection resulting in removal of plate	7	2.8
Infection responding to treatment	2	0.8
Malocclusion with corrective op required	13	5.3
Removal of plates	10	4.0
TMJ discomfort	3	1.2
TMJ ankylosis, bilateral reconstruction	1	0.4
Non union	1	0.4
TOTAL	**39**	**15.8**

The complication rate was compared to the severity of the fracture as recorded by the alpha numeric system of computer based coding for craniofacial fractures (Cooter and David 1989) (Table 9).

Table 9

Fracture Score	**1**	**2**	**3**	**4**	**5**	**6**	**>6**
Number of cases	14	60	47	47	14	16	9
Complications	1	8	10	9	4	5	3
Complication rate (%)	7	13.3	21.3	19	28.6	31.25	33.3

The complication rate was contrasted with the groups who had and had not had teeth extracted at the time of surgery. Of the 247 cases that underwent open reduction and internal miniplate fixation, 107 (43.3%) had a tooth in the fracture line extracted during surgery whilst 140 (56.7%) did not. The incidence of complications in the two groups is shown in table 10.

Table 10

Complication	Tooth Extracted	No Tooth Extracted	Total	Percent
Plate fracture	1 (0.9)	1 (0.7)	2	0.8
Infection resulting in removal of plate	4 (3.7)	3 (2.1)	7	2.8
Infection responding to treatment	2 (1.9)	-	2	0.8
Malocclusion with corrective op required	**2 (1.9)**	**11 (7.9)**	13	5.3
Removal of plates	6 (5.6)	4 (2.9)	10	4.0
TMJ discomfort	-	3 (2.1)	3	1.2
TMJ ankylosis, bilateral reconstruction	-	1 (0.7)	1	0.4
Non union	-	1 (0.7)	1	0.4
Total	**15 (14.0%)**	**24 (17.1%)**	**39**	**15.8%**

The complication rate for each of the main systems used on this unit (Aus Systems, Würzburg, Luhr non-compression) were then considered individually to attempt to identify any difference between the complication rates associated with the use of each plating system (Tables 11,12,13). The Medicon and Luhr compression plates were excluded due to the small numbers involved.

Table 11 Aus System

Complication	Nº of Cases	Percentage
Plate fracture	2	1.9
Infection resulting in removal of plate	1	1.0
Infection responding to treatment	1	1.0
Malocclusion with corrective op required	2	1.9
Removal of plates	4	3.8
TMJ discomfort	2	1.9
TMJ ankylosis, bilateral reconstruction		
Non union		
Total	**12 / 105**	**11.4%**

Table 12 Würzburg

Complication	Nº of Cases	Percentage
Plate fracture		
Infection resulting in removal of plate	1	2
Infection responding to treatment		
Malocclusion with corrective op required	4	8
Removal of plates		
TMJ discomfort	1	2
TMJ ankylosis, bilateral reconstruction	1	2
Non union		
Total	**7 / 50**	**14%**

Table 13 Luhr non-compression

Complication	Nº of Cases	Percentage
Plate fracture		
Infection resulting in removal of plate	4	6.5
Infection responding to treatment	1	1.6
Malocclusion with corrective op required	4	6.5
Removal of plates	5	8.1
TMJ discomfort		
TMJ ankylosis, bilateral reconstruction		
Non union		
Total	**14 / 62**	**22.5%**

4.5 DISCUSSION

A large amount of information has been extracted from the comprehensive data collected on the facial fracture forms. Similar studies by other units reporting their own experience have already been published. Thus the information presented here will serve to complement and contrast with that already presented. In addition, data have been presented on a large series of patients contrasting the use of different makes of non-compression miniplates, which is the first review of its kind of which I am aware. This has allowed not only comparison with those results achieved in other units, but also a comparison of the various miniplates used within this unit.

The study presented here comprises all operatively treated fractures managed during a three year period, and is thus not selected in any way; moreover, the data were collected prospectively, thus eliminating the errors often inherent in retrospective case note studies.

Proportion of mandibular fractures

The proportion of facial fractures comprising at least one fracture of the mandible is consistent with figures published elsewhere. Approximately 38.9% of patients presenting to the Royal Adelaide Hospital with a facial fracture had sustained a mandibular fracture as part of their injury pattern. Ellis et al. (1985) analysed 4711 patients with facial fractures presenting to the oral and maxillofacial surgery unit at the Canniesburn Hospital in Glasgow, Scotland over the ten year period from 1974 to 1983. He found 2137 (45.4%) of these to have a mandibular fracture.

Method of Injury

The method of injury reported in this series is contrasted in table 14 with results reported in the literature (Fridrich et al. 1992, Ellis et al. 1985, Iizuka and Lindqvist 1992, Olson et al. 1982). These results, whilst showing broad agreement across most categories, do vary significantly in a number of instances. For example, the results published by Ellis et al. (1985) differ in a number of categories, with a noticeably lower number of motor vehicle accidents, and a significantly higher number of falls.

Table 14

Method of Injury	**ACFU**	**Fridrich (1992)**	**Ellis (1985)**	**Iizuka (1992)**	**Olson (1982)**
Assault	53.1	47.5	54.7	59.8	34.4
Road Traffic Accident	21.0	31.5	15.1	17.3	47.8
Sport	13.0	5.4	3.51	blunt object 3.7	2.2
Industrial	0.93	3.0	2.48	-	0.7
Fall	8.02	7.1	21.3	13.5	8.4
Gunshot	1.23			0.9	-
Other	2.78	5.5	2.96	4.6	6.5
Total	**100%**	**100%**	**100%**	**100%**	**100%**

He postulates that the former can be explained by the low rates of private ownership of motor vehicles in Scotland and consequently greater use of public transport. The high incidence of falls occurred predominantly in females and, according to Ellis, may indicate a number of non-reported assaults. This statistic suggestive of domestic violence was also noticed by Voss (1983) in a study of jaw fractures treated at the Department of Maxillofacial Surgery, Ulleval Hospital in Oslo, Norway. In contrast, Olson et al. (1982) reporting 580 cases of mandibular fractures presenting to the University of Iowa hospitals between 1972 to 1978 found the reverse, with fractures resulting from motor vehicle accidents exceeding those caused by assaults, indeed the incidence was three times that found by Ellis et al. (1985). Olson believes the explanation for this lies in the location of the hospital in a small university city near a busy highway. Melmed and Koonin (1975) also explored the relationship between aetiology of mandibular fractures and socio-economic group. In a study of 909 patients with mandibular fractures presenting to the Plastic Surgery Department at the Groote

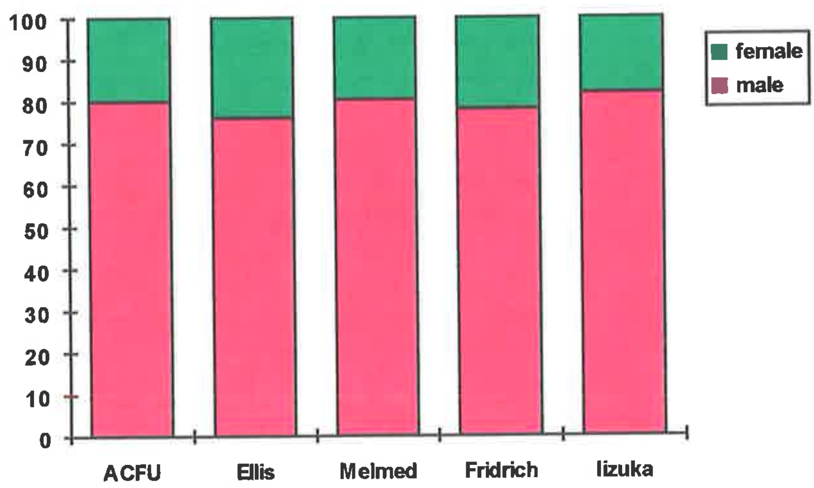
Schuur Hospital in Cape Town, South Africa, a significant difference was found between the white population as compared to the Bantu (black African) population. Whereas 64% of the Bantu population were injured in assaults, 67% of the white population were injured as a result of motor vehicle accidents or sporting injuries. When contrasted with these results, the Adelaide figures would appear to have a remarkably low proportion of fractures sustained in motor vehicle accidents, as Adelaide is, after all, heavily dependant on motorised private transport. However it is difficult to compare these two societies. One might suggest that the greater public awareness of road trauma, improvements in motor vehicle design and safety, and the introduction of compulsory wearing of seat-belts would go a long way to explaining this apparent discrepancy.

An alternative explanation for the discrepancy in these results is provided by Voss (1983) who investigated the changing trend in the aetiology of mandibular fractures between 1970 and 1980. There were 332 mandibular fractures in 1970 presenting to the Ullveal Hospital, Oslo, Norway. This is contrasted with 283 mandibular fractures in 1980, a reduction of 14.8%. Significant shifts in the aetiological patterns were observed. Assaults increased from 44% of cases in 1970, to 59% in 1980. There was a corresponding fall in the motor vehicle accident category, from 21% in 1970 to just 11% in 1980. Voss attributes these changes to the increasing trend of violence in their community, coupled to a reduction in the total number of traffic accidents and the introduction of compulsory helmets for motor cycle riders and seat belts for motorists.

Sex distribution

Mandibular fractures, as for all facial injuries, are overwhelmingly more common in males than females (Tables 2 and 3). The preponderance of males over females sustaining these fractures is no doubt related to their predisposition to most violent injuries. This figure compares with those reported in the literature (Figure 4.6). For example, Fridrich (1992) reported an incidence of 78% of mandibular fractures occurring in males in a series of 1067 patients presenting with mandibular fractures to the University of Iowa Hospitals between 1979 and 1989. A similar distribution was identified by Ellis et al. (1985) who found 76% of fractures to have occurred in males and 24% in females. Melmed and Koonin (1975) reported a sex distribution of 80.3% males to 19.7% females. Iizuka and Lidqvist reported 81.8% of mandibular fractures occurring in male patients for patients presenting to the University Central Hospital in Helsinky.

Figure 4.6



Not surprisingly males dominated most aetiological categories (table 3). The proportionate representation of males and females was relatively similar for road traffic accidents and assaults, however there was a preponderance of females sustaining mandibular fractures as a result of falls, whilst a much larger proportion of males sustained their fractures from sporting injuries (Table 3). (It is important to note that no attempt was made to separate out 'assaults' from 'accidents', any fracture occurring during sport was listed as a sporting injury. A significant proportion of these may represent malicious assaults, but the distinction is often blurred and the history inaccurate.) These findings correlate with those of Ellis et al. (1985). They reported 33.92% of females had sustained their fracture as a result of falls, whilst none had been similarly injured as a result of a sporting accident.

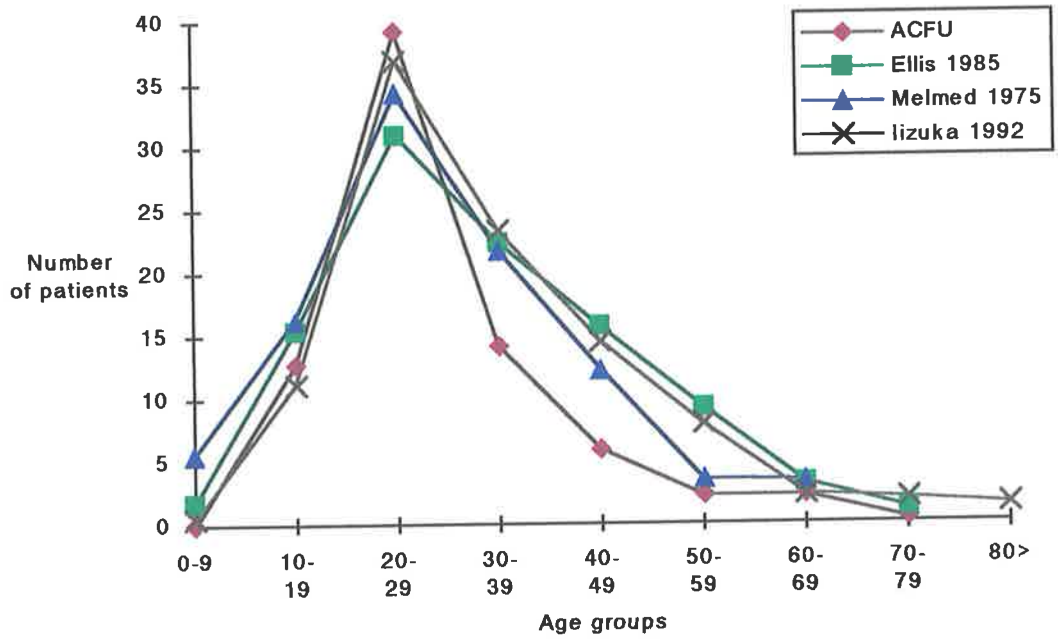
Influence of alcohol

The link between alcohol and mandibular fractures has long been established (Lamberg 1978, McDade et al. 1982). Alcohol was commonly found as a strong aetiological factor. Iizuka and Lindqvist (1992) found 43% of patients under the influence of alcohol on admission to hospital, and one third of patients had a history of alcohol abuse. This was noticeably higher than the 29.9% of patients affected by alcohol in our study. The broader question of alcohol abuse and alcoholism was not addressed in our study. Voss (1983) found that the involvement of alcohol in mandibular fractures had increased over the ten year period from 1970 to 1980. In 1970 alcohol was a factor in 28% of mandibular fractures, however this had increased to 47% in 1980. This may reflect the corresponding increase in assaults resulting in mandibular fractures over that period.

Age distribution

The age distribution is similar for our figures when contrasted with Ellis et al. (1985) and Melmed and Koonin (1975) and Iizuka and Lindqvist (1992) (Figure 4.7). Note that our figures do not include the 0-14 age group as our figures are taken from an adult hospital. Mandibular fractures are mainly seen in younger people, with a peak in the 20-29 year old age group.

Figure 4.7



Anatomic location of fractures

A comparison of the anatomic location of mandibular fractures at the ACFU and elsewhere is presented in table 15.

Table 15

	ACFU (%)	Ellis 1985 (%)	Olson 1982 (%)
Condyle	20.2	29.3	29.1
Coronoid process	0.2	2.2	1.3
Ramus	3.05	2.6	1.7
Angle	36.46	23.1	24.5
Body	16.50	33.0	16.0
Symphyseal	23.82	8.4	22.0

It is interesting to speculate why there is a variation in the common fracture locations in these large series. I suspect that the low rate of symphyseal fractures recorded by may be due to interpretation as the sum of symphyseal fractures and body fractures in the three series is similar (40.32%, 41.4%, and 38.0% respectively). Ellis may well have included only pure symphyseal fractures in this category, describing parasymphyseal fractures as body fractures, whereas the other two studies have included parasymphyseal fractures in the symphyseal group. The significant variant is the low number of condylar fractures and high rate of angle fractures at the ACFU compared to the other two studies. Ellis (1985) suggested that angle fractures were more common in assaults, whilst motor vehicle accidents more commonly resulted in condylar fractures. This reasoning would explain the discrepancy between the ACFU and the results of Olsen who had a lower incidence of assaults and a higher incidence of motor vehicle accidents. However Ellis and the ACFU had similar incidences of these two factors and hence the difference is difficult to explain.

Alpha-numeric code and complication rate

All mandibular fractures were coded according to the alpha numeric system of computer based coding for craniofacial fractures as described by Cooter and David (1989). This system divides the craniofacial region into 10 bilateral major anatomical zones, each of which is composed of minor zones. An alphabetic code is assigned to each zone. The fracture is then assigned a numerical value where an undisplaced fracture is scored 1, a displaced fracture 2, and a comminuted fracture 3.

The ten major zones are;

Cranial:
- frontal
- parietal
- sphenoidal
- temporal
- occipital

Facial	- nasoethmoidal
	- zygomatic
	- orbital
	- maxillary
	- mandibular

Each of the major zones is divided into a number of minor zones. For the mandible these zones are;

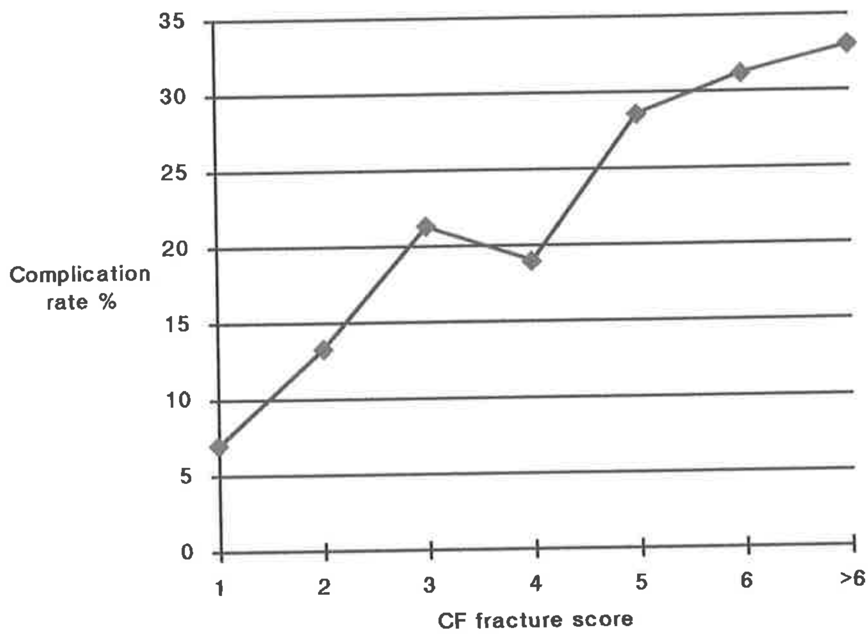
condyle	coronoid process
ramus	angle
body	symphyseal
dentoalveolar	

In the usual situation, the maximum score allowable for a major ipsilateral zone is 5, thus the total points for the ten bilateral zones is 100. This enables the total fracture score to be expressed as a percentage.

For the purposes of this study the total mandibular fracture score was considered, regardless of whether it exceeded the allowable 5 points. Thus the fracture severity was then contrasted with the incidence of complications. As shown in Fig 4.8 It is apparent that the incidence of complications with miniplate fixation increases as the severity of the fracture (as given by the alpha-numeric coding score) worsens.

These figures demonstrate that the incidence of complications associated with the management of mandibular fractures is higher for fractures of greater severity, with a correlation of 0.96 between fracture severity and complication rate. Previously this association, although intuitively recognised, has not been shown statistically due to the absence of an objective and reproducible system of classification of these fractures that includes the location, number, and severity of fractures.

Figure 4.8



The development of the alpha numeric system of coding for craniofacial fractures has allowed an objective and standardised assessment of the degree of severity of the fracture to be made. The recognition of predictor factors such as this enables the clinician to identify patients at greater risk of complications, and may facilitate the development of techniques to reduce the incidence of these complications. This system also would be useful in the establishment of collaborative trials which I shall discuss later.

Operative Results and Complications

For the initial analysis of the management of mandibular fractures at the Australian Craniofacial Unit I intend to compare the operative results and complications with similar series published in the literature. It is prudent before embarking on such a comparison to recognise the confounding factors inherent in such a comparison. The most obvious of these is that we are comparing results of treatment of different populations. As already shown, the aetiology and pattern of fractures may vary between these populations for a variety of reasons. A different proportionate representation of certain fracture patterns may strongly influence the incidence of certain complications. In addition, some units may encounter a higher proportion of severe fractures which, as shown in figure 4.8, have a higher complication rate as the degree of severity increases. Perhaps most significantly the cases selected for open reduction and internal fixation with miniplates vary greatly between the various units. For example, at the ACFU 76% of all mandibular fractures were treated by this method, whereas Iizuka and Lindqvist out of 1823 patients with mandibular fractures managed only 214 (13%) by open reduction and internal fixation with miniplates. This degree of selection of cases for surgery may well influence the outcome, for example it may result in a higher complication rate if the more severe fractures were selected for surgery, or conversely it may result in a lower incidence of post operative malocclusion if difficult condylar fractures were not chosen for this method of treatment. The operators in each unit will vary markedly. For example the ACFU results are those of the entire unit from junior registrar to senior consultant. Other publications may reflect the results of one person with experience, or a unit with a small case load and little experience. Thus while comparisons of results are important and valid, it is important to bare all these factors in mind when analysing the results.

The complications noted by the Australian Craniofacial Unit have been listed in table 8. There were two significant classes of complications affecting the patients of this unit. The first was a 5.3% incidence of post operative malocclusion which required corrective surgery. This amounted to 13 cases overall. The second major class of complication was infection, which occurred in 3.6% of cases.

Of the 9 cases of infection, there were no episodes of osteomyelitis, hence all cases were superficial infection. The policy of the unit has been to treat all but the mildest cases of infection by removal of the plate, debridement and irrigation as necessary, followed by replating the fracture with Luhr compression plates. In some cases where the fracture appears rigidly fixed and an abscess has been drained, the existing plate will be left in situ. Resolution of the infection and satisfactory union of the fracture was the ultimate outcome for all cases of post operative infection.

As stated earlier, plates are not routinely removed on the ACFU. Plates will be removed for a variety of reasons, including treatment of infection, exposure of the plate consequent on soft tissue breakdown, and occasionally due to request of the patients when they can feel the plates under the soft tissues. In all 6.8% of patients had their plates removed, 2.8% as part of management of infection and 4.0% for other reasons. The inclusion of these factors in the overall complication rate figures should be recognised as those who routinely remove plates post operatively will not necessarily document these as complications.

Compression vs Non compression plating.

In the first instance, I have compared the results of treatment at the ACFU with published results of the use of compression plating (table 16).

Table 16

Complication	ACFU	Ardary	Anderson	Ellis	Iizuka
Plate fracture	0.8	-	-	-	-
Infection resulting in removal of plate	2.8	8.5	5.8	-	6.1
Infection responding to treatment	0.8	4.2	17.3	12.9	-
Malocclusion with corrective op required	5.3	2.8	-	-	18.2
Removal of plates	4.0	-	-	16.1	-
TMJ discomfort	1.2	-	-	-	-
TMJ ankylosis, bilateral reconstruction	0.4	-	-	-	-
Non union	0.4	2.8	-	-	-
Total	**15.8%**	**21.1%**	**23.1%**	**29%**	**37.3%**

The greatest concentration of literature has been centred around the use of the compression plating technique, probably indicating the prevalence of this technique as the method of choice for the internal fixation of mandibular fractures in recent times.

Iizuka and Lindqvist (1992) recently reviewed their management of 270 mandibular fractures in 214 patients presenting to the University Central Hospital, Helsinky, Finland. During the period of the study from 1983 to 1989 their unit managed 1823 patients, so only 25% were managed by open reduction and internal fixation. All patients were treated by the AO/ASIF compression plating system. The extraoral approach was used for 78.5% of the fractures, and plates were routinely removed at 12-15 months post operatively. The overall complication rate reported in this study appears high at 37.3%. The most significant complication was the high incidence of malocclusion, quoted at 18.2%. Whilst this would appear to be unacceptably high, Iizuka and Lindqvist have included even the most mild post operative malocclusion that required minor dental attention. Unfortunately they do not describe what proportion of these required corrective surgery. The infection rate was lower than many other series regarding compression plates applied via the extraoral approach. However there was a significant morbidity related to the use of compression plates applied via the extraoral approach that being damage to neural structures. Long term weakness of the lower lip was experienced by 3.1% of patients, whilst 9.9% of patients developed lower lip hypoaesthesia.

Iizuka and Lindqvist (1992) relate many of the complications directly to the use of the rigid compression plate system. In particular, they relate the post operative malocclusion to difficulties in plate bending. The extraoral approach was commonly complicated by the appearance of cosmetically undesirable skin scars, and by temporary (or less often permanent) damage to the mandibular branch of the facial nerve. Damage to the inferior alveolar nerve secondary to surgery was also relatively common and due to the lower border placement necessary for compression plating. There were also problems with sensitivity to the cold which Iizuka and Lindqvist relate to the large amount of metal involved in the plating system. They justify the use of the rigid compression plating system over monocortical miniplate fixation as they believe that the rigid compression plating system is indicated in patients prone to infection, as many of their patients are.

Ardary (1989) conducted a prospective evaluation of 71 patients (102 mandibular fractures) presenting to the LAC-USC Medical Center, Los Angeles, USA between 1986 and 1988. These patients were exclusively treated with the Luhr Mandibular Compression Screw System. Ardary lists his complications as a percentage of the number of fractures rather than the total number of patients. For the purpose of this comparison I have converted these figures to a percentage of the number of patients in order to present a meaningful comparison with the other statistics.

Ardary lists an overall complication rate of 21.1%. The most significant contributing factor is the high incidence of infection, 12.7% in total. The breakdown shows that of the nine cases of infection, six were treated by removal of the compression plate, whilst three responded to conservative management. One of those having the plate removed progressed to osteomyelitis. Ardary relates the high incidence of infection in this series to the use of the extraoral approach and to the site of the fracture. It is difficult to see how he arrived at the former conclusion. Of the nine cases that became infected, six had plates applied by the extraoral route (66.7%). However 60.8% of all the fractures in this study were approached by the extraoral route, indeed 75% of all angle fractures (the most common site of infection) were approached extraorally. Thus a causal relationship between post-operative infection and the extraoral approach is not clear from these figures. Of the nine infections. five occurred in angle fractures (55.6% of infections) and three in body fractures (33.3%). Accordingly it follows that 15.6% of angle fractures became infected, 12.5% of body fractures, and 4.8% of symphyseal fractures, whilst no infections were reported in condylar fractures.

Another study of the AO/ASIF method was presented by Anderson and Alpert (1992). This study describes the treatment of 75 mandibular fractures in 52 patients presenting in Louisville USA. Again I have adjusted some figures to comply with complication rate expressed per patient. The overall complication rate in this study was 23.1%. The most striking feature of these figures is the high infection rate of 23.1%, amounting to 12 infections in 52 patients. Anderson and Alpert (1992) describe this as an "appallingly high rate of infection when compared with other series". They are unable to identify with certainty the reason behind this high infection rate. Interestingly all the infections occurred in cases where a tooth was in the line of the fracture. One factor that is suggested is the influence of approach to the fracture. The extraoral approach was used for 22 fractures, and of these 5 (22.7%) became infected. When the intraoral approach was used for the remaining 53 fractures only 7 (13.2%) became infected. However the extraoral approach was predominantly used for angle and body fractures which may have a higher infection rate regardless.

Non compression plating comparison.

The major plating systems used were then compared with each other to identify any influences on complication rate that could be attributed to the non compression miniplate selected. The Medicon plate was excluded from this part of the study as the number of plates used was too small to give a reliable result.

Unfortunately the selection of miniplate was not randomised, as the value of this comparison was not recognised when the data acquisition system was established. However a number of points regarding bias of selection can be made. Firstly the consultants, fellows, and registrars at the ACFU all used a variety of the systems, and no surgeon exclusively used one system. There was no protocol in place for the selection of a given plating system for a given situation. Using the computer based coding for craniofacial fractures, there was no significant variation in the distribution of fracture severity in the various miniplate groups (table 17). In addition the distribution of fractures (symphyseal, body, angle, ramus, condylar) showed no significant bias (table 18). Finally there was no statistically significant variation in the rate of teeth in the fracture line requiring dental extraction.

TABLE 17

	Craniofacial fracture score						
	1	**2**	**3**	**4**	**5**	**6**	**>6**
Würzburg	6	22	26	24	10	8	4
Luhr	5	45	19	19	2	5	5
Aus Systems	8	25	30	23	7	5	4

Table 18

	Fracture site		
	Angle/ramus	**Condylar**	**Symphyseal/body**
Würzburg	29 (33%)	19 (21%)	41 (46%)
Luhr	40 (43%)	12 (13%)	42 (45%)
Aus Systems	65 (41%)	27 (17%)	65 (41%)

As can be seen from table 19, the complication rate was similar in the case of the Aus System and Würzburg plates, but higher for the Luhr mini-compression plates.

Table 19

COMPLICATIONS as a percentage	**Overall**	**Aus Systems**	**Würzburg**	**Luhr**
Plate fracture	0.8	1.9	-	-
Infection resulting in removal of plate	2.8	1.0	2	6.5
Infection responding to treatment	0.8	1.0	-	1.6
Malocclusion with corrective op required	5.3	1.9	8	6.5
Removal of plates	4.0	3.8	-	8.1
TMJ discomfort	1.2	1.9	2	-
TMJ ankylosis, bilateral reconstruction	0.4	-	2	-
Non union	0.4	-	-	-
TOTAL	**15.8%**	**11.4%**	**14%**	**22.5%**

These results were compared with a chi square analysis (table 20).

Table 20

	Aus Systems	Würzburg	Luhr	**Total**
Complication	12	7	14	**33**
No complication	93	43	48	**184**
Total	**105**	**50**	**62**	**217**

$$X^2 = \sum_{ij} \frac{(N_{ij} - E_{ij})^2}{E_{ij}}$$

$X^2 = 3.842$ (two degrees of freedom)

Therefore $0.15 > p > 0.10$, hence there is no evidence that the complication rate is influenced by the selection of miniplate. If the Luhr minicompression plate which experienced the highest incidence of complications is taken out of the equation, then two similar non compression miniplates with different bending characteristics can be compared, also using the chi square analysis (table 21).

Table 21

	Aus Systems	Würzburg	**Total**
Complication	12	7	**19**
No complication	93	43	**136**
Total	**105**	**50**	**155**

Here $X^2 = 0.096$ (one degree of freedom)

Therefore $p > 0.25$, and hence there is no evidence of a significant difference between the complication rate experienced by either plating system. So although the Aus systems plates were the most malleable as found in the engineering component of the study, no significant adverse clinical results could be detected in the in vivo study when compared with other plates, indeed the Aus System plates compared favourably.

COST ANALYSIS

In the current climate of health care funding, treatment protocols not only must show acceptable results, they must be cost effective also. I have already discussed in chapter one the cost effectiveness of the miniplate osteosynthesis techniques in comparison to the internal or external suspension techniques. However the individual plates and screws are expensive, as is the special instrumentation required, and significant cost variation exists between the systems available.

To investigate the cost differential, the price hardware for miniplate osteosynthesis of a common parasymphyseal and angle fracture of the mandible was considered. Using the modified Champy approach, this would require three four hole miniplates and twelve screws. The prices given are those as quoted to the Royal Adelaide Hospital during the period of the study in Australian dollars.

Luhr mandibular compression:	2 x 4 hole plate ($68)	$136
	8 x 10mm screws ($62)	$496
		$632
Luhr minicompression:	3 x 4 hole plate ($85)	$255
	12 x 6mm screws ($29)	$348
		$603
Medicon:	3 x 4 hole plate ($29)	$87
	12 x 5mm screws ($9.70)	$116.40
		$203.40
Aus Systems	3x4 hole plate ($16.63)	$49.89
	12 x 7mm screws ($11)	$132
		$181.89
Würzburg	3 x 4 hole plate ($25)	$75.00
	12 x mm screws ($10.50)	$125.00
		$200.00

Thus it is clear that the cost of these implants is a significant variable and must hence enter into any selection criteria.

4.6 CONCLUSION

It is now accepted amongst clinicians in many (but not all) centres that non compression miniplate osteosynthesis is the treatment of choice for mandibular fractures, but that significant differences in design, materials, mechanical properties, and cost exist between the commercially available miniplates. For this reason miniplates should not be considered as interchangeable. However despite these differences, no significant variation in treatment outcome has been identified between the non compression miniplates examined in this study. Thus miniplate selection should be based on the unit cost, the biocompatability of the implant, and the CT compatibility of the implant. Further research is required to establish the most appropriate miniplate for a given discrete region, by properly randomised trials.

In view of the clinical results of this study, I advocate the use of the Aus Systems miniplate in the open reduction and internal fixation of mandibular fractures. The Aus System plate produces equal or superior results as shown in this study. The plates are titanium and hence have superior biocompatibility and produce less scatter on CT scans. Finally it is the most cost effective system available in our region.

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CONCLUSION AND RECOMMENDATIONS

The introduction of the technique of miniplate osteosynthesis for the treatment of facial fractures revolutionised their management, and is now accepted as the state of the art for those fractures which require reduction and internal fixation. However each region of the face is unique with respect to the forces applied and the direction of these forces. This information is vital to the selection of a system designed to resist a given force whilst the fracture heals, but despite this accurate data regarding these forces are scarce. The technical difficulties of calculating the complex three dimensional forces exerted on the facial skeleton have prevented accurate assessment of such data, as witnessed by the number of experimental laboratory models that have been reported. In addition, the availability of a treatment modality that produces largely acceptable results, and certainly superior results to earlier treatment modalities such as external fixateurs and interfragmentary wiring is not a stimulus for further research. However it is only by research that the refinement of this new process of miniplate osteosynthesis must come.

There are numerous reasons for selection of a miniplate with the smallest size, lowest profile, and least stiffness that will still rigidly fix a fracture and resist the expected forces applied across the fracture. Small size will reduce the dissection necessary for placement of the implant. Low profile may reduce the need for subsequent implant removal on grounds of contour deformity in regions where the covering soft tissue is thin, such as on the infraorbital rim. Finally a ductile implant allows easy and accurate contouring of the implant to the complex shapes of the facial skeleton.

It is not sufficient to attempt to analyse these parameters in an experimental model, as these have been shown to be too simplistic. Models are unable to reflect the complex force vectors that exist in the facial skeleton, and do not take into account the possible beneficial effects of some of these forces on the fracture, that is the inherent stability of the fracture itself.

This thesis has attempted to learn more about the effectiveness of a new more ductile plating system using fractures of the mandible as a model. This analysis has taken place in three parts. Firstly the material properties of miniplating systems were compared. Significant differences in composition and design were identified, and importantly the miniplates tested were found to have significantly different bending characteristics. The Aus System miniplate was found to have the lowest yield point and to be the least stiff of the miniplates tested. Secondly, the Aus System miniplate, as this was the least strong and stiff, was selected to have its in vivo performance analysed radiologically. No deformation of the plate was seen at a force on the fracture that was painful for the subject, suggesting that the protective pain reflex is activated prior to the force exceeding the yield point of these plates in fractures of the mandible. Thirdly the Aus System miniplates were tested against others in a clinical trial. No differences in outcome were identified suggesting that the lower strength plates were sufficient in producing stable rigid reduction and acceptable long term results.

This work creates as many questions as it answers, and should prove a stimulus to further research. For example the Aus System miniplates are less stiff and strong than the Würzburg plates yet have the same size and profile. If it is accepted that the results of treatment are similar for each plate, is this not an argument to produce a plate using the material of the Würzburg plate which is smaller and has a lower profile, yet with the more malleable bending characteristics of the Aus System miniplate.

The need for different plates in different regions of the craniofacial skeleton has been recognised, as exemplified by the new microsystems produced by Luhr and Synthes. However the selections of the plates for different regions and age groups remains largely empirical. It is not satisfactory to select one of these systems for a given region based on a "best guess" of what the forces might be, and whether or not the plate will be deformed by those forces. Studies similar to this one need to be established in large series of patients to demonstrate the effectiveness of a plate in a region, and then to challenge that with a smaller, lower profile, less strong and less stiff plating system.

APPENDIX A

INVESTIGATION OF THE STABILITY OF FACIAL FRACTURE FIXATION

Investigator:

Timothy JC Edwards, MBBS
Master of Surgery Candidate
The University of Adelaide
and
WG Norman Research Fellow
The Australian Craniofacial Unit
Adelaide Medical Centre for Women and Children

Supervisors: Mr DJ David, Department of Plastic and Reconstructive Surgery, RAH.
Dr AH Abbot, Australian Craniofacial Unit.
Prof DA Simpson, Department of Neurosurgery, AMCWC.

PURPOSE OF STUDY

The purpose of this study is to investigate the stability of the current plating systems currently in use for the internal fixation of facial fractures. There are five major plating systems in use at present, each exhibiting different design principles and materials used in construction. Although these systems have been investigated in vitro, significant difficulties exist as barriers to in vivo studies. For this reason the few studies conducted in vivo have been restricted to animal models or cadaver models. The purpose of this study is to investigate the stability of facial fracture fixation using the popular commercially available miniplates under physiological strain that could reasonably be expected to occur during the period prior to the fracture uniting.

BACKGROUND AND PRELIMINARY STUDIES

The treatment of facial fractures during the first seventy years of this century was dominated first by the external fixation devices and later by the internal wire suspension methods devised by Adams in 1946 (1). However the treatment of facial fractures was revolutionised by Luhr in 1968 who published his work on the treatment of mandibular fractures using a compression plate and screw system. This work was closely followed by others including Michelet, Champy, and Spiessl who further developed the techniques of internal miniplate fixation of facial fractures (2,3,4).

The use of miniplate osteosynthesis as the treatment of choice in the treatment of facial fractures (and also for osteosynthesis of surgical osteotomies used in craniofacial surgery) is now accepted in most centres in the world. Currently there are four major commercially available plating systems; Luhr, Champy, AO Group, and Howmedica (Wurzburg). Recently an Adelaide company Aus Systems have developed their own miniplate design which is now being marketed in Australia and Asia. These miniplating systems are of different design, and are made from a variety of materials. The combination of these two factors results in the plates showing markedly differing mechanical properties.

Research to gauge the effectiveness of the various plating systems has mainly centred around clinical impressions of post-operative results and complications. There has been little work done on comparing the various plating systems available. In addition, few authors have investigated the stability of the fixation achieved in vivo, short of assuming that a satisfactory post-operative result infers stable fracture fixation during the healing process, due to the hitherto absence of accurate radiological measuring devices.

The evaluation of the effectiveness of miniplate fixation has taken the form of two broad areas of research. The first involves clinical studies which broadly assess the results of treatment based on clinical evaluation in categories such as post operative occlusion, complication rates, re-operation rate etc (5,6,7,8). The second category of research has involved in vitro, cadaver, and in vivo studies. These have calculated the stability afforded by miniplate fixation across osteotomies cut through facial bones (in dogs, rabbits, and cadavers) or perspex models (9,10,11). Kroon et al found that the fixation techniques commonly used were inadequate to stabilise an osteotomy across a perspex model (12). These studies have significant errors built in to them as a result of the method employed. They fail to appreciate the added stability afforded by the ragged ends of the fracture as opposed to the clean ends of an osteotomy. In addition, the in vitro methods must use basic uni-directional forces assumed to be acting across the osteotomy. These forces cannot take into account the complex multi directional forces of facial musculature, both prime movers and synergists. In addition, these studies assume that movement at the fracture site in the experimental model is indicative of failure, despite there being no concise evidence to support this view. Whilst the proponents of dynamic compression plates claim that best results are achieved by allowing no movement at the fracture site, and hence direct (primary) bone healing (13,14), Ikemura proved that non compression plating was equally effective (10). Further evidence supporting this view is provided by the excellent results achieved by the time honoured techniques of external fixation of long bone fractures which allow limited movement at the fracture site (15). In addition, these studies have invariably assessed only one plating system rather than comparing results of the different systems.

Some of these authors have drawn conclusions from their results and hence made recommendations regarding such factors as placement of miniplates across fracture lines, the number of miniplates to be used at certain fracture sites, and the strength of plate required.

As the miniplates used in fixation of facial fractures have been refined, they have seen a shift towards use of materials such as vitallium and titanium, and to different grades of titanium which are more ductile and malleable. As the miniplates are usually expected to remain in situ for the rest of the patients life, manufacturers have also tended towards thinner smaller miniplates to reduce the incidence of removal of the plates due to cosmetic contouring deformities. The aim of this study is to assess wether this refinement of the miniplates has compromised the stability and rigidity of the fracture fixation.

SUBJECTS

Subjects for this study will be those presenting to the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital with a fracture of the mandible that requires internal fixation with miniplate osteosynthesis.

STUDY PLAN AND DESIGN

The initial part of this study has involved an analysis of the mechanical properties of the major miniplate systems mentioned above. This is being arranged with the assistance of Prof Miller of the Department of Chemical Engineering at The University of Adelaide. Following the calculation of the stress-strain curves of each plate the Aus System plate currently in use at the Royal Adelaide Hospital has been assessed as the most ductile of the miniplates. Thus to assess the stability of fixation this plate has been selected for study.

Mandibular fractures have been selected for study

Subjects for this study will be those presenting to the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital with a fracture of the mandible that requires internal fixation with miniplate osteosynthesis. At day three post operatively these patients would ordinarily undergo a complete set of radiological facial views. In place of this these patients would be taken to the Adelaide Medical Centre for Women and Children to be assessed with biplanar cephalometric radiology. Two sets of films would be taken. The first would be simple biplanar cephalometric radiology. Following this the patient would be asked to bite on a dental transducer up to a force of 30 Newtons. This force is comparable to that exerted on a soft diet which is allowed during the six weeks post fracture (the maximum bite force is in the order of 300 N).

The biplanar cephalometric radiology allows measurements of any fracture opening that may occur when a force as described above is applied across the fracture. These results will then be compared with the final post operative result achieved.

ETHICAL CONSIDERATIONS

The usual post operative radiological assessment of the patient will be deleted and replaced by the biplanar radiology. This will provide adequate post operative assessment of the patient and avoid any increased exposure to radiation. It is important to note that the bite force being investigated is no greater than that which is allowed during the fracture healing phase. The possibility exists that some patients may experience discomfort when biting on the transducer. Subjects will be instructed to cease the experiment if they experience distressing pain. As the bite force to be employed is no greater than that allowed patients in the normal post operative period, we do not expect to see any increase in the incidence of shift at the fracture site resulting in malocclusion.

ANALYSIS AND REPORTING OF RESULTS

Results of the investigation of each fracture will be correlated with the final clinical result before any conclusions are made. The aim of the study is to investigate the stability of the fracture fixation, and to correlate the degree to which this is achieved with the final clinical result.

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Ethics Committees Submitted To:

Submitted to: Adelaide Medical Centre for Women and Children for approval of radiology services to be utilised at the AMCWC.

Royal Adelaide Hospital for approval of the use of and method of investigation of patients from the RAH.

Date of Commencement

The initial phases of the study including the metals analysis and Le Fort I analysis are already underway. The mandibular study will begin as soon as approval is given.

Dr R Webb
Medical Director
The Royal Adelaide Hospital

re: research protocol application
"analysis of the stability of facial fracture fixation"

The project will require little financial help from the RAH. The only cost implication of the protocol will be transport of patients to and from the AMCWC where biplanar cephalometric radiographs will be performed. Transport could either be via volunteer assist or via taxi.

Medical Records should not be required as the investigations will take place whilst the patients are inpatients.

All staffing and equipment for the project will be provided by the Craniofacial Unit.

Thank you for considering this proposal.

Yours sincerely,

TIMOTHY EDWARDS
RESEARCH FELLOW
AUSTRALIAN CRANIOFACIAL UNIT

Dr B Fotheringham
Medical Director
Adelaide Medical Centre for Women and Children

re: research protocol application
"analysis of the stability of facial fracture fixation"

Dear Dr Fotheringham,

The project will require little financial help from the AMCWC. The only cost implication of the protocol will be the production of biplanar cephalometric radiographs at the Dept. of Radiology at the AMCWC.

All staffing and equipment for the project will be provided by the Craniofacial Unit. The computer facilities are already in place in the Research Department of the Craniofacial Unit.

Thank you for considering this proposal.

Yours sincerely,

TIMOTHY EDWARDS
RESEARCH FELLOW
AUSTRALIAN CRANIOFACIAL UNIT

APPENDIX B

Adelaide Medical Centre For Women & Children

72 King William Road,
North Adelaide.
South Australia. 5006.

Incorporating :
Adelaide Children's Hospital
Queen Victoria Hospital

16th June 1992

Dr. T. Edwards
Cranio-Facial Unit
ADELAIDE CHILDREN'S HOSPITAL

Dear Dr. Edwards

Re: Investigation of the Stability of Facial Fracture Fixation REC 414

Thank you for submitting the above protocol to the Research Ethics Committee, which reviewed the project at its meeting on the 3rd June 1992. This study was approved on ethical grounds, but we believe that our approval must be conditional upon receiving a formal radiation dosimetry report. We would therefore ask you to speak directly with Mr Giovanni Bibbo, who is the Radiation Safety Officer of this hospital (Ext 6640). I understand that he can perform this service within a matter of days and he will then forward on the report to the Committee.

We would also ask that the Information Sheet should include a contact person and phone number if subjects seek further information on the study. The Information Sheet should also include a reference to the likelihood of risk of fracture shift. This needs to be put in simple but clear terms.

I would remind you that approval is given subject to the submission to the Committee of a brief annual report on the state of progress of the study. Approval is given for a period of 3 years only, and if the study is more prolonged than this a new submission will be required.

Kind regards

Yours sincerely

PAUL HENNING
CHAIRMAN
RESEARCH ETHICS COMMITTEE

Telephone : (08) 204 7000 Fax : (08) 204 7459

1840–1990

ROYAL ADELAIDE HOSPITAL
Office of the Chief Executive
North Terrace, Adelaide, South Australia, 5000
Telephone (08) 223 0230
Fax: National: (08) 223 4761
International: 61-8-223-4761

Direct dial: 224 5335

22nd July, 1992

Mr.T.J.C. Edwards
Research Fellow
Australian Cranio Facial Unit
72 King William Road
NORTH ADELAIDE SA 5006

Dear Mr. Edwards,

Re:**"Investigation of the stability of facial fracture fixation." No: 920713**

I am writing to advise that ethical approval has been given to the above project. Please note that the approval is ethical only, and does not imply an approval for funding of the project.

As a matter of Human Ethics Committee Policy, copies of the Declaration of Helsinki and N.H. and M.R.C. Guidelines on Human Experimentation adopted by the Human Ethics Committee, are attached for your information and guidance.

Adequate record-keeping is important and you should retain at least the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them if necessary, in the future. The Committee will seek a progress report on this project at regular intervals and would like a brief report upon its conclusion.

If the results of your project are to be published, an appropriate acknowledgement of the Hospital should be contained in the article.

Yours sincerely,

Dr.R.Webb
Chairman
ROYAL ADELAIDE HOSPITAL HUMAN ETHICS COMMITTEE

Women's and Children's Hospital
ADELAIDE

Incorporating:
Adelaide Children's Hospital
Queen Victoria Hospital

ADELAIDE CHILDREN'S HOSPITAL
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9th September 1992

Dr. T. Edwards
Australian Cranio-Facial Unit
ADELAIDE CHILDREN'S HOSPITAL

Dear Timothy

Re: Investigation of stability of facial fracture fixation REC 414

Thank you for your recent correspondence in relation to the above project. The Research Ethics Committee reviewed the documentation provided at its recent meeting of the 2nd September 1992, when formal approval was granted for this project to proceed. However, I would be grateful if you could provide me with information on how many adult patients this procedure has been performed on.

Please note that the approval number applicable to this project is REC 414, and should be quoted in any future correspondence.

I would remind you that approval is given subject to the submission to the Committee of a brief annual report on the state of progress of this study. Approval is given for a period of three (3) years only, and if the study is more prolonged than this, a new submission will be required.

Kind regards

Yours sincerely

DR. R. COUPER
ACTING CHAIRMAN
RESEARCH ETHICS COMMITTEE

APPENDIX C

ANALYSIS OF THE STABILITY OF FACIAL FRACTURE FIXATION

INFORMATION SHEET

The Australian Craniofacial Unit at The Royal Adelaide Hospital and The Adelaide Medical Centre for Women and Children is conducting a study to look at whether the plates and screws that we use to fix the fractures are as effective as those used in other hospitals around the world.

The reason that we use the plates we do, is that they are made in South Australia, and are less expensive than those made overseas. In addition these plates are easier to bend to the contours of the bones in the face. However the danger is that these "bendable" plates may be deformed by the force of the muscles of the face whilst the bones are still healing.

To see if the plates are bending we want to take X-Rays of patients who have had their fractured jaw fixed with these plates. We will ask you to bite on a device which measures the force of your bite. You will not be asked to bite any harder than you would normally when consuming the soft diet that patients with fractured jaws are allowed to eat.

The X-Rays will be taken at the Adelaide Medical Centre for Women and Children (Adelaide Children's Hospital) as the special X-Ray equipment is not available at the Royal Adelaide Hospital. These X-Rays will also be used to assess the position of your fracture after surgery as is usually done for patients with a fractured jaw.

APPENDIX D

ANALYSIS OF THE STABILITY OF FACIAL FRACTURE FIXATION

CONSENT FORM

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it, and agree to taking part.

2. I understand that I will not be directly benefited by taking part in the trial.

3. I understand that while information gained in the study may be published, I will not be identified and information will be confidential.

4. I understand that I can withdraw from the study at any stage and that this will not affect the medical care.

5. I understand that there will be no payment to me for taking part in this study.

6. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

7. I am aware that I should retain a copy of the Consent Form when completed and the Information Sheet.

Signed:

Full name of Patient:
Date: / /1992

I certify that I have explained the study to the patient and consider that he/she understands what is involved.

Signed:

Title:

APPENDIX E

THE TRAUMA FORM

Trauma F1	PATIENT INFORMATION	UR:

Completed by : Research Coordinator, S5, RAH ( ) Date:____________

(to be completed at/during admission or at discharge).

PATIENT DATA

Surname:______________________________ Forename:______________

Address:____

______________________________________ Post code:______________

Country:______________________________ Race:__________________

Telephone No. (H):____________________ (W):__________________

Date of Birth:________________________ Age:__________________

Sex:__________________________ Marital Status:________________

Religion:_____________________ Occupation:____________________

Insurance Status:_______________

Next of Kin Relationship:_______________

Surname:______________________________ Forename:______________

Address:____

______________________________________ Post code:______________

Telephone No. (H):____________________ (W):__________________

Hospital:_______ Date of Admission:_____________ Time:__________(24 Hrs)

Consultant:____

Referred by:____

Address:____

______________________________________ Post code:______________

Telephone No. (H):____________________ (W):__________________

Referral Diagnosis:____

Trauma F2	PATIENT HISTORY	UR:

Completed by : SURGEON ( ) at time of operation. Date: ____________

Informant: ______________________________ Date of Injury: ____________________

Time of Injury: ____________ Place of Injury: ________________________________

Mechanism of Injury	
Road traffic accident	
Assault	
Sport	
Industrial	
Fall/Collapse	
Other	

Details: ____

____

____

____

____

PAST HISTORY

Craniofacial trauma: ____

____

____

General Medical: ____

____

____

____

SYSTEMS REVIEW

Please delete the inappropriate responses -

Dentition	dentate/partially edentulous/edentulous	
Denture(s)	worn/not worn/not applicable	type: FU/FL/PU/PL
Visual aids	contact lens/spectacles	worn/not worn/not applicable
Helmet	worn/not worn/not applicable	
Seatbelt	worn/not worn/not applicable	

Other: ____

____

____

Trauma F3.1	CLINICAL EXAMINATION	UR:

Completed by : SURGEON (   ) at time of operation. Date: ____________

REGIONAL EXAMINATION - SOFT TISSUES

Enter scale in box as Mild = 1, Moderate = 2, Severe = 3, NAD = Empty box

Region	Injury									
	Abrasion		Laceration		Tissue Loss		Burn		Haematoma	
	R	L	R	L	R	L	R	L	R	L
Neck										
Scalp										
Ears										
Forehead										
Eyebrows										
Eyelids										
· upper										
· lower										
Nose										
Cheek										
Lips										
· upper										
· lower										
Intraoral										
· labial/buccal										
· lingual/floor										
· tongue										
· palate										
· pharynx										

	R	L
Ears		
· blood in ext. canal	☐	☐
Forehead/Eyebrow		
· frontalis br. facial nerve injury	☐	☐
· supraorbital nerve injury	☐	☐
Naso-orbito-zygomatic		
· Nose		
· CSF rhinorrhoea	☐	☐

	R	L
Naso-orbito-zygomatic (cont)		
· Eyelids		
· lacrimal injury		
· upper	☐	☐
· lower	☐	☐
· medial canthal injury	☐	☐
· conjuctiva injury	☐	☐
· Infraorbital nerve injury	☐	☐
· Zygo. br. facial nerve injury	☐	☐

Trauma F3.2	CLINICAL EXAMINATION	UR:

REGIONAL EXAMINATION - SOFT TISSUES (Cont)

	R	L
Cheek		
· buccal br. facial nerve injury	☐	☐
· parotid duct injury	☐	☐
Lips		
· Upper		
· buccal br. facial nerve injury	☐	☐
Lips (cont)		
· Lower		
· mand. br. facial nerve injury	☐	☐
· mental nerve injury	☐	☐
Intraoral		
· Lingual nerve injury	☐	☐

REGIONAL EXAMINATION - HARD TISSUES

	R	L
Calvarium		
· Frontal bone		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
· frontal sinus		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
· supraorbital ridge		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
· Parietal		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
· Temporal		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
· Occipital		
· outer cortical injury	☐	☐
· depressed skull #	☐	☐
Naso-orbito-zygomatic		
· Lat. orbital rim #	☐	☐
· Inferior rim #	☐	☐
Naso-orbito-zygomatic (cont)		
· Naso-maxillary #	☐	☐
· Nasal #	☐	☐
· Zygomatic body #	☐	☐
· Zygomatic arch #	☐	☐
Mandible		
· Condylar head subluxed	☐	☐
· Subcondylar/ramus #	☐	☐
· Angle #	☐	☐
· Body #	☐	☐
· Symphyseal #	☐	☐
Intraoral		
· Mandibular arch		
· dental #	☐	☐
· dento-alveolar #	☐	☐
· compound #	☐	☐
· Maxillary arch		
· dental #	☐	☐
· dento-alveolar #	☐	☐
· mid-facial #	☐	☐
· level	☐	☐

Level of Consciousness:______________________________(Glasgow Coma Scale)

MICROBIOLOGY

☐ Swabs and cultures
(if clinically infected)

Specify details:

RADIOLOGY

Specify examination:

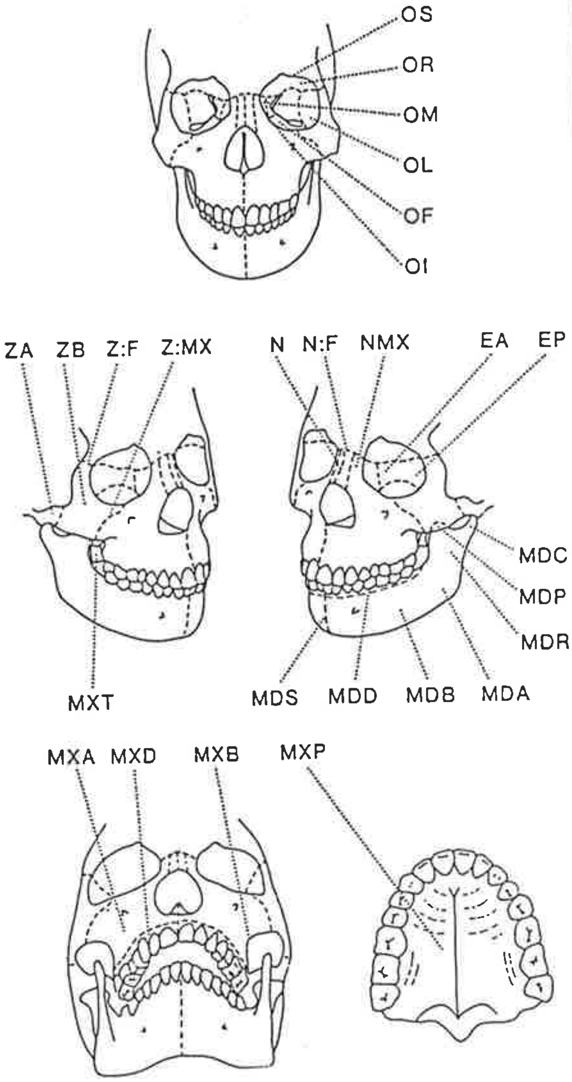
Trauma F5	FACIAL FRACTURE CODING	UR:

Completed by : SURGEON (   ) immediately pre-operation. Date: _______

Minor Zone Coding
(enter on dotted lines below, the degree of disruption in each minor zone)

0 = no #
1 = undisplaced #
2 = obviously displaced #
3 = comminuted +/or compound #

Major Zone Score (in boxes)
enter in boxes below, the sum of minor codes; for any sum ≥5, enter the number 5.



		R	L
NASO-ETHMOIDAL			
nasal bone	N	....	....
naso-frontal sut	N:F	....	....
naso-maxill.	NMX	....	....
ant.ethmoid	EA	....	....
post.ethmoid	EP	....	....
NE SCORE		☐	☐
ZYGOMATIC			
arch	ZA	....	....
body	ZB	....	....
zyg-frontal sut.	Z:F	....	....
Zyg-maxill sut.	Z:MX	....	....
Z SCORE		☐	☐
ORBITAL			
superior rim	OS	....	....
roof	OR	....	....
med. wall	OM	....	....
lat. wall	OL	....	....
floor	OF	....	....
inferior rim	OI	....	....
O SCORE		☐	☐
MAXILLARY			
ant. wall	MXA	....	....
buttress	MXB	....	....
palate	MXP	....	....
dento-alveolar	MXD	....	....
pterygoid	MXT	....	....
MX SCORE		☐	☐
MANDIBULAR			
condyle	MDC	....	....
coronoid process	MDP	....	....
ramus	MDR	....	....
angle	MDA	....	....
body	MDB	....	....
symphyseal	MDS	....	....
dento-alveolar	MDD	....	....
MD SCORE		☐	☐

Facial # Score = ___ / 50
(sum of the 10 major zone scores - in boxes)

Cranial Fracture Present:
yes ☐ no ☐

Trauma F6	OPERATIVE PROTOCOLS - EXPOSURES	UR:

Completed by : SURGEON ( ) in theatre at end of operation. Date: ______

☐ **BICORONAL FLAP** - for
- ☐ pan-facial #
- ☐ supraorbital or frontal sinus #
- ☐ orbital rim # - which is severely displaced or comminuted
- ☐ lateral orbital # associated with lateral wall comminution (i.e. zygomatic arch exposure required)
- ☐ naso-ethmoid #
- ☐ unstable zygomatic arch #
- ☐ subcondylar #
- ☐ other - specify:

☐ **LOWER EYELID INCISION** - ☐ conjunctival or ☐ subciliary - for
- ☐ zygomatic # requiring open reduction
- ☐ orbital floor blowout #
- ☐ midfacial # involving the orbit
- ☐ other - specify:

☐ **TEMPORAL INCISION (Gillies approach)** - for
- ☐ zygomatic body #
- ☐ zygomatic arch #
- ☐ other - specify:

☐ **PRE-AURICULAR INCISION** - for
- ☐ displaced or telescoped subcondylar #
- ☐ other - specify:

☐ **UPPER VESTIBULAR INCISION** - for
- ☐ zygomatic # requiring open reduction
- ☐ all maxillary #
- ☐ maxillary dento-alveolar #
- ☐ other - specify:

☐ **LOWER VESTIBULAR INCISION** - for
- ☐ mandibular angle and body #
- ☐ mandibular dento-alveolar #
- ☐ other - specify:

☐ **SUBMANDIBULAR INCISIONS** - for
- ☐ intraoral or pre-auricular exposure alone does not allow accurate reduction
- ☐ blood supply considerations preclude intra-oral approach
- ☐ other - specify:

☐ **LACERATIONS** - for
- ☐ upper and lower eyelid laceration approximate underlying #
- ☐ submandibular laceration aproximates underlying #
- ☐ other - specify:

Trauma F7.1	OPERATIVE PROTOCOL	UR:

INTUBATION

- ☐ non-occlusal # - oral tube
- ☐ occlusal # (not involving nose) - nasal tube
- ☐ occlusal # (involving nose) - armoured tube orally behind last molar
- ☐ tracheostomy where oral or nasal intubation impossible

SEQUENCE OF REDUCTION AND FIXATION

Key to completing Type of plate used	Eg.
No. of holes on each side of # -	4H, 6H
Type of metal :	
Titanium, Cobalt-Chrome -	Ti, CC
Variety :	
Non-compression -	NC
Compression - large	C(l)
- small	C(s)

☐ Ligation of arch bars

☐ Dental extractions:

48 47 46 45 44 43 42 4131 32 33 34 35 36 37 38

☐ Closed reduction	R	L
☐ zygoma suspension	☐	☐
☐ frontal suspension	☐	☐

☐ Mandibular fixation

Fracture Site	Method of Fixation								Tissue +	
	Plates				Lag Screws		I/O Wires		BG or VBF	
	Type		No. of screws		No.		No.			
	R	L	R	L	R	L	R	L	R	L
Mandible	--	--	--	--	--	--	--	--	--	--
☐ body										
☐ angle										
☐ ramus										
☐ subcondylar										
☐ comminut.										

☐ Dento-alveolar splinting: 48 47 46 45 44 43 42 41 31 32 33 34 35 36 37 38

☐ Lateral fixation

Fracture Site	Method of Fixation								Tissue +	
	Plates				Lag Screws		I/O Wires		BG or VBF	
	Type		No. of screws		No.		No.			
	R	L	R	L	R	L	R	L	R	L
☐ Zygo. Arch										
☐ Fronto-zygo										
☐ Sup. Orb. Rim										

☐ Neurosurgical intervention (Yes = ✓ or No = ×)

Trauma F7.2	OPERATIVE PROTOCOL	UR:

☐ Upper Mid-Face fixation

Fracture Site	Method of Fixation								Tissue +	
	Plates				Lag Screws		I/O Wires		BG or VBF	
	Type		No. of screws		No.		No.			
	R	L	R	L	R	L	R	L	R	L
☐ Fronto-max.										
☐ Naso-ethm.										
☐ Nasal										
☐ Ant Lac Crest + med canthal lig.										

☐ Dental extractions: 18 17 16 15 14 13 12 11 21 22 23 24 25 26 27 28

☐ Maxilla placed into occlusion using wafer and intermaxillary fixation applied

☐ Mid-Face fixation

Fracture Site	Method of Fixation								Tissue +	
	Plates				Lag Screws		I/O Wires		BG or VBF	
	Type		No. of screws		No.		No.			
	R	L	R	L	R	L	R	L	R	L
☐ Pyriform marg										
☐ Zygo-max but.										
☐ Inf. Orb. Rim										

☐ Dento-alveolar splinting: 18 17 16 15 14 13 12 11 21 22 23 24 25 26 27 28

☐ Bone grafting

Fracture Site	Bone Grafting	
	R	L
☐ Orbital Walls	—	—
☐ roof		
☐ floor		
☐ medial		
☐ lateral		
☐ Ant Maxilla		

☐ Med canthopexies if canthal lig. detached from lacrimal bone - R ☐ or L ☐

☐ Release intermaxillary fixation

☐ Where accompanied by bilateral mandibular condylar fractures - no surgery to condyles, and maxill buttresses reconstructed with jaws in intermax fixation.

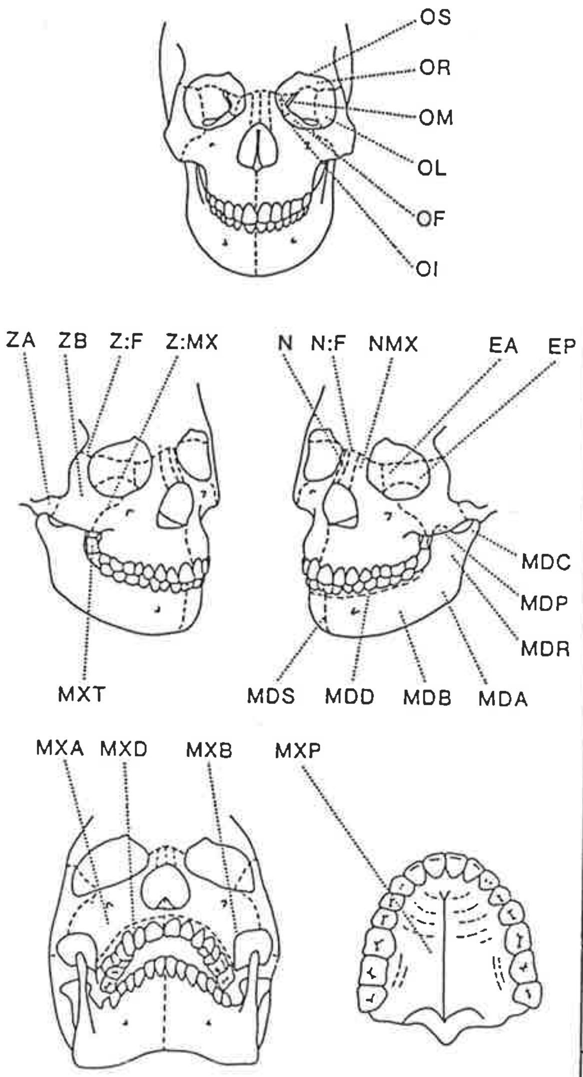
Trauma F8	OPERATIVE SUMMARY	UR:

Photocopy operation sheet from RAH casenotes. Insert here :

Clinical Description:

Trauma F9	FACIAL FRACTURE CODING	UR:

Completed by : SURGEON (   ) immediately post-operation. Date: ______



Minor Zone Coding
(enter on dotted lines below, the degree of disruption in each minor zone)

0 = no #
1 = undisplaced #
2 = obviously displaced #
3 = comminuted +/or compound #

Major Zone Score (in boxes)
enter in boxes below, the sum of minor codes; for any sum ≥5, enter the number 5.

		R	L
NASO-ETHMOIDAL			
nasal bone	N	....	....
naso-frontal sut	N:F	....	....
naso-maxill.	NMX	....	....
ant.ethmoid	EA	....	....
post.ethmoid	EP	....	....
NE SCORE		☐	☐
ZYGOMATIC			
arch	ZA	....	....
body	ZB	....	....
zyg-frontal sut.	Z:F	....	....
Zyg-maxill sut.	Z:MX	....	....
Z SCORE		☐	☐
ORBITAL			
superior rim	OS	....	....
roof	OR	....	....
med. wall	OM	....	....
lat. wall	OL	....	....
floor	OF	....	....
inferior rim	OI	....	....
O SCORE		☐	☐
MAXILLARY			
ant. wall	MXA	....	....
buttress	MXB	....	....
palate	MXP	....	....
dento-alveolar	MXD	....	....
pterygoid	MXT	....	....
MX SCORE		☐	☐
MANDIBULAR			
condyle	MDC	....	....
coronoid process	MDP	....	....
ramus	MDR	....	....
angle	MDA	....	....
body	MDB	....	....
symphyseal	MDS	....	....
dento-alveolar	MDD	....	....
MD SCORE		☐	☐

Facial # Score = ____/50
(sum of the 10 major zone scores - in boxes)

Cranial Fracture Present:
yes ☐ no ☐

Trauma F10.1.1	POST-OPERATIVE FOLLOW-UP	UR:

To be completed by : Outpatient Consultant - Insert name or initials.

OCCLUSAL FRACTURE **First Week** O/P Consultant( ) Date:__________

- Intermaxillary fixation Yes ☐ No ☐
- Jaw movements
  - interincisal distance__________(mm)
- Dental hygiene good/average/poor
- Inferior alveolar n fn:____
- Occlusion:____
- Radiology:____

Complications:____

____

Third Week O/P Consultant ( ) Date:__________

- Intermaxillary fixation Yes ☐ No ☐
- Jaw movements
  - interincisal distance__________(mm)
- Dental hygiene good/average/poor
- Inferior alveolar n fn:____
- Occlusion:____
- Radiology:____

Complications:____

____

Sixth Week O/P Consultant ( ) Date:__________

- Intermaxillary fixation Yes ☐ No ☐
- Jaw movements
  - interincisal distance__________(mm)
- Dental hygiene good/average/poor
- Inferior alveolar n fn:____
- Occlusion:____
- Radiology:____

Complications:____

____

Trauma F10.1.2

Late O/P Consultant ( ) Date:___________

- Jaw movements:____________________ Infer. alv. n fn:________
- Dental hygiene:____________________ Occlusion:____________
- Radiology:____

Complications:____

____

Late O/P Consultant ( ) Date:___________

- Jaw movements:____________________ Infer. alv. n fn:________
- Dental hygiene:____________________ Occlusion:____________
- Radiology:____

Complications:____

____

Late O/P Consultant ( ) Date:___________

- Jaw movements:____________________ Infer. alv. n fn:________
- Dental hygiene:____________________ Occlusion:____________
- Radiology:____

Complications:____

____

Trauma F10.2.1	POST-OPERATIVE FOLLOW-UP	UR:

To be completed by : Outpatient Consultant - Insert name or initials.

ORBITAL FRACTURE **First Week** O/P Consultant( ) Date:__________

· Clinical appearance:____

· Infraorbital n: Normal fn-R☐☐ L: Para/Hyperaesthia-R☐☐ L: Total numbness-R☐☐ L

· Vision

  · diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L

· Epiphora: Right : No/Yes Side_ Left : No/Yes Side_

· Eyelid symmetry: Right : No/Yes Left : No/Yes

· Enophthalmos (measure in mm): Right :__ mm Left :_____m m

Complications:____

____

Third Week O/P Consultant ( ) Date:__________

· Clinical appearance:____

· Infraorbital n: Normal fn-R☐☐ L: Para/Hyperaesthia-R☐☐ L: Total numbness-R☐☐ L

· Vision

  · diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L

· Epiphora: Right : No/Yes Side_ Left : No/Yes Side_

· Eyelid symmetry: Right : No/Yes Left : No/Yes

· Enophthalmos (measure in mm): Right :__ mm Left :_____m m

Complications:____

____

Sixth Week O/P Consultant ( ) Date:__________

· Clinical appearance:____

· Infraorbital n: Normal fn-R☐☐ L: Para/Hyperaesthia-R☐☐ L: Total numbness-R☐☐ L

· Vision

  · diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L

· Epiphora: Right : No/Yes Side_ Left : No/Yes Side_

· Eyelid symmetry: Right : No/Yes Left : No/Yes

· Enophthalmos (measure in mm): Right :__ mm Left :_____m m

Complications:____

____

Trauma F10.2.2	POST-OPERATIVE FOLLOW-UP	UR:

ORBITAL FRACTURE **Late** O/P Consultant( ) Date:__________

- Clinical appearance:______________________________
- Infraorbital n: Normal fn-R ☐☐ L: Para/Hyperaesthia-R ☐☐ L: Total numbness-R ☐☐ L
- Vision
  - diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L
- Epiphora: Right : No/Yes Side_ Left : No/Yes Side_
- Eyelid symmetry: Right : No/Yes Left : No/Yes
- Enophthalmos (measure in mm): Right :__ mm Left :____m m

Complications:______________________________

____

Late O/P Consultant ( ) Date:__________

- Clinical appearance:______________________________
- Infraorbital n: Normal fn-R ☐☐ L: Para/Hyperaesthia-R ☐☐ L: Total numbness-R ☐☐ L
- Vision
  - diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L
- Epiphora: Right : No/Yes Side_ Left : No/Yes Side_
- Eyelid symmetry: Right : No/Yes Left : No/Yes
- Enophthalmos (measure in mm): Right :__ mm Left :____m m

Complications:______________________________

____

Late O/P Consultant ( ) Date:__________

- Clinical appearance:______________________________
- Infraorbital n: Normal fn-R ☐☐ L: Para/Hyperaesthia-R ☐☐ L: Total numbness-R ☐☐ L
- Vision
  - diplopia : up gaze R☐☐ L : down gaze R☐☐ L : lateral gaze R☐☐ L
- Epiphora: Right : No/Yes Side_ Left : No/Yes Side_
- Eyelid symmetry: Right : No/Yes Left : No/Yes
- Enophthalmos (measure in mm): Right :__ mm Left :____m m

Complications:______________________________

____

APPENDIX F

PUBLISHED PAPERS

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

The Relationship Between Fracture Severity and Rate of Complications in Miniplate Osteosynthesis of Mandibular Fractures.

The British Journal of Plastic Surgery 1994; 47:310-311.

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

Patterns of Mandibular Fractures in Adelaide, South Australia.

The Australian and New Zealand Journal of Surgery 1994; 64:307-311.

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

A Comparative Study of Miniplates Used in the Treatment of Mandibular Fractures.

Plastic and Reconstructive Surgery

In print.

The Relationship Between Fracture Severity and Complication Rate in Miniplate Osteosynthesis of Mandibular Fractures.

Edwards T.J.C., David D.J., Simpson D.A., Abbott A.H.

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This work has been supported by the W G Norman Fellowship of the Royal Australasian College of Surgeons.

ABSTRACT

There are many factors influencing the outcome of mandibular fracture management, however the relationship between fracture severity and complication rate has only been recognised intuitively due to the absence of an accepted system of classification of the severity of these fractures. In 1989 Cooter and David described the alpha numeric system of computer based coding for craniofacial fractures. Using this system, a prospective sample of 324 patients with mandibular fractures presenting to the Royal Adelaide Hospital was coded for fracture severity and their progress followed with respect to complication rate. A strong correlation between complication rate and fracture severity was established.

INTRODUCTION

Mandibular fractures are common, and in order to achieve a satisfactory cosmesis and occlusion, open reduction and internal fixation is often necessary. This is associated with a significant morbidity, including infection, malocclusion, non union, plate fracture, and the need for removal of plates as a second procedure in some cases (Ardary 1990, Iizuka 1992, Moore 1990). This study was designed to investigate the relationship between the severity of the fracture being treated, and the incidence of complications that develop following surgery.

METHOD

The patients included in this study included all patients with a facial fracture presenting to the Department of Plastic and Reconstructive Surgery at The Royal Adelaide Hospital during the three year period from 1/7/89 up to and including 30/6/92. Prior to this, members of the Department of Plastic and Reconstructive Surgery met and designed a form known as the 'Trauma Form'. This form remained with the patient's case notes for the duration of his inpatient and outpatient treatment and details of management were entered as they occurred, thereby eliminating the need for retrospective case note analysis. In particular, the operative description was completed by the surgeon who performed the surgery, and the outpatient details were entered at the time of the examination by the clinician conducting the outpatient examination.

Alpha-numeric code and complication rate

All mandibular fractures were coded according to the alpha numeric system of computer based coding for craniofacial fractures as described by Cooter and David (1989). This system divides the craniofacial region into 10 bilateral major anatomical zones, each of which is composed of minor zones. An alphabetic code is assigned to each zone. The fracture is then assigned a numerical value where an undisplaced fracture is scored 1, a displaced fracture 2, and a comminuted fracture 3 points.

The ten major zones are;

Cranial:	- frontal	Facial	- nasoethmoidal
	- parietal		- zygomatic
	- sphenoidal		- orbital
	- temporal		- maxillary
	- occipital		- mandibular

Each of the major zones is divided into a number of minor zones. For the mandible these zones are;

condyle	coronoid process
ramus	angle
body	symphyseal
dentoalveolar	

In the usual situation, the maximum score allowable for a major ipsilateral zone is 5, thus the total points for the ten bilateral zones is 100. This enables the total fracture score to be expressed as a percentage.

For the purposes of this study the total mandibular fracture score was considered, regardless of whether it exceeded the allowable 5 points. Thus the fracture severity was then contrasted with the incidence of complications.

The patients included in this study were all those whose fractures required open reduction and internal fixation. This was carried out using monocortical miniplate osteosynthesis, according to the principles espoused by Champy (1976,1978,1986). Any complications that ensued were recorded on the trauma form as an inpatient, and also at the following outpatient visits. These were recommended at one week, three weeks, and six weeks post operatively, and on a needs basis thereafter.

RESULTS

During the period of the study, 324 patients with at least one fracture of the mandible were treated. Of these patients, 247 (76%) were treated by open reduction and internal fixation using non-compression monocortical miniplate osteosynthesis. Overall there were 39 complications, resulting in a complication rate of 15.8% (Table 1).

Table 1

The complication rate was then compared with the severity of fracture, as determined by the alpha numeric coding score, to see whether or not post operative complication rate was related to fracture severity.

It is apparent from Fig 1 that the incidence of complications with miniplate fixation increases as the severity of the fracture (as given by the alpha-numeric coding score) worsens, correlation = 0.96.

Figure 1

CONCLUSION

These figures demonstrate that the incidence of complications associated with the management of mandibular fractures is higher for fractures of greater severity, with a correlation of 0.96 between fracture severity and complication rate. Previously this association, although intuitively recognised, has not been shown statistically due to the absence of an objective and reproducible system of classification of these fractures that includes the location, number, and severity of fractures The development of the alpha numeric system of coding for craniofacial fractures has allowed an objective and standerdised assessment of the degree of severity of the fracture to be made. The recognition of predictor factors such as this enables the clinician to identify patients at greater risk of complications, and may facilitate the development of techniques to reduce the incidence of these complications.

REFERENCES

Ardary WC (1989). Prospective clinical evaluation of the use of compression plates and screws in the management of mandible fractures. *Journal of Oral and Maxillofacial Surgery,* 47, 1150-3

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Champy M, Lodde JP, Schmitt R (1978). Mandibular osteosynthesis by miniature screwed plates via a buccal approach. *Journal of Oral and Maxillofacial Surgery*, 6(1), 14-21.

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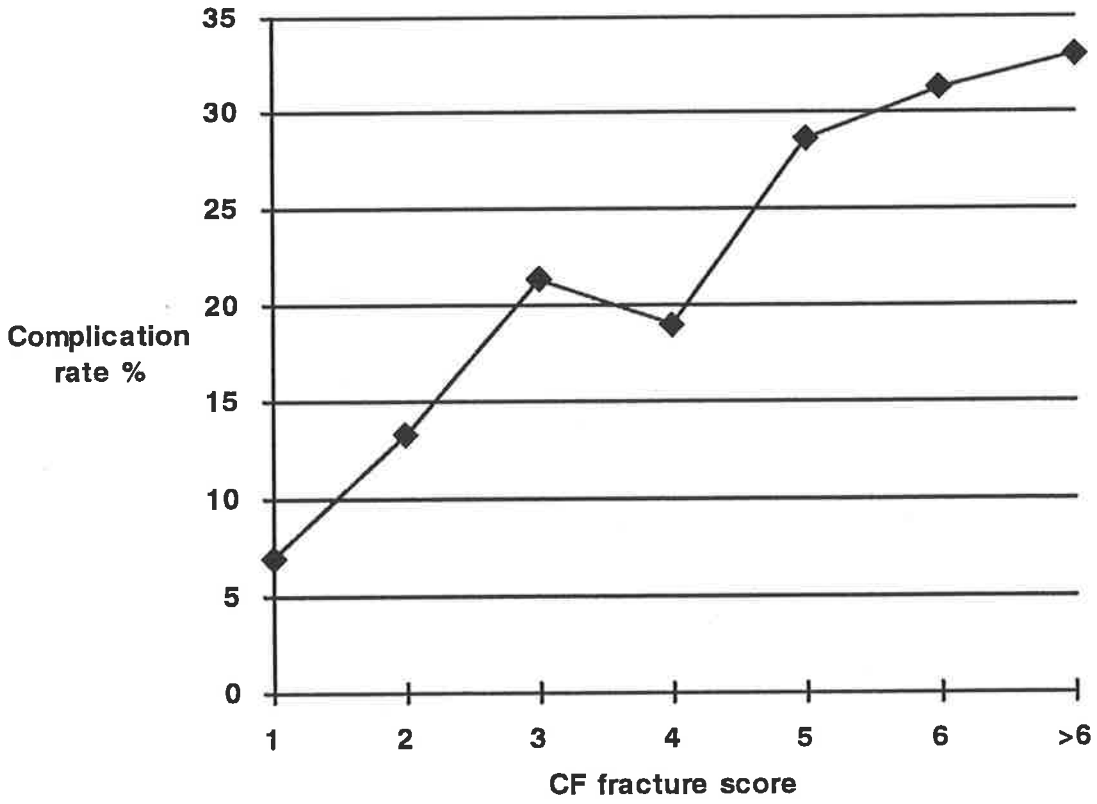
Cooter RD, David DJ (1989). Computer based coding of fractures in the craniofacial region. *British Journal of Plastic Surgery*, 42, 17-26.

Iizuka T, Lindqvist C (1992). Rigid internal fixation of mandibular fractures. An analysis of 270 fractures using the AO/ASIF method. *International Journal of Oral and Maxillofacial Surgery,* 21, 65-9.

Moore MH, Abbott JR, Abbott AH, Trott JA, David DJ (1990). Monocortical non-compression miniplate osteosynthesis of mandibular angle fractures. *Australian and New Zealand Journal of Surgery,* 60, 805-9.

Figure 1



35
30
25
20
15
10
5
0
Complication rate %
1
2
3
4
5
6
>6
CF fracture score

Table 1

COMPLICATIONS	**Nº**	**%**
Plate fracture	2	0.8
Infection resulting in removal of plate	7	2.8
Infection responding to treatment	2	0.8
Malocclusion with corrective op required	13	5.3
Removal of plates	10	4.0
TMJ discomfort	3	1.2
TMJ ankylosis, bilateral reconstruction	1	0.4
Non union	1	0.4
TOTAL	**39**	**15.8**

PATTERNS OF MANDIBULAR FRACTURES IN ADELAIDE.

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This work has been supported by the W G Norman Fellowship of the Royal Australasian College of Surgeons.

ABSTRACT

Facial fractures are exceedingly common, and fractures of the mandible are the most common facial fracture. Over the past two decades a changing trend in the aetiology of these fractures has been apparent, with a decline in the percentage resulting from motor vehicle trauma, and an increase in the percentage resulting from assaults. A three year prospective study of 324 patients presenting to the Royal Adelaide Hospital with a mandibular fracture was conducted and the patient groups, influence of alcohol, aetiology, and type of fracture were examined and compared with other large series from around the world.

Key Words:

Mandibular
Facial Fractures
Aetiology

INTRODUCTION

Facial fractures are common in our community, and mandibular fractures, along with fractures of the zygoma, constitute the majority of all facial fractures. Mandibular fractures will often require open reduction and internal fixation, and this is associated with a significant morbidity, including infection, malocclusion, non union, plate fracture, and the need for removal of plates as a second procedure in some cases.[1,2,3] In addition to the morbidity associated with such an injury, the cost of treatment is high, due to the large numbers of patients, and the expensive hardware involved. The first step in attempting to reduce the incidence of these injuries is to identify the aetiology of these fractures, and to compare these results from other large series, in order to identify any aetiological factors that may be targeted.[4,5]

The aim of this study was to examine the aetiological factors of mandibular fractures presenting to the Royal Adelaide Hospital, and to compare these results with those of other large series. This base line study will enable trends to be identified over the ensuing years, and will also facilitate the identification of areas where prevention may be of some benefit.

METHOD

The patients included in this study included all patients with a facial fracture presenting to the Department of Plastic and Reconstructive Surgery at The Royal Adelaide Hospital during the three year period from 1/7/89 up to and including 30/6/92. Prior to this, members of the Department of Plastic and Reconstructive Surgery met and designed a form known as the 'Trauma Form'. This form remained with the patient's case notes for the duration of his inpatient and outpatient treatment and details of management were entered as they occurred, thereby eliminating the need for retrospective case note analysis. In particular, the operative description was completed by the surgeon who performed the surgery, and the outpatient details were entered at the time of the examination by the clinician conducting the outpatient examination. The content of the Trauma Form was intentionally comprehensive to allow as much information as possible to be collected.

The Royal Adelaide Hospital is a major teaching hospital of 630 beds associated with The University of Adelaide, and is located centrally within the City of Adelaide. It is the major referral centre of South Australia for a number of surgical specialties. The Department of Plastic and Reconstructive Surgery is a large department offering General Plastic Surgery, Craniofacial Surgery, Microsurgery, Head and Neck Surgery, Hand and Upper limb Surgery, and a specialised Burns injury unit.

RESULTS

During the three year period of the study, 832 patients with facial fractures received treatment from the Department of Plastic and Reconstructive Surgery at the Royal Adelaide Hospital. Of these, 324 (38.9%) had sustained a fracture of the mandible.

The method of injury was recorded at the time of presentation to the Department of Accident and Emergency Medicine wherever possible. These were recorded under the categories as shown in Table 1.

table 1

The overwhelming majority of persons sustaining mandibular fractures in Adelaide were males (table 2).

table 2

There was a marked preponderance of males in most aetiological categories. The proportionate representation of males and females was relatively similar for road traffic accidents and assaults, however there was a preponderance of females sustaining mandibular fractures as a result of falls, whilst a much larger proportion of males sustained their fractures from sporting injuries (Table 3). (It is important to note that no attempt was made to separate out 'assaults' from 'accidents', any fracture occurring during sport was listed as a sporting injury. Undoubtably a significant proportion of these were malicious assaults.)

table 3

A significant proportion (30%) showed alcohol consumption as a contributing factor to the injury. Alcohol was more likely to be associated with male persons sustaining mandibular fractures than female (table 4). Whilst 32.7% of male patients were under the influence of alcohol to some degree, only 20% of females were similarly affected. It is important to note that these figures only apply to alcohol consumption by the person sustaining the injury, unfortunately no figures are available regarding those also involved, such as the assailant, or the driver of cars involved in a road traffic accident.

table 4

The age of patients with mandibular fractures in this study ranged from 15 to 79 years. The average age of persons sustaining fractures of the mandible was 28.37 years. However, as seen from Figure 1, the graph is strongly skewed to the right, partially due to the fact that children less than the age of 15 are not included in this study as the Royal Adelaide Hospital functions as an adult institution, but mainly due to the preponderance of patients in the 20-25 year age group. As the mean is strongly influenced by such a skewed distribution, the median gives a better indication of age distribution. In this case the median age was 25 years.

Anatomic Distribution of Fractures

The 324 patients in this study suffered 491 fractures of the mandible. In all, 46.9% of patients suffered fractures in two places, whilst 2.5% sustained fractures in three places. Half of all patients (50.6%) sustained a single fracture. The anatomical distribution of the facial fractures is listed in table 5.

table 5

The most common fracture patterns identified are listed in table 6. Of the patients included in this study, nineteen different fracture patterns were identified where more than one fracture occurred.

table 6

DISCUSSION

A large amount of information has been extracted from the comprehensive data collected on the facial fracture forms, the aetiological findings of which are listed above. Similar studies by other units reporting their own experience have already been published. Thus the information presented here will serve to complement and contrast with that already presented.

Proportion of mandibular fractures

The proportion of facial fractures comprising at least one fracture of the mandible is consistent with figures published elsewhere. There is naturally a bias inherent in considering only those patients presenting to one hospital due to the demographics and referral base of the institution. The Royal Adelaide Hospital is located centrally within the city and is the principal tertiary trauma referral centre. Thus it receives most of the major trauma from the country areas of South Australia, and also referral from two of the four metropolitan teaching hospitals that do not provide a maxillofacial service. Other hospitals in Adelaide would therefore see smaller numbers of mandibular fractures presenting largely from their local area, and often not in association with major injuries which would see those patients transferred to the Royal Adelaide Hospital. Approximately 38.9% of patients presenting to the Royal Adelaide Hospital with a facial fracture had sustained a mandibular fracture as part of their injury pattern. Ellis et al. analysed 4711 patients with facial fractures presenting to the Oral and maxillofacial surgery unit at the Canniesburn Hospital in Glasgow, Scotland over the ten year period from 1974 to 1983.[3] He found 2137 (45.4%) of these to have a mandibular fracture.

Method of Injury

The method of injury reported in this series is contrasted in table 7 with results reported in the literature.[3,6,7,8]

table 7

These results, whilst showing broad agreement across most categories, do vary significantly in a number of instances. For example, the results published by Ellis et al. differ in a number of categories, with a noticeably lower number of motor vehicle accidents, and a significantly higher number of falls.[3] He postulates that the former can be explained by the low rates of private ownership of motor vehicles in Scotland and consequently greater use of public transport. The high incidence of falls occurred predominantly in females and, according to Ellis, may indicate a number of non-reported assaults. This peculiar statistic was also noticed in a study of jaw fractures treated at the Department of Maxillofacial Surgery, Ulleval Hospital in Oslo, Norway.[9] In contrast, Olson et al. reporting 580 cases of mandibular fractures presenting to the University of Iowa hospitals between 1972 to 1978 found the reverse,[8] with fractures resulting from motor vehicle accidents exceeding those caused by assaults, indeed the incidence was three times that found by Ellis et al.[3] Olson believes the explanation for this lies in the location of the hospital in a small university city near a busy highway. Melmed and Koonin in 1975 also explored the relationship between aetiology of mandibular fractures and socio-economic group.[10] In a study of 909 patients with mandibular fractures presenting to the Plastic Surgery Department at the Groote Schuur Hospital in Cape Town, South Africa, a significant difference was found between the white population as compared to the indigenous population. Whereas

64% of the indigenous population were injured in assaults, 67% of the white population were injured as a result of motor vehicle accidents or sporting injuries. When contrasted with these results, the Adelaide figures would appear to have a remarkably low proportion of fractures sustained in motor vehicle accidents, as Adelaide is, after all, heavily dependant on private transport. However it is difficult to compare these two societies. One might suggest that the greater public awareness of road trauma, improvements in motor vehicle design and safety, and the introduction of compulsory wearing of seat-belts would go a long way to explaining this apparent discrepancy.

An alternative explanation for the discrepancy in these results is provided by Voss who investigated the changing trend in the aetiology of mandibular fractures between 1970 and 1980.[9] There were 332 mandibular fractures in 1970 presenting to the Ullveal Hospital, Oslo, Norway. This is contrasted with 283 mandibular fractures in 1980, a reduction of 14.8%. Significant shifts in the aetiological patterns were observed. Assaults increased from 44% of cases in 1970, to 59% in 1980. There was a corresponding fall in the motor vehicle accident category, from 21% in 1970 to just 11% in 1980. Voss attributes these changes to the increasing trend of violence in their community, coupled to a reduction in the total number of traffic accidents and the introduction of compulsory helmets for motor cycle riders and seat belts for motorists. Shepherd also comments on the dramatic increase in the number of assaults recorded in Britain, reports of which had doubled in the period 1974 - 1984.[11]

Sex distribution

Mandibular fractures, as for all facial injuries in our series, are overwhelmingly more common in males than females, the preponderance of males over females sustaining these fractures is no doubt related to their predisposition to most violent injuries. This figure compares with those reported in the literature. For example, Fridrich reported an incidence of 78% of mandibular fractures occurring in males in a series of 1067 patients presenting with mandibular fractures to the University of Iowa Hospitals between 1979 and 1989.[6] A similar distribution was identified by Ellis et al. who found 76% of fractures to have occurred in males and 24% in females.[3] Melmed and Koonin reported a sex distribution of 80.3% males to 19.7% females.[10] Iizuka and Lidqvist reported 81.8% of mandibular fractures occurring in male patients for patients presenting to the University Central Hospital in Helsinki.[7]

Not surprisingly males dominated most aetiological categories. The proportionate representation of males and females was relatively similar for road traffic accidents and assaults, however there was a preponderance of females sustaining mandibular fractures as a result of falls, whilst a much larger proportion of males sustained their fractures from sporting injuries (Table 3). (It is important to note that no attempt was made to separate out 'assaults' from 'accidents', any fracture occurring during sport was listed as a sporting injury. Undoubtably a significant proportion of these were malicious assaults.) These findings correlate with those of Ellis et al.[3] They reported 33.92% of females had sustained their fracture as a result of falls, whilst none had been similarly injured as a result of a sporting accident.

Influence of alcohol

The link between alcohol and mandibular fractures has long been established.[12,13] Alcohol was commonly found as a strong aetiological factor. Iizuka and Lindqvist found 43% of patients under the influence of alcohol on admission to hospital, and one third of patients had a history of alcohol abuse.[7] This was noticeably higher than the 29.9% of patients affected by alcohol in our study. The broader question of alcohol abuse and alcoholism was not addressed in our study. Voss found that the involvement of alcohol in mandibular fractures had increased over the ten year period from 1970 to

1980.[9] In 1970 alcohol was a factor in 28% of mandibular fractures, however this had increased to 47% in 1980. This may reflect the corresponding increase in assaults resulting in mandibular fractures over that period.

Unfortunately the role of drugs other than alcohol was not addressed in our study as it was felt that any figures based purely on patient history would be unreliable in this regard. We are not aware of any statistical reports of the role of drugs other than alcohol in the aetiology of mandibular fractures.

Age distribution

The age distribution is similar for our figures when contrasted with other studies as shown in Figure 1.[3,7,10] Note that our figures do not include the 0-14 age group as our figures are taken from an adult hospital.

figure 1

Anatomic location of fractures

A comparison of the anatomic location of mandibular fractures at the ACFU and elsewhere is presented in table 8. These results are closely correlated, save for the apparently low incidence of symphyseal fractures observed by Ellis.[3] However he does report a correspondingly higher rate of body fractures, raising the possibility that parasymphseal fractures have been included in this group.

table 8

CONCLUSION

Fractures of the mandible in Adelaide are common. They occur predominantly in a young adult male population, and assault is by far the most common aetiological agent, followed by motor vehicle accidents and sporting injuries. The age, sex, aetiology, and anatomical distribution of the fractures appears to mirror that of other large series reported in the literature. Whilst there is a suggestion that public health measures associated with road safety have reduced the incidence of mandibular fractures occurring in this way, there has been a corresponding increase in the proportion of mandibular fractures resulting from assaults. It is difficult to imagine what public health measures could be employed to reduce the latter. In his study of Surgical, Socio-economic, and Forensic aspects of assault, Shepherd found that a large proportion of violence was often concentrated in a small inner city area containing a large number of public houses.[11] This observation, he argues, may enable the formulation of strategies aimed at reducing the incidence of inner city violence, such as those proposed by Hope in 1985.[14] Adelaide is no different than other cities in having its own concentrated area of public houses, and future collection of data by the ACFU will attempt to determine whether a similar link to that reported by Shepherd does indeed exist, thereby establishing a basis for the implementation of policies to reduce violence, and the injuries that result.

The collection of data at the ACFU will continue, with the aim that further reports will be produced in order to establish trends occurring in South Australia.

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Table 1

Method of Injury	**Total**	**Percentage**
Assault	172	53.1
Road Traffic Accident	68	21.0
Sport	42	13.0
Industrial	3	0.9
Fall	26	8.0
Gunshot	4	1.2
Other	9	2.8
Total	**324**	**100%**

Table 2

	Male	Female
Mandibular fractures	260 (80%)	64 (20%)

Table 3

Method of Injury	Male	% of males	Female	% of females
Assault	143	55	29	45
Road Traffic Accident	51	20	17	27
Sport	40	15	2	3
Fall	12	5	14	22

Table 4

	Alcohol involved	Alcohol not involved
Male	85 (32.7%)	175
Female	12 (20%)	52
Total	**97 (29.9%)**	**227**

Table 5

Fracture Type	Tot	%
Condylar Fracture	99	20.2%
Coronoid process	1	0.2%
Ramus	15	3.05%
Angle	179	36.46%
Body	81	16.50%
Symphyseal	116	23.82%

Table 6

Fracture Type	Total	% of multi fractures	% of total cases
Parasymphyseal, symphyseal	20	11	6.2
Bilateral angle	10	5.5	3.1
Parasymphyseal, angle	40	22.1	12.3
Parasymphyseal, subcondylar	30	16.6	9.3
subcondylar, body	10	5.5	3.1
angle, body	26	14.4	8.0
other	45	24.9	13.9
	136	**100%**	**55.9**

Table 7

Method of Injury	**ACFU**	**Fridrich (1992)**	**Ellis (1985)**	**Iizuka (1992)**	**Olson (1982)**
Assault	53.1	47.5	54.7	59.8	34.4
Road Traffic Accident	21.0	31.5	15.1	17.3	47.8
Sport	13.0	5.4	3.51	blunt object 3.7	2.2
Industrial	0.93	3.0	2.48	-	0.7
Fall	8.02	7.1	21.3	13.5	8.4
Gunshot	1.23	-	-	0.9	-
Other	2.78	5.5	2.96	4.6	6.5
Total	**100%**	**100%**	**100%**	**100%**	**100%**

Figure 1

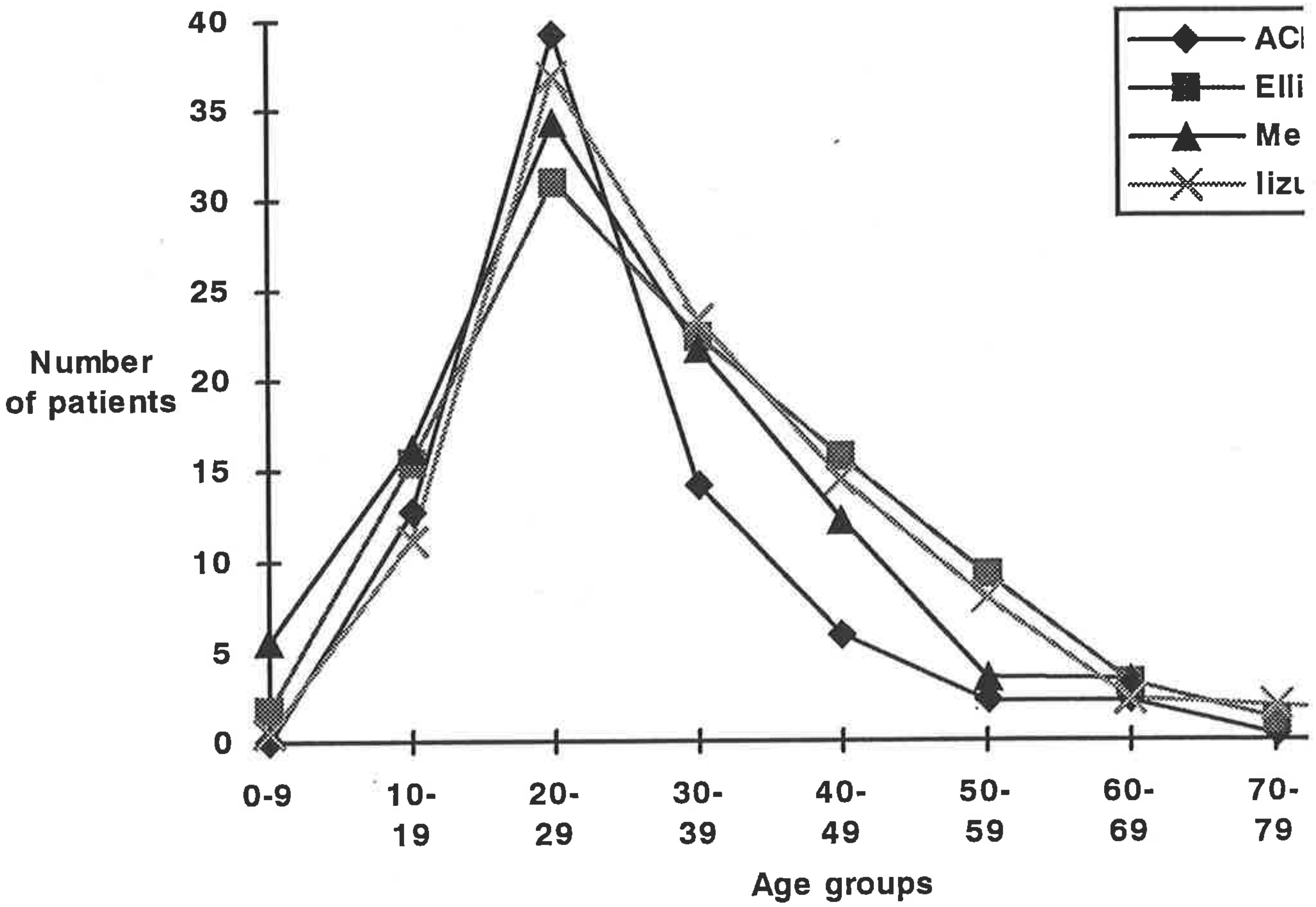
ACI
Elli
Me
Iizu
Number of patients
40
35
30
25
20
15
10
5
0
0-9
10-19
20-29
30-39
40-49
50-59
60-69
70-79
Age groups

Table 8

	ACFU (%)	Ellis 1985 (%)	Olson 1982(%)
Condyle	20.2	29.3	29.1
Coronoid process	0.2	2.2	1.3
Ramus	3.05	2.6	1.7
Angle	36.46	23.1	24.5
Body	16.50	33.0	16.0
Symphyseal	23.82	8.4	22.0

A Comparative Study of Miniplates Used in the Treatment of Mandibular Fractures.

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ABSTRACT

This article aims to investigate the differences in mechanical properties of major miniplating systems used for non compression miniplate osteosynthesis of mandibular fractures, and to determine whether these properties influence treatment outcome. The study was conducted in two parts. Six of the major miniplate systems currently used at the Royal Adelaide Hospital were subjected to bending tests at the University of Adelaide Engineering Department to quantify the relative stiffness of each plate. Secondly, a prospective sample of patients presenting with mandibular fractures was analysed. These patients were treated with a variety of the miniplating systems. The results of treatment as a whole were compared to identify any direct benefit consequent on the miniplate selected. Whilst significant differences in stiffness were identified between the plating systems, no significant differences in treatment outcome were identified between the non-compression plates employed. As no observable benefits have been identified by choice of miniplate, selection should be based on surgical preference, biocompatibility, CT compatibility, and unit cost. Due to the variations in materials, design, properties, CT compatibility and unit costs, it is important not to regard all miniplates as equal and interchangeable.

INTRODUCTION

The fixation of mandibular fractures by non compression monocortical miniplate osteosynthesis according to the tension band principle was introduced by Michelet (1) and Champy (2) based on the experimental work of Champy who showed that distraction forces operate at the upper border of the mandible, whilst compression forces operate at the lower border (3). This theory has since been contradicted by Rudderman and Mullen who showed that zones of tension and compression may be reversed when forces are generated along the posterior teeth (4). Thus the original theory upon which this treatment modality was based has been challenged, however the method has been retained as the post operative results and complication rate comparable to those reported around the world, and holds significant advantages over bicortical compression plate osteosynthesis.

The advantages of monocortical miniplate osteosynthesis over bicortical compression plates include (5);

- compression plating often requires an extraoral approach which is technically more difficult. The necessity for the extraoral approach has been quoted at 60.8% to 78.5% of cases (6,7).
- bicortical plates risk damage to the inferior alveolar nerve, whereas the risk of damage to the inferior alveolar and mandibular nerves using the monocortical plates is negligible..
- routine use of intraoral incisions with monocortical plates requires minimal dissection, avoids an external scar.

- the technique is easily taught, and excellent results are achieved by junior registrars (8).
- in simple fractures of the mandible, monocortical osteosynthesis provides rigid fixation and found no complications are caused by inadequate stability of fixation (9,10).
- it is difficult to make compression plates adapt to the bony curvatures (9).

The Australian Craniofacial Unit (ACFU) uses a modified Champy approach to the treatment of mandibular fractures, as described by Moore et al. (5). To recognise monocortical miniplate osteosynthesis as the treatment of choice for the open reduction and internal fixation of mandibular fractures is to oversimplify the issue. There is now a myriad of commercially available miniplating systems, and these vary in their materials, design, physical properties, and cost.

With this in mind, the specific aims of this study were; firstly to scientifically compare the engineering properties of miniplates commonly used in fracture treatment, and secondly in a clinical setting to compare the in vivo performances of the same miniplates to identify which of these properties influence treatment outcome

PART 1:

COMPARISON OF THE BIOMECHANICAL PROPERTIES OF MINIPLATES.

Manufacturers have sought to improve miniplates by varying their design, properties, profile and material composition. This has resulted in a great deal of choice afforded to the clinician. However, despite the large number of obviously different systems, little comparative work has been published to date

The ideal miniplate will exhibit a number of features. It will be;

- cost effective
- easy to mould to the contours of the facial skeleton
- sufficiently stiff to maintain rigid fixation, and strong enough to resist deformation across the plate during fracture healing
- completely biocompatible
- low profile so as not to be palpable
- of composition so as not to produce scatter on CT scans
- not intrinsically responsible for producing complications

Any comparison of the engineering properties of miniplates must take into consideration their metal composition. This is of particular importance as many of these plates are often left in situ indefinitely, so biologically inert metals are preferred. The three commonly used implant materials are stainless steel, Vitallium, and titanium. The choice of the implant material will influence the strength and stiffness of the implant, the biocompatibility of the implant, and the imaging properties of the implant, particularly with regard to CT investigations. The AO/ASIF group suggests that titanium is the most biologically inert of the three and therefore has the least chance of producing any low grade immunological response. No allergic reactions to titanium have been reported (11). With regard to CT compatibility titanium is also the preferred implant as it is the most radiolucent (12).

In choosing a plating system from the product information of the various manufacturers the clinician may be confounded by the terminology used. For example the hardness of the component metal may be expressed in a variety of units such as the Vickers hardness number (VHN) and the Rockwell scale (R_B and R_C). The tensile strength and elongation to fracture of the core metal are other parameters often quoted. This information often refers to tests carried out on the core metal and does not take into account the structural performance of the individual plates. Thus the clinician is not provided with a simple guide to directly compare different plates. In addition, most of the manufacturers make no attempt to link the information they have provided with clinical trials that demonstrate the reasoning behind the miniplate design.

As a result of the lack of experimental data, clinicians are left to select plating systems based on inadequate information. Taking this one step further, the science of selection of the size and strength of plating system for various regions of the craniofacial skeleton has also been neglected, leaving clinicians to estimate the strength of plate that might be required for a specific area, eg a 'heavy plate' for a mandibular fracture due to the perceived forces applied across the mandible, or a 'small plate' to stabilise a nasoethmoid fracture due to the absence of large muscular forces applied across this fracture.

Recently some literature has appeared analysing the biomechanical properties of miniplates. Damron et al compared the biomechanical properties of Luhr Vitallium minifragment plates, Synthes titanium minifragment plates, and Synthes stainless steel minifragment plates designed for craniofacial uses but in this study used for dorsal plate fixation of proximal phalangeal fractures (13). Hegtvedt et al have compared the Luhr minisystem with the Luhr microsystem to provide a comparison of the biomechanical properties of each system (14). They showed that there is a significant difference in the force required to bend miniplates compared with microplates. They then review some of the expected forces that occur in vivo, and make some guarded conclusions about correlating the in vitro biomechanical properties with in vivo forces. For example, if a plate is shown to withstand a certain force in a biomechanical model, does this mean it can withstand a similar occlusal force in vivo. The authors make it clear that clinical studies are needed to confirm such an assumption.

The aim of this study was to produce a clinically relevant comparison of the different mechanical properties of the miniplates. The most important indicators to the clinician are the stiffness of the miniplate, and the force required to permanently deform the plate. The clinician will then be able to select a miniplate (taking into account the cost, biocompatibility, and CT compatibility of the plate) able to withstand the expected forces, yet still malleable enough to be shaped to the contours of the bone and hence 'operator friendly'. As the complex in vivo forces are difficult to calculate, this must be coupled with clinical trials which confirm miniplate effectiveness in individual regions.

MATERIALS AND METHODS

This study was conducted at the department of materials engineering at the University of Adelaide. Five miniplate systems were selected for investigation, these being the five systems available for use at the Royal Adelaide Hospital, ie the Würzburg, AO/ASIF, Medicon, and Aus Systems and Champy miniplates, along with the Luhr minicompression plates.

Mechanical Properties

When considering the mechanical properties of miniplates, the prime consideration should be their stiffness and strength in bending. As the aim of this study was to test the miniplates already in use, not to develop new miniplate design, it was possible to test each miniplate system and its screws as a functional unit, rather than testing a standard form of the pure alloy or metal.

Stress versus strain behaviour may be represented graphically (Fig 1). In the elastic section, the strain is reversible, that is to say that the metal returns to its original shape after the stress is removed. Hookes law suggests that, for a linear elastic material, strain increases in direct proportion to the applied stresses. The slope of the linear elastic section (denoted by E) is Young's modulus of elasticity. Young's modulus of elasticity is a measure of the rigidity of the material, and is therefore a property of the material.

At a certain point, the deformation of the material ceases to be elastic (reversible) and becomes plastic (permanent). In the plastic region strain changes are no longer directly proportional to the applied stress. The point at which this occurs is known as the yield point, and is the most important value for design.

The critical properties of the plate in vivo are those which resist the bending forces across a fracture line, that is the stiffness of the plate and its yield load.

If E = Young's modulus of elasticity

and I = the moment of inertia of the cross sectional axis at mid span

then E × I = the stiffness of the plate

E x I is found by (Fig 2);

$$\text{Stiffness} = E.I = \frac{w.L^3}{48y}$$

where;

w = load

y = displacement at the centre of the span

l = length

In conjunction with the Department of Materials Engineering of The University of Adelaide, a testing rig was designed (Fig 3). A four hole miniplate was screwed into a brass template with two holes on each side, and a 0.25 mm gap to simulate a fracture. The screw holes were pre-tapped to accept the particular systems screws. This allowed each plating system to be tested as a functional unit. As the length l is the distance between the grips, then the equation gives the empirical value of stiffness for the composite structure (miniplate and brass plates). However in this model the brass plates were assumed to be infinitely stiff, thus only the deformation of the miniplating system could account for any deformation recorded. Obviously the distance between the grips is empirically chosen , and does not attempt to reflect the real case in vivo. This system was then placed in an Instron 1026 tensile testing machine, which is a three point bender exerting a known load on the simulated fracture line. Each plate was tested ten times and an average stiffness and yield point was established.

RESULTS

The results of the engineering component of the study are shown in table 1. The miniplates were shown to have similar yield points, however the stiffness of the plates varied significantly.

Thus the clinician is now provided for the first time with a direct comparison of the stiffness and yield point of these plating systems as functional units, ie a four hole plate and screws fixed to an unyielding template.

PART 2:

CLINICAL ANALYSIS OF INTERNAL FIXATION OF MANDIBULAR FRACTURES USING MONO-CORTICAL NON-COMPRESSION MINIPLATES

The in vivo performance of these miniplates was then investigated in a clinical trial designed to identify any difference in treatment outcome related to the selection of miniplate. The clinical sample included all patients with a mandibular fracture requiring surgical fixation under the care of the Department of Plastic and Reconstructive Surgery at The Royal Adelaide Hospital during the three year period from 1989 to 1992. During this period, 832 patients with facial fractures were seen. A total of 324 patients had sustained a fracture of the mandible, and of these 247 were managed by non compression osteosynthesis.

Surgical Techniques

During the period of this study, the ACFU has used Luhr, Medicon, Würzburg, and Aus Systems miniplates interchangeably. Unfortunately the selection was not randomised, however the consultants, registrars and fellows all used a variety of the systems. No surgeon exclusively used one system, and no protocol was in place for the use of any one system for any particular situation.

MATERIALS AND METHOD

The patients included in this study included all patients with a facial fracture presenting to the Department of Plastic and Reconstructive Surgery at The Royal Adelaide Hospital during the three year period from 1/7/89 up to and including 30/6/92. The data was collected in a prospective fashion separate from the case notes, thereby eliminating the need for retrospective case note analysis.

RESULTS

A total of 324 patients with mandibular fractures presented during the three year period of the study, and of these 247 (76%) were treated by open reduction and internal fixation with miniplates. A total of 77 patients were treated by other methods, the majority being non displaced fractures managed conservatively, or minimally displaced condylar fractures also managed conservatively or by elastic intermaxillary fixation. Two patients had their fractures treated by lag screws.

The miniplates used were the Aus Systems non-compression monocortical miniplates, the Würzburg non-compression monocortical miniplates, the Medicon non-compression monocortical miniplates, Luhr minicompression plates (used in a non compression fashion as described by Munro in 1989 (15)), and Luhr compression plates.

Although the selection of miniplate was not randomised, no bias has been identified regarding plate selection. Fractures were coded according to severity according to the alpha numeric system of computer based coding for craniofacial fractures (16). The complication rate correlated closely with the craniofacial fracture coding score, the correlation being 0.96 (17). However there was no significant variation in the distribution of fracture severity between the various miniplates (table 2). In addition, analysis of the distribution of fractures (symphyseal, body, angle, ramus, condylar) shows no significant bias in use between the miniplate groups (table 3). Finally there was no statistically significant variation in the rate of teeth in the fracture line requiring dental extraction. It was not feasible to look at comparison of individual fracture patterns, as 26 patterns were observed.

The results of open reduction and internal fixation at the Australian Craniofacial Unit will be presented in two parts. Firstly the results as a whole will be tabled, and secondly the results of treatment will be examined to compare the different miniplates in use at the unit to identify any discrepancies in outcome related to the type of plates used. The miniplates used during the period of the study are listed in table 4. The overall complication rate was 15.8% and is listed in table 5.

The complication rate for each of the main systems used on this unit (Aus Systems, Würzburg, Luhr non-compression) were then considered individually to attempt to identify any difference between the complication rates associated with the use of each plating system (table 6). Only these three major systems are compared as the others used in this series had too few numbers to be statistically analysed. These results were compared with a chi square analysis (table 7).

$X^2 = 3.842$ (two degrees of freedom)

ie $0.15 > p > 0.10$

DISCUSSION

The information that has been presented on a large series of patients contrasting the use of different makes of non-compression miniplates is the first review of its kind of which we are aware. The complications noted by the Australian Craniofacial Unit have been listed in table 5. Comparing results with those published in the literature is difficult due to the different populations these studies may represent. A different proportionate representation of certain fracture patterns may strongly influence the incidence of complications. The selection of cases for open reduction and internal fixation may also vary between units. At the ACFU 76% of patients with mandibular fractures underwent miniplate fixation of their fractures compared with only 13% by Iizuka and Lindqvist (7). The complication rate quoted is that per patient, not per fracture as is quoted in many series. Reports in the literature of overall complication rates from compression plate osteosynthesis have ranged from 21 - 37% (7,18,19,20). Ellis in 1994 compared the use of double miniplate fixation for angle fractures and found only a slight improvement in complication rate as compared with compression plate osteosynthesis (28% vs 32%) (21). He suggests that it is unlikely that fracture instability is the major reason for the development of infections in this area. When pure angle fractures are extracted from our data the complication rate was 24.1%, with an infection rate of 8.6%. This would appear to be in line with the low complication rates reported by authors employing miniplate fixation according to the techniques espoused by Champy (5,8,9,10,22,23,24). There were two significant classes of complications affecting the patients of this unit. The first was a 5.3% incidence of post operative malocclusion which required corrective surgery. This amounted to 13 cases overall. The second major class of complication was infection, which occurred in 3.6% of cases. Of the 9 cases of infection, there were no episodes of osteomyelitis. The policy of the ACFU has been to treat all but the mildest cases of infection by removal of the plate, debridement and irrigation as necessary, followed by replating the fracture with Luhr compression plates. In some cases where the fracture appears rigidly fixed and an abscess has been drained, the existing plate will be left in situ. Resolution of the infection and satisfactory union of the fracture was the ultimate outcome for all cases of post operative infection.

As stated earlier, plates are not routinely removed on the ACFU. Plates will be removed for a variety of reasons, including treatment of infection, exposure of the plate consequent on soft tissue breakdown, and occasionally due to request of the patients when they can feel the plates under the soft tissues. In all 6.8% of patients had their plates removed, 2.8% as part of management of infection and 4.0% for other reasons. The inclusion of these factors in the overall complication rate figures should be recognised as those who routinely remove plates post operatively will not necessarily document these as complications.

Non compression plating comparison.

The major plating systems used were compared with each other to identify any influences on complication rate that could be attributed to the non compression miniplate selected. As can be seen from table 6, the complication rate was similar in the case of the Aus System and Würzburg plates, but higher for the Luhr mini-compression plates, however this observed difference was not statistically significant ($0.15>p>0.10$).

Therefore there is no evidence that the complication rate is influenced by the selection of miniplate in this case. If the Luhr minicompression plate (which showed the highest complication rate) is taken out of the equation, then two similar non compression miniplates with different bending characteristics can be compared, also using the chi square analysis.

Here $X^2 = 0.096$ (one degree of freedom)

ie $p > 0.25$

Thus as $p > 0.25$, there is no evidence of a significant difference between the complication rate experienced by either the Aus Systems or Würzburg plating system. So although these plates exhibit different stiffness, yield points, design and materials, no relationship between plate selection and treatment outcome was identified. Aus systems plates were the most malleable as found in the engineering component of the study, yet no significant adverse clinical results could be detected in the in vivo study when compared with other plates, indeed the Aus System plates compared favourably.

CONCLUSION

It is well known amongst clinicians that non compression miniplate osteosynthesis is the treatment of choice for mandibular fractures, but that significant differences in design, materials, mechanical properties, and cost exist between the commercially available miniplates. For this reason miniplates should not be considered as interchangeable. The absence of true randomisation in this study prevents a clear demonstration of the differences in treatment outcome, however no significant variation in treatment outcome has been identified between the non compression miniplates examined in this study. If this is the case, then miniplate selection should be based on the unit cost, the biocompatibility of the implant, and the CT compatibility of the implant. Further research is required to establish the most appropriate miniplate for a given discrete region, by properly randomised trials. In order to gather sufficient data for such trials, a multicentre approach may be necessary, and in this situation the alpha numeric system of computer based coding for craniofacial fractures would be useful in comparing results.

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TABLE 1

	Yield Point (kg)	Stiffness (EI)
Aus Systems miniplates	1.12	2951.1
Würzburg miniplates	1.25	5494.1
Medicon miniplates	2.2	4864.2
AO non comp^{n} miniplates	1.8	2951.1
Champy miniplates	1.25	3699.1
Luhr mini comp^{n} plates	25	73981.0

TABLE 2

	Craniofacial fracture score						
	1	**2**	**3**	**4**	**5**	**6**	**>6**
Würzburg	6	22	26	24	10	8	4
Luhr	5	45	19	19	2	5	5
Aus Systems	8	25	30	23	7	5	4

Table 3

	Fracture site		
	Angle/ramus	**Condylar**	**Symphyseal/body**
Würzburg	29 (33%)	19 (21%)	41 (46%)
Luhr	40 (43%)	12 (13%)	42 (45%)
Aus Systems	65 (41%)	27 (17%)	65 (41%)

TABLE 4

MINIPLATE	NUMBER
Aus Systems	105
Würzburg	50
Medicon	11
Luhr non-compression	62
Luhr compression	19

TABLE 5

COMPLICATIONS	N^o	%
Plate fracture	2	0.8
Infection resulting in removal of plate	7	2.8
Infection responding to treatment	2	0.8
Malocclusion with corrective op required	13	5.3
Removal of plates	10	4.0
TMJ discomfort	3	1.2
TMJ ankylosis, bilateral reconstruction	1	0.4
Non union	1	0.4
TOTAL	**39**	**15.8**

TABLE 6

	Number of cases (percentage)		
Complications	**Aus Systems**	**Würzburg**	**Luhr non-compression**
Plate fracture	2 (1.9)		
Infection resulting in removal of plate	1(1.0)	1 (2.0)	4 (6.5)
Infection responding to treatment	1 (1.0)		1 (1.6)
Malocclusion with corrective op required	2 (1.9)	4 (8.0)	4 (6.5)
Removal of plates	4 (3.8)		5 (8.1)
TMJ discomfort	2 (1.9)	1 (2.0)	
TMJ ankylosis, bilateral reconstruction		1 (2.0)	
Non union			
Total	**12 (11.4%)**	**7 (14%)**	**14 (22.5%)**

TABLE 7

	Aus Systems	Würzburg	Luhr	**Total**
Complication	12	7	14	**33**
No complication	93	43	48	**184**
Total	**105**	**50**	**62**	**217**