Colorado Microdissection Needle versus Cold Steel Scalpel for incisions in third molar surgery

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A mini-thesis submitted in partial fulfilment of the requirements for the degree of MChD in the Department of Maxillo-Facial and Oral Surgery, University of the Western Cape

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Supervisor:
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Key words:

Third Molar, Steel Scalpel, Colorado Microdissection Needle, Electrosurgery.

DECLARATION

I declare that *Colorado Microdissection Needle versus Cold Steel Scalpel for incisions in third molar surgery* is my own work, that it has not been submitted for any degree or examination at any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Full name: Allie Mohamed

Date.....

Signed.....

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ABSTRACT

Background and aims

Third molar surgery is the most commonly performed procedure by maxillo-facial and oral surgeons, and is associated with expected but transient sequelae such as pain, swelling and trismus. Modalities to reduce the severity of these sequelae are desirable. Several studies report that the use of conventional electrosurgical instruments and the Colorado Microdissection Needle (CMN) resulted in significant reductions in cutting time, incisional blood loss, postoperative pain, with no evidence of increased incidence of wound complications such as dehiscence and infection.

Materials and methods

This study compares the CMN to the steel scalpel by assessing incision time, incisional blood loss, postoperative pain, wound healing, and the incidence of lingual and long buccal nerve injury. Twenty standardised cases were included in an analytical prospective case series. Each case had one side cut with CMN and the other side with steel scalpel.

Results

The results showed no difference in incision time and decreased postoperative pain. There was no statistically significant difference in the risk of wound complications or nerve injury between the two techniques. The CMN resulted in statistically significant reduction in blood loss, however this was a subjective measure and its reliability could be questioned.

Conclusion

This study reveals that neither cutting modality is superior to the other.

CHAPTER 1

INTRODUCTION

The removal of impacted third molars is the most commonly performed procedure in the field of maxillo-facial and oral surgery (Majid & Mahmood 2011, p. 647; Farish & Boulox 2007, p. 23). The goals of third molar surgery should therefore include successful removal of the impacted teeth, while minimising the severity of postoperative sequelae, and reducing the incidence of perioperative complications. Various techniques, modifications and modalities have been described to help reduce the severity of postoperative sequelae (Majid et al.2011, p. 647).

Conventional monopolar diathermy and the Colorado Microdissection Needle (CMN) has been shown to result in less intraoperative blood loss, reduced surgical time and improved patient comfort following tonsillectomy, abdominal and thoracic surgery (Sheikh 2004, p. 43; Akkielah et al. 1997, p. 737, Rideout & Shaw 2004, p. 15; Chau et al. 2009, p. 430-431; Kearns et al. 2001, p. 43-44; Shamim 2009, p. 1598). To the author's knowledge, there is no literature available on the use of the CMN for third molar surgery. This study compares the CMN to the steel scalpel by assessing incision time, incisional blood loss, postoperative pain, wound healing, and the incidence of lingual and long buccal nerve injury. Should the CMN prove superior to the steel scalpel in the reduction of surgical time and postoperative sequelae, it could serve as a useful addition to the surgeon's armamentarium.

CHAPTER 2

LITERATURE REVIEW

The surgical removal of impacted third molars is the most frequently performed procedure by oral and maxillofacial surgeons (Majid & Mahmood 2011, p. 647; Farish & Boulox 2007, p. 23). The surgeon requires a thorough understanding of basic surgical principles and patient management skills so that the procedure may be performed as atraumatically as possible while, at the same time, minimising the incidence of complications.

The general technique for removal of third molars involves incising the oral mucosa and elevation of a full thickness mucoperiosteal flap to adequately expose the impacted tooth in order to provide visual and mechanical access to the surgical site. This is followed by bone removal (if indicated), crown and root sectioning, elevation of roots, surgical site inspection, debridement and irrigation followed by closure with suture placement (Farish & Boulox 2007, p. 23-24).

Sequelae and complications associated with third molar surgery

Sequelae most often associated with third molar surgery are postoperative pain, swelling and trismus resulting from the postoperative inflammatory response. These are expected and typically transient and are therefore not considered as complications of third molar surgery (Boulox et al. 2007, p. 117). These sequelae, however, may have a significant impact on the patient's quality of life. Developing techniques aimed at reducing these sequelae, is thus desirable. Various modalities aimed at reducing postoperative sequelae have been described and investigated. These modalities include medications, ice-pack therapy, variation of surgical technique and jaw physiotherapy (Majid & Mahmood 2011, p. 647).

Complications associated with third molar surgery are relatively rare with a reported overall incidence range of 4.6%-30.9%, and may occur intra-operatively or ensue during the postoperative period (Bui et al. 2003, p. 1379; Boulox et al. 2009, p. 117; Sisk et al. 1986, p. 855). The most common complications reported in the literature are bleeding, infection, paraesthesia and alveolar osteitis (AO). Other complications include mandible fracture, displaced teeth, periodontal pocket formation, damage to adjacent teeth and soft tissue and oro-antral communication (Boulox et al. 2007, p. 117; Benediktsdottir et al. 2004, p. 438). The possibility of these events have to be discussed with patients prior to surgery and written informed consent obtained (Boulox et al. 2007, p. 117).

Several factors contributing to the occurrence and severity of postoperative sequelae and complications following third molar surgery have been identified. These factors may be patient related, procedure related or surgeon related. Patient factors include age, medical history, gender, oral contraceptive use, presence of pericoronitis, smoking, oral hygiene, type of impaction, and relationship of the tooth to the inferior alveolar nerve or maxillary sinus. Procedure and surgeon related factors include surgical time, difficulty of the procedure, surgeon's experience, use of peri-operative antibiotics, surgical technique, use of topical antiseptics and intrasocket medicaments and anaesthetic technique (Boulox et al. 2007, p. 117-118; Haug et al. 2005, p. 1106; Marciani 2007, p. 8-10).

Among the postoperative sequelae, pain is probably the most important to the patient, and the intensity of the pain is one of the primary factors influencing the patient's sense of well-being. Pain related to third molar surgery most often begins once anaesthesia from the procedure subsides and reaches peak levels 6-12 hours postoperatively (Susarla et al. 2003, p. 177). Pain is a subjective, complex experience and it cannot be measured objectively. There are several pain assessment methods that have been used to measure pain. Pain assessment techniques may be multidimensional (McGill pain questionnaire), or unidimensional. The latter is most frequently used in pain research. Unidimensional scales such as the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal Rating Scale (VRS) and the Faces Pain Rating Scale (FPRS) are the best known, most frequently preferred

and effective scales. These scales attempt to quantify the magnitude and intensity of pain experienced by the individual (Isik et al. 2011, p. 715-717; McLafferty et al. 2008, p. 42-46; Williamson et al. 2005, p. 798-802).

A VAS is characterised as a ten centimetre line anchored by verbal descriptors such as “no pain” and “worst imaginable pain”. The patient is requested to designate a point on the line to denote the total intensity of pain experienced. The NRS consists of a series of numbers, usually 0-5 or 0-10, where 0 denotes no pain and 5 or 10 denotes worst imaginable pain. It is easily comprehended, simple to use, and can be administered verbally. A VRS employs a list of adjectives to represent rising pain intensity. The most commonly used words include “no pain”, “mild pain”, “moderate pain” and “severe/excruciating pain”. The patient is requested to choose an adjective that closely represents his/her pain. The FPRS was originally devised for use with children, but has been used with success in adults, patients with weak language skills or learning disabilities. Six faces are depicted ranging from a happy, smiling face to a sad and crying face, with each becoming increasingly sadder. The faces are numbered from 0 (happy face-no pain) to 10 (saddest face-most pain), with the numbers escalating in increments of two (0, 2, 4, 6, 8, 10). The patient chooses the face that best illustrates their pain and the corresponding number is then allocated to that face (McLafferty et al. 2008, p. 42-46).

Alveolar osteitis (dry socket) is one of the most frequently reported complications relating to third molar surgery (Larsen et al. 1992, p. 393; Muhonen et al. 1997, p. 39). It is diagnosed clinically by the development of severe, throbbing pain that usually begins 3-5 days postoperatively, and is often accompanied by halitosis (Larsen et al. 1992, p. 393). The extraction socket is filled with debris, with loss of the blood clot (Boulox et al. 2007, p. 118). The incidence of alveolar osteitis ranges from 0.3-26% and is known to occur more frequently with mandibular third molars (Haug et al. 2005, p. 1106; Bui et al. 2003, p. 1379; Sisk et al. 1986, p. 855; Benediktsdottir et al. 2004, p. 440; Chiapasco et al. 1993, p. 417-418). The aetiology of alveolar osteitis is not completely understood and is subject to controversy. Several aetiological mechanisms have been proposed and are generally considered to be related to malformation or disruption of blood clots in the extraction

socket. One theory suggests that alveolar osteitis is the net result of the release of tissue factors leading to activation of plasminogen and subsequent fibrinolysis of the blood clot (Birn 1973, p. 211). Another theory suggests that alveolar osteitis is mainly the result of a localised bacterial infection causing destruction of the formed thrombus (Nitzan 1983, p. 706). From this, it is clear that the aetiology is complex and multifactorial. Risk factors identified and associated with increased risk of alveolar osteitis are: female sex, older age, oral contraceptive use, smoking, surgical trauma, pre-existing pericoronitis and poor oral hygiene (Alexander 2000, p. 393).

The incidence of infections following third molar surgery have been reported to vary from 0.8 % to 4.2 %, with higher infection rates seen following mandibular third molar surgery (Bui et al. 2003, p. 1379; Benediktsdottir et al. 2004, p. 443; Chiapasco et al. 1993, p. 415; Haug et al. 2005, p. 1106; Larsen 1992, p. 393; Sisk et al. 1986, p. 855). Several risk factors for the development of postoperative infections have been identified and include: higher age, degree of impaction, presence of soft tissue infection/pericoronitis, surgeon's experience, location of surgery (hospital versus office-based procedure) and the use of antibiotics (Boulox et al. 2007, p. 119). The use of perioperative and postoperative prophylactic antibiotics is controversial and its efficacy remains unclear (Boulox et al. 2007, p. 119; Susarla et al. 2003, p. 178).

Delayed wound healing following third molar surgery may follow alveolar osteitis and postoperative infection. Risk factors for poor wound healing have been identified and include: tobacco use, older age, pathogenic accumulation and periodontal compromise adjacent to the wound site (AAOMS 1994, p. 1109-1110).

Bleeding associated with third molar surgery may be classified as intraoperative or postoperative, with aetiology that may be due to local or systemic causes (Boulox et al. 2007, p. 119-120). The reported range of clinically significant bleeding associated with third molar surgery is 0.2%-5.8%. The reported frequency of significant intraoperative bleeding

ranges from 0.6%-0.7% (Bui et al. 2003, p. 1379; Chiapasco et al. 1993, p. 417; Haug et al. 2005, p. 1106; Sisk et al. 1986, p. 855). Excessive intraoperative bleeding has been associated with disto-angular impactions, deep impactions, older patients, and lack of use of local anaesthetics with vasoconstrictors (Chiapasco et al. 1993, p. 418). A soft tissue blood vessel injury represents the most common cause of perioperative haemorrhage. Bleeding due to local factors respond best to local control, which includes meticulous surgical technique, application of pressure packs, topical haemostatic agents, electrocautery and suture placement (Boulox et al. 2007, p. 119-120).

Nerve injuries are viewed as the more serious complications related to third molar surgery. Injuries to the inferior alveolar and lingual branches of the fifth (Trigeminal) cranial nerve have been reported. The overall incidence of inferior alveolar nerve injury ranges from 0.5% - 5%, and fortunately most cases resolve spontaneously (Susarla et al. 2003, p. 181). The incidence of lingual nerve injury varies greatly in different clinical studies, and ranges from 0% - 22% (Ziccardi et al. 2007, p. 106). Patients with lingual nerve injury report drooling, tongue biting, thermal burns, changes in speech and swallowing and taste perception alterations. Nerve injuries may occur as a result of direct or indirect forces. Direct injuries may occur as a result of anaesthetic injections, injury sustained during tooth extraction or soft tissue management, instrumentation and crush injuries. Indirect injuries may result from physiologic phenomena including root infections, pressure from haematomas and post-surgical oedema (Susarla et al. 2003, p. 182-183).

Use of Electrosurgical instruments for creating surgical incisions

Incisions into the oral mucosa are usually made with a steel scalpel, but the use of electrosurgery for soft tissue cutting has been described and often used for oral surgery. Incisions into oral mucosa with a steel scalpel have been associated with unfavourable side-effects such as excessive blood flow with inadequate visibility caused by blood in the operating field. It does, however, have the advantages of low cost, ease of use and relatively uneventful and fast healing (Bashetty et al. 2009, p. 139).

Electrosurgery is frequently used in various aspects of medicine and involves the controlled application of electrically generated heat energy to human tissue to surgically alter it for therapeutic purposes (Ravishankar et al. 2011, p. 492). Electrosurgery can be defined as the intentional passage of high frequency currents through the tissues of the body, via an electrode, to achieve a controllable surgical effect (Massarweh et al. 2006, p. 520). As a variation on the mode of application of this type of current, the surgeon can use electrosurgery for cutting or coagulating soft tissue. The passage of electrical current into tissue results in injury to the cell membrane with disruption of cell structure in the cutting mode. Tissue coagulation occurs when heat is locally concentrated in an area. A pulsed current output from the current generator results in coagulation, whereas a continuous output results in a cutting mode. Cutting and coagulation can be achieved simultaneously in the cutting mode, and offers the advantage of achieving better haemostasis (Sharma 2011, p. 1063). The heat generated by electrosurgical devices is influenced by the duration of contact between the electrode tip and tissue, the size of the electrode tip, current intensity and electrosection waveform. A larger tip increases the operating power, amount of lateral heat and tissue damage (Bashetty et al. 2009, p. 141; Massarweh et al. 2006, p. 522; Ravishankar et al. 2011, p. 494). The majority of studies performed to evaluate electrocautery pertain to abdominal and thoracic surgery. These studies showed significant reduction in cutting time, blood loss, improved early postoperative pain and analgesia requirement and no increased incidence of wound dehiscence (Allan et al. 1982, p. 52-54; Eisenmann et al. 1970, p. 662; Groot et al. 1994, p. 602; Kearns et al. 2001, p. 44). Its use on oral tissue has been associated with minimal bleeding and postoperative pain (Bashetty et al. 2009, p. 141).

One of the reported benefits of electrosurgery is the significant reduction in cutting time (Sheikh 2004, p. 43; Akkielah et al. 1997, p. 737, Rideout et al. 2004, p. 15; Chau et al. 2009, p. 430-431; Kearns et al. 2001, p. 43-44; Shamim 2009, p. 1598). These studies report mean differences in cutting time (scalpel-cautery) of 28.73 seconds (Chau et al. 2009, p. 430-431), 40 seconds (Kearns et al. 2001, p. 43-44) and 16.79 seconds (Shamim 2009, p. 1598) in

favour of electrosurgical incisions. Heterogeneity between these studies was significant as a direct result of the variability of the size and location of the incisions (Aird et al. 2012, p. 219).

Absolute incisional blood loss with electrosurgical incisions is reportedly significantly less when compared to steel scalpel incisions (Kearns et al. 2001, p. 44; Shamim 2009, p. 1598). Kearns and co- workers, and Shamim, reported a significant difference of 0.9 ml/cm and 0.76 ml/cm respectively when comparing steel scalpel to diathermy to create surgical incisions for various operations (Kearns et al. 2001, p. 44; Shamim 2009, p. 1598). Although these reported differences are significant, there is significant heterogeneity between these studies, and this was reported as a factor of the difference in length and location of the incisions (Mittal et al. 2012, p. 617).

The level of postoperative pain was compared between steel scalpel and electrosurgery in several studies. Using the visual analogue scale, Kearns and co-workers, found a statistically significant difference in pain severity during postoperative days 1 and 2 with the electrosurgical group measuring less severe pain. There was also a statistically significant difference (P=0.036 and P=0.011 respectively) in the level and days of patient-controlled analgesia required for the electrosurgical group (Kearns et al. 2001, p. 44). Shamim recorded the severity of postoperative pain using the pain verbal rating scale. Here postoperative days 1 and 2 showed significantly less pain in the electrosurgical group (both having a P <0 .05) (Shamim 2009, p. 1598). There, thus appears to be a definite indication of less postoperative incisional pain using electrosurgery.

A meta-analysis of studies comparing wound complications in scalpel and electrosurgery showed no difference in wound complication rates with either cutting modality (Mittal & Windsor 2012, p. 614-615).

The Colorado Tip Microdissection Needle

The Colorado Tip Microdissection Needle (CMN) (Stryker-Leibinger, Freiburg, Germany) was introduced into clinical practice in 1997, with various applications described (Rideout & Shaw 2004, p. 15-16). The instrument tip is a delicately machined, insulated tungsten diathermy needle that is compatible with any standard cautery handpiece. The advantage of this microdissection needle has been described by Farnworth and colleagues (Farnworth et al. 1993, p. 165). They microscopically examined and compared incisions made with standard electrosurgery, the microdissection needle and the Shaw haemostatic scalpel. The study showed that by decreasing the surface area of the electrosurgery device, higher power densities are sustained at comparatively low wattage. The net result permits reduced dissipation of heat energy into the surrounding tissue. This results in a smaller zone of tissue necrosis than conventional cautery devices (Farnworth et al. 1993, p. 165).

The use of the microdissection needle for skin incisions in the head and neck region has been reported. Sheikh reported the use of the microdissection needle for skin incisions in neurosurgery. He performed 177 skin incisions with a microdissection needle, half of each incision performed with a steel scalpel, and the other half with a microdissection needle. He reported a significant reduction in time taken for skin opening with the microdissection needle, 3-5 times less blood loss and only 2 cases of wound dehiscence. He reported that the average time taken for a 10 cm incision was 5.5 minutes with a steel scalpel (average 0.3 mm/s), whereas the time taken for the same incision averaged 45 seconds (average 2.3 mm/s) with the CMN (Sheikh 2004, p. 270-271). The use of the CMN in craniofacial surgery has been investigated by Sharma. He performed 117 skin incisions including coronal, pre-auricular, submandibular, retromandibular, subciliary and lateral brow incisions. All patients tolerated the procedures well and only one case showed wound dehiscence (Sharma 2011, p. 1062-1063).

The use of the CMN on oropharyngeal mucosa during tonsillectomies has been investigated by several authors (Akkielah et al. 1997, p. 735-738; Rideout & Shaw 2004, p. 11-17).

Akkielah and colleagues first described its use in tonsillectomy. In their prospective study, they compared bipolar electrosurgery with microdissection needle cautery. Here each patient served as their own control as they employed bipolar forceps on one side and the microdissection needle on the other. The authors found significantly less eschar formation in the site operated with the microdissection needle. They assessed postoperative pain by VAS and showed that there was, on average, 1.5 pain score units less pain on the CMN side (Akkielah et al. 1997, p. 735-738). Rideout and Shaw reported the use of CMN for tonsillectomy in a prospective case series of 25 patients. Their results show minimal blood loss, postoperative pain and peri-operative complications, as well as a significant reduction in operation time (Rideout & Shaw 2004, p. 11-17). They reported a mean blood loss of 9.0 ml, mean surgical time of 9.0 minutes and an average of 4.5 days of a pain rating above 5 as measured by VAS of 1-10. They compared these results to those of other studies evaluating various modalities for tonsillectomy, and found that their results showed significantly less intraoperative blood loss and reduced cutting time (Rideout & Shaw 2004, p. 11-17).

Potential benefits of CMN use for incisions in third molar surgery

The use of the CMN for oral mucosal incisions for third molar surgery has, according to the author's knowledge, not been investigated. It has been demonstrated that the use of electrosurgical instruments, including the CMN, is associated with decreased intraoperative bleeding, decreased surgical time, decreased postoperative pain and favourable wound healing (Bashetty et al. 2009, p. 141, Sheikh 2004, p. 270-271, Sharma 2011, p. 1062-1063, Akkielah et al. 1997, p. 735-738, Rideout & Shaw 2004, p. 11-17). The benefits of the use of the CMN in third molar surgery were thus investigated.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

AIM AND OBJECTIVES

Aim

The aim was to compare the use of a CMN versus a conventional steel scalpel for intra-oral incisions in the removal of impacted third molars.

Objectives

The objectives were to compare:

- Cutting time between the two techniques
- Intra-operative soft tissue bleeding at the incision site
- Postoperative pain between the two techniques
- Postoperative wound healing between the two techniques
- The incidence of postoperative long buccal and lingual nerve injuries.

Null Hypothesis

There was no difference between the use of a CMN and a conventional steel scalpel.

METHODOLOGY

Study design

This study was an analytical prospective case series of patients selected for the removal of third molars at our Maxillo-Facial and Oral Surgery clinic. Twenty standardised cases were included, each having one side operated with a CMN and the other side with a steel scalpel.

Study population

The study population comprised of patients on the waiting list at the Department of Maxillo-Facial and Oral Surgery, Tygerberg Oral Health Centre, University of the Western Cape, who were booked for elective removal of impacted third molars under general anaesthetic.

Patients and methods

The sample size was 20 patients who met the inclusion criteria.

Inclusion criteria:

- American Society of Anaesthesiology category 1 patients scheduled for removal of impacted third molars at the UWC Oral Health Centre, Tygerberg
- Any sex or race
- Four impacted third molars that were mirror images of each other as evaluated by orthopantomograph
- Complete soft tissue impaction of third molars.

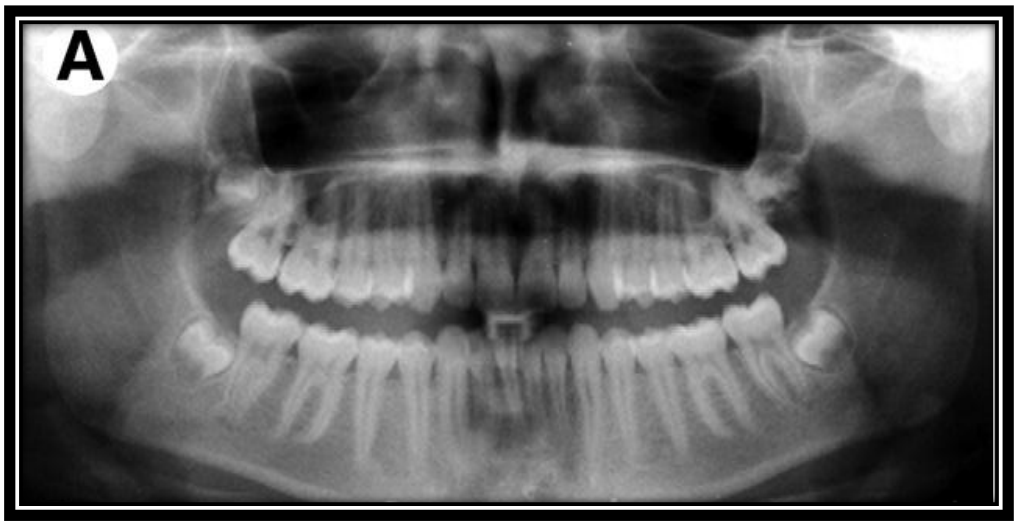

Figure 1. Orthopantomograph demonstrating four impacted third molars that are mirror images of each other

Exclusion criteria:

- Patients with a history of blood dyscrasias
- Patients with a history of immune compromise/deficiency
- Presence of infection at the third molar area
- Patients on pre-operative non-steroidal anti-inflammatory, and/or herbal drugs, and/or steroid therapy.

Anaesthetic and surgical techniques

All surgery was performed under standardised general anaesthesia. Patients had an intravenous catheter inserted. At induction they received Propofol 2 mg/kg and Fentanyl 50-200 mcg. As a muscle relaxant they received Rocuronium bromide (Esmeron®) 1.6 mg/kg. Laryngoscopy and nasotracheal intubation was performed with placement of a ribbon gauze throat pack. During the surgical procedure the patient was kept anaesthetized with Sevoflurane or Isoflurane. At the conclusion of surgery the action of the muscle relaxant was reversed with Neostigmine 0.05 - 0.07 mg/kg and Glycopyrolate 0.2 mg. Patients were extubated once airway protective reflexes had returned.

The split mouth technique was used in an analytical prospective case series. Two impacted third molars (on one side) were removed using a CMN (for incision) plus a conventional drill, while a steel scalpel and conventional drill was used on the opposite side (Figure 2). The patient therefore served as their own control. The flip of a coin determined which side the CMN was to be used. The surgical procedures were performed by a single operator. No local anaesthesia was administered. This was done to eliminate its vasoconstrictor effect and to allow immediate postoperative pain assessment.

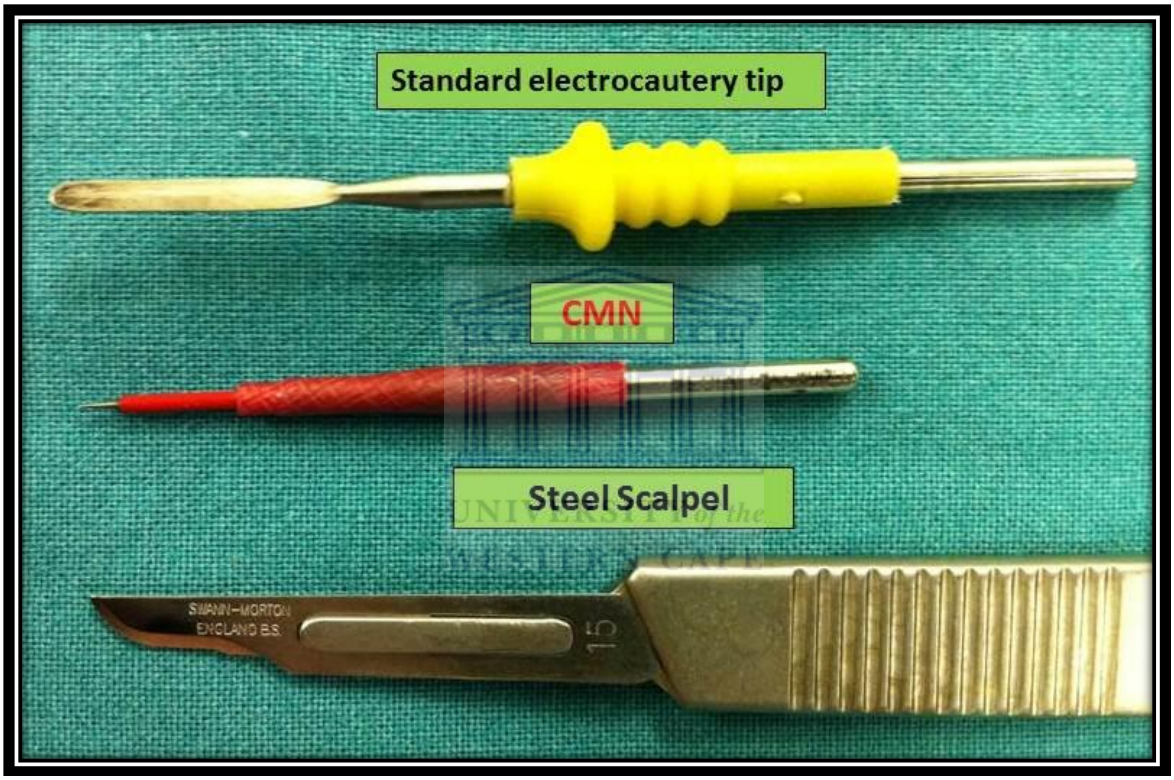

Figure 2. A standard electrocautery tip, CMN and Steel Scalpel

For lower third molars a full thickness incision was made extending from the distal aspect of the first molar to the ramus with lateral divergence of the posterior extension. A full thickness envelope mucoperiosteal flap was raised using a Freer periosteal elevator (Figure 3). The lingual nerve was protected by placing a Howarth periosteal elevator subperiosteally medial to the lingual cortex of the mandible. The flap was reflected and ostectomy and odontotomy (when required) was performed with a conventional surgical handpiece, number 8 round bur and/or fissure bur. All parts of the tooth were mobilised and removed with Coupland, Warwick-James and/or Cryer elevators. After completing the surgical removal the socket was curettaged and irrigated with sterile saline. The flap was then

repositioned and sutured hermetically, using simple interrupted 3-0 Catgut Chromic sutures for all cases.

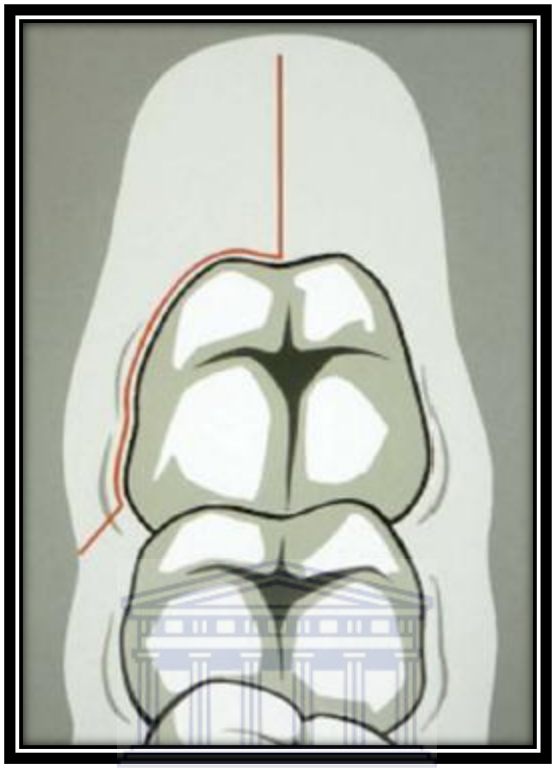

Figure 3. Standard surgical incision used for surgical approach to impacted third molars (Monaco et al. 2009, p. 17)

Patients were discharged with the following:

- 1 g Paracetamol orally 6-hourly for five days
- 400 mg Ibuprofen orally 6-hourly for five days
- 500 mg Amoxicillin orally 8-hourly for 48 hours
- If penicillin allergy was present – 150 mg clindamycin orally 6-hourly for 48 hours
- 0.2% Chlorhexidine gluconate mouthrinse - 15 ml rinse after meals
- Standard post third molar surgery patient instruction letter.

Criteria that were evaluated

1. Cutting time was evaluated as start to end of incision on either side
2. Intra-operative bleeding
3. Pain
    - When fully recovered in the immediate postoperative period by numerical scale
    - 24 and 72 hours postoperatively – numerical scale obtained telephonically
4. Soft tissue wound healing at seven and 14 days postoperatively - assessed by presence/absence of wound dehiscence, infection and alveolar osteitis
5. Incidence of lingual and long buccal nerve injury - fallout of nerve function at 24 hours postoperatively.
6. Intra-operative complications.

Data management and statistical analysis

All data were collected and transferred from the data collection sheet (Appendix I) to a spreadsheet (Microsoft Excel®) and analysed statistically using a standard statistics programme (Statistics R:R development Core Team 2013. R Foundation for Statistical Computing Vienna, Austria).

Ethical statement

The research protocol was presented to the Research Committee of the Faculty of Dentistry, UWC, and approved as a research project.

Patient participation in the project was voluntary. Each patient had the right to withdraw from the study at any stage and the latter did not prejudice the patient in any way with regard to further treatment at the facility. Every patient was informed about the project and handed a formal information leaflet in English. All patients were asked to give informed consent or refusal for the research project through a formal written consent procedure. Patient confidentiality was protected at all times. All information was stored in password-

protected computers and printed information was stored in a locked office. All personal identifiers were changed when the data were published. Photographs were used with informed consent and eyes were blocked out.

CHAPTER 4

RESULTS

The study sample contained 20 patients with ages ranging from 14-36 years, with an average age of 24 years. Of the 20 patients, 10 were male and 10 female.

Incision time (seconds) of CMN versus steel scalpel

Incision time for the CMN and the steel scalpel were recorded by a theatre assistant. The results are tabulated in Table 1.

Case #	CMN		Steel Scalpel	
	Upper	Lower	Upper	Lower
1	5.58	16.05	8.68	12.08
2		12.3		28.5
3		7.41		8.34
4	3.71	7.95	13.56	13.47
5	5.02	19.1	9.2	9.12
6	5.39	8.84	7.94	5.47
7		5.18		7.53
8	7.21	7.28	7.08	11.36
9		7.05		20.61
10	4.92	8.87	8.81	7.22
11	7.16	11.25	8.19	12.03
12	6.25	5.52	3.43	6.13
13	7.42	8.02	4.69	7.98
14		9.45		4.55
15		8.18		4.24
16		6.7		10.32
17	4.67	4.49	6.38	6.96
18	2.87	7.48	2.87	9.39
19		6.73		4.42
20	4.63	5.12	7.22	5.98

Table 1. Incision time (sec) of CMN vs. Steel Scalpel

In Table 2 the means for the four columns of Table 1 are depicted. The Mean Difference column depicts the difference of the means and the P-value as a result of a paired t-test of significance of difference of the means. The result shows that there was no significant difference in time taken for upper or lower incisions at level 0.05.

Mean	CMN	Scalpel	Mean diff	P-value
Upper	5.402	7.338	1.935	0.074
Lower	8.649	9.785	1.136	0.404

Table 2. Mean incision time for CMN and Steel Scalpel, mean difference and P-value

Incisional soft tissue bleeding

Case #	CMN bleeding
1	Less
2	Same
3	Less
4	Less
5	Less
6	Same
7	Same
8	Less
9	Same
10	Less
11	Less
12	Less
13	Less
14	Less
15	Less
16	Less
17	Same
18	Less
19	Less
20	Less

Table 3. Incisional soft tissue bleeding CMN vs. Steel Scalpel

The surgeon's judgement was used to compare the incisional bleeding between the CMN and the steel scalpel. In 15 of the 20 cases the CMN resulted in less incisional bleeding. In the other five cases, there was no difference in the incisional bleeding between the two techniques. The null hypothesis (H0) was that there was no difference between the incisional soft tissue bleeding. An exact binomial test was applied and gave P <0.00001, so H0 was rejected. The estimated probability of less bleeding was 15/20 cases = 0.75, with two-sided 95% confidence limits of 0.509 and 0.913. The estimated probability of more bleeding was 0/20 cases, with two-sided 95% confidence limits of 0.000 and 0.168.

Postoperative pain

Postoperative pain was assessed in the recovery room, at 24 hours, and at 72 hours. The results and statistical analysis are tabulated below.

Case #	Pain score-recovery	
	Steel Scalpel	CMN
1	2	3
2	0	0
3	2	4
4	3	5
5	5	3
6	4	4
7	4	5
8	3	4
9	2	3
10	4	3
11	3	3
12	4	3
13	1	4
14	1	3
15	3	4
16	3	4

17	4	1
18	4	2
19	3	4
20	3	4
mean	2.95	3.33
StdDev	1.25	1.21

Table 4. Recovery room pain scores

The mean pain score for the CMN was 3.33 (SD= 1.21) and the mean pain score for the steel scalpel was 2.95 (SD=1.25). Of the 20 differences (Steel Scalpel-CMN) three were zero, 12 negative, five positive. Considering only the non-zero differences, and applying an exact binomial test, as above, the test of H0: Pr(negative) = Pr(positive) against Pr(negative) ≠Pr(positive) gave P=0.144, so H0 was accepted.

Case #	Pain score-24 hours	
	Steel Scalpel	CMN
1	2	4
2	0	1
3	2	4
4	0	1
5	4	3
6	3	3
7	3	4
8	2	4
9	1	3
10	4	3
11	3	3
12	2	1
13	4	2
14	1	2
15	2	3
16	2	2

17	2	1
18	3	1
19	3	4
20	2	3
mean	2.33	2.60
StdDev	1.12	1.14

Table 5. Pain score at 24 hours

The mean pain score for the CMN was 2.6 (SD=1.14) and 2.33(SD=1.12) for the steel scalpel. Of the 20 differences (Steel Scalpel-CMN) three were zero, 11 negative, six positive. Considering only the non-zero differences, and applying an exact binomial test, as above, the test of H0: Pr(negative) = Pr(positive) against Pr(negative) ≠ Pr(positive) gave P=0.332, so H0 was accepted.

Case #	Pain score-72 hrs	
	Steel Scalpel	CMN
1	0	3
2	0	1
3	0	3
4	0	0
5	2	1
6	2	1
7	1	2
8	1	2
9	2	1
10	3	2
11	3	2
12	1	0
13	1	3
14	1	1

15	1	2
16	0	1
17	0	0
18	1	0
19	1	1
20	1	2
mean	1.01	1.40
StdDev	0.92	0.99

Table 6. Pain score at 72 hours

The mean pain scores for the CMN was 1.4 (SD=0.99) and 1.01 (SD= 0.92) for the steel scalpel. Of the 20 differences (Steel Scalpel-CMN) four were zero, nine negative, and seven positive. Considering only the non-zero differences, and applying an exact binomial test, as above, the test of H0: Pr(negative) = Pr(positive) against Pr(negative) ≠ Pr(positive) gave P=0.804, so H0 was accepted.

	Mean pain score recovery	Mean pain score 24 hours	Mean pain score 72 hours
Steel Scalpel	2.95	2.33	1.01
CMN	3.33	2.60	1.40
Mean difference	-0.38	-0.27	-0.39
P- value	0.144	0.332	0.804

Table 7. Mean pain scores, mean difference and P-values

Wound healing

Case #	Soft tissue healing day 7	
	Steel Scalpel	CMN
1	Normal	dehiscence
2	Normal	dehiscence
3	Normal	normal
4	Normal	normal
5	Normal	normal
6	Normal	normal
7	Normal	normal
8	Normal	normal
9	Normal	dehiscence
10	Normal	normal
11	Normal	normal
12	Normal	normal
13	Normal	normal
14	Normal	normal
15	Normal	dehiscence
16	Normal	normal
17	Normal	normal
18	Normal	normal
19	Normal	normal
20	Normal	normal

Table 8. Wound healing at day 7

All soft tissue incisions with the steel scalpel revealed normal wound healing at day 7. Four of the 20 sides (20%) incised with the CMN showed clinical wound dehiscence. H0 is that the probability of dehiscence with the steel scalpel = probability of dehiscence with the CMN. Comparing only cases where neither results were normal, the probability of this event is 1/16>0.05, so H0 was accepted at significance level 0.05.

Case #	Soft tissue healing day 14	
	Steel Scalpel	CMN
1	Normal	Dehiscence
2	Normal	Dehiscence
3	Normal	Normal
4	Normal	Normal
5	Normal	Normal
6	Normal	Normal
7	Normal	Normal
8	Normal	Normal
9	Normal	Normal
10	Normal	Normal
11	Normal	Normal
12	Normal	Normal
13	Normal	Dehiscence
14	Normal	Normal
15	Normal	Normal
16	Normal	Normal
17	Normal	Normal
18	Normal	Normal
19	Normal	Normal
20	Normal	Normal

Table 9. Wound healing at day 14

At day 14, all steel scalpel incisions were healing well with no dehiscence. However, three of the 20 cases (15%) operated with the CMN, showed wound dehiscence. A comparison between the wound healing with the steel scalpel and the CMN is depicted in Chart 1. H0 is that the probability of dehiscence with scalpel=probability of dehiscence with the CMN. The probability of this event was1/8>0.05, so H0 was accepted at significance level 0.05.

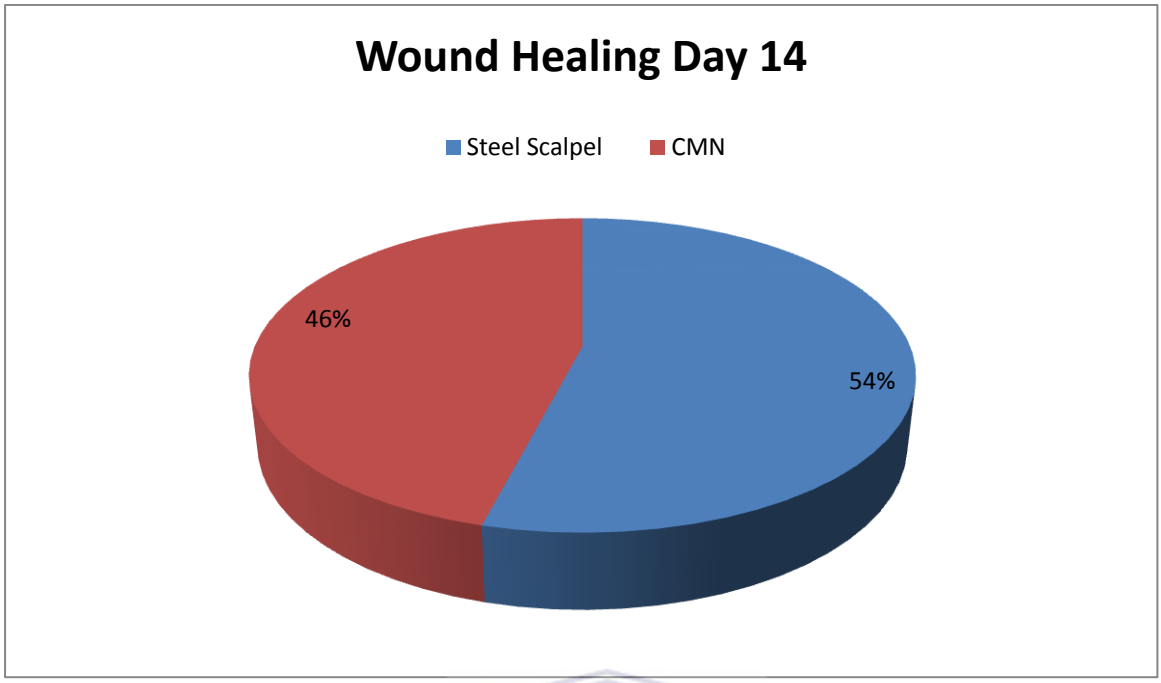

Chart 1. Comparing wound healing on day 14 between the Steel Scalpel and CMN

Incidence of lingual and long buccal nerve injury

Case #	Nerve Injury	
	Lingual	Buccal
1	no	no
2	yes	no
3	no	no
4	no	no
5	no	no
6	no	no
7	no	no
8	no	no
9	no	no
10	no	no
11	no	no
12	no	no

13	yes	no
14	no	no
15	no	no
16	no	no
17	no	no
18	no	no
19	no	no
20	no	no

Table 10. Lingual and long buccal nerve injury associated with the CMN

There were only two cases with lingual nerve paraesthesia associated with the CMN use and none with the steel scalpel. No cases of buccal nerve injury were seen. H0 was that there was no difference in the probability of nerve injury with the CMN or the steel scalpel. The significance probability is ¼>0.05, so H0 was accepted.

CHAPTER 5

DISCUSSION

Third molar surgery remains the most commonly performed procedure by maxillo-facial and oral surgeons, and is associated with expected but transient sequelae such as pain, swelling and trismus. Although these are accepted sequelae of third molar surgery, they may have a significant impact on the patient's perception of well-being. Therefore the goals of third molar surgery should include successful removal of the impacted teeth, while minimising the severity of postoperative sequelae and reducing the incidence of perioperative complications.

The use of electrosurgical instruments to create surgical incisions is well described in the literature. Several studies report that the use of conventional electrosurgical instruments result in a significant reduction in cutting time, incisional blood loss, postoperative pain, with no evidence of an increased incidence in wound complications such as dehiscence and infection (Allan et al. 1982, p. 53; Eisenmann et al. 1970, p. 662; Groot & Chappell 1994, p. 603; Kearns et al. 2001, p. 43). Similar results have been reported for the use of electrosurgery on oral mucosa (Bashetty et al. 2009, p. 143). The CMN was introduced into clinical practice in 1997, with various applications described (Rideout & Shaw 2004, p. 15). To the author's knowledge, no studies comparing electrosurgery versus steel scalpel incisions in third molar surgery were reported in the literature. Thus, the aim of this prospective study was to evaluate and compare the use of the CMN and the steel scalpel for oral mucosal incisions.

One of the reported benefits of electrosurgery is the significant reduction in cutting time (Sheikh 2004, p. 43; Akkielah et al. 1997, p. 737, Rideout & Shaw 2004, p. 15; Chau et al. 2009, p. 430-431; Kearns et al. 2001, p. 43-44; Shamim 2009, p. 1598). These studies report mean differences in cutting time (scalpel vs. cautery) of 28.73seconds (Chau et al. 2009, p.

430-431), 40 seconds (Kearns et al. 2001, p. 43-44) and 16.79 seconds (Shamim 2009, p. 1598) in favour of electrosurgical incisions. Heterogeneity between these studies was significant as a direct result of the variability of the size and location of the incisions (Aird et al. 2012, p. 219). This study showed a mean difference (Steel Scalpel vs. CMN) of 1.94 seconds and 1.13 seconds for upper and lower third molar incisions respectively. These differences were not statistically significant (P=0.074 and 0.404) therefore H0 is accepted. However, it should be noted that cutting time in third molar surgery is generally much shorter than in laparotomy incisions or tonsillectomy dissections.

Absolute incisional blood loss with electrosurgical incisions is reportedly significantly less when compared to the steel scalpel incisions (Kearns et al. 2001, p. 44; Shamim 2009, p. 1598). Although these reported differences are significant, there is significant heterogeneity between these studies, and this was reported as a factor of the difference in length and location of the incisions (Mittal & Windsor 2012, p. 617). Sheikh reported approximately four times more blood loss with a steel scalpel when compared to the CMN for scalp incisions in neurosurgical procedures (Sheikh 2004, p. 269). This estimate was based on bloodstaining of gauze swabs used intra-operatively. The present study showed that fifteen of twenty cases had less incisional blood loss with CMN, a statistically significant result (P<0.00001). However, this was a subjective assessment based on the clinician's judgement of which modality was associated with less bleeding, and did not attempt to quantify the amount of incisional blood loss in millilitres or grams. This result, similar to that reported by Sheikh, could be questioned for its reliability.

Among all the postoperative sequelae following third molar surgery, pain is probably the most important to the patient. Akkielah and co-workers reported statistically significant reductions in postoperative pain, assessed by VAS, for tonsillectomies done with the CMN when compared to bipolar electrosurgery (Akkielah et al. 1997, p. 737). In this study, as expected, the mean pain scores for both modalities decreased at each pain assessment after surgery. The mean pain scores for steel scalpel were less (mean difference -0.38, -0.27,

-0.39), but not statistically significant. Thus this study shows that there is no difference in postoperative pain suffered by the study subjects.

One of the concerns regarding electrosurgery was the theoretical risk of increased wound complications due to the lateral heat production which results in a zone of tissue necrosis adjacent to the incision. It was proven by several studies that electrosurgically created incisions showed no increased incidence of wound complications such as dehiscence and infection (Kearns et al. 2001, p. 44; Shamim 2009, p. 1598). Farnworth and co-workers demonstrated that the microdissection needle produced less lateral heat and a smaller zone of necrosis than conventional electrocautery blades (Farnworth et al. 1993, p. 165). This is theorized to translate into lower incidences of wound complications. This was proven by Sheikh (Sheikh 2004, p. 43) and Sharma (Sharma 2011, p. 1063). No data investigating the wound complications for oral mucosal incisions with the CMN could be found. In the present study, none of the control (steel scalpel) incisions showed wound complications at day seven or day 14. This study showed a 20% incidence of wound dehiscence at day seven, and a 15% incidence at day 14 for the incisions fashioned with the CMN. Statistical analysis revealed that there was no significant difference between the probability of dehiscence with either modality.

The reported incidence of lingual nerve injury varies greatly in different studies and ranges from 0% to 22% (Ziccardi et al. 2007, p. 106), and several risk factors influencing its occurrence have been described (Susarla et al. 2003, p. 182-183). This study shows two (10%) cases of lingual nerve paraesthesia associated with the use of the CMN. This falls well within the reported range of lingual nerve injury. A literature search found no specific reports of long buccal nerve injury. This study showed no incidences of long buccal nerve injury. Although the long buccal nerve may be at risk of injury during incision, the effects of such an injury may not be clinically significant as it is probably unlikely to cause any functional or aesthetic disturbance to the patient.

One of the limitations of this study was its small sample size. The data regarding nerve injury and wound dehiscence may thus not be an accurate reflection.

CONCLUSION

The aim of this study was to compare the CMN to the steel scalpel for incisions in third molar surgery. The results showed no significant difference in incision time, postoperative pain, wound healing and incidence of wound complications. There was a significant difference in the incisional blood loss, but this result may not be reliable, as it was a subjective assessment of a variable that would yield a more accurate result if measured in millilitres or grams. Another limitation was that the small sample size may have yielded an inaccurate reflection of the incidence of wound complications and nerve injury. Hence a larger study sample would have been desirable.

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APPENDIX I

Data Capture Sheet

Case Nr :……

Patient:…… Folder nr:……

Age:

Medical History:

Device

Right side:…… Left side:……..

Teeth:……Teeth:……..

…….. ……

Incision time (seconds):

Left upper: …….. Right upper: ……..

Left lower: …….. Right lower: ……

Bleeding Assessment:

Cutting Modality	More bleeding	Same bleeding	Less bleeding
Steel Scalpel			
CMN			

Pain

Numerical scale to evaluate pain : reference values given to patients

0	No pain	The patient feels well
1	Slight pain	If the patient is distracted, he or she does not feel the pain
2	Mild pain	The patient feels the pain even when concentrating on some activity
3	Severe pain	The patient is very disturbed but nonetheless can continue with normal activities
4	Very severe pain	The patient is forced to abandon normal activities
5	Extremely severe pain	The patient must abandon every type of activity and feels the need to lie down

Left side:

In recovery : ……

24hrs post op : ……

72 hrs post op : ……

Right side:

In recovery : ……

24hrs post op : ……

72 hrs post op : ……

Soft tissue wound healing:

Day	Normal	Dehiscence	Infection	Alveolar osteitis
7				
14				

Incidence of long buccal and lingual nerve injury at 7days post operatively

Nerve	Injury	
	Yes	No
Lingual		
Long buccal		

Intraoperative Complications

1.
2.
3.
4.
5.

APPENDIX II

Department of Maxillo-Facial and Oral Surgery

Faculty of Dentistry and WHO Oral Health Collaborating Centre

University of the Western Cape

Cape Town

Patient Information Letter

I, Dr A Mohamed (currently a qualified dentist enrolled in a specialist training program), plan to conduct a clinical study to compare 2 types of surgical "gum cutting" techniques used to remove your wisdom teeth. The one is a standard surgical blade and the other an electrical blade that is routinely used in surgery, but has now been refined. Both techniques are routinely used in oral surgery. We do not think there is a difference between the 2 techniques. The only way we can find out if the one is superior to the other, is to do such a study. I will measure and compare the amount of bleeding during surgery, the time taken to do the surgery, the amount of pain you experience after surgery and the healing of the area after surgery.

Participating in the study is on a voluntary basis. You may withdraw from 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 study will definitely benefit future patients. All information will be kept strictly confidential.

Thanking you in anticipation.

Dr A Mohamed (Researcher)
Registrar (Maxillo-Facial and Oral Surgery)
Department of Maxillo-Facial and Oral Surgery
Oral Health Centre Tygerberg
Contact details: Tel: (021) 937 3119
Mobile: 082 550 3496

If you have any other queries, you are welcome to contact my supervisor, Prof J Morkel at 021 938 3119

I, (patient name)....., fully understand the information supplied to me by Dr A Mohamed in the above information letter.

Signature: .....

Date: .....

APPENDIX III

UNIVERSITY *of the*
WESTERN CAPE

Department of Maxillo-Facial and Oral Surgery

Faculty of Dentistry and WHO Oral Health Collaborating Centre

University of the Western Cape

Cape Town

Consent form

I, Mr/Mrs/Miss.....

Date of Birth:..... File no./Hosp. Sticker.....

am willing to participate in the study as described to me in the patient information letter by Dr A Mohamed. I understand that participation in the study is voluntary.

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

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

Patient's/patient's parent or guardian's name:.....

Patient's/patient's parent or guardian's signature:.....

Witness's name:.....

Witness's signature:.....

Researcher's signature:.....

Dr A Mohamed

Date:.....