UNIVERSITY OF THE WESTERN CAPE

FACULTY OF DENTISTRY

Title: Comparison of an intra-oral approach using a contra-angle hand piece with the transbuccal technique for mandibular angle fracture repair

Student: AS de Waal

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Comparison of an intra-oral approach using a contra-angle hand piece with the transbuccal technique for mandibular angle fracture repair

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A mini-thesis submitted in partial fulfillment of requirements for the degree MAGISTER CHIRURGIAE DENTIUM in discipline Maxillo-Facial and Oral Surgery

2010

Declaration:

I declare that the study entitled "*Comparison of an intra-oral approach using a contra-angle hand piece with the transbuccal technique for mandibular angle fracture repair*" is my own work, that this has not been submitted for any degree or examination at any other university, and that the sources I have used or quoted have been indicated and acknowledged by complete references.

Andre Stephanus de Waal January 2010

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Abstract:

Purpose: To compare the intra-oral approach using a contra-angled hand piece with the standard transbuccal approach in the treatment of mandibular angle fractures.

Patients and Methods: Thirty patients with isolated fractures of the mandibular angle were treated by open reduction and internal fixation using one three-dimensional “strut” or “geometric” Synthes® angle plate. Patients were selected randomly for placement of two-millimeter self-threading screws, either through the standard transbuccal technique or with an intra-oral approach using a contra-angle hand piece. None of the patients were placed into post-surgical maxillomandibular fixation (MMF). Swelling and pain were measured pre-operatively and again twenty-four hours after surgery. The actual cutting time from first incision to placement of last suture was documented, as well as the perception of difficulty of the specific case by a single operating surgeon.

Results: No statistically significant difference in perception of pain was experienced between the two groups of patients during the first twenty-four hours after surgery. There was also no statistically relevant difference in cutting time between the two placement techniques. A small statistically relevant difference (p-value = 0.089) was found in the amount of swelling post-operatively between the two groups, with more swelling in the control group.

Conclusion: The use of a contra-angle hand piece to place screws in the compression band area in a mandible angle fracture is an acceptable alternative to the transbuccal approach.

Introduction:

The mandible angle fracture is one of the most common facial fractures (Ellis and Walker 1996). Its treatment is both well documented and widely debated.

Independent of the technique used to treat the angle fracture, different approaches can be taken. To avoid maxillomandibular fixation (MMF) after surgery, proper stable fixation has to be used (Ewers and Härle 1985).

In order to ensure stable fixation, a second compression band plate or a load-bearing plate needs to be placed at the lower border. This poses the challenge of inserting screws at a 90 degree angle (Ellis 2009). The conventional way to place these screws is via a transbuccal assembly with a trocar through the cheek (Luhr 1982).

It was therefore decided to research various patient, surgical and time factors to assess the viability of an approach other than the conventional transbuccal assembly technique.

Literature review:

Fracture through the angle of the mandible is one of the most common maxillofacial injuries sustained in modern times (Ellis and Walker 1996). In Europe it is ranked as the second most prevalent facial fracture after zygoma complex fractures (Exadaktylos and Eggensperger 2004). In the US it is second only to nasal and nasal complex fractures. Among the population of the Western-Cape, mandibular fractures are ranked as the most prevalent facial fractures according to Nortje *et al.* (2004).

The treatment of the condylar process and the mandible angle fracture is widely debated in the literature (Ellis and Walker 1996). It has the highest post-surgical complication rate of all mandible fractures (Wegner *et al.* 1979; Iizuka *et al.* 1991) with a complication rate as high as 17% presenting in some populations (Passeri *et al.* 1993).

To define the mandible angle is controversial. However, in 1996 Ellis reached consensus about the term “angle” and the location of the fracture through the superior aspect of the mandible. The superior aspect stretches from the distal border of the second molar, to the area where the anterior border of the mandibular ramus meets the body of the mandible. The literature (Ellis 2009) states that the angle fracture extends to the inferior border anterior to the gonial angle. About 8% of angle fractures involve the gonial angle (Ellis 2009). Any fracture that crosses the inferior alveolar canal will most likely result in neurosensory fallout in the distribution of the mental nerve (Marchena *et al.* 1998).

Technological advances in imaging (Markowitz *et al.* 1999) have enhanced the ability to correctly diagnose and characterize mandibular fractures. These advances allow the surgeon to direct surgical efforts with precision and also help to decrease morbidity. An important principle in the imaging of mandibular fractures is to obtain images that allow evaluation of the fracture in at least two planes (Ellis and Miles 2007). Plain film imaging (panoramic radiograph combined with a posteroanterior radiograph), remains the evaluation technique of choice for most mandibular fractures (Ellis and Miles 2007).

The region of the mandibular angle is bound by the strong elevator muscles (temporalis, masseter, medial pterygoid) which allow the generation of significant bite forces of 300 - 400 N (Tate *et al.* 1994). These forces are significantly reduced for several weeks after a fracture of the mandible, presumably by the central nervous system inhibiting full contraction when it perceives an injury from the mechano-receptors in the bone and soft tissue around the fracture (Gerlach and Schwarz 2002).

Despite the reduction of masticaton muscle forces, upward displacement of the proximal segment in a mandible ramus fracture is common (Ellis 2009). Hence the angle fracture [historically] frequently requires some form of fixation in addition to maxillomandibular fixation (MMF) to control the position of the ramus (Ellis 2009). Clinical observations and bio-mechanical investigations have shown that during normal jaw function, tension occurs at the level of the dentition, whereas compression occurs along the lower border of the mandible (Champy *et al.* 1978; Kroon *et al.* 1991). According to Ellis (2009), fixation devices applied directly across the fragments are mechanically most advantageous when placed in the area where the fragments tend to separate under the influence of muscle function.

There are two general opinions regarding plate and screw fixation for mandibular fractures. The first is that plate and screw fixation should provide sufficient rigidity to fragments to prevent inter-fragmentary mobility during active use of the mandible. Those holding this opinion include the AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/Association for the Study of Internal Fixation) surgeons (Luhr 1982; Spiessl 1989). The AO/ASIF thus recommends placing one large and one small bone plate, or two small plates, fastened with bicortical bone screws, to provide sufficient rigidity (Spiessl 1976). The goal here is the immobilization of bone fragments and primary bone union (Choi *et al*. 1995). Clinical studies have proved the usefulness of this technique (Ewers and Härle 1985). The second opinion is that absolute immobilization of bone fragments and primary bone union is unnecessary (Champy *et al*. 1995).

In 1973, Michelet *et al* reported on the treatment of mandibular fractures using small, easily bendable, non-compression bone plates placed transorally and attached with monocortical screws. Champy *et al.* (1978) performed several investigations with a mini-plate system to validate the technique. In their experiments, they determined the “ideal lines of osteosynthesis” in the mandible, or the locations where bone plate fixation should provide the most stable means of fixation. For fractures of the mandibular angle, the most effective plate location was found to be along the superior border of the mandible (Champy *et al.* 1978). Because the bone plates were small and the

screws monocortical, fixation could be applied in the mechanically most advantageous areas without damaging teeth (Champy *et al.* 1977; 1978). Raveh *et al.* (1987), Luhr (1976), and the AO/ASIF advocates are not convinced that the plates offer adequate stabilization of the fracture to eliminate the need for MMF (Becker 1974). Some surgeons who routinely used the more rigid AO/ASIF plates have also begun using mini-plates (Ewers and Härle 1985).

It is also noteworthy that there are many situations in which MMF is contra-indicated. These include the treatment of epileptics, alcoholics and patients with drug addiction, those with chronic obstructive airway disease and any condition in which the airway is compromised (Kuriakose *et al.* 1996).

Establishing and maintaining the pre-injury occlusion is one of the primary goals when treating mandibular fractures. Careful evaluation of the dentition and significant manipulation of fractures may be required to attain the appropriate occlusal relationship. Anatomical reduction of the fractures may often be necessary to recapture the appropriate occlusal relationship. Internal fixation should be of sufficient rigidity to maintain this relationship when the MMF is removed. Anatomical reduction of mandibular fragments is an important goal as well, although it is secondary to occlusal considerations (Ellis and Miles 2007).

The vast majority of mandibular fractures may be approached intra-orally using the fixation systems presently available. However, indications for external approaches remain, depending on the fracture pattern and the experience of the surgeon (Toma *et al.* 2003). Rigid internal fixation is a term applied to the application of sufficient hardware to prevent movement across the fracture site when normal functional forces are in effect. Examples of rigid internal fixation include locking/non-locking reconstruction bone plates, multiple bone plates at the fracture site, and multiple lag screws. Rigid fixation permits primary bone healing without callus formation, and immediate return to full function (Ellis and Miles 2007).

When treating mandibular fractures, rigid fixation is often not necessary, and there are multiple functionally stable hardware constructs that result in healing and excellent post-operative results (Potter, Ellis 1999, Tate *et al.* 1994, Ellis, Walker 1994 and Kroon *et al.* 1991). These hardware constructs do not prevent micro-motion across the fracture site, but permit healing of the fracture by secondary bone healing with the formation of callus (Ellis, Miles 2007). An example of non-rigid fixation is the use of a single mini-plate for a fracture of the angle of the mandible (Champy *et al.* 1978).

Load-bearing fixation commonly consists of reconstruction plates where the unstable portion of the mandible is bridged by the bone plate. In contrast, load-sharing fixation refers to a fixation scheme where the functional load is shared between the fixation hardware and the bone along the fracture site (Ellis and Miles 2007).

Various types of internal fixation devices, from wire to reconstruction bone plates, have been used to provide stability across the fractured angle of the mandible. Most of the confusion and debate about the most appropriate treatment of fractures of the mandibular angle arises from the great difference in stability of these devices. When wire fixation is applied, post-operative MMF is required for at least four to five weeks to immobilize the fractured fragments and allow osseous union to commence (Juniper and Awty 1973).

It is generally accepted that more stability between fractured bone fragments provide a better environment for bone healing (Ellis 2009). Thus bio-mechanical models with two points of fixation (two bone plates), provide much more stability than one (Choi *et al.* 1995a; Shetty *et al.* 1995).

Several bio-mechanical studies have shown that three-dimensional ‘‘strut’’ plates provide more stability than one mini-plate (Alkan *et al.* 2007; Guimond *et al*. 2005). These models have also shown that a single mini-plate cannot control bending or torsional forces, especially when the mandible is loaded ipsilaterally (Zix *et al.* 2007). Some studies thus advocate the use of two mini-plates for fractures of the mandibular angle rather than one (Fox and Kellerman 2003). A second mini-plate applied further inferiorly than the first, provides rigid fixation of the angle fracture. A more rigid plate, or one of the ‘‘geometric’’ strut or three-dimensional bone plates could also be used (Ellis 2009). However it should be noted that Ellis and Walker (1994) found a high incidence of major complications (29%) in their patient population when angle fractures were treated with two mini-plates. These complications related mostly to infections.

It has been advocated that compound fractures of the mandibular angle should be treated with antibiotics as soon after injury as possible to help prevent infection (Zallen and Curry 1975) and should be continued at least till surgical treatment has been provided (Chole and Yee 1987). Greenberg, 1979 showed that pre-operative antibiotics significantly reduce the number of post-operative infections. Abubaker (2001) has shown that prophylactic antibiotics given pre-operatively and for no longer than twelve hours post-operatively are just as effective as long-term antibiotic use in preventing post-operative infections. Short term prophylaxis, according to Laskin (2003), can only be applied to fractures that are treated within eight hours after the injury has occurred. He

also advocated that delayed treatment of fractures should be considered dirty wounds and should receive therapeutic antibiotics post-operatively (Laskin 2003). In studies by Abubaker and Rollert 2001 and Miles *et al.* 2006, the value of antibiotics admnistered post-operatively only, have not been demonstrated.

In general, compound fractures of the mandible should be treated as soon as possible. Champy and colleagues (1978) and Cawood (1985) recommended that, to minimize the incidence of dehiscence and infection, mini-plate osteosynthesis must be performed soon after injury. Champy and colleagues (1978) recommended that fixation of the fracture has to be done within twelve hours of injury. Cawood (1985) extended this period to twenty-four hours after injury. Fortunately, a delay is unlikely to cause problems. No relationship has yet been demonstrated between post-operative complications and the time between injury and treatment (Barnard and Hook 1991). It seems reasonable to attend to a compound fracture of the mandibular angle as soon as possible, but there is no evidence that it should be treated as an emergency (Smith 1991).

The problem of teeth in the line of fracture has been the subject of some debate in the literature (Ellis 2002). Various factors, such as tooth mobility, interference with fracture reduction, apical pathology, and others, have been used in the decision regarding whether or not to maintain a tooth in the line of fracture (Kahnberg and Ridell 1979). Although no universally accepted criteria exist, most teeth in the line of fracture - with the exception of the third molars - are usually maintained unless they are grossly mobile, infected, or inhibiting fracture reduction (Ellis 2002).

Spiessl (1989) lists three undesirable effects of extracting an unerupted tooth in the line of an angle fracture: the creation of a definite open fracture, the possibility of losing the bony buckle buttress and loss of bone to such an extent that placement of a tension band plate will not be possible. Spiessl (1989) also recommends extraction of an erupted third molar when the apex is ‘‘open’’ to the fracture, the root is fractured, or the third molar is partially erupted. The presence of a third molar associated with a fracture through the angle of the mandible increases the risk of infection irrespective of whether or not the tooth is erupted or impacted, or whether or not the tooth is removed during surgery (Ellis 2002). For closed treatment, there seems to be no difference in the rate of infection irrespective of whether the tooth was removed or left in place (Rubin *et al*. 1990; Anastassov and Vuvakis 2000).

The management of mandibular angle fractures has traditionally been associated with a high (up to 33%) post-operative complication rate (Gabrielli

et al. 2003). These complications can be divided into intra-operative and post-operative complications. The main intra-operative hazard is injury to the inferior alveolar neurovascular bundle (Wagner *et al.* 1979). By using 5 mm or 6 mm screws and careful drilling, injury can be avoided (Ellis and Karas 1992).

In the literature the incidence of reported minor complications varies widely. However, in a study by Ellis and Walker (1996), minor complications constituted the majority of total complications (85%) when a single mini-plate was used. Minor complications are those that are amenable to treatment in the outpatient clinic. These include minor infections, swelling without discharge of pus or complaints of pain in the area of the bone plate. With simple treatment, such as oral antibiotics and wound care, most patients with minor complications heal uneventfully.

Major complications are uncommon when a single mini-plate is used for treatment of mandibular angle fractures (Ellis 2009). The most common major complications are infections requiring extra-oral incision and drainage, intravenous antibiotics, debridement of non-vital bone, and removal of the bone plate. However, on occasion, and especially after an infection, the result is a fibrous union that requires more stable fixation and possibly bone grafting (Ellis 2009).

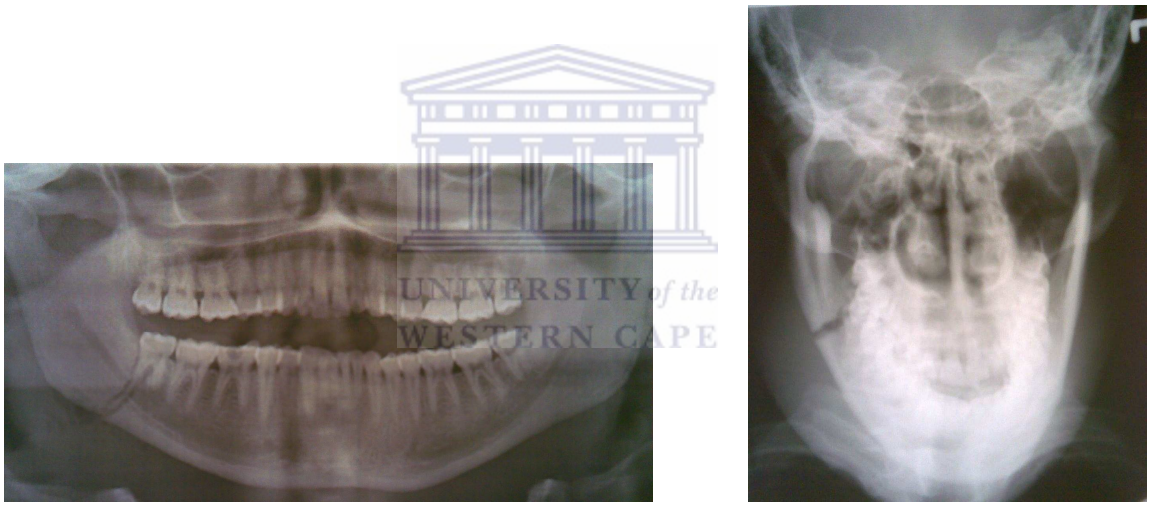
Major complications are greater with the use of two rather than one mini-plate (Ellis and Walker 1996). According to this study, a significant occurrence (28%) of complications such as late dehiscence of the incision, swelling, granulation tissue formation, and the need for plate removal or debridement of non-vital bone was noted.

Swelling can be measured with a technique described by Holland (1979). This entails a method of measuring post-operative facial swelling following third molar surgery. Three critical aspects were identified, i.e. assessment of accuracy, measurement in volume units, and a method that is both practical and ethical in the clinical situation and not limited by static apparatus. No published method satisfies all of these criteria. In an attempt to develop a satisfactory method, direct physical measurements using a face bow, was investigated.

Patients and methods:

Patients attending the Maxillo-Facial and Oral surgery out-patient clinic at the Faculty of Dentistry and World Health Organization (WHO) Collaborating Centre of UWC were selected according to the inclusion criteria of the approved protocol.

All patients above the age of 18 years that presented with a left or right isolated non-comminuted mandible angle fracture were included in the study (Figures A and B). Each patient was radiologically evaluated to exclude a possible second mandibular or condyle neck fracture. A pantomograph as well as a posterior anterior view (PA view) of the mandible was obtained for all the patients. Dentate, as well as edentulous patients were accepted. There was no discrimination with regard to sex and/or race in this study.



A: Pantomagraph of isolated right mandible angle fracture. B: PA view of same patient.

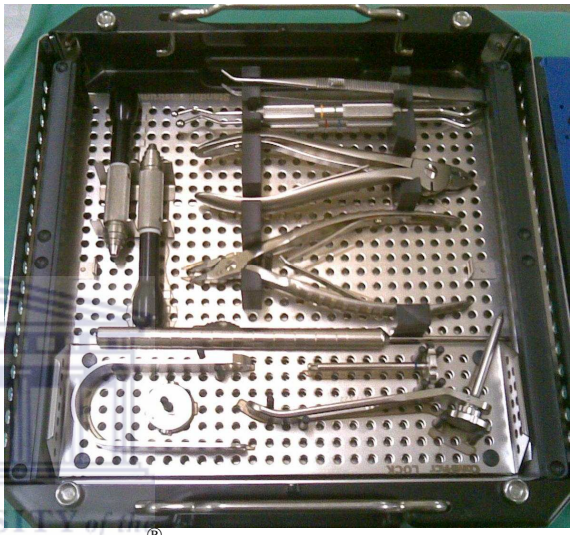
The following were criteria for exclusion from the study. Open skin lacerations in the area of the mandible fracture, comminution of the fracture, bilateral fractures and severely atrophic mandibles, infected mandible fractures with clear pus formation and drainage, patients with underlying medical conditions like rheumatic heart disease and blood dyscrasias, patients with any underlying associated pathology or with reduced immunity and psychiatric or mentally challenged patients (since it was essential to record their data accurately)

All patients were informed about the study and the intended procedure, using an information sheet in their home language (Appendix 1). Written informed consent for the procedure in English, Afrikaans or Xhosa was also obtained (Appendix 2).

Thirty patients requiring open reduction and internal fixation were then randomly selected and numbered as they presented to the unit. A computer generated numbering system was used to allocate patients to the transbuccal assembly approach (control) or contra-angle hand piece approach (Appendix 3). All data collected were noted on a standardised data sheet (Appendix 4).

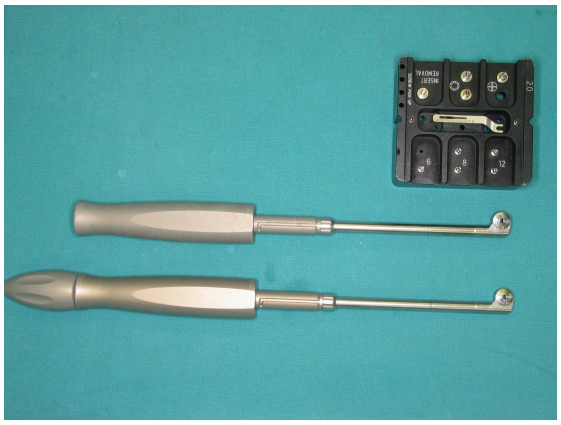
Fifteen patients were treated with the transbuccal assembly approach. The Synthes® transbuccal assembly set (Figures C and D) was used in combination with the Synthes® 2 mm Mandibular Combi® screw set.

C: Transbuccal assembly.

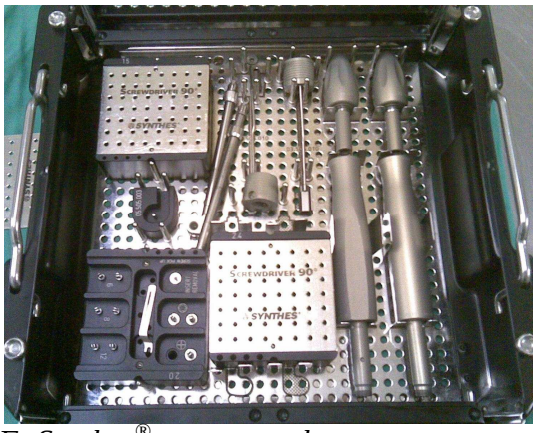


D: Synthes® transbuccal set.

The other fifteen patients were treated with the use of the new 90 degree hand-piece, without any extra-oral skin incisions. The Synthes® contra-angle drill and screwdriver set (Figures E and F), in combination with the Synthes® 2 mm Mandibular Combi® screw set, was used in these cases.



E: Contra-angle drill and screw driver.



F: Synthes® contra-angle set.

Anaesthetic management:

An anaesthetist administered a standardized general anaesthesia. Nasotracheal intubation was performed after intravenous induction with propofol (2 mg/kg), and alcuronium (0.3 mg/kg). General anaesthesia was maintained with isoflurane, nitrous oxide and 35% oxygen. Cardiac function was monitored with an electrocardiograph and the blood pressure was monitored with an intermittent automated sphygmomanometer. Respiratory function was monitored via capnography and pulse oxymetry.

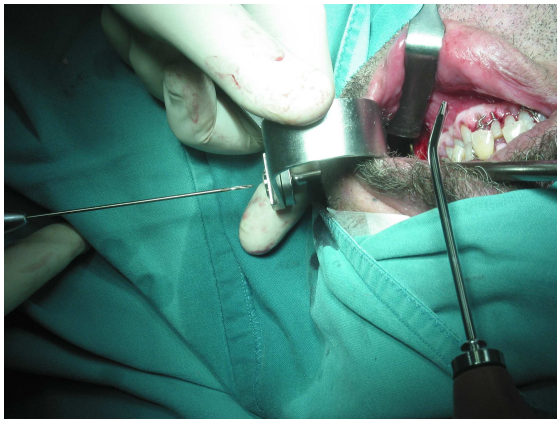
Surgery:

Surgery was performed by the same surgeon (registrar within the department of MFOS at UWC). Local anaesthetic with adrenalin was administered intra-orally in the fracture area. At least six eyelets were placed for MMF to help stabilize the fracture after reduction. The tooth in the line of the fracture was removed if it needed post-operative root canal treatment when the patient did not have the means or finances for post-operative root canal treatment of these teeth. A crestal intra-oral incision approach was taken to access the mandible angle fractures. The fracture was then located, debrided and mobilized.

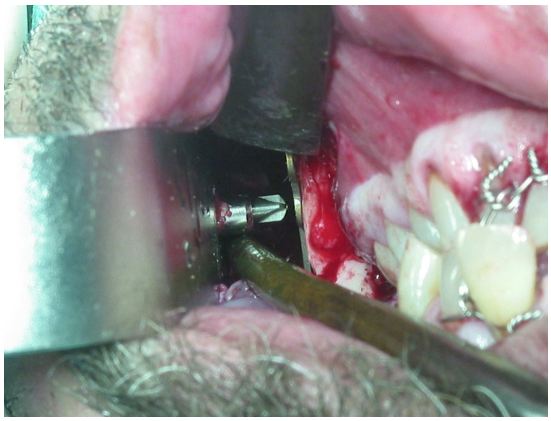
The bony defect was reduced, with the help of MMF (if the patient had teeth and a functional occlusion). An eight-hole, pre-formed, curved Synthes® angle (strut) plate was then used for fracture fixation (Figure G, L, M and N). All of the above was done with care to protect the inferior alveolar nerve.

G: Synthes® 2mm 8 hole angle (strut) plate.

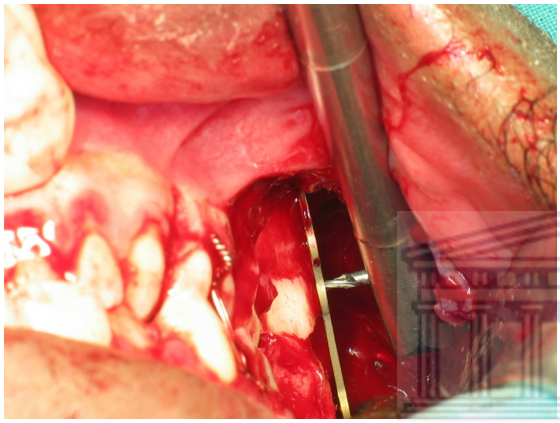
Depending on the randomized number allocated to the patient, either the transbuccal assembly (Figure H and I) or the contra-angle hand piece (Figures J and K) was used to pre-drill the holes and place the screws.



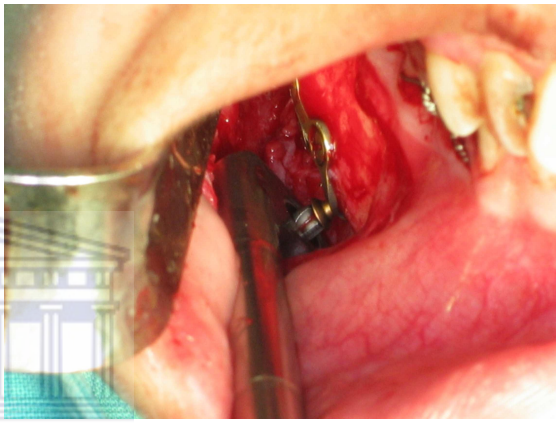
H: Transbuccal approach for drilling.



I: Transbuccal screw placement.



J: Contra-angle approach for drilling.

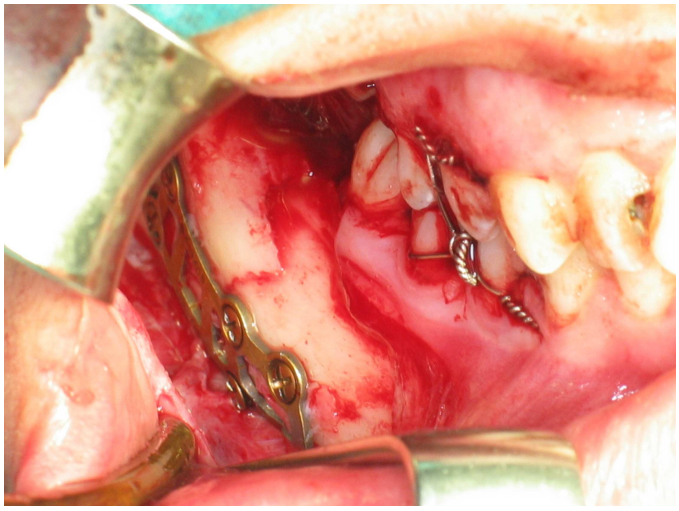


K: Contra-angle screw placement.

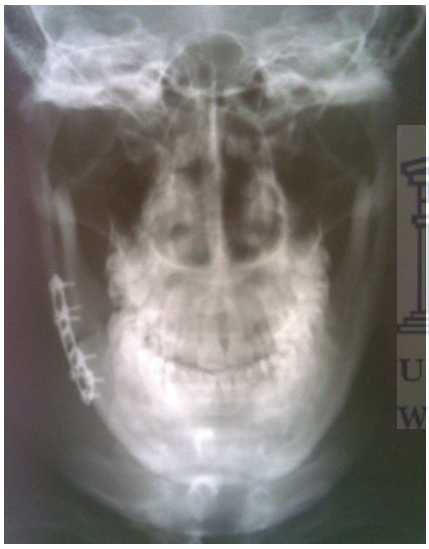
The 2 mm Synthes® Combi® set was used and only 4 mm and 6 mm screws were placed. These screw lengths were selected in an attempt to minimize damage to the inferior alveolar canal and nerve. With the transbuccal assembly, an extra-oral incision was made parallel to the mandible fracture to facilitate the application of the assembly in addition to the normal intra-oral retromolar oblique ridge incision. A small skin incision with blunt dissection was used to make a tract. In some cases a second tract was made to access all the holes of the strut plate still using the single skin incision.

The same intra-oral retromolar approach was used with the contra-angle assembly. As with the transbuccal approach, no extra incisions were made. After placement of the plate with eight screws, the wound was closed with 3.0 chromic sutures. All the eyelet wires, placed during surgery, were removed.

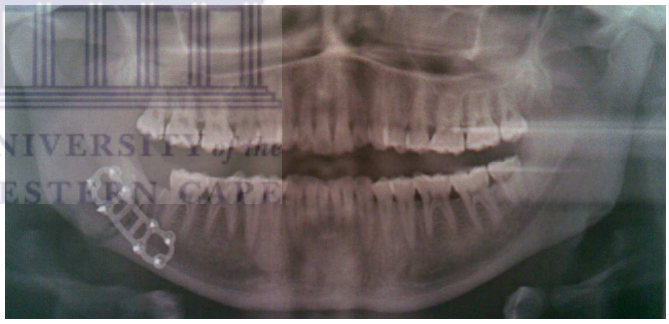
None of the patients from either of the approaches received post-operative MMF.



L: Post-op reduction before closure.



M: PA post ORIF radiograph.



N: Post ORIF pantomagraph view.

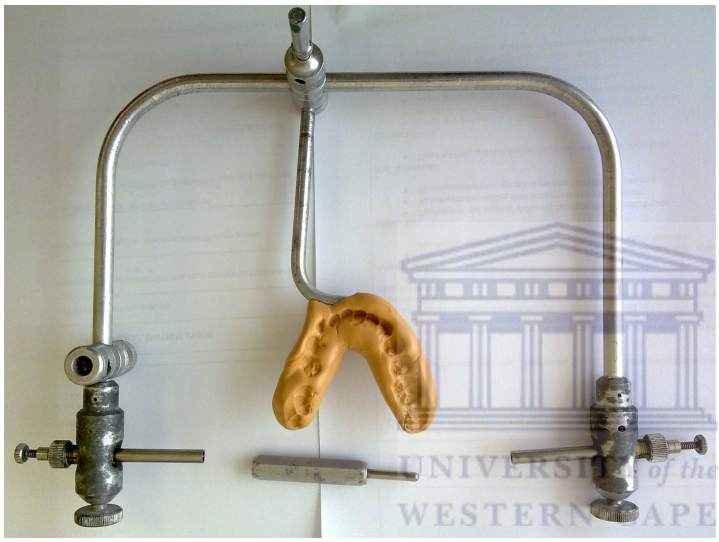
Peri-operative medication:

Patients in both groups received the same intra- and post-operative medication. As none of the patients were allergic to penicillin, intra-operative Augmentin® 1.2 g intravenously (IV) was administered just after intubation. Pain was managed by the prescription of 1000 mg of paracetamol and 400 mg of ibuprofen six-hourly for five days and began as soon as the patients were awake. All the fractures were either classified as contaminated or dirty using the modified classification of Laskin (2003). It was therefore decided to treat all patients with 500 mg amoxicillin and 400 mg metronidazole for five days post-operatively. The patients were also given a 0.2% chlorhexidine mouth rinse to use eight-hourly.

Study design:

A data sheet (appendix 4) was prepared and used to collect all necessary data pre- and post-operatively.

The main evaluation criteria were total anaesthesia time from intubation to extubation of the nasotracheal tube, cutting time from the first incision until the last suture was placed and swelling, which was measured using a pre-operative vinyl polysiloxane impression attached to a face bow (Figure O) as per the technique described by Holland (1979).



O: Face bow with precision impression for each patient.

A precise measurement of the trans-facial (inter-gonial soft tissue) distance between the soft tissue outer margins in the mandible angle area was taken and documented pre-operatively using the face bow. This measurement was repeated twenty-four hours later with the same precise bite and face bow appliance. The differecce between the two measurements was calculated and documented as the amount of swelling in that patient after twenty-four hours.

Pain was evaluated on a visual analogue scale (Appendix 4) and patients were asked to indicate the amount of pain on the scale just before surgery and again twenty-four hours post-surgery.

The difficulty of the operation was also assessed on a visual analogue scale (Appendix 4) by the single operator immediately after surgery. All the collected data collected were analyzed statistically.

Ethics:

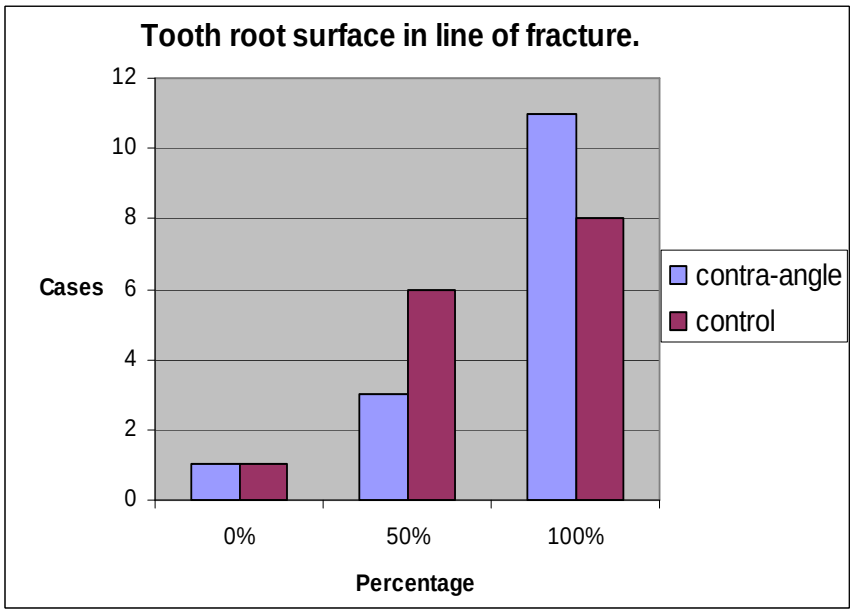
The University of the Western Cape (UWC) approved and registered the protocol with regard to content and ethics.

Results:

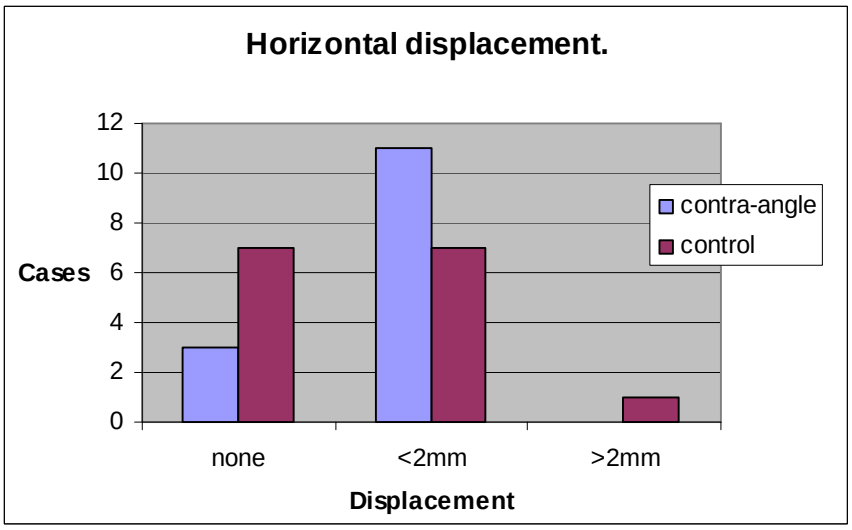
Statistical analysis was performed by Theodata® using Microsoft Excel®. In total thirty patients – twenty-five males and five females - were treated at the MFOS unit, UWC, Tygerberg. Fifteen were right mandibular angle fractures and fifteen were fractures of the left mandibular angle. Of these thirty patients, fifteen were treated with the conventional transbuccal assembly technique and fifteen were treated with a contra-angle assembly unit that can house a drill or a driver to place the screws. The latter technique enables the operator to place a lower border plate on the angle of the mandible through an intra-oral approach with no skin incisions.

Twenty-eight patients had a third molar in the line of the fracture, of which nineteen had 100% of the molar root exposed to the fracture (Graph 1). The vertical displacement of the fracture according to panoramic evaluation and horizontal displacement according to a posterior anterior radiograph of the mandible was documented (Graphs 2 and 3).

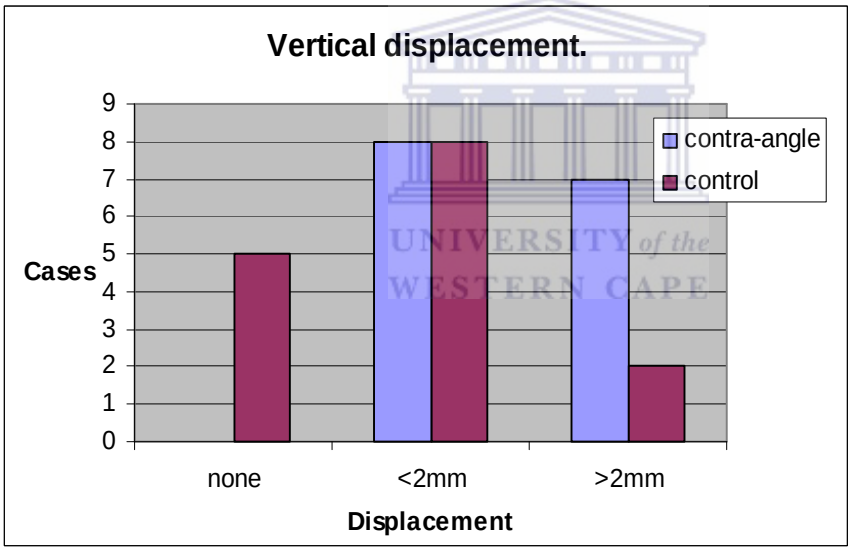
Graph 1



Graph 2

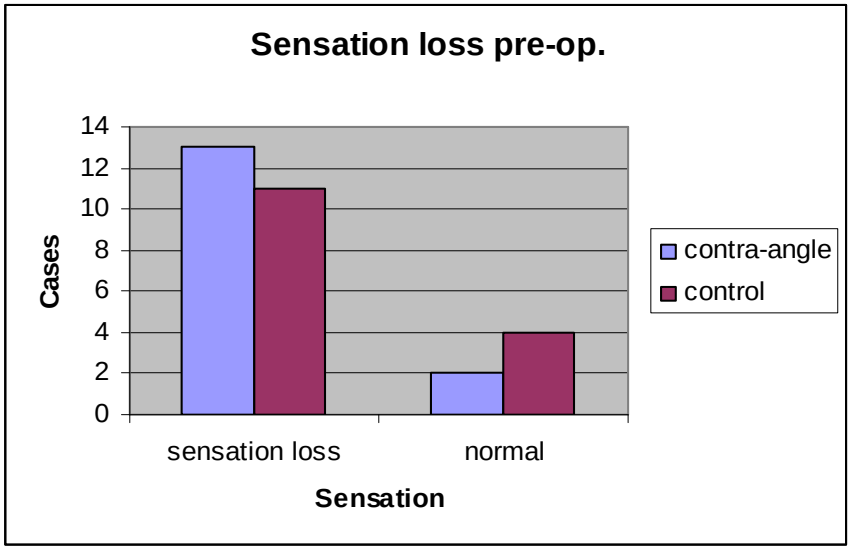


Graph 3

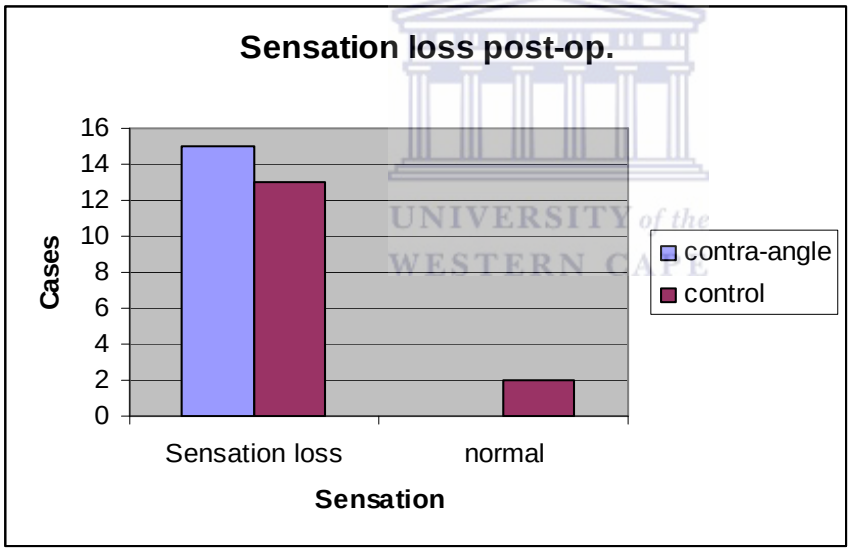


A total of twenty-four out of thirty patients presented with neuropraxia before treatment. Six had no loss of sensation before surgery (Graph 4). Twenty-four hours after surgery, the sensation was evaluated and twenty-eight patients had symptoms of neuropraxia (Graph 5).

Graph 4

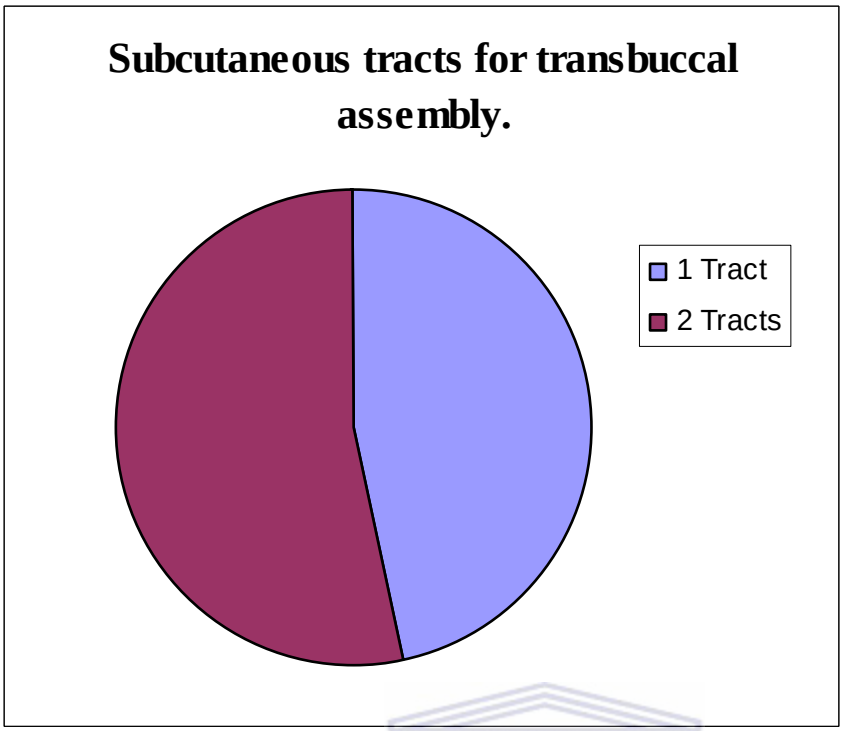


Graph 5



With the use of the transbuccal assembly approach, a small extra-oral incision was made to facilitate the trocar. In all fifteen of these cases, a single incision was made in the skin. In 53.33% of these cases more than one subcutaneous tract had to be made to drill the hole and place the screw at a 90 degree angle to the bone (Graph 6). Much more tissue trauma was caused with this procedure in comparison to the contra-angle approach.

Graph 6



The average age of the patients treated was thirty years for the control group and thirty-three years for the contra-angle group (Table 1).

Table 1

Average age in years.

Data	Contra-angle	Control	Total
Number of patients	15	15	30
Average age in years	30.13	33.60	31.87
Std dev of age in years	7.59	8.89	8.31
Min age in years	19	20	19
Max age in years	40	48	48

Patients indicated pain on a visual analogue scale of 1 to 10. The averages are indicated in the following tables for pain before and after the two different procedures (Table 2 and 3).

Table 2

Average pain experienced pre-op (scaled).

Data	Contra-angle	Control	Total
Number of patients	15	15	30
Average pain pre-op (scaled)	1.53	2.00	1.77
Std dev of pain pre-op (scaled)	2.07	1.36	1.74
Min pain pre-op (scaled)	0.00	1.00	0.00
Max pain pre-op (scaled)	6.00	4.00	6.00

Table 3

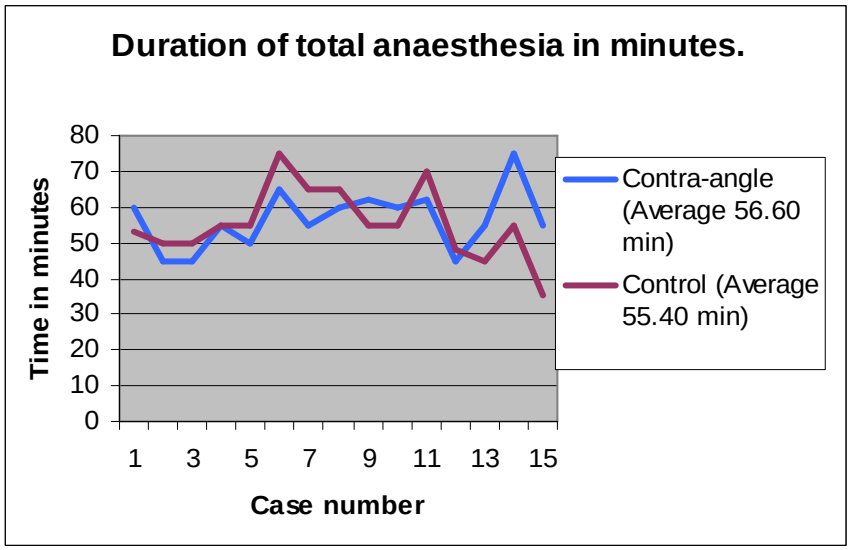
Average pain experienced post-op (scaled).

Data	Contra-angle	Control	Total
Number of patients	15	15	30
Average pain post-op (scaled)	1.67	2.40	2.03
Std dev of pain post-op (scaled)	1.80	1.55	1.69
Min pain post-op (scaled)	0.00	0.00	0.00
Max pain post-op (scaled)	6.00	5.00	6.00

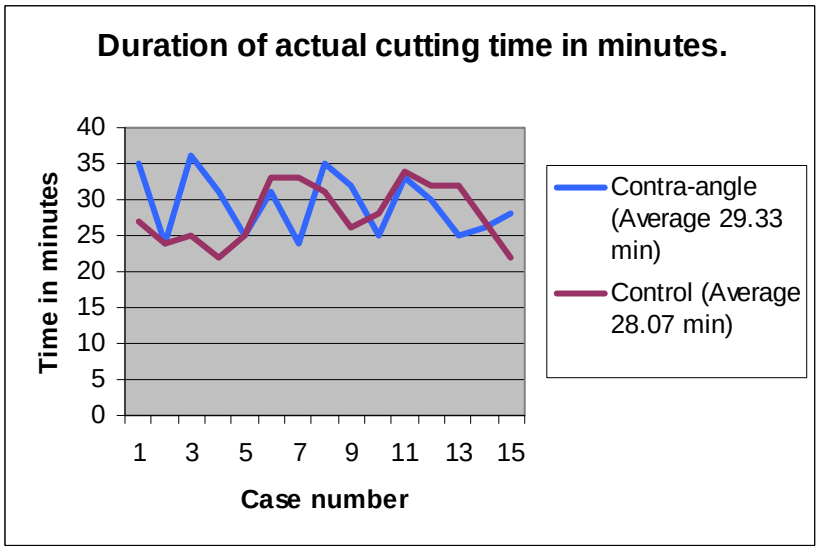
Two measurements pertaining to time were taken during the procedure, namely, total anaesthesia time in minutes (Graph 7) and actual cutting time in minutes from the first incision until placement of the last suture (Graph 8).

The average difference in total anaesthesia time and actual cutting time was also calculated. For the control group the average difference was 27.33 minutes and for the contra-angle group the average difference was 25.60 minutes.

Graph 7



Graph 8



The total blood loss was recorded by adding up all the fluid in the suction unit and deducting all the sterile water used during the procedure. The correlation between blood loss in the control and contra-angle group was taken to be an indication of the amount of bleeding that occurred during the two procedures. The averages are indicated in the following table (Table 4).

Table 4

Average of total blood loss (ml).

Data	Contra-angle	Control	Total
Number of patients	15	15	30
Average total blood loss (ml)	62.33	93.67	78.00
Std dev of total blood loss (ml)	33.43	63.65	52.43
Min total blood loss (ml)	25	20	20
Max total blood loss (ml)	150	250	250

Swelling was also measured, just before surgery and again twenty-four hours after surgery. The difference was calculated and the average values indicated in Table 5.

Table 5

The difference in swelling before and after surgery in millimeters.

Data	Contra-angle	Control	Total
Number of patients	15	15	30
Average swelling difference	6.67	8.80	7.73
Std dev of swelling difference	3.27	3.45	3.47
Min swelling difference	2	3	2
Max swelling difference	13	15	15

Non-parametric tests were done for swelling, pain and cutting time. Different statistical correlations were made after the statistical relevance was calculated. No statistically significant difference was found (p-value = 0.2902) between the pre-surgery measurements of the control and the contra-angle group (Table 6). However, when it came to swelling, there was a definite statistically significant difference (p-value = 0.089) in the post-surgery swelling measurements of the control group as compared to the contra-angle group. The difference between the pre-operative and post-operative swelling had a median value of 8 for the control and 7 for the contra-angle group. This also indicates more swelling in the control group. Statistical relevance could have been more significant if more cases had been included in the study.

Table 6

Statistical indication of swelling difference before and after surgery.

	Control	Contra-angle		Control	Contra-angle	
	Swelling pre-op (mm)	**Swelling pre-op (mm)**		**Swelling post-op (mm)**	**Swelling post-op (mm)**	
Minimum	120.00	114.00		126.00	119.00	
Q1	125.50	124.50		133.50	128.00	
Median	129.00	126.00		139.00	135.00	
Q3	132.00	129.00		143.50	139.00	
Maximum	141.00	142.00		146.00	151.00	
	Sample	*RankSum*	*SampSize*	*Sample*	*RankSum*	*SampSize*
	1	258	15	1	273.5	15
	2	207	15	2	191.5	15
	Wilcoxon Rank Sum Test			**Wilcoxon Rank Sum Test**		
	Large Sample Approximation			*Large Sample Approximation*		
	Test Statistic Z = 1.0577			*Test Statistic Z = 1.7006*		
	P-Value = 0.2902			*P-Value = 0.089*		

With p-values above 0.41 for both the control and contra-angle group, there was no statistically significant difference in this study between the two groups for total anaesthesia time (p-value = 0.6936) and cutting time (p-value = 0.4429).

Patients recorded pain values on a visual analogue scale from 1 to 10 before surgery as well as twenty-four hours after surgery. Statistical values were calculated to determine any difference in pain perception between the two groups (Table 7). No statistically relevant difference was found between the

control group and the contra-angle group for pain experienced before surgery (p-value = 0.1409) and after surgery (p-value = 0.1249).

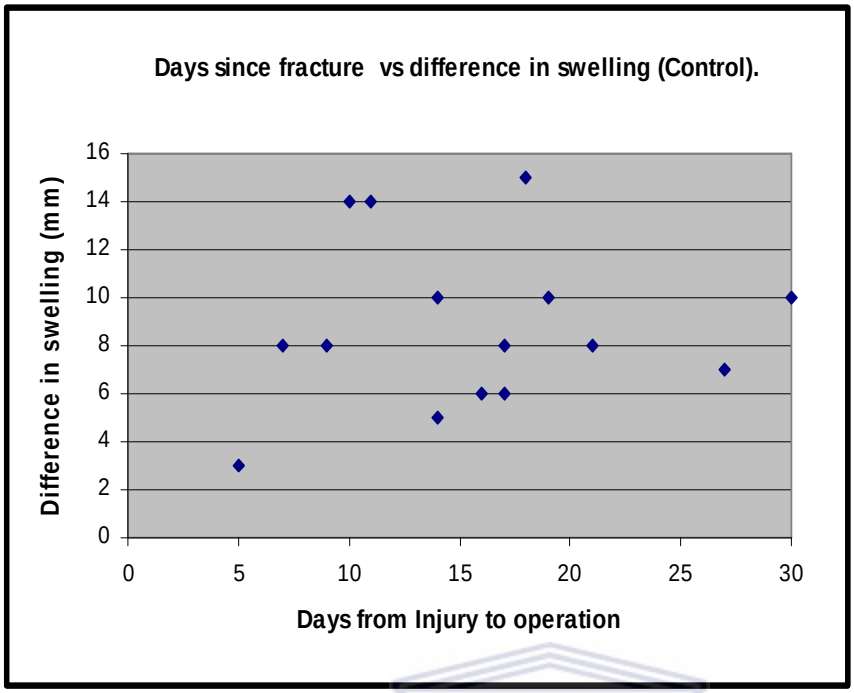
Table 7

Statistical indication of pain (scaled) before and after surgery.

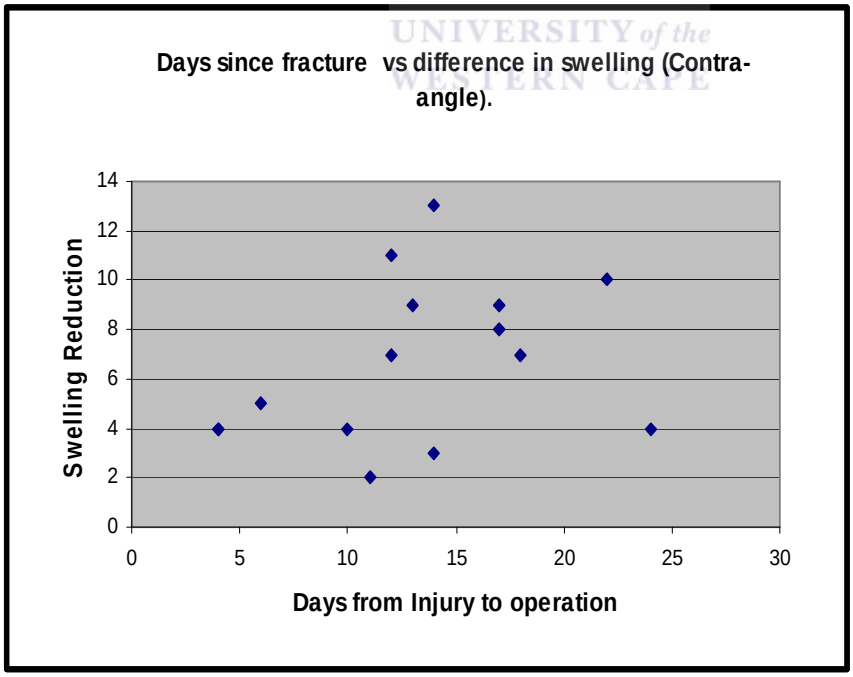
	Control	Contra-angle		Control	Contra-angle	
	Pain pre-op scaled	**Pain pre-op scaled**		**Pain post-op scaled**	**Pain post-op scaled**	
Minimum	1.00	0.00		0.00	0.00	
Q1	1.00	0.00		2.00	0.50	
Median	1.00	1.00		2.00	1.00	
Q3	3.50	1.50		3.50	2.00	
Maximum	4.00	6.00		5.00	6.00	
	Sample	*RankSum*	*SampSize*	*Sample*	*RankSum*	*SampSize*
	1	268	15	1	269.5	15
	2	197	15	2	195.5	15
	Wilcoxon Rank Sum Test			**Wilcoxon Rank Sum Test**		
	Large Sample Approximation			*Large Sample Approximation*		
	Test Statistic Z = 1.4725			*Test Statistic Z = 1.5347*		
	P-Value = 0.1409			*P-Value = 0.1249*		

The study also considered whether there was a correlation between the time elapsed between injury/fracture and surgery, and post-operative swelling after twenty-four hours. Values for both these variables were plotted on a graph for the control and contra-angle groups (Graphs 9 and 10). No statistical correlation between these two variables was found for either of the groups in the study.

Graph 9



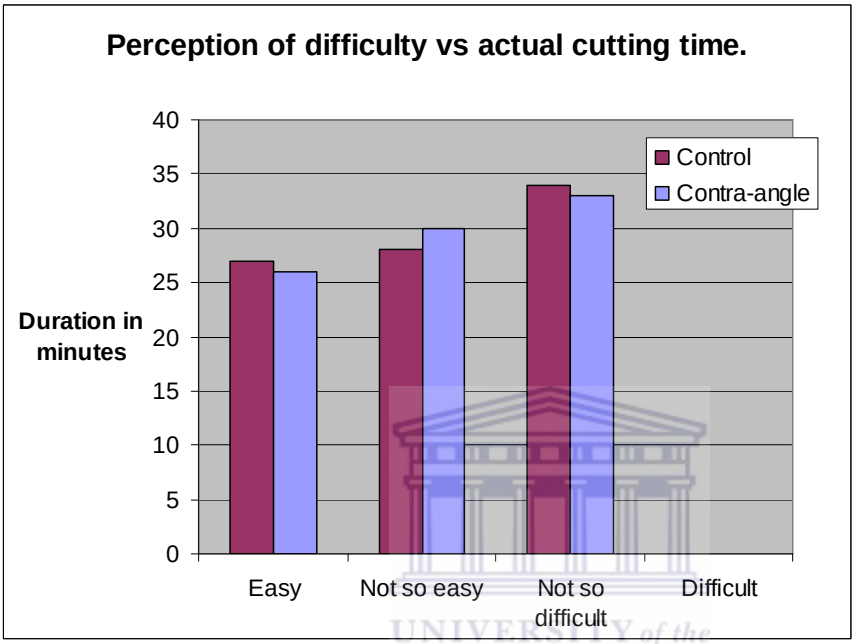
Graph 10



The study also considered whether there was a correlation between the single surgeon's perception of the difficulty of the procedure and the actual cutting time. In Graph 11, cases are grouped according to difficulty against the

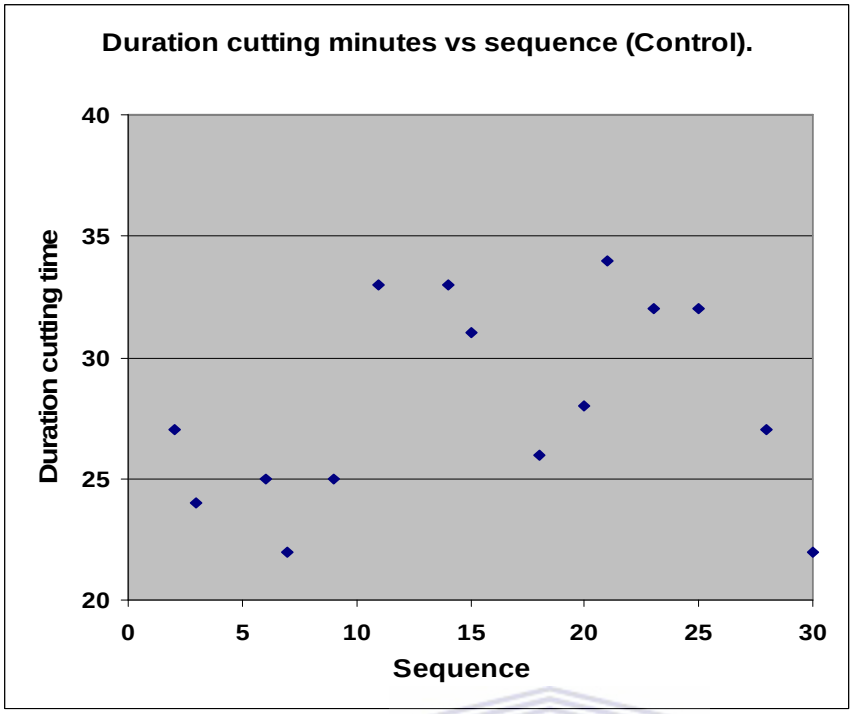
average cutting time. The graph indicates a small increase in duration according to the perceived increase in difficulty of the cases. In the contra-angle group three cases ranked as not too difficult in comparison to only one in the control group. However there was no statistically significant difference between perceived grade of difficulty and cutting time for the two groups.

Graph 11

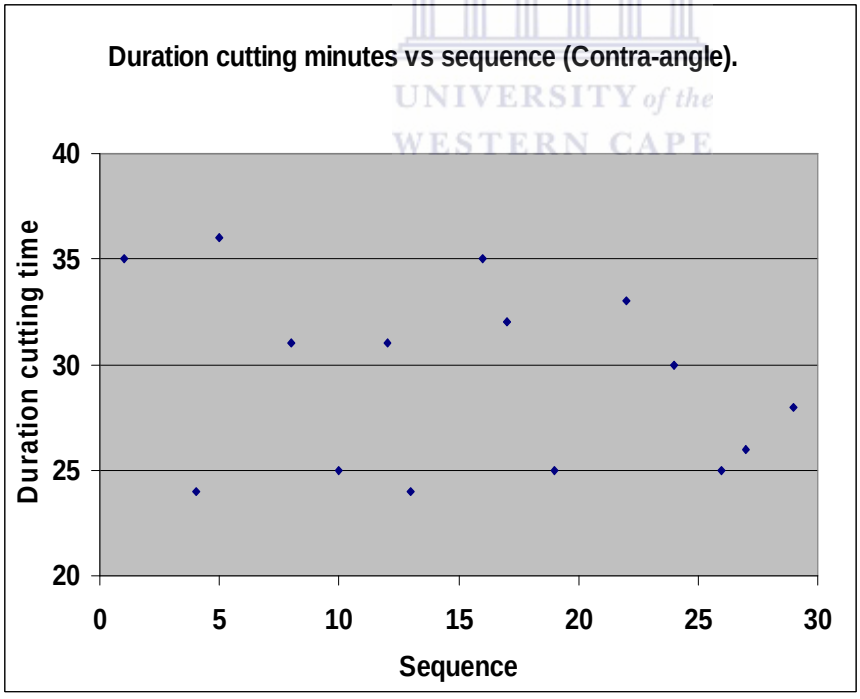


In order to assess whether there was a significant learning curve to especially the contra-angle hand piece procedure, the correlation between the sequence of cases done compared to the actual cutting time was plotted and indicated in Graph 12 (for the control group) and Graph 13 (for the contra-angle group). The cases that were “perceived” to be more difficult, took longer to complete.

Graft 12



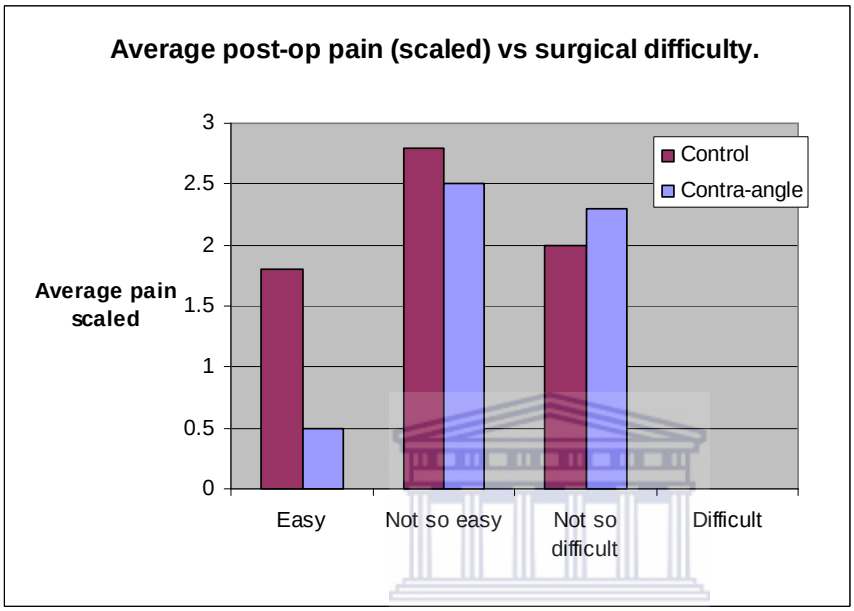
Graft 13



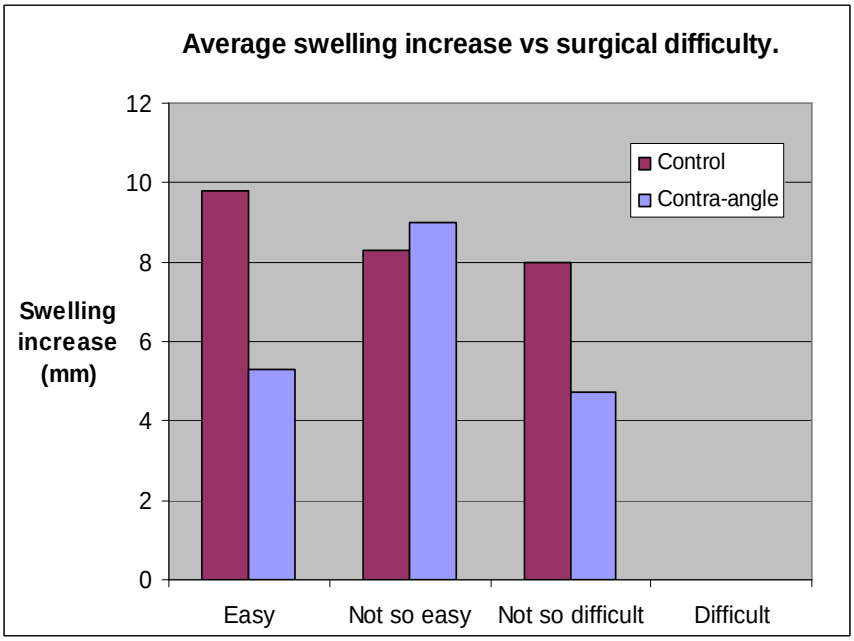
The correlation between surgical difficulty and pain, as well as surgical difficulty and swelling for both the control and contra-angle groups are indicated in Graphs 14 and 15. In the control group there was a small decrease in post-operative swelling in relation to an increase in the difficulty of the case. But in the contra-angle group a small increase in post-operative swelling

was noted with an increase in the difficulty of the operation. Thus, in terms of swelling vs. difficulty, the two groups presented an inconsistent pattern. An inconsistent pattern was also noted in terms of the average post-operative pain vs. surgical difficulty (Graph 14). An increase in pain perception was noted in the "not so easy" group.

Graph 14



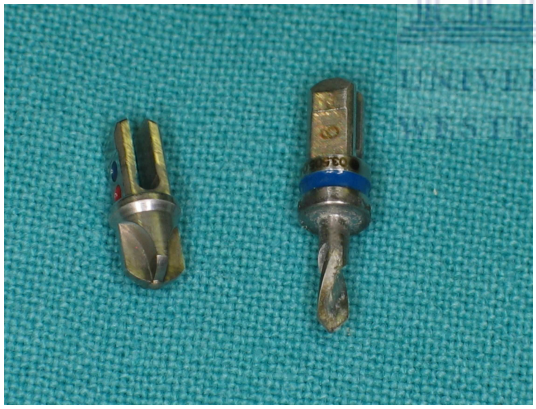
Graph 15



Discussion:

The main aim of this study was to determine if the contra-angle drill and screw driver would be a better alternative to the well documented transbuccal assembly technique when primary bone healing is intended. No extra-oral incisions are needed with the contra-angle set. Only an intra-oral incision was made. The Synthes® 2 mm Combi® plating set was used and only screw lengths of 4 mm and 6 mm. In an effort to standardize the technique, an eight hole Synthes® "strut" plate (Figure G) and eight screws for the angle fracture was used (Alkan *et al*. 2007; Guimond *et al*. 2005). It was found that the Synthes® transbuccal assembly worked well presenting no assembly, placement, removal or sterilization problems.

In contrast, the Synthes® contra-angle hand piece had a definite learning curve for assembly and sterilization. With consecutive cases, proper dismantling with thorough removal of blood and debris is needed to make sure no mechanical failure (bearing failure) will occur. The pick-up of the drill or screwdriver inserts (Figure P) also presented a definite learning curve. The overall use of the contra-angle hand piece was easy and it was small enough to use in the mandibular angle area.



P: Contra-angle hand piece inserts, small, needs precise pick up.

It was found that there was no statistically significant difference in the actual cutting time using the contra-angle assembly technique vs. the standard transbuccal assembly technique (Graph 8). Both procedures had no statistically significant difference in total theatre time and actual cutting time (Graph 7 and 8). The sequence in which patients were operated was also compared to the actual cutting time to establish whether a decrease in cutting time occurred with more exposure to the contra-angle hand piece technique. No correlation was found between sequence and cutting time (Graphs 12 and 13). The single operator perception of difficulty was also compared to the amount of cutting time. A very small increase in cutting time for both groups

in correlation to difficulty was found (Graph 11). According to this study, the cost of theatre time will thus be similar for both approaches.

The amount of pain which patients experienced prior to and twenty-four hours after surgery was compared. No statistically significant difference could be found to indicate one being better or worse than the other (Tables 2 and 3). Pain experienced compared to difficulty of the procedure was also evaluated. A slight increase in pain perception was experienced in both groups with an increase in surgical difficulty (Graph 14).

There was a marked statistically significant difference in the post-operative swelling between the contra-angle hand piece group and the transbuccal (control) group (Table 6). When the difference between pre-operative and post-operative swelling was calculated, the contra-angle group had less post-operative swelling (Table 5). However, it should be noted that a larger study sample could have resulted in more conclusive results. A comparison between the amount of swelling and time elapsed before surgery, was also done. For both groups, there was no correlation between the amount of swelling and the time it took to operate the patient (Graphs 9 and 10). Swelling was also compared with the single surgeon's opinion regarding the difficulty of the case. No correlation was found that indicated more or less swelling in a specific group (Graph 15).

Other parameters were also documented, i.e. pre- and post-operative neuropraxia and blood loss during the procedure. In this study, twenty-four out of thirty patients had pre-operative sensation loss of the affected inferior alveolar nerve (Graph 4). Twenty-eight out of thirty patients had post-operative sensory loss (Graph 5). All the fractures were cleaned, mobilized and properly reduced by the surgeon. Care was taken not to manipulate or damage the inferior alveolar nerve and canal. Four additional patients had post-operative neuropraxia, but there were no cases with immediate resolution of their neuropraxia.

Blood loss was measured by the single operator. The average values were 93.67 ml respectively for the control group and 62.33 ml for the contra-angle group. A statistical p-value = 0.1524 was non-conclusive although a difference in blood loss was indicated during these procedure (Table 4).

Conclusion:

With the exception of swelling (Table 6), no significant statistical difference in pain, actual cutting time or the perception of difficulty was found in the study. It can be concluded that the use of the contra-angle hand piece would be a valuable contribution in the armament of an oral and maxillofacial surgeon.

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(Appendix-1)

Patient Information Letter

I, Dr A de Waal (currently a qualified dentist enrolled in a specialist training program), plan to conduct a clinical study or research to compare 2 types of surgical techniques used to place screws at a 90 degree angle to fix your jaw fracture. Both techniques are routinely used. We do not think there is a difference in the 2 techniques. The only way we can find out if the one is superior to the other, is to do such a study. This will obviously benefit all future patients.

Participating in the study is on a voluntary basis. You may refuse participation in the study at any time. Participating in the study or refusing to participate, will not harm or prejudice you in any way. Participating in the research/study will definitely benefit future patients. All information will be kept strictly confidential.

Thanking you in anticipation.

Dr A de Waal (researcher)

Registrar, Maxillo-Facial and Oral Surgery

Department of Maxillo-Facial and Oral Surgery.

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Contact details: Tel: 021 937 3087

Cell: 0829210666

I patient, name……., fully understand the information supplied to me by Dr A de Waal in the above information letter.

Signature: ……..

Date:……...…

Department of Maxillo-Facial and Oral Surgery
Faculty of Dentistry & WHO Oral Health Collaborating Centre

University of the Western Cape

Cape Town

(Appendix-1)

Pasiënt Informasie Brief

Ek, Dr A de Waal (ek is tans 'n gekwalifiseerde tandarts in 'n spesialis opleidingsprogram), beplan 'n kliniese studie om die effektiwiteit te evalueer van 2 tegnieke om skroewe teen 90 grade te plaas om u kaak te herstel. Beide tegnieke word roetinelik gebruik. Ons dink nie daar is 'n verskil in sukses tussen die twee tegnieke nie. Ons wil graag uitvind of die een tegniek wel superior is. Om deel te neem in die studie of om deelname ann die studie/navorsing te weier, sal u nie nakom nie. U kan enige tyd deelname an die studie weier/ Deelname is totaal vrywillig en alle informasie sal vertroulik hanteer word. Deelname in die studie sal toekomstige pasiënte bevoordeel agv die inwin van nuwe kennis.

Dankie vir u samewerking

Dr A de Waal (Navorser)

Kliniese assistant, Dept Kaak-, Gesig- en Mondchirurgie

Fakulteit Tandheelkunde

Tygerberg.

Kontak details: Tel: 021 937 3087

Sel: 0829210666

Ek, pasiënt, naam……., verstaan volledig die informasie wat Dr Waal aan my verskaf het in die bg. informasie brief.

Handtekening: ……..

Datum:…….....

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Cape Town

(Appendix-1)

Patient Information Letter

Mna, Dr A. De Waal, ndenza uphando ngeendlela zokunyanga imihlathi eyophukileyo.Ndisebenzisa iindlela ezimbini ezohlukeneyo.Enye indlela isebenzisa idrili estreyiti ize enye isebenzise idrili egobileyo.Zombini ezindlela zisetyenziswa rhoqo ukunyanga imihlathi eyophukileyo. Andicingi ukuba kukho umahluko kwezindlela zimbini.Kodwa oluphando lungasinceda ukuba sifumane eyona ndlela ibhetele yokunceda abantu.Ukuba ugqiba ekuthatheni inxaxheba koluphando ndizakusebenzisa enye yezindlela kuwe.Ukuthatha inxaxheba koluphando kukuwe. Unelungelo lokungavumi.Ukuthatha inxaxheba koluphando akunabungozi kuwe. Nokuba akuthathanga nxaxheba koluphando uzakulufumana uncedo olwaneleyo. Ngokuthatha inxaxheba uyakunceda nabanye abantu.

Thanking you in anticipation.
Dr A de Waal (researcher)

Registrar, Maxillo-Facial and Oral Surgery

Department of Maxillo-Facial and Oral Surgery.

Oral Health Centre Tygerberg.

Contact details: Tel: 021 937 3087

Cell: 0829210666

I patient, name……., fully understand the

information supplied to me by Dr A de Waal in the above information letter.

Signature: ……..

Date:……...

Department of Maxillo-Facial and Oral Surgery

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University of the Western Cape

Cape Town

Consent form:

(Appendix-2)

I Mr/Miss/Mrs.

…….

Date of birth_____File no: or sticker:

am willing to participate in the above mentioned study. I understand that the study is voluntary.

This study is approved by the Ethical and Research Committee of the University of the Western Cape and participation in this study is on voluntary basis. I have being adequately informed about the objectives of the trial. I also know that I have the right to withdraw from the study at any stage which will not prejudice me in way regarding future treatments. My rights will be protected, and all my details will be kept confidential, and no details regarding me, personally will be published.

I hereby consent to be part of the research/study.

Patient's name: _____ Signature: _____

Name of the Witness: _____ Signature: _____

Date: _____

Signature of the Researcher:_____

Dr A de Waal

Date: _____

Department of Maxillo-Facial and Oral Surgery

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University of the Western Cape

Cape Town

Toestemmings vorm:

(Appendix-2)

Ek,Mr/Mej/Mev.

…….

Geboorte datum_____Lêer nr: of plakker:

Is gewillig om aan die bogenoemde studie deel te neem. Ek verstaan dat dit totaal vrywillig onderneem word.

Hierdie studie is goedgekeur deur die Etiese Navorsings Komittee van die Universiteit van Wes Kaapland en deelname aan hierdie studie is totaal vrywillig. Ek is voldoende ingelig oor die doelwitte van die studie. Ek weet ook dat ek die volste reg het om op enige stadium aan hierdie studie te ontrek en dat my besluit geensins vedere behandeling sal beinvloed nie. My regte sal beskerm word, en al my persoonlike inligting sal vertroulik gehou word. Geen persoonlike inligting sal gepubliseer word nie.

Hiermee gee ek toestemming tot deelname aan die studie/navorsing:

Pasiënt Naam: _____ Handtekening: _____

Naam van Getuie: _____ Handtekening: _____

Datum: _____

Handtekening van Navorser:_____

Dr A de Waal

Datum: _____

Department of Maxillo-Facial and Oral Surgery

Faculty of Dentistry & WHO Oral Health Collaborating Center

University of the Western Cape

Cape Town

<u>Nxalenye Yeformu (Consent form)</u>

(Appendix-2)

Mna
Mnumzana/Nkosazana……

Umhla wokuzalwa……inombola yefile:

Ndinomdla uluthatha inxaxheba kwesizifundo zibhale ngentla. Ndiyaqonda ukuze ukwazi ukwenza ezizifundo kuyakunyanzeleka uvolontiyele.
Ezizifundo zivunyiwe yi Uphando ngendlela lokuziphatha (Ethical and Research Committee) ye Dyunivesiti yase Ntshona Koloni (University of the Western Cape), kuze ukwazi ukwenza ezizifunda funeka uyavolontiye. Ndiyavuma ukuba ndifumene ulwazi okuphangaleleyo malungana nezizifundo. Ndiyayazi ukuba ndinawo amalungelo wokungaqhubekeki nezizifundo, ndikwazi ukungaphatheki kakubi nakweziphi izinto endiyokuthi ndizinqwnelele ingaphazamisani nekamva lam. Amalungelo wam azakuba selungcinweni, nengcukaca zam kuzakubaseluvalelweni zigcineke kakuhle. Azikho igcukaca zam zizakupapashwa.
Ndenza isicelo sokuba ndibeyinxalenye kwizifundo ze (Research) zophando.

Igama lomzali: _____ Sayina: _____
Igama lenqina: _____ Sayina: _____
Umhla: _____

Umsayino we zophando(Researcher): _____
Dr A de Waal
Umhla: _____

Appendix 3:

Computer generated randomized numbers.

Sequence of patients	Random number	AA	BB
1a&b	0.562	CONTRA ANGLE	CONTROL
2a&b	0.396	CONTROL	CONTRA ANGLE
3a&b	0.592	CONTRA ANGLE	CONTROL
4a&b	0.371	CONTROL	CONTRA ANGLE
5a&b	0.357	CONTROL	CONTRA ANGLE
6a&b	0.188	CONTROL	CONTRA ANGLE
7a&b	0.594	CONTRA ANGLE	CONTROL
8a&b	0.209	CONTROL	CONTRA ANGLE
9a&b	0.674	CONTRA ANGLE	CONTROL
10a&b	0.765	CONTRA ANGLE	CONTROL
11a&b	0.186	CONTROL	CONTRA ANGLE
12a&b	0.467	CONTROL	CONTRA ANGLE
13a&b	0.341	CONTROL	CONTRA ANGLE
14a&b	0.940	CONTRA ANGLE	CONTROL
15a&b	0.692	CONTRA ANGLE	CONTROL
16a&b	0.473	CONTROL	CONTRA ANGLE
17a&b	0.955	CONTRA ANGLE	CONTROL
18a&b	0.702	CONTRA ANGLE	CONTROL
19a&b	0.694	CONTRA ANGLE	CONTROL
20a&b	0.814	CONTRA ANGLE	CONTROL
21a&b	0.877	CONTRA ANGLE	CONTROL

Appendix 4:

Data collection sheet:

			Randomisation No	.....
Randomised treatment	Control	Contra Angle		
Patient Name	.....			
Gender	Male	Female		
Age in years		Years		
Days since fracture		Days		
Displaced horizontal		none	Somewhat (>2mm)	More than (2mm)
Displaced vertical		None	Somewhat (>2mm)	More than (2mm)
Tooth in line of fracture (%)	0% not in line of fracture	50% of root in line of fracture	100% root completely in line of fracture	Tooth lost with trauma
Swelling Pre Op (mm)	.....			
Pain Pre Op	No pain			Severe pain
Anaesthetic time (in minutes)	.....			
Total blood loss	.....	ml		
Cutting Time (from 1st incision to last suture)	.....			
Surgeon's perception of difficulty	Easy	Not so easy	Not too difficult	Difficult
Swelling Post Op (mm) (24 hours later)	.....			
Pain Post Op (24 hours later)	No pain			Severe pain
Neuropraxia	Pre-op _____ Post-op _____			
L or R Angle	Left Angle _____		Right Angle	_____
Transbuccal incisions	1	2	3	

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