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Comparison between local anaesthetic agents, lidocaine and bupivacaine, in patients undergoing third molar extraction in terms of patient satisfaction.

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DClinDent Thesis

University College Cork

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Table of Contents

1.0 Introduction 9

2.0 Literature Review 13

2.1 The Surgical Removal of Third Molars 13

2.1.1 Third Molar Extraction 13

2.1.2 Impacted teeth 13

2.1.3 Assessment of Difficulty of Third Molar Surgery 14

2.1.4 Surgical Technique and Expertise 15

2.1.5 Normal Recovery 16

2.1.6 Complications 18

2.2 Anaesthesia in Oral Surgery 20

2.2.1 The Choice of Anaesthesia in Third Molar Surgery 20

2.2.2 Day Case General Anaesthesia 21

2.2.3 Local Anaesthetics in Dentistry 22

2.2.4 Lidocaine versus Bupivacaine 23

2.3 Post-Surgical Pain 24

2.3.1 Pain 24

2.3.2 Acute and Chronic Pain 25

2.3.3 Pain and Personality 26

2.3.4 Pain and Gender 27

2.3.5 Pain Relief Regimes for Third Molar Extraction 29

2.3.6 Pain Assessment 32

2.4 Patient Satisfaction and Third Molar Surgery 35

2.4.1 Patient Satisfaction 35

2.4.2 Patient Education 36

2.4.3 Measurement tools for Patient Satisfaction 37

2.4.4 Patient Reported Outcomes in Third Molar Surgery 39

2.5 Summary of the Literature Review 41

2.5.1 The Surgical Removal of Third Molars 41

2.5.2 Anaesthesia in Oral Surgery 41

2.5.3 Post-Surgical Pain 42

2.5.4 Patient Satisfaction and Third Molar Surgery....43

3.0 Methodology....44

3.1 Aims....44

3.2 Hypotheses....44

3.3 Ethical Approval....45

3.4 Sample size....45

3.5 Recruitment....45

3.6 Method....46

3.7 Data Collection....47

3.8 Statistical Analysis....49

4.0 RESULTS....51

4.1 Demographics....51

4.1.1 Age....51

4.1.2 Gender....51

4.1.3 ASA Grade & Smoking Status:....52

4.2 Pre-operative assessment....53

4.2.1 Pre-Operative Pain Catastrophizing Scale 53

4.2.2 Pre-Operative Hospital Anxiety and Depression Scale 54

4.2.3 Pre-Operative Short Form McGill Pain Questionnaire 55

4.2.4 Effect of Pre-Operative Assessments on Pain Scores 56

4.3 Third Molar Assessment.....57

4.3.1 Classification of Third Molars 57

4.3.2 Surgical Technique 58

4.3.3 Surgical Time 61

4.4 Post- operative Assessment 62

4.4.1 Pain Assessment: Visual Analogue Scale 62

4.4.2 Effect of Third Molar Orientation on VAS Scores 68

4.4.3 Post-Operative Pain Catastrophizing Scale 68

4.4.4 Post-Operative Hospital Anxiety and Depression Scale 69

4.4.5 Post-Operative Short-Form McGill Pain Questionnaire.....70

4.4.6 Effect of Post-Operative Assessments on Pain Scores 71

4.4.7 Dental Visit Satisfaction Scale 72

4.4.8 Patient Preference 75

4.4.9 Pain Diary 77

5.0 DISCUSSION 81

5.1 Study Design 81

5.2 Sample Characteristics 81

5.3 Psychological variables 83

5.4 Pre-operative pain assessment 85

5.5 Assessment of difficulty and technique of third molar surgery 85

5.6 Post-operative pain assessment 86

5.7 Post-operative Complications 88

5.8 Satisfaction Measures 88

5.9 Patient preference 90

5.10 Limitations and Suggestions for Further Study 90

6.0 Conclusion 92

8.0 Appendices 94

Appendix I.....94

Appendix II.....96

Appendix III.....97

Appendix IV 99

Appendix V 100

Appendix VI 101

Appendix VII 102

Appendix VIII 104

References 105

Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism.

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Caroline McCarthy

1.0 Introduction

Third molars when present are the last teeth to erupt into the oral cavity. As a result, there is often minimal space remaining to allow these teeth erupt into a functional position. They are subsequently removed for a number of reasons; pericoronitis, unrestorable caries (including adjacent teeth), periodontal disease, and cystic changes. Elective removal of third molars may be warranted in cases where they impede prosthesis provision or prior to orthognathic surgery to help prevent an unfavourable saggital split (1). The impact of third molars on lower incisor crowding has been a source of much debate. Evidence accumulating over the last 20 years suggests third molars do not play a role in increased interdental pressure (2, 3). Despite guidelines issued by the National Institute of Clinical Excellence (NICE) on the indications for the removal of third molars in 2000, third molar extraction remains the most common procedure carried out under general anaesthetic in Ireland (4).

The treatment options given to patients on initial assessment largely depend on the facilities available to the clinicians, expected difficulty of the surgery, patient's medical history, anxiety and preference(5). Patient satisfaction with general anaesthesia (GA) and its amnesic effects is no doubt a driving force for continued high rates of extraction under GA (6, 7). For third molars removed in this manner, admission has changed from in-patient to outpatient care. In order for the definition of day-case to be adhered to, patients must be admitted and discharged on the same day. Patients requiring removal of third molars are typically fit and healthy young adults (8) and suitable for ambulatory care. Pain is one of the main obstacles to predictable discharge(9, 10) and its control is the responsibility of both the surgeon and anaesthetist. Experienced surgeons may reduce post-operative pain and

swelling by minimising surgical trauma and time (11). Effective local anaesthesia to the area reduces post-operative pain (12, 13)

Much research has been carried out to investigate the effect of local anaesthesia on post-operative dental pain. Lidocaine and bupivacaine are two commonly used amide based local anaesthetic agents in dentistry. While latency times vary between studies (14, 15), they are in agreement that bupivacaine has a longer onset of action than lidocaine. Due to greater lipid solubility and protein binding (16), bupivacaine exhibits a longer duration of action, (14, 17). Although bupivacaine may be expected to exhibit longer analgesia, the sensation of numbness is not always considered a pleasant sensation (17).

Maximum pain after third molar surgery is typically felt during the first 8-12 hours (18, 19). Based on this fact, many studies have compared lidocaine and bupivacaine using the third molar pain model. Many of these studies used a “split-mouth” approach to compare these agents on the same patient but at different times (18, 20-22). This has the advantage of eliminating patient variables and reducing sample size. Split-mouth designs have been criticised due to “spill over” effects of the treatment and treatments being carried out at different times. This study was designed to prevent these flaws(23) and based on the fact that patients are better able to reliably compare two agents when their effects (or lack of) are recorded at the same time. All patients acted as their own control under the same operating conditions.

Pain is subjective and non-surgical factors including individual and demographic factors have been shown to impact on pain experience (24). Individual factors include psychological variables such as a predisposition to catastrophize, as well as baseline levels of anxiety and

depression. Any surgery, including third molar removal can be stressful for a patient. The association between anxiety and pain is not a new one with several studies showing a positive correlation between greater levels of anxiety and post-operative pain (25-27). It is important to consider the role of anxiety and catastrophizing in patients due to have third molar surgery. Assumptions can be drawn from validated questionnaires to aid the clinician with surgical planning and anticipating pitfalls in the recovery period.

Patient reported outcomes refer to information gained from patients and are central to a patient-centred approach to healthcare. Patient *reported* outcomes are distinct from patient *based* outcomes which may not necessarily come from the patient themselves. Outcomes measure a patient's perspective of recovery in terms of lifestyle, pain and oral function, as well as other aspects related to the surgery (28). Third molar surgery is not without morbidity. Lifestyle interruption including ability to work lasts for ~3 days (29, 30). Analysis of patient reported outcomes may help provide a more specific outlook for the post-operative period for oral surgery patients.

Patient satisfaction is an integral part of modern healthcare. The Dental Visit Satisfaction Scale, developed by Corah et al in 1984, assesses patient satisfaction with the dentist on one specific visit (31). Hence it is an appropriate tool to assess satisfaction with third molar surgery in this study as treatment was carried out on a single visit. Evaluating patient preference with different treatment modalities is often not a primary objective of research. In this study, pain scores as well as patient preference are considered.

In conclusion, the purpose of this research is two-fold:

1. To determine if longer acting anaesthetic agent bupivacaine, has a prolonged effect on the period of acute postoperative pain when compared to shorter acting agent lidocaine.
2. To determine patient's post-operative satisfaction and preference with regard to anaesthetic choice.

2.0 Literature Review

2.1 The Surgical Removal of Third Molars

2.1.1 Third Molar Extraction

Third molar extraction remains the most common procedure carried out under general anaesthetic in Ireland (4). Removal of third molars is primarily warranted due to the existence or risk of pathology. Pathology may include pericoronitis, unrestorable caries, periapical infection, cystic change or risk of caries to adjacent teeth. Since guidelines issued by the National Institute of Clinical Excellence (NICE) on the indications for the removal of third molars in 2000,removal of asymptomatic third molars has decreased (32). Despite these guidelines, there remains some dispute over prophylactic removal of third molars. Hill and Walker (33) looked at 427 lower third molars, which at initial assessment, did not require extraction according to NICE guidelines. These were monitored for 5 years and one third subsequently required extraction due to pericoronitis.

2.1.2 Impacted teeth

An impacted tooth is one that fails to erupt into the dental arch within a specific time. Third molars normally emerge into the oral cavity between 18-24 years, although there is a wide variation (34). Impaction is primarily due to lack of sufficient space for eruption in the posterior maxilla and mandible (35) . The obstruction to the path of eruption can be caused

by hard (bone or tooth) or soft tissue. The impaction rate for third molars is higher than for any other tooth in the arch (36). There is large variation in the literature regarding the prevalence of impacted wisdom teeth. Dachi and Howell (36) examined 3,874 routine full-mouth radiographs which found the incidence of impaction was 21.9 per cent for maxillary third molars and 17.5 per cent for mandibular third molars. A further study by Hugoson (37) reported a prevalence of impaction of at least one third molar as high as 72.7%.

2.1.3 Assessment of Difficulty of Third Molar Surgery

There have been many attempts to classify the type of impaction of third molars in order to predict operative difficulty. Various extraction difficulty indices exist but controversy remains over their validity in predicting surgical outcomes. A recent study has shown surgical difficulty prediction is not affected by surgeon experience (38). In 1926, Winter described the depth and angulation of the impaction using three imaginary lines (39, 40). In 1933, Pell and Gregory predicted surgical difficulty radiographically, based on the depth of the third molar within bone, its relation to the ramus of the mandible and the long axis of the mandibular second molar. This assessment has been shown to be insensitive in predicting surgical difficulty (41, 42).

Winter's assessment tool was further developed by MacGregor in 1985 to WHARFE, which includes Winter's lines, height of the mandible, angulation, root morphology, follicle development and exit pathway (43).

In recent years, more emphasis has been placed on patient variables to predict assessment of difficulty (44). Age is a significant factor, with studies showing surgical difficulty increased

with increasing age (39). Increasing age is associated with increased radiographic bone density and surgical difficulty according to Peterson (45). Ethnic diversity and male gender have been shown to impact on surgical time and difficulty (46). Again, differences in bone properties are implicated as the reason for this (39). Arduous manipulation of the soft tissues in patients with increased body mass index can also increase surgical difficulty (47).

There have been various efforts at determining a reliable model for assessment of difficulty. Although many have been postulated, none could be said to be universally acceptable. It is clear a combination of both radiographic and patient variables need to be considered when predicting difficulty of third molar surgery. Age, BMI, curvature of roots, and depth from point of elevation appear to be four of the most important variables to measure (47).

2.1.4 Surgical Technique and Expertise

Traditionally various methods have been used to remove third molars. A lingual split approach was routinely used which involved removing bone mesially and distally with a chisel and mallet to provide an application point, as well as splitting the lingual plate to allow delivery of the tooth. While post-operative pain and swelling has been shown to be less using this technique, there is also a greater risk of lingual nerve impairment (48).

The most common procedure for removal of impacted third molars involves raising a full mucoperiosteal flap and the use of rotary burs with coolant to remove buccal bone to expose the tooth. The tooth is then often sectioned to avoid excessive bone removal (49).

The piezoelectric technique was tested in oral surgery during the 1970s and has since gained a strong foothold in the surgical extraction of teeth including third molars. Advantages of

this technique include reduced postoperative swelling and trismus when compared to more conventional rotary osteotomy techniques (50). Another advantage of piezosurgery is its selective cut that recognises the hardness of tissues and works only on mineralised structures, so preventing damage to soft tissues including the mucoperiosteal flap and nearby blood vessels and nerves (51). The major disadvantage of this surgical technique is greater operative time it requires (52). Controversy exists in the literature whether such an increase in operative time is associated with increased pain levels (51, 53).

It is widely acknowledged that surgical experience is a factor in reducing post-operative pain post third molar surgery (54). More experienced surgeons typically take less time to extract third molars than their junior colleagues (55). Longer operative procedures are typically associated with more pain.

2.1.5 Normal Recovery

Extraction of third molars is recognised by patients as a potentially painful procedure. Part of the informed consent process involves a discussion on the anticipated recovery period. Clinical and health-related quality of life (HRQOL) questionnaires have been used to evaluate patient's perception of this post-operative period in terms of pain, lifestyle, oral function, and other symptoms related to the procedure (28, 56). Pain, difficulty eating and speaking, swelling and mouth opening are some of the variables that may be affected during this recovery period (56).

Pain tends to be the most feared consequence of surgery from a patient's perspective. Several studies have shown that pain will have reduced to "very weak" or "none" by the

seventh post-operative day (28, 56). While age has been shown to impact on surgical difficulty, it does not appear to correlate with increased pain and analgesic use (56, 57).

Various analgesic regimes have been advocated to combat post-operative dental pain, with an expanse of research carried out on the topic. A non-steroidal anti-inflammatory (NSAID) used in combination with acetaminophen (paracetamol) has been shown to be superior to use of either drug alone (58). Corticosteroids used in combination with an NSAID have also shown increased efficacy (59, 60). NSAIDs provide analgesia by inhibiting the cyclooxygenase (COX) enzymes COX-1 and COX-2, enzymes which are needed for the production of inflammatory mediators such as prostaglandins, prostacyclins, and thromboxanes. Glucocorticoids exert their action at virtually every step in the inflammatory process, which leads to decreased capillary dilatation, decreasing circulating lymphocytes, inhibiting fibroblast proliferation, and inhibiting prostaglandins and leukotrienes (61). Corticosteroids can be administered by intra-muscular or submucosal route to similar effect (62), although debate exists in the literature whether submucosal administration has an effect on post-operative pain or trismus (60, 62).

Lifestyle interruption, including time off work, is an important consequence of third molar surgery. Normal recovery requires an average of 3 days off work (29, 30). An interesting article by M. Colorado-Bonnin showed that greater pre-operative information regarding post-operative complications was associated with increased time off work (63).

2.1.6 Complications

Surgery is not without risks and complications. Complications can be intra-operative or post-operative and can be associated with known risk factors. Intra-operative complications of lower third molar removal include bleeding, nerve injury, incomplete removal of roots, and fracture of the mandible. Post-operative complications include alveolitis, delayed healing, postoperative infection, hematoma, osteomyelitis, or persistent pain, or swelling (11).

The most common intra-operative complication is bleeding (11). Patients with risk factors for increased bleeding include those on anti-coagulants e.g. aspirin, warfarin and heparin (64), and those with inherited or acquired coagulopathies e.g Von Willebrands, haemophilia and thrombocytopenia. The type of anaesthesia used is an important decision when operating on patients with a known bleeding disorder (65). Fortunately, the vast majority of patients requiring removal of third molars are fit and healthy young adults (8).

The most common post-operative complication is alveolar osteitis, more commonly known as dry-socket. Alveolar osteitis is identified by pain, increasing in severity in the post-operative period, recognised by absence or partial absence of a blood clot. The incidence of this varies greatly within the literature, with incidence reaching over 30% for impacted lower third molars (66). Tobacoo use and operator inexperience have been implicated in higher rates of alveolar osteitis (67, 68). Various measures have been taken to reduce the incidence of alveolar osteitis including the use of dressings and chlorhexidine preparations and are well documented in the literature (69-71). To date, no single method has gained universal success or acceptance (72).

The inferior dental nerve (IDN) and lingual nerve (LN) often run in close proximity to lower third molars. Injury to these nerves can lead to a sensory deficit presenting as numbness to the lip/ chin and tongue respectively. Experience of the operator has been shown to impact on the incidence of nerve injury (57, 58).

The reported frequency of IAN injury associated with third molar removal ranges from 0.6% and 5.3% (73).Radiographic analysis is crucial in predicting the risk of surgical damage to the IDN, which is usually closely related to the apices of lower third molar roots. An orthopantomogram is the most commonly used radiographic view to determine if a third molar is intimately related to the IDN, and has proven to be effective (73). In cases where there appears to be an intimate relationship, cone beam computed tomography (CBCT) has been shown to be more accurate in determining proximity (74).

There is marked variation of reported LN injuries in the literature from 0% to 10% (75). The LN typically runs through the lingual mucosa medial to lower third molars. Injury to this nerve has been attributed to direct injury from the scalpel or perforating the lingual plate with a surgical bur (75). Lingual flap retraction is also thought to be responsible for LN damage and is not recommended for experienced surgeons (76, 77).

Recent research has suggested administration of local anaesthetic may be a cause injury to these nerves. The aim of local anaesthetic administration for routine dentistry is to deposit the local anaesthetic close to the nerve, without inadvertent intraneural injection. Direct nerve injury can result in altered sensation or dysaesthesia, an unpleasant sensation (78).

On rare occasions, ~1%, hospitalization is required for serious infections (79). The rate of admission for infection following prophylactic removal of third molars is low (80). Antibiotic prophylaxis to prevent postoperative infection is routinely undertaken in many centres with much literature published to support and oppose this practice (81, 82) .

2.2 Anaesthesia in Oral Surgery

2.2.1 The Choice of Anaesthesia in Third Molar Surgery

The technique for removal of third molars varies little, whether carried out under local anaesthetic (LA), sedation or general anaesthesia (GA). The treatment options given to patients on initial assessment largely depend on the facilities available to the clinicians, expected difficulty of the surgery, patient's medical history, anxiety and preference (29). For dentally anxious patients refusing treatment under LA only, conscious sedation is often sufficient for third molar extractions. In-office sedation is much more cost effective than GA (83). Despite this, the literature would suggest that there has been little decrease in the number of patients having third molars extracted under general anaesthetic (XGA). According to a prospective investigation of 522 patients having third molars removed in the Eastman Dental Hospital, 52% were operated on under GA. A further 44% had extractions under LA and 3.5% had additional IV sedation(5, 29). Worrall et al. (7) found almost 70% of third molar extractions were carried out under GA, while less than a quarter were performed under local anaesthesia alone. Dunne et al.(84) found there was an increase in the number of patients having treatment under LA (31%-41%) +/- IV sedation (4%-13%) between 1995 and 2002.

2.2.2 Day Case General Anaesthesia

Despite the continuing high number of extractions under GA, the trend has changed from the traditional inpatient care to day case surgery. The definition of day surgery in the UK and Ireland is clear: the patient must be admitted and discharged on the same day, with day surgery as the intended management (85) . In the UK, the Department of Health has guided the transition from traditional in-patient procedures to surgeries being performed on an outpatient basis, through the provision of an operational guide to day case surgery (86).

While patients undergoing third molar surgery are typically young, fit and healthy, this does not mean patients with systemic disease cannot be treated on an outpatient basis. The Association of Anaesthetists of Great Britain & Ireland concludes fitness for a procedure should relate to the patient's health as determined at pre-operative assessment and not limited by arbitrary limits such as American Society of Anaesthesiologists (ASA) status, age or BMI (85).

Patient satisfaction with day case surgery has been investigated by Ross et. al. (87) who evaluated 106 patient's preoperative attitude to third molar extraction under general anaesthetic as a day case. He found 96% of patients were happy to be treated as such. Postoperatively, 91% were satisfied. Pain and nausea were the two commonest reasons for dissatisfaction post-op.

In order to ensure patients are suitable and happy to be discharged on the day of surgery, it is crucial that post-operative pain and nausea is kept to as low a level as possible. This is the responsibility of both the surgeon and the anaesthetist.

2.2.3 Local Anaesthetics in Dentistry

The origins of local anaesthesia date back to 1884 when a young ophthalmologist, discovered that cocaine instilled into his own eye produced localised insensitivity to touch and injury (88) . Local anaesthesia in dentistry also began with the clinical use of cocaine (89). This promising but controversial discovery led to the development of ester and later amide type local anaesthetics. Nowadays, due to their superior characteristics, amide anaesthetics have completely replaced ester based anaesthetics in dentistry (90). Lidocaine and bupivacaine are commonly used amide anaesthetics used in medicine and dentistry.

Local anaesthetics work by reversibly blocking voltage-gated sodium channels to prevent nerve conduction. To do this they must first cross the lipophilic lipoprotein membrane in a neutral unionised form. If a sufficient number of sodium channels are blocked, the threshold potential will not be reached and pain signalling is prevented (88).While the mechanism of action is the same for lidocaine and bupivacaine, they differ in their affinity to the sodium channels. Lidocaine binds and dissociates rapidly from the channel, whereas bupivacaine binds rapidly, but dissociates more slowly. The onset of action is directly related to the pK_a of the local anaesthetic solution with smaller pK_a values being associated with shorter latency. Bupivacaine has a pK_a of 8.1 while lidocaine has a pK_a of 7.7. Bupivacaine's higher value means that a normal tissue pH of 7.4, it would have fewer free molecules to diffuse through the nerve membrane resulting in a slower onset time (14).

Lidocaine was first introduced in the market in 1948(91) and now comes available in 2% and 3% solution, with or without epinephrine. Lidocaine remains the most commonly used anaesthetic, against which others are compared (20). Lidocaine (with epinephrine) has been shown to provide soft tissue anaesthesia from 50 minutes (dental pulp) to 120 minutes (soft tissue) (92). Latency time varies from ~2-3 minutes (93) to ~4-5 minutes (14) depending on whether the onset of soft tissue or pulpal anaesthesia was tested. Max dose for lidocaine with epinephrine is 7mg/kg.

Bupivacaine is also an amide but tends to have a longer duration of action due to its superior protein-binding characteristics (16). It demonstrates greater lipid solubility resulting in lower concentrations being required in practice to produce clinical effectiveness. Bupivacaine can provide analgesia during the first 8–12 hours depending on the strength of solution and presence of a vasoconstrictor (14, 17, 94). Latency time also varies according to testing criteria and varies from ~3 minutes (15) to ~6 minutes (14). Max dose of the drug (without adrenaline) is 2mg/kg.

2.2.4 Lidocaine versus Bupivacaine

A vast amount of research has been carried out to compare the efficacy of lidocaine and bupivacaine in dentistry. These local anaesthetic agents have been compared using the third molar pain model, as the pain model's reproducibility has been well established (95).

Many of these studies compare lidocaine and bupivacaine using the patient as their own control on separate occasions (20-22, 92, 96). The objectives of these studies varied with

few considering patient preference (21, 96). The majority of these studies focused on pain relief provided by each anaesthetic on separate occasions (22, 97, 98).

Pain intensity following third molar surgery reaches a maximum between 3 and 5 hours following surgery (19). This would imply bupivacaine would be the anaesthetic of choice for third molar surgery, which is associated with prolonged periods of post-operative pain. A disadvantage of bupivacaine is the longer onset of action time, when compared to lidocaine(99), if treatment is carried out under LA only.

2.3 Post-Surgical Pain

2.3.1 Pain

Pain is not simply a signal for tissue injury, but is primarily a signal to the organism to seek repair and recuperation. –P. D. Wall(100)

Pain associated with tissue damage or inflammation is described as nociceptive pain, which involves the normal neural processing of pain when free nerve endings are activated. Surgical incision leads to cell disruption and subsequent intracellular release of phospholipids and a state of widespread inflammation depending on the degree of surgical trauma (101). Nociception involves the processes of transduction, transmission, and perception. Tissue damage, such as surgery, releases chemical mediators, prostaglandins, bradykinin, serotonin, substance P, and histamine. These substances activate nociceptors, resulting in the generation of an action potential. The action potential is then transmitted

along afferent nerve fibres to the spinal cord. From the spinal cord it travels to the thalamus and midbrain and finally to several regions in the brain where pain is then “perceived” (102).

2.3.2 Acute and Chronic Pain

Acute pain is provoked by a specific disease or injury, serves a useful biologic purpose, and is self-limited (103). Third molar removal typically requires surgery which results in tissue injury and moderate to severe post-operative pain. As third molar surgery is a common procedure, it is the model most used in acute pain trials (104).

Patients become increasingly more sensitive to painful stimulus the longer the pain is uncontrolled (100). Hyperalgesia is the state where a painful stimulus causes more pain than normally expected. With increased irritation, nerve fibers normally not associated with pain sensation are recruited, with nonpainful stimuli now inducing pain; a state of allodynia (105).

If acute pain is not managed appropriately, it may progress to chronic pain. Because definitions of chronic pain vary widely, chronic pain may be loosely described as pain that extends beyond the expected period of healing (106). Plasticity refers to changes that occur in the established nervous system in chronic pain. Injury, inflammation, and disease can all cause neuronal plasticity and increased pain by means of increased excitatory or decreased inhibitory mechanisms (107). Chronic pain post third molar removal is not a frequently occurring event (107). Nonetheless, it is imperative as clinicians that we recognize pain, as failure to do so can have detrimental effects on our patients (100).

2.3.3 Pain and Personality

Pain is subjective, as can be explained by the same stimulus initiating different reactions in different individuals' e.g local anesthetic administration. The concept of a "pain-prone" personality attempted to explain this phenomenon (108), but pain perception and interpretation is a more complex matter.

Dental fear is one of the most frequent common fears (109), with fear of experiencing pain a constant worry, particularly for patients undergoing dental surgery(110). Such anxiety can be based on previous exposure to pain, experiences of family and friends or a general anxiety trait(111).

Many attempts have been made to evaluate a patient's predisposition to anxiety through use of questionnaires. In 1983, Zigmond and Snaith developed The Hospital Anxiety and Depression Scale (HADS) to identify anxiety disorders and depression in non-psychiatric hospital settings. This tool has proven to be brief, but as effective as other more arduous questionnaires (112, 113) in determining pre-existing anxiety and depression. Other questionnaires such as Corah's Anxiety Scale (DAS), and the Dental Fear Survey (DFS) (114) may aid in predicting how a patient may react to surgery.

The anxiety scale of the State-Trait Anxiety Inventory (STAI) may be used to assess if the patient is predisposed to anxiety (114, 115) which may impact on the ability to carry out the intended treatment.

Studies have shown anxiety relating to the pain-inducing stimulus will exacerbate pain (116, 117). It is important that anxiety prior to third molar surgery is addressed in order to foresee potential difficulties in the intra and post-operative period.

The term catastrophizing was first introduced by Ellis in 1962 to describe mal-adaptive cognitive style employed by patients with anxiety or depression. Pain catastrophizing can impact on post-operative expectations and pain. It is described by Quartana et al as a "negative cognitive-affective response to anticipated or actual pain" (118). In 1995, O' Sullivan et al developed a pain catastrophizing scale (PCS) which asks patients to reflect on previous painful experiences, in an attempt to foresee future problems and tailor individual treatment plans (119).

It is important to consider the role of anxiety and catastrophizing in patients due to have third molar surgery. Assumptions can be drawn from these validated questionnaires to aid the clinician with surgical planning, and anticipating pitfalls in the recovery period.

2.3.4 Pain and Gender

Research in the area of pain and gender suggests that females have a greater propensity for experiencing and complaining of pain (120). Chronic pain conditions are more frequently reported by females than males (121). This study also suggests depression as a co-morbidity is twice as likely to occur in females as in males with chronic pain.

So why do females report pain more frequently than their males counterparts? Sociocultural, psychological and biological factors are believed to be responsible (122). It is believed females are more likely to report pain and seek medical attention for pain related

matters (123, 124). "Gender norms" may account for why males do not admit to pain as easily as women (125).

Numerous animal and experimental studies have been carried out to investigate if a biological reason for these observed differences exist. It is generally well accepted that female rodents have a lower pain threshold to hot thermal, chemical, inflammatory and mechanical nociception (126). Animal studies have also speculated that female and male animals respond differently to opioid antinociception. Again conflict exists as to whether this is a one dimensional assumption that male animals have a more robust response to opioids, which does not take into account variation in animal strain and opioid receptor subtypes (126). The concept does suggest that analgesia should be tailored based on whether the patient is male or female.

Animal research resulted in a change in American research policy in 1994 to ensure all human clinical trials had a representative female sample. This led to several studies which supported the evidence that females have less tolerance to noxious stimulation than their male counterparts (127). The reproductive and menstruation status of a female patient has been implicated in contributing to lower pain thresholds in females. Smith et al found higher pain reports during the low estradiol phase of the menstrual cycle (128). Conversely, high estradiol phases revealed similar pain thresholds to men (129).

Many studies on post-operative pain following third molar surgery have revealed more post-surgical pain in females than males (56, 130). Painkiller consumption however has not been shown to vary between male and female patients (54, 57). This may reflect the fact that situational and psychological factors can play a major role in symptom perception.

2.3.5 Pain Relief Regimes for Third Molar Extraction

Pre-emptive anaesthesia is not a new phenomenon. The concept of pain prevention was first introduced by Crile in 1913, and further developed by Woolf in 1983. Pain associated with tissue damage results in prolonged modulation of the somatosensory system, with increased responsiveness of both peripheral and central pain pathways. Pre-emptive analgesia is a treatment that is initiated before and is operational during the surgical procedure in order to reduce the physiological consequences of nociceptive transmission provoked by the procedure. It aims to provide analgesia to 'pre-empt' the neurophysiological and biochemical consequences of a noxious (painful or injurious) input to the CNS, rather than to begin treatment when these consequences are already established (131).

Theoretically, local anaesthetics administered prior to surgery commencing should prevent impulses being transmitted to the central nervous system. Gordon et al. (132) showed that preoperative local anaesthetic may reduce the post-operative demand for analgesics. Møiniche et al. (133) however carried out a systematic review of pre-emptive analgesia for postoperative pain relief. Results did not advocate implementation of pre-emptive analgesia. Similar results of studies involving third molar surgery suggest that pre-emptive analgesia using local anaesthetic does not prevent the onset of pain but merely delays it (134). Wishing to clarify the theory of pre-emptive analgesia in third molar removal, Nayyar and Yates (18) carried out a randomised controlled trial of 45 patients who had bilateral impacted third molars. These were treated under general anaesthetic and acted as their own control whereby bupivacaine was given to one side only. The opposite side did not

receive LA. The authors found that bupivacaine was effective in blocking peripheral nociceptors with a resultant reduction in postoperative pain. Differences in pain 24 h, 48 h and 7 days post-op were not significant however.

Acute post-operative pain following third molar removal is largely treated with combination therapy. Paracetamol and NSAIDs provide mild to moderate pain relief, with opioids providing additional relief for severe pain (135). The benefits of this multimodal approach comes from the differing pathways in which these drugs combat pain. When using these combination analgesics one should still follow the principle of maximizing the non-opioid before adding the opioid.

Paracetamol is considered an anti-pyretic analgesic drug with the advantage of having few adverse effects (136). Due to the lack of anti-inflammatory properties, paracetamol alone is not commonly considered to be sufficient for the treatment of post-operative pain following third molar removal (58). Some studies however have rejected this concept with a study by Bjørnsson et al showing comparable results in terms of post-operative pain and swelling following a three day regime of ibuprofen versus paracetamol (137). Paracetamol in combination with an opioid, typically codeine, has been shown to provide enhanced analgesia (136, 138, 139).

NSAID's have been used and studied extensively in all aspects of surgery; pre-, intra-, and post-operatively. Ibuprofen, diclofenac sodium and (dex)ketoprofen are commonly prescribed for their analgesic properties. Ibuprofen tends to be the drug of choice when comparisons are made between NSAID's and placebo or other drug groups, and has a long history in the dental setting (140-142). Ibuprofen can be purchased over the counter and

has less adverse effects than other traditional NSAID's (143). Conventional NSAID's e.g ibuprofen, diclofenac and naproxen, are non-selective and have a propensity for adverse gastrointestinal events. This is believed to be caused by impairment of prostaglandin induced mucosal protective mechanisms (144). Selective COX 2 inhibitors e.g rofecoxib and celecoxib have been developed to reduce these adverse effects, but long term high dose use has been associated with increased incidence of myocardial infarction and stroke (145). Pain post third molar surgery is typically relatively short in duration and therefore traditional NSAID's can be utilised without major risk of serious gastrointestinal injury.

Opioids are used for relief of moderate to severe dental pain, often in combination with paracetamol and a NSAID (146). Opioids act on three major receptors on neuronal cell membranes; mu, delta and kappa to prevent neurotransmitter release causing analgesia (147). Tramadol is stronger than codeine or a paracetamol/ codeine combination (148), and can be used effectively for break through pain post third molar surgery (149, 150). Fentanyl, a short acting opioid can be used at induction of general anaesthetic or for post-operative pain relief (151). The use of opioids should be restricted due to significant side effects. All opioids result in dose dependent respiratory depression, constipation, nausea and vomiting, and sedation, as well as mood disturbance and dependence in certain cases (152).

There is no gold standard for pain relief following third molar surgery with ongoing dispute over the most effective pharmacological management (136). Prescribed analgesia should be tailored depending on age, co-morbidities, surgical difficulty on a case by case basis.

2.3.6 Pain Assessment

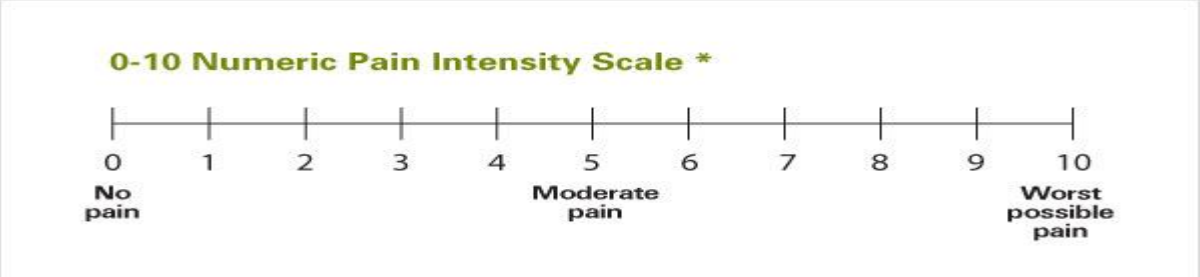
Pain is an expected outcome of surgery, and one that requires measurement. With an abundance of tools available to measure patient outcomes, Fitzpatrick *et al (153)* have provided a framework to choose the correct instrument through the provision of 8 criteria. They believe the chosen instrument should be;

- appropriate, i.e. it should match the specific purpose of the study;
- reliable, in terms of reproducibility and internal consistency;
- valid, in that it measures patients' perceptions of pain;
- responsive to changes of importance to patients;
- precise (accurate and discriminating);
- interpretable, in that meaningful scores are produced;
- acceptable to those completing it;
- feasible, i.e. the degree of burden and effort involved in using it is acceptable.

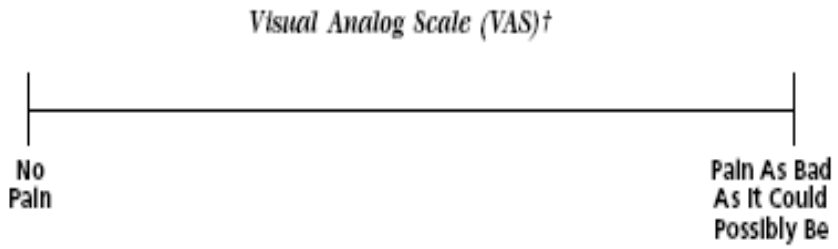
The Verbal Descriptor/ Rater Scale (VD/RS) was devised by Keele in 1948 using three to five numerically ranked words to indicate level of pain e.g. "none", "mild", "moderate". This has since been adapted and used in combination with various questionnaires and other pain measures (154). While still popular, patients are restricted to using one word only to indicate pain intensity. Different pain thresholds and subjectivity may result in ambiguous results.

The Numerical Rating Scale (NRS), devised by Downie *et al* in 1978 (155), describes pain as a numerical value with 0 indicating no pain and 10 indicating severe pain. A NRS has the

advantage of using numbers rather than words, which can be interpreted differently. A sound knowledge of the English language is also unnecessary. This tool may be limited for use with those of extremes of age (154).



The Visual Analogue Scale was developed in 1978 by Maxwell *et al*. It consists of a 100mm horizontal line with anchors at each end. The left end represents no pain, with the right side representing unbearable pain. Patients are asked to make a mark on the line to indicate their level of pain. The mark is then measured in mms which can then be analysed by a researcher using parametric tests. In contrast to the VDS and the NRS, patients need not express their level of pain using a discrete word or number. Non-parametric tests are required for ordinal data produced by VDS and NRS, which are less sensitive than parametric tests used for analysis of VAS data. Concern however has been raised over its use in the post-operative period if the patient has had a general anaesthetic, due to potential nausea and visual disturbance affecting its completion (156). Despite the range of tools available, the VAS is still the preferred method used for measurement of a patient's pain (157).



Pain assessments help guide the provision of analgesics post-surgery. However results of such assessments do not always correlate with a requirement for analgesics (158).

In order to gain a more rounded view of pain, questionnaires are often utilised. The McGill Pain Questionnaire is another self-reporting method, used to demonstrate and address the multidimensional nature of pain. Developed by Melzack, in its full form it is divided into three categories to evaluate patient pain; sensory, affective and evaluative (159). It provides quantitative measures of clinical pain which can be analysed statistically. Where time is limited, and a short form is now available which has shown to be as reliable as the original (160). Prediction of post-operative pain using an electrical pain stimulus has been used in other medical settings (161) but has not been tested using the third molar pain model.

2.4 Patient Satisfaction and Third Molar Surgery

2.4.1 Patient Satisfaction

In 2012, the Health Information and Quality Authority (HIQA) of Ireland developed *National Standards for Safer Better Healthcare (162)*. "Person- centred care and support" was one of the key themes discussed. In order to fulfil this recommendation, it is advised that patients be at the core of all aspects of health provision. Input from service users should be sought in the planning and design of healthcare services, and feedback mechanisms should be in place in order to review and improve services provided.

These recommendations led the Health Service Executive (HSE) to release a staff guide for using patient feedback to improve health services(163). As satisfaction is subjective, the HSE have advised patient experience be the measures outcome, rather than patient satisfaction. This is to be done through use of quantitative patient experience surveys, analysis of received complaints, population surveys and forums, and focus groups. Using a range of these methods leads to a well-rounded insight into patient experience of service provision.

Patient satisfaction affects clinical outcomes, malpractice claims and patient retention (164). Feedback can be used to facilitate changes to improve provision of care at various levels within a health system. Likewise, poor patient satisfaction correlates to increased litigation (165, 166). Nowadays patient dissatisfaction can all too quickly progress to litigation.

However a dissatisfied patient is less likely to instigate legal proceedings if they have had prompt, clear communication following a complaint(167).

Studies on the deterioration of a patient's quality of life following surgery for removal of third molars has been well documented over the past twenty years (168, 169). Patient satisfaction is more likely once they have been given sufficient information regarding the procedure and post-operative period (170).

2.4.2 Patient Education

Providing patients with sufficient information before a procedure is carried out is a fundamental and legal aspect of dental surgery. Patients are educated regarding their third molar surgery and post-operative effects at consultation, often with a combination of oral and written explanations. Video modelling to aid patient's decision making has been shown to be successful (171, 172), however video demonstrations to provide information prior to third molar surgery has been shown to increase anxiety (170).

Three types of coping styles exist; vigilant, avoidant and fluctuating coping (173). "Vigilant" patients are those who benefit from obtaining as much information as possible, and in whom information reduces anxiety. Avoidant copers avoid excess information as knowledge increases anxiety. Fluctuating copers fall between the two categories. Baume et al (174) found avoidant copers were less anxious during dental surgery.

Conflicting theories exist regarding the effect the process of informed consent has on patients awaiting third molar surgery. Torres et al (175) found verbal and/ or written information had no patient reported effect on anxiety prior to third molar surgery. On the

other hand, Casap et al (176) found statistically significant changes in physiological parameters in patients who received detailed informed consent, compared to another group who were given a simplified version.

A delicate balance exists between providing enough information in order to give *informed* consent, and giving too much information which may deter a patient from going ahead with a necessary surgery. An assessment should be made by the clinician to decide how much information should be given. With information being readily available via the internet, patients are often over informed. Clinicians should be aware that patients may be obtaining information of variable quality online and should be prepared to offer suggestions for reliable online resources for those patients (177).

Patient education is required from a medico-legal, as well as patient care point of view. Patients given sufficient postoperative preparatory information are more likely to be satisfied in the post-operative period, as well as reporting less pain (170).

2.4.3 Measurement tools for Patient Satisfaction

Donabedian's name is synonymous with the concept of quality assessment in healthcare, a notion first described in 1966 (178) and built on by further research (179-181). Patient satisfaction is a core element of assessment of quality in these studies and is now mandatory in many countries (182). Its definition is as controversial as the way in which it should be measured. Patient satisfaction has been variously defined as 'an individual's positive evaluations of distinct dimensions of health care' (180) and more recently as the "extent of an individual's experience compared with his or her expectations"(183). Patient

satisfaction may be interpreted as subjective and objective. For example waiting time can be measured objectively in hours/ days and also interpreted subjectively by a patient who may feel this waiting time was longer/ shorter than expected (184). Patient socio-demographics have been shown to influence patient satisfaction outcomes. Greater age and lower education have shown significant association with greater satisfaction with medical care (184, 185). Patient- practitioner interaction has also been shown to impact greatly on overall patient satisfaction with a service (186, 187).

Feedback can be solicited from patients in a variety of ways: phone surveys, written surveys, focus groups or personal interviews (188). The issue of social desirability, for example participants providing a response they feel is more desirable or socially expected, is debated in the literature with conflicting evidence as to whether or not it exists (189, 190). Questionnaires have been the most common assessment tools for recording patient satisfaction (191). These can be carried out via telephone, interview based or patient self-completing and all are expected to yield equivalent responses (192). Standardised questionnaires have the advantage of greater validity and reliability, however the range of questions available are limited. Private vendors often provide questionnaires for inpatient care, while in-house compilations of standardised and private questionnaires are often used for feedback of outpatient services (182).

Involvement of patient opinion in the Irish health care system stems from the health strategy “Quality and fairness: a health service for you’ (193). Work has been carried out to standardise how feedback is recorded, however the majority of studies have focused on inpatient care. To address this, the Royal College of Surgeons Ireland published

recommendations for developing and using questionnaires to capture patient feedback with outpatient services (190). This document advises questions be clearly numbered or sequenced, logical and easily understandable by patients, and as short as possible. An example of such is the dental visit satisfaction scale (DVSS).

The DVSS was developed by Corah et al in 1984 to assess patient satisfaction with the dentist on one specific visit (31). Hence it is an appropriate tool to be used to assess satisfaction with third molar surgery which is often carried out in a single visit. The questionnaire assesses satisfaction using three subscales; information/communication, understanding/acceptance and technical competence. An overall measure of satisfaction was also addressed. Patients rate their response to standardised statements on a 5 point scale, each of which is allocated a score that can then be analysed.

2.4.4 Patient Reported Outcomes in Third Molar Surgery

Patient reported outcomes refers to information gained from patients. It is distinct from patient based outcomes which may not necessarily come from the patient themselves. Outcomes measure a patient's perspective of recovery in terms of lifestyle, pain and oral function, as well as other aspects related to the surgery (28).

Outcomes are normally evaluated through use of questionnaires. In 1994, a 49 point questionnaire developed by Slade it al (194) evaluated the dysfunction, disability and discomfort associated with oral conditions. This was then condensed to a 14 point questionnaire in 1997. In 1999, Conrad et al (56) developed a 21 point quality of life questionnaire to assess patient's perception of recovery following third molar surgery. Four

main areas were assessed using Likert type scales: lifestyle, oral function, general activities and other symptoms.

Various versions and adaptations of these oral health impact profiles exist which all aim to provide a more holistic approach to understanding what a patient will expect following dental surgery. Such feedback is also important for clinicians providing accurate information for informed consent.

2.5 Summary of the Literature Review

2.5.1 The Surgical Removal of Third Molars

- Despite guidelines introduced by the National Institute of Clinical Excellence (UK), third molar surgery remains the most common procedure carried out under general anaesthetic in Ireland.
- Pericoronitis, associated pathology and caries are the most common reasons for extraction.
- Assessment of difficulty is based on the nature of impaction both clinically and radiographically, as well as patient variables such as age, gender, race and BMI.
- Pain and swelling is dependent on surgical technique as well as operator experience. Such morbidity is responsible for an average of 3 days off work.
- Complications of surgery include bleeding, iatrogenic nerve damage, incomplete removal of roots, and fracture. Alveolar osteitis is the most common inflammatory complication.

2.5.2 Anaesthesia in Oral Surgery

- Choice of anaesthesia largely depends on the facilities available, expected difficulty of the surgery, patient's medical history, anxiety and preference.

- Patients undergoing third molar surgery are typically young, fit and healthy and are a suitable cohort of patients for day case surgery. Consistent discharge is dependent on the absence of pain and nausea.
- Pain intensity following third molar surgery reaches a maximum between 3 and 5 hours following surgery.
- Lidocaine and bupivacaine are commonly used amide anaesthetics in third molar surgery. Bupivacaine has a longer onset and duration of action.

2.5.3 Post-Surgical Pain

- Third molar removal typically requires surgery which results in tissue injury and moderate to severe post-operative pain
- Pain is subjective and the concept of a “pain-prone” personality attempts to explain how patient variables affect post-operative pain. Females experience greater pain than their male counterparts following third molar surgery.
- It is important to consider the role of anxiety and catastrophizing in patients due to have third molar surgery.
- Evidence for pre-emptive analgesia is equivocal.
- There is no gold standard for pain relief following third molar surgery with ongoing dispute regarding the most effective pharmacological management. A multimodal approach is the typical means to achieve effective pain relief.
- Prescribed analgesia should be tailored depending on patient factors, and surgical difficulty on a case by case basis.

- Despite the range of tools available, the VAS is still the preferred method used for measurement of patient's pain for scientific research.
- The McGill Pain Questionnaire is a self-reporting method, used to demonstrate and address the multidimensional nature of pain.

2.5.4 Patient Satisfaction and Third Molar Surgery

- "Person- centred care and support" ensures patients are at the core of all aspects of health provision.
- Patient satisfaction is more likely once they have been given sufficient information regarding the procedure and post-operative period.
- Standardised questionnaires have the advantage of greater validity and reliability, however the range of questions available are limited.
- The Dental Visit Satisfaction Scale assesses satisfaction using three subscales; information/communication, understanding/acceptance and technical competence.
- Patient outcomes measure a patient's perspective of recovery in terms of lifestyle, pain and oral function, as well as other aspects related to the surgery.

3.0 Methodology

Following a review of the literature we decided to carry out a prospective interventional clinical trial to examine the differences in pain perception comparing lidocaine to bupivacaine in terms of patient satisfaction.

3.1 Aims

The aims of the study were twofold:

1: To determine patient's post-operative preference and satisfaction with regard to anaesthetic choice.

2: To determine if longer acting anaesthetic agent bupivacaine, has a prolonged effect on the period of acute postoperative pain when compared to shorter acting agent lidocaine.

3.2 Hypotheses

1. $H_{0:}$ There is no difference in patient satisfaction and preference when lidocaine is compared to bupivacaine for removal of third molars.

   $H_{1:}$ There is a difference in patient satisfaction and preference when lidocaine is compared to bupivacaine for removal of third molars.

1. $H_{0:}$ There is no difference in level of pain experienced by patients following surgery when lidocaine is compared to bupivacaine.

H_1: There is a difference in level of pain experienced by patients following surgery when lidocaine is compared to bupivacaine.

3.3 Ethical Approval

Ethical approval was obtained from the Clinical Research Ethics Committee Cork in April 2013. This study commenced in May 2013.

3.4 Sample size

The very approximate standard deviation of VAS score difference (s.d.=22) from an unpublished study to compare lidocaine with 'no anaesthetic' was used in determining an approximate sample size. To allow for a difference of 10mm VAS to be seen in the 3-8 hours post-operatively, and for a non-compliance rate of 30%, 80 patients were required in order to achieve a power of 90% at the 5% level of significance.

3.5 Recruitment

85 ASA I or II patients having both similarly impacted lower third molars teeth surgically extracted under general anaesthetic were recruited following informed consent, (Appendix I).

Exclusion criteria:

- Use of analgesics for any reason within 24hrs of the operation
- Pre-existing pain conditions other than that relating third molars

- Pregnancy, poorly controlled systemic disease e.g diabetes & hypertension, psychiatric illness, neurological disease, learning difficulties
- Prisoners
- Patient refusal

3.6 Method

Standardised general anaesthetic was provided by one of two experienced anaesthetists. Standard monitoring was in place including pulse oximetry, electrocardiography, non-invasive arterial blood pressure, and monitoring of inspired and end-tidal partial pressures of sevoflurane, carbon dioxide and oxygen. Anaesthesia was induced using propofol and maintained using clinically indicated concentration of sevoflurane in an oxygen/air mixture. Muscle relaxation was achieved with atracurium and the patients' tracheas intubated with an appropriately sized nasal endotracheal tube.

Standard preoperative analgesia included solpadeine (paracetamol and codeine), diclofenac sodium and oxycontin. Intraoperative analgesia included intravenous fentanyl. Dexamethasone 8mg IV was administered routinely as an antiemetic. Further analgesia (tramadol, fentanyl or morphine) was administered postoperatively as required.

Bilateral wisdom tooth removal was carried out by one experienced surgeon. The anaesthetic containing 2% lidocaine with 1:80000 adrenaline was administered on one side of the mouth. A 2.2 ml cartridge was administered as an inferior dental block, with a further 2.2ml administered as a buccal infiltration.

0.5% plain bupivacaine (*marcain*) was administered on the opposite side of the mouth. 5ml of solution was drawn up in a 5ml syringe from a 10ml bottle. 2ml was administered as an inferior dental block using a 22 gauge needle and a further 2ml administered as a buccal infiltration. Extractions involved incision/ raising of a full mucoperiosteal flap, ± buccal bone removal, ± tooth division. All sockets were irrigated with saline and sutured using 4.0 vicryl.

In each case the surgeon completed a standard pro forma post operatively to allow comparison of right and left third molars. This included:

- State of eruption (partially erupted, unerrupted)
- Type of impaction based on Winters classification system (vertical, mesioangular, distoangular, horizontal)
- Technique employed (elevation only, bone removal and elevation, bone removal, tooth division and elevation)
- Duration of surgery

At discharge all patients were given standard post-operative instructions and received a prescription for paracetamol 500mg two tablets 6 hrly orally, dexketoprofen 25mg tablet 8 hrly orally, and oxynorm 5mg 6hrly orally as required for three days.

3.7 Data Collection

Patient demographics including patient's date of birth, gender, ASA grade, contact details and smoking status were recorded preoperatively. The following assessments were carried out by a single investigator (CMC):

The McGill Pain Questionaire (short form) (SFMPQ), Pain Catastrophising Scale (PCS), and Hospital Anxiety and Depression Scale (HADS).These were applied preoperatively and repeated at discharge.

Pain assessment using a 100mm visual analogue scale (VAS) was used to assess pain for both right and left sides independently. This was carried out by the patient immediately post operatively, at 30mins, and at 1 hour prior to discharge (phase I) (Appendix II). VAS was marked at 3, 4, 6, and 8 hours on the day of surgery (phase II) (Appendix III), and every 24 hours for seven days (phase III). These were used to compare the pattern and level of pain experienced on both sides.

Additional analgesic use and satisfaction were recorded prior to discharge. Satisfaction ratings were assessed using a modified version of the Dental Visit Satisfaction Scale (DVSS). This included a free text section to comment on matters not covered.

Each patient included in the study was given a pain diary to complete nightly for 7 days following surgery, and a further DVSS to complete on the 7th postoperative day (POD). The pain diary consisted of VAS pain scores for right and left sides of the mouth, a record of analgesic consumption and impact on daily life. All patients were contacted by telephone or email one week following surgery to determine whether they were still experiencing any adverse outcomes and to ensure return of the pain diary by post.

3.8 Statistical Analysis

Data was analysed using SPSS 18.0 (SPSS, Chicago, Illinois, USA). Frequency counts, percentages, means, standard deviations, medians and quartiles were used to summarize data. Data was assessed for normality using histograms, Normal Q-Q plots and the Shapiro Wilk tests. The Shapiro Wilk test was not used to test for normality for variables with relatively few distinct values. In such cases normality was judged graphically. Differences were computed for paired data and tested for normality. A bootstrap paired samples test (based on 5,000 bootstrap samples) was applied when differences were not normally distributed and where suitable transformations were not found. Many of these *difference* variables were rejected for normality due to either skewness or kurtosis. Although the paired t-test is robust to violations of the normality assumption and similar conclusions would be reached using the test, we opted to report the more accurate bootstrap significance levels and confidence intervals where applicable.

"Bootstrapping is a method for deriving robust estimates of standard errors and confidence intervals for estimates such as the mean, median, proportion, odds ratio, correlation coefficient or regression coefficient." It may also be used for constructing hypothesis tests. Bootstrapping is most useful as an alternative to parametric estimates when the assumptions of those methods are in doubt…." SPSS

Group comparisons of highly skewed variables and ordinal data were analysed using the Wilcoxon signed-rank test and the Kruskal- Wallis test as appropriate. For categorical

variables Chi-squared test was performed. Spearman's Rho correlation coefficients were computed to test for association between highly skewed interval and/or ordinal variables. All statistical tests were two-tailed.

4.0 RESULTS

4.1 Demographics

4.1.1 Age

Eighty five patients were enrolled in this study. Age ranged from 16 to 44 years with a median age of 20.3 (lower quartile 17.7 years, upper quartile 26.25 years), Table 1.

Table 1: Age Groups of Study Participants

Age	Frequency	Percentage
16-20	46	54.1
21-25	17	20
26-30	18	21.2
31-35	2	2.4
36-40	1	1.2
41-45	1	1.2
Total	85	100

4.1.2 Gender

There were 26 males and 59 females enrolled in the study accounting for approx. 30% and 70% respectively, as shown in Table 2.

Table 2: Gender of Study Participants

Gender	Frequency	Percentage
Male	26	30.6
Female	59	69.4
Total	85	100

4.1.3 ASA Grade & Smoking Status:

This study was limited to ASA I and II patients. Over 90% of these patients were ASA grade I representing a healthy cohort of patients.

Non-smokers accounted for 88% of the overall number of subjects, Table 3

Table 3: Smoking Status of Study Participants

Smoker	Frequency	Percentage
Yes	10	11.8
No	75	88.2
Total	85	100

A test for association was conducted between ASA grade and smoking status (Table 4) and this was statistically significant (Fishers Exact Test; p= 0.049). Results revealed 3/10 (30%) of

smokers were ASA 2, compared to 5/75 (6.7%) of non-smokers. However according to Phi this association is weak p= - 0.257.

Table 4: ASA Grade by Smoking

ASA	Smoker	Non-Smoker	Total
1	7	70	77
2	3	5	8
Total	10	75	85

4.2 Pre-operative assessment

4.2.1 Pre-Operative Pain Catastrophizing Scale

A Pain Catastrophizing Scale (PCS) was used pre- and post-operatively to detect those study participants who may be predisposed to catastrophizing or viewing a situation as considerably worse than what it actually is. This questionnaire includes 13 statements which refer to the thoughts and feelings of those who are in pain (Appendix IV).

Each statement is rated on a scale of 0 to 4. The maximum score for the questionnaire is 52. The higher the score, the more likely the patient is to catastrophize. A score of 30 or more is thought to be clinically relevant. In this study, 8.4% of patients scored above this level. Table 5 outlines the descriptive statistics computed following analysis of PCS scores.

Table 5: Descriptive Statistics PCS Scores

N		85
Median		11
Minimum		0
Maximum		38
Percentiles	25	5
	50	11
	75	22

4.2.2 Pre-Operative Hospital Anxiety and Depression Scale

A questionnaire to determine the level of anxiety and depression experienced by patients participating in the study was completed pre- and post-operatively. The Hospital Anxiety and Depression Scale (HADS) is a questionnaire with 14 statements, 7 relating to anxiety, and 7 relating to depression (Appendix V).

For each question patients were asked to tick one of the four options which best described them. Each item is scored from 0-3 with a maximum score of 21 for both anxiety and depression. A score of 8/21 is considered "borderline" for either anxiety or depression, with a score > 11 representing "moderate" psychological morbidity. See Table 6 and Table 7 for "anxiety" and "depression" subsets respectively.

Table 6: Pre-op HADS Anxiety

Pre-op HADS Anxiety	Frequency	Percent
Normal (0-7)	79	92.9
Borderline (8-10)	6	7.1
Total	85	100

Table 7: Pre-op HADS Depression

Pre-op HADS Depression	Frequency	Percent
Normal (0-7)	79	92.9
Borderline (8-10)	6	7.1
Moderate (>11)	2	2.4
Total	85	100

4.2.3 Pre-Operative Short Form McGill Pain Questionnaire

The Short Form McGill Pain Questionnaire (SF-MPQ) consists of 15 descriptors of pain which are rated on an intensity scale (Appendix VI). Eleven of these are sensory descriptors while the remaining 4 are affective terms. All patients were asked to indicate the level of pain they were experiencing at that moment in time by ticking the appropriate circle ranging from “none” to “severe”. Each question was scored from 0-3 with a maximum score of 33

for the sensory subset, and a maximum of 12 for the affective subset. Three pain scores were calculated and are shown in Table 8.

1. The sum of the intensity rank values for sensory words chosen
2. The sum of the intensity rank values for the affective words chosen
3. The total sum of the descriptors (sensory & affective)

Table 8: Frequency Distribution of Pre-Operative SF-MPQ

Score	***Sensory***	***Affective***	***Sum total of sensory and affective***
0	74 (87%)	79 (93%)	70 (82%)
1-6	11 (13%)	6 (7%)	14 (17%)
7-12	0 (0%)	0 (0%)	1 (1%)

4.2.4 Effect of Pre-Operative Assessments on Pain Scores

Spearman's Rho (r_s) was used to measure the strength of the association between two variables where the values were ranked.

There was no evidence of an association between pre-operative PCS scores and total phase I VAS scores (r_s =0.107; p= 0.343).

Greater total phase I VAS scores were not associated with higher HADS scores for anxiety and depression. Spearman's correlation coefficient, based on original data of Vas Phase I

and HADS pre-anxiety and depression were r_s = 0.181 and r_s = -0.061, respectively and both were not statistically significant.

There was no evidence of an association between VAS for phase I and pre-operative sensory (r_s =-0.147; p= 0.194), affective (r_s =0.054 p= 0.633) and total sum (r_s = -0.080; p= 0.479) MPQ scores.

4.3 Third Molar Assessment

4.3.1 Classification of Third Molars

Winters classification for lower third molars was recorded by the surgeon for each case. Here 81% (69/85) of cases were symmetrical, Table 9.

Table 9: Winters Classification Comparing Right and Left Third Molars

		Left Third Molar				Total
		Vertical	Mesioangular	Distoangular	Horizontal	
Right Third Molar	Vertical	21	1	1	1	24
	Mesioangular	5	36	2	2	45
	Distoangular	0	2	8	1	11
	Horizontal	0	1	0	4	5
Total		26	40	11	8	85

4.3.2 Surgical Technique

Surgical technique was recorded by the surgeon for each case. Surgical technique was identical in 74% of cases. Of the 16 asymmetrical third molars (according to Winter's classification), 9 (56%) had different techniques employed on the right and left sides (**Error! eference source not found.**).

Table 10: Surgery Technique of Right and Left Molars

		Left Third Molar					Total
		E	TS & E (Osteotome)	TS & E	BBR & E	BBR, TS & E	
Right Third Molar	E	12	2	0	2	2	18
	TS & E (Osteotome)	2	4	0	0	1	7
	FLAP & E	0	1	0	0	0	1
	TS & E	1	0	1	0	0	2
	BBR & E	3	0	0	11	5	19
	BBR, TS & E	3	0	0	1	34	38
Total		21	7	1	14	42	85

To determine if post-operative pain severity was influenced by surgical technique, VAS scores for phases I, II and III were averaged for those with three scores. These composite scores were compared across surgical technique in order of increasing surgical difficulty separately for bupivacaine and lidocaine. There was a positive and significant correlation (Spearman's rho= .308, p= .010) between ordered surgery type and VAS scores during phase II for the lidocaine side. A similar but non-significant trend was observed for bupivacaine. The range of the mean rank scores were similar for both groups, see Table 11 and Table 12 .

Table 11 Mean Rank VAS Scores/ Surgical Technique: Lidocaine

	Lidocaine	N	Mean Rank
Phase I	E	19	38.66
	TS (Osteotome) & E	7	41.50
	BBR & E	15	49.10
	BBR, TS & E	40	38.99
	Total	81	
Phase II	E	16	26.94
	TS (Osteotome) & E	7	27.14
	BBR & E	12	33.67
	BBR, TS & E	34	40.88
	Total	69	
Phase III	E	17	28.38
	TS (Osteotome) & E	7	37.07
	BBR & E	12	40.92
	BBR, TS & E	35	37.80
	Total	71	

Table 12 Mean Rank VAS Scores/ Surgical Technique: Bupivacaine

	Bupivacaine	N	Mean Rank
Phase I	E	19	45.11
	TS (Osteotome) & E	7	24.14
	BBR & E	17	41.62
	BBR, TS & E	38	41.78
	Total	81	
Phase II	E	18	29.94
	TS (Osteotome) & E	7	29.21
	BBR & E	11	32.59
	BBR, TS & E	33	39.79
	Total	69	
Phase III	E	18	27.86
	TS (Osteotome) & E	7	37.00
	BBR & E	13	42.92
	BBR, TS & E	34	38.51
	Total	72	

4.3.3 Surgical Time

Surgical time was recorded by the surgeon for both the left and right side, *Table 13*. The difference between the two sides was computed and the difference between bupivacaine and lidocaine sides was also computed. There were at most ten distinct different values, because time was measured to the nearest minute, and therefore normality was assessed graphically. Histograms of both *difference* variables looked symmetrical and approximately normal and the Q-Q plot was acceptable. When analysed according to right versus left side, and bupivacaine versus lidocaine, no statistical difference was found between the mean surgical times p= 0.325 and p= 0.552 respectively, Table 14.

Table 13 Descriptive Statistics Surgical Duration (mins)

	Mean	N	Std. Deviation
Right Third Molar Surgical Duration in minutes	4.15	85	1.524
Left Third Molar Surgical Duration in minutes	4.31	85	1.834
Bupivacaine Surgical Duration (mins)	4.24	85	1.681
Lidocaine Surgical Duration (mins)	4.33	85	1.707

Table 14 Paired Samples T-Test; Surgical Duration (mins)

Difference in minutes	Mean	Std. Error	95% Confidence Interval- Lower	95% Confidence Interval- Upper	t	df	Sig. (2-tailed)
RTM - LTM Surgical Duration	-.153	.155	-.460	.154	-.990	84	.325
Bupivacaine-Lidocaine Surgical Duration	-.094	.158	-.407	.219	-.597	84	.552

4.4 Post- operative Assessment

4.4.1 Pain Assessment: Visual Analogue Scale

Patients were asked to indicate their level of pain by marking a 100mm VAS. This was carried out by the patient on three occasions prior to discharge; immediately post-op, 30 minutes and 1 hour post awakening fully from the general anaesthetic. The patients were given four additional VAS to complete at 3, 4, 6 and 8 hours. These were returned at a later date. For analysis, the variables were separated into 2 groups; bupivacaine (long acting side) and lidocaine (short acting side). The pattern of VAS scores over time was examined, Figure 1 and it was decided to sub-divide the scores into 3 distinct phases for analysis and to reflect patient's changing situation,

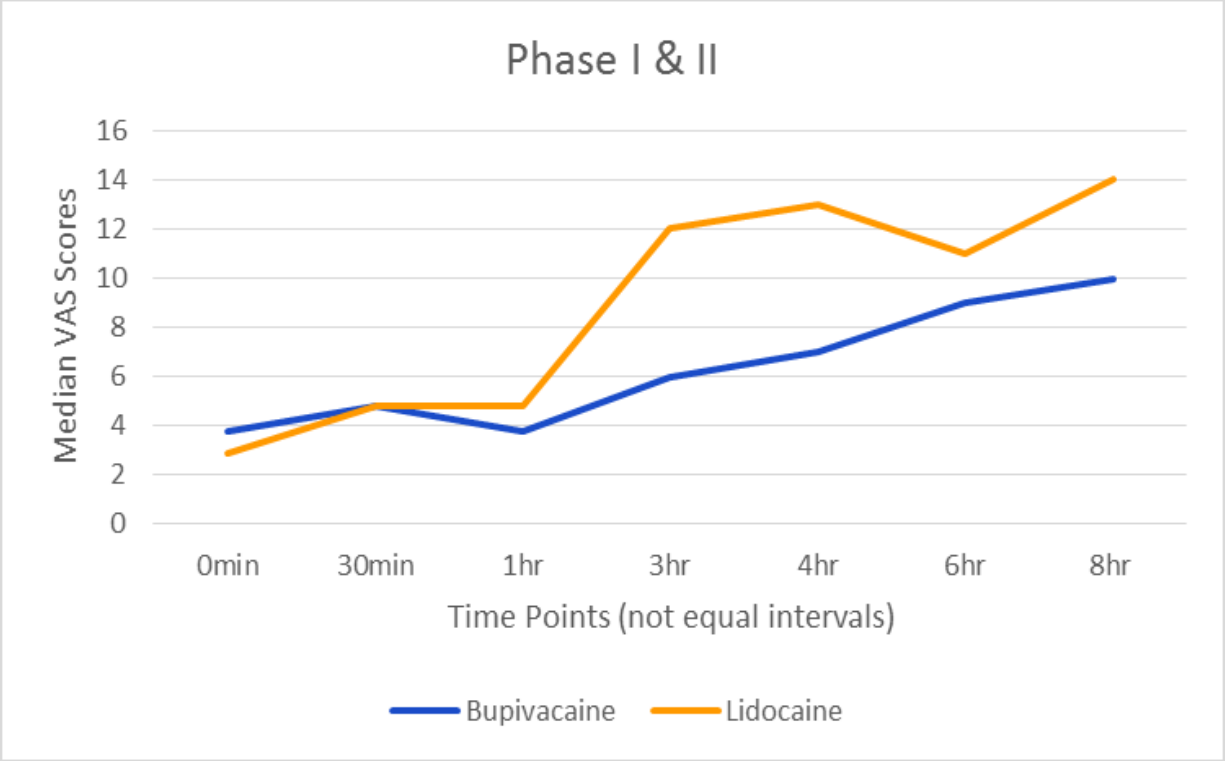
Phase I- VAS scores recorded up to 1hr post-op (i.e prior to discharge)

Phase II- Vas scores from 3- 8 hours post-op

Phase III- Vas scores from day 1- day 7 post-op.

Figure 1 demonstrates a more noticeable upward trend in median VAS scores for the lidocaine group at 3hr and 4hrs post-op.

Figure 1 Median VAS scores of phases I and II



Average VAS scores per patient were calculated for each of the three phases when complete data within a phase was recorded. An example of the highly skewed distribution of VAS

scores seen during the three phases is shown in Figure 2. Summary VAS statistics and mean pain levels for each side are outlined in Table 15.

Figure 2 Histogram demonstrating skewed distribution of VAS scores

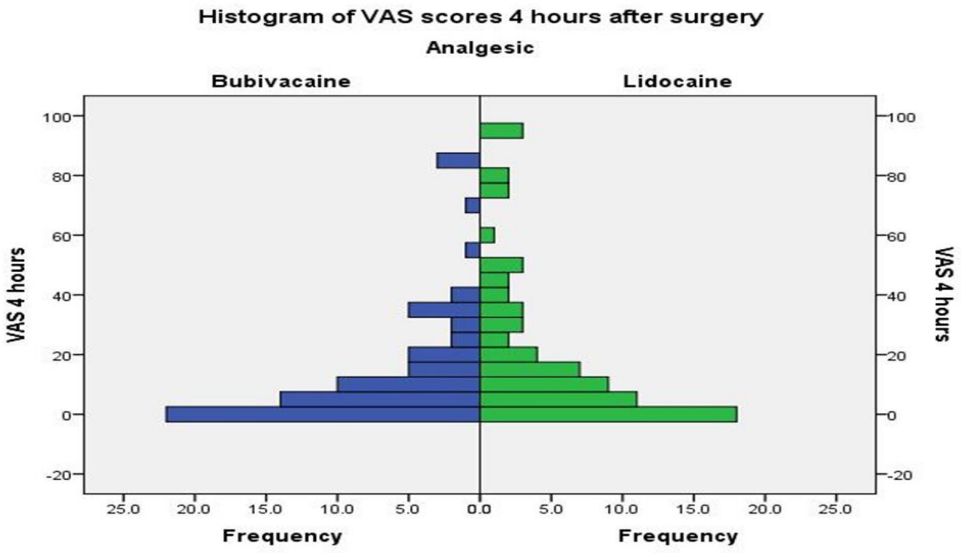


Table 15 Summary Statistics for VAS Phase I & II

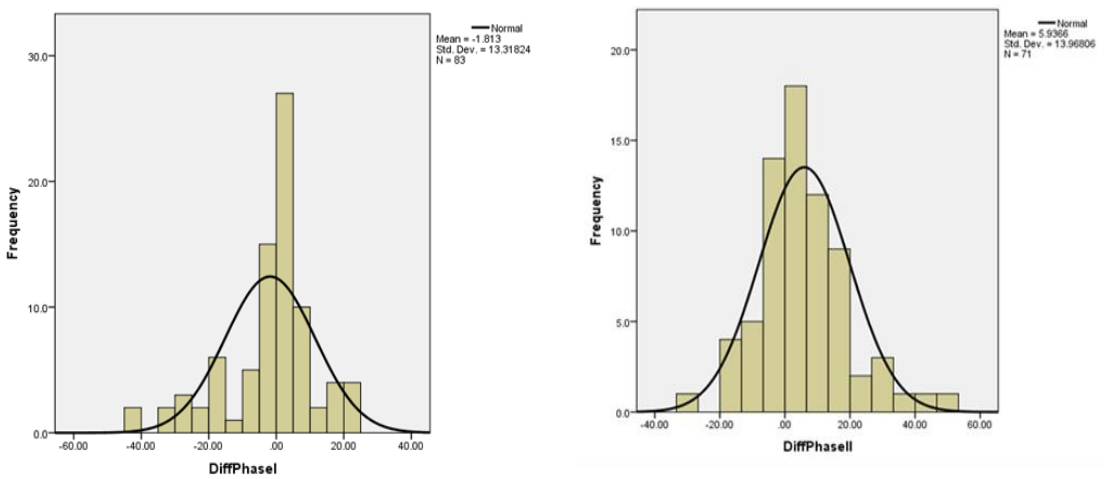
PAIN	ANAESTHETIC AGENT	N	MEAN	MEDIAN	MIN	MAX
Phase I	Bupivacaine	83	12.65	5.7	0	78.1
	Lidocaine	83	10.84	6.8	0	54.0
Phase II	Bupivacaine	71	16.38	8.4	0	93.3
	Lidocaine	71	22.32	14.6	0	95.8

Differences between VAS scores for bupivacaine and lidocaine sides were computed (short acting side minus long acting side) and tested for normality. Normality was rejected for phase I (see Figure 3 & Table 16). Differences based on log transformations were also rejected for normality. Comparisons between bupivacaine and lidocaine sides were compared using a bootstrap paired samples test.

Table 16 *Shapiro-Wilk Normality Testing*

	Shapiro-Wilk		
	Statistic	**df**	**Sig.**
Difference Phase I	.907	83	.000
Difference Phase II	.967	71	.059

Figure 3 Graphical Representation of Rejection of Normality



Phases I and II:

Two patients had missing/ incomplete data for phase I VAS scores, and 14 had missing/incomplete data for phase II. No statistically significant difference was revealed in phase I with P>.05. A statistically significant reduction in pain was found when bupivacaine was compared to lidocaine during phase II, P=0.001. The mean difference was 5.94 and the upper confidence interval for phase II was 9.04, Table 17.

Table 17 VAS Bootstrap for Paired Samples Test

VAS	N	Long Mean	Short Mean	Mean Difference Short-Long	Bootstrap			
							95% Confidence Interval	
					Std. Error	Sig. (2-tailed)	Lower	Upper
Phase I	83	12.65	10.84	-1.81	1.46	.222	-4.75	1.02
Phase II	71	16.38	22.32	5.94	1.65	.001	2.81	9.04

Mean Differences for VAS during the 3hr to 8 hrs of phase II are given in Table 18 to identify the time when largest difference between lidocaine and bupivacaine occurred. The sample size was determined using a 10mm difference which was considered large enough for the longer acting anaesthetic to be considered useful in pain relief post-surgery. The upper limit of the 95% confidence interval was 10.0 or above at 3hours and 4 hours post-surgery.

Table 18 Mean Differences and 95% Bootstrap Confidence Intervals of Phase II VAS during 3hr to 8h post-surgery.

VAS	**Mean Difference Short-long N=71**	**Std. Error**	**Bootstrap 95%Confidence Interval**	
			Lower	Upper
3hr	6.61	1.80	3.17	10.01
4hr	8.39	2.30	3.99	12.91
6hr	5.01	1.87	1.68	8.44
8hr	4.00	2.06	-0.24	7.98

4.4.2 Effect of Third Molar Orientation on VAS Scores

Winter's classification and surgical type were assessed for both lidocaine and bupivacaine sides in terms of pain during the three phases. The null hypothesis was accepted indicating that surgical technique and Winter's classification did not impact on VAS scores in either group during each of the three phases

4.4.3 Post-Operative Pain Catastrophizing Scale

The PCS was repeated prior to discharge to assess if the presence or possibility of pain impacted on scoring. See Figure 4 for graphical comparison of pre- and post-operative PCS scores. The difference between the scores pre-op minus post-op was computed and its distribution tested for normality. Normality was rejected (Shapiro Wilk; p=.006) and the bootstrap for Paired Samples Test was performed. Scores were considerably lower post-operatively (mean = 8.81) when compared to the pre-operative (mean= 13.1) results, P<0.001, Table 19.

Figure 4: Pre- and Post-operative PCS Scores

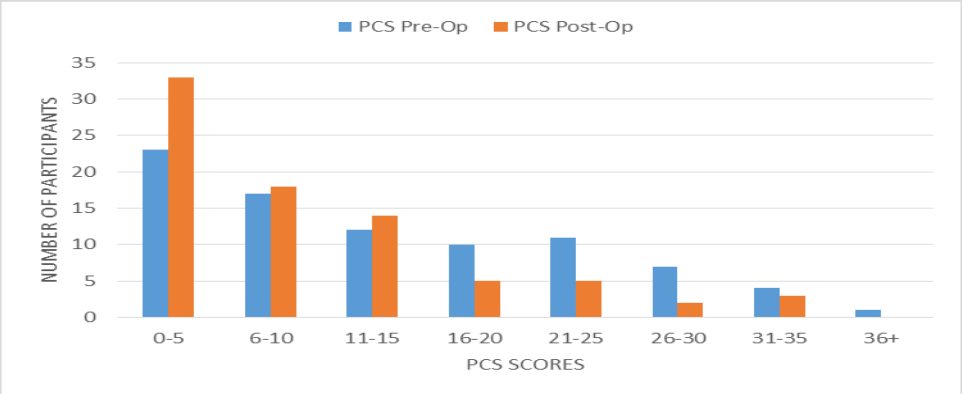


Table 19 PCS Bootstrap for Paired Samples Test

N	PCS Pre Mean	PCS Post Mean	Mean Difference Pre-Post	Bootstrap			
						95% Confidence Interval	
				Std. Error	Sig. (2-tailed)	Lower	Upper
80	13.0	8.81	4.19	0.672	.000	2.90	5.55

4.4.4 Post-Operative Hospital Anxiety and Depression Scale

The HADS questionnaire was repeated prior to discharge. This was carried out to assess if completion of the planned procedure had an impact on anxiety and depression levels of the study participants. Both scores decreased after surgery with anxiety showing a difference that was statistically significant (P= 0.025), Table 20.

Table 20 HADS Pre- and Post-operative

HADS	N	Pre Mean	Post Mean	Mean Difference	Std. Error	t	Sig. (2-tailed)	95% Confidence Interval	
								Lower	Upper
Anxiety	81	3.62	3.07	.543	.238	2.285	.025	.070	1.016
Depression	81	3.62	3.22	.395	.288	1.372	.174	-.178	.968

4.4.5 Post-Operative Short-Form McGill Pain Questionnaire

The SF-MPQ was repeated prior to discharge. xon Signed Rank Test: p<.001). and Figure 6 demonstrate an increase in post-operative sensory and affective SF-MPQ scores. This increase was statistically significant (Wilcoxon Signed Rank Test: p<.001).

Figure 5

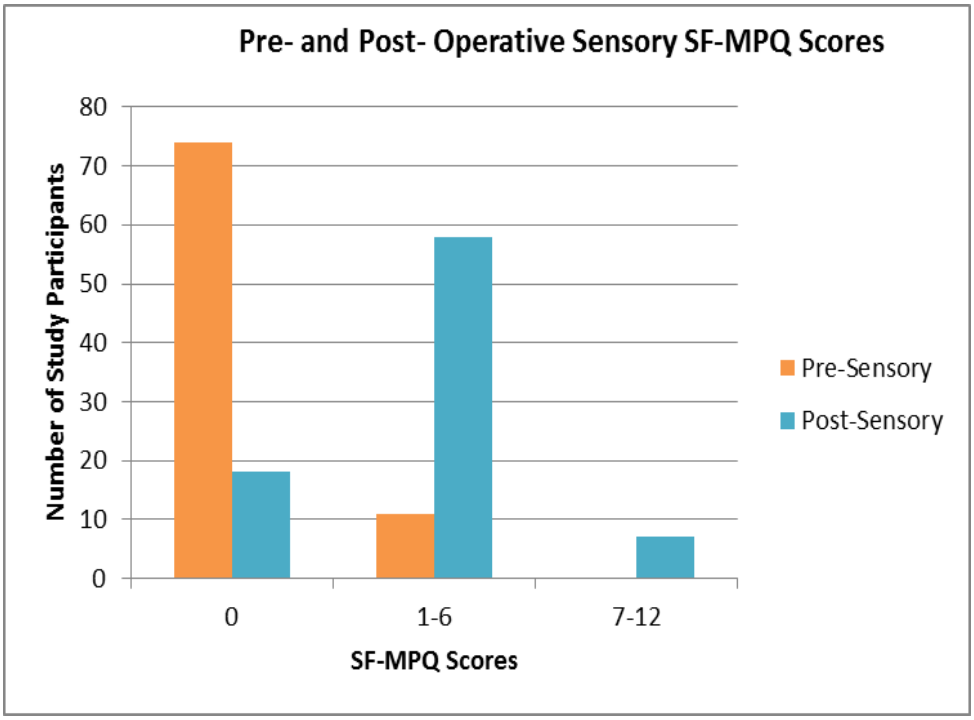
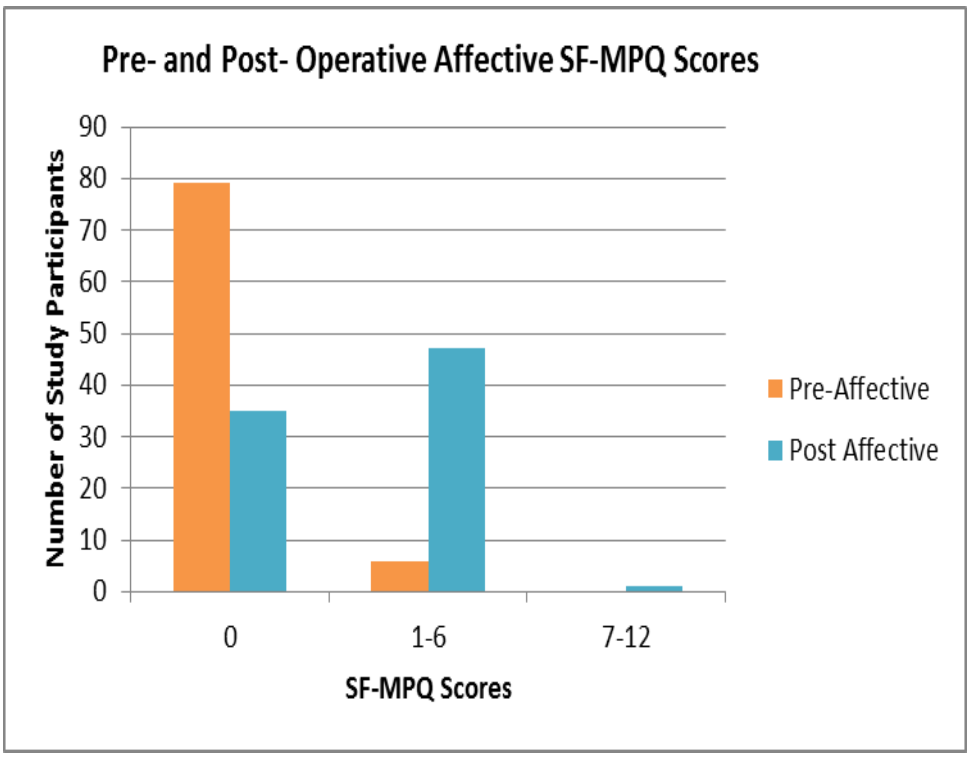


Figure 6



4.4.6 Effect of Post-Operative Assessments on Pain Scores

There was no significant correlation found between post-operative PCS and total VAS scores for phase I (Spearman's Rho; 0.212; p= 0.066).

Greater total Phase I VAS scores were not associated with higher HADS scores for anxiety and depression. Spearman's correlation coefficient, based on original data of VAS phase I and HADS post anxiety and depression were $r_s = 0.193$ and $r_s = 0.072$, respectively and both were not statistically significant.

There was a significant correlation between post-operative MPQ scores and total Phase I VAS scores, Table 21.

Table 21 Correlation MPQ Scores and Total VAS Scores for Phase I

Variables	Spearman's rho	Sig (2-tailed)
Post-MPQ (Sensory)	0.438	0.000
Post- MPQ (Affective)	0.347	0.002
Total Sum (Sensory + Affective)	0.629	0.000

4.4.7 Dental Visit Satisfaction Scale.

Patients were asked to fill out a satisfaction survey prior to discharge and on POD 7. The survey consisted of 10 items which described different aspects of the dental experience. Question 8,"*The dentist was too rough when he worked on me*" was omitted as the surgery was carried out under general anaesthetic and therefore patients could not answer this question. Each question was rated using a score from one to five, with higher scores representing greater levels of satisfaction. Compliance rate for completion and return of the 7 day DVSS was 78% (66/85).

Two participants scored 9 and 10 in the discharge DVSS. One of those gave a score of 39 for the 1 week DVSS which may indicate that this patient misinterpreted the marking at discharge. The other patient did not return the 1 week DVSS. The distribution of DVSS scores is presented in Table 22. There were 64 patients with DVSS scores at both stages (outlier excluded). The scores at discharge were higher than at 7 day.

Table 22 *Dental Visit Satisfaction Scores (DVSS) at discharge and 7 days*

Scores	Discharge DVSS	Day 7 DVSS
9-10	2 (2%)	0 (0%)
28-30	0 (0%)	2 (3%)
31-35	3 (4%)	5 (8%)
36-40	14 (18%)	18 (27%)
41-45	61 (78%)	41 (62%)
Total	80 (100%)	66 (100%)

Normality of the DVSS difference was rejected due to kurtosis and by the Normal Q-Q Plot (Figure 7). The bootstrap for Paired Samples Test was performed. A small but significant fall in satisfaction was seen between discharge and one week post-surgery (p=.007), Table 23.

Figure 7 *Graphical Representation of Rejection of Normality*

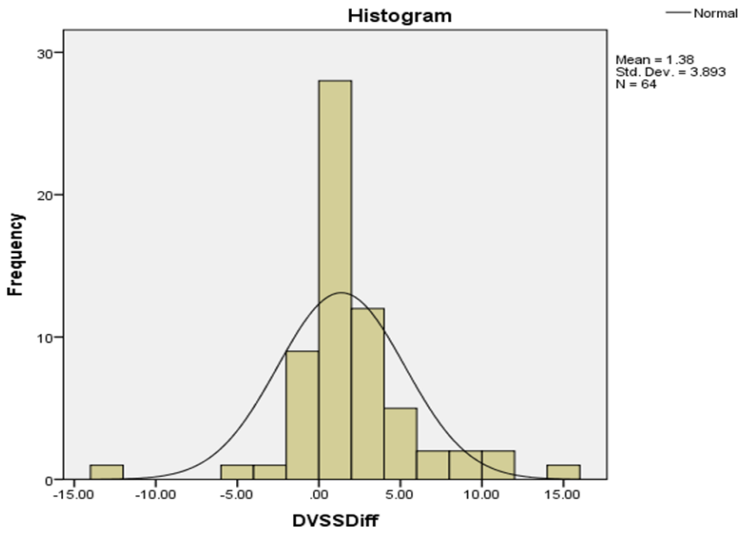


Table 23 DVSS Bootstrap for Paired Samples Test

N	Discharge DVSS Mean	7 Day DVSS Mean	Mean Difference Discharge-7 Day	Bootstrap			
						95% Confidence Interval	
				Std. Error	Sig. (2-tailed)	Lower	Upper
64	42.66 (Std Dev 3.143)	41.28 (Std. Dev 4.351)	1.375	0.481	.007	0.462	2.281

A free comment was left by 36% of patients at 7 days. Negative comments related to the presence of pain/infection, and aspects relating to medication. A longer than expected recovery time was also cause for complaint. For example:

"*I didn't realise that I would have pain for 2 weeks after the procedure. I wasn't prepared for the length of time I would have discomfort eating"*

Preference regarding long- and short-acting anaesthetics was conflicting with some patients wishing to have pain rather than be numb.

"I would prefer to feel the pain. I got a shock Tuesday early hours when the freeze wore off. Feel I would have dealt with the pain better".

"*Longer lasting freeze much better as it didn't wear off till 2.30am the next day so the pain killers and anti-inflammatories had taken an effect in my system. With the shorter freeze only seemed to be home about an hour and the pain was there*" Preferred long lasting

Reference to the persistent presence of numbness to the lip/ tongue was made by three patients. This was confused with the use of a long lasting anaesthetic on that side.

"Why is my tongue still numb, if not I would choose the longer lasting one".

A number of the comments were of a positive nature. A sample of these is reported here:

"Very happy with the care I received. The nurses and staff were very friendly and made me feel completely at ease

"Whichever one was used on the LHS because I had least pain there L side" = lidocaine"

"Very good thorough care. Nurses were kind and sympathetic. Pain peaked after 2-3 days but medication was effective in relieving pain. Was thoroughly advised on what to expect. All in all very happy"

"I was very happy with the procedure overall. I was given good pain relief and was hardly ever in pain"

4.4.8 Patient Preference

Patients were asked to indicate which side (right or left) they preferred on two occasions during the first day: prior to discharge and at the end of the day. After 1 week, patients were again asked to indicate their preference, this time regarding the long or short acting anaesthetic (Table 24). Approximately two-thirds of patients stated that they preferred bupivacaine one week post-op.

Table 24 Patient preference

	Lidocaine/ Short-acting	Bupivacaine/ Long- acting	No Preference
Discharge	27%	36.5%	36.5%
End of day of surgery	36%	61%	3%
1 week post-op	30%	67%	3%

Patients who preferred bupivacaine had higher scores on the 'short acting' side than on the 'long acting' side. For those who preferred lidocaine they experienced similar pain levels on both sides (see Table 25 and Table 26). However the mean Vas scores were similar for both preference groups for the 'long side' (16.33 vs 17.39).

Table 25 VAS Bootstrap for Paired Samples Test for patients with a preference for Bupivacaine 7 days post-surgery.

VAS	N	Long Mean	Short Mean	Mean Difference Short-Long	Bootstrap			
							95% Confidence Interval	
					Std. Error	Sig. (2-tailed)	Lower	Upper
Phase I	47	13.00	12.51	-0.49	2.04	.812	-4.82	3.55
Phase II	45	16.33	25.04	8.71	2.23	< .001	4.40	13.06
Phase III	46	28.15	30.23	2.08	3.15	.517	-4.49	8.28

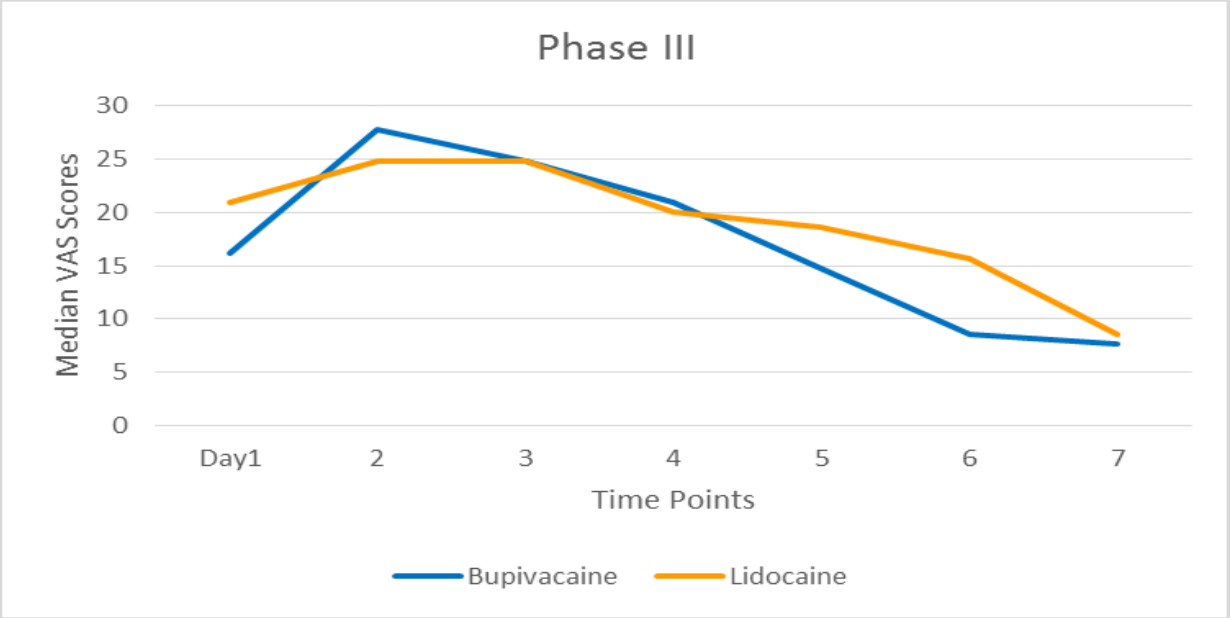
Table 26 *VAS Bootstrap for Paired Samples Test for patients with a preference for Lidocaine 7 days post-surgery.*

VAS	N	Long Mean	Short Mean	Mean Difference Short-Long	Bootstrap			
							95% Confidence Interval	
					Std. Error	Sig. (2-tailed)	Lower	Upper
Phase I	22	8.90	7.70	-1.20	2.27	.603	-5.91	3.52
Phase II	22	17.39	18.24	0.86	2.10	.687	-3.50	5.22
Phase III	22	26.01	27.72	1.72	2.74	.537	-3.97	7.41

4.4.9 Pain Diary

Patients were asked to record pain experience for both right and left sides on one occasion for seven days post- surgery (phase III). For continuity, this was analysed according to the anaesthetic administered, Figure 8. Twelve patients had missing data for phase III.

Figure 8 Median VAS scores of phases III



Differences between VAS scores for bupivacaine and lidocaine sides were computed (short acting side minus long acting side) and tested for normality. Normality was rejected (Shapiro- Wilk= .920). Summary VAS statistics and mean pain levels for each side are outlined in Table 27.

Table 27 Summary Statistics for VAS Phase I & II

Pain	Anaesthetic Agent	N	Mean	Median	Min	Max
Phase III	Bupivacaine	73	26.76	22.7	0	94.7
	Lidocaine	73	28.32	23.0	0	90.1

Comparisons between bupivacaine and lidocaine sides were compared using a bootstrap paired samples test. No statistically significant difference was revealed in phase III with P>.05, Table 28.

Table 28 VAS Bootstrap for Paired Samples Test

VAS	N	Long Mean	Short Mean	Mean Difference Short-Long	Bootstrap			
							95% Confidence Interval	
					Std. Error	Sig. (2-tailed)	Lower	Upper
Phase III	73	26.76	28.32	1.56	2.19	.483	-2.73	5.72

Pain diaries (Appendix VIII) were returned by 74 patients (86%) of patients via post. Question 1 of the pain diary related to the presence of post-operative pain. Of those who returned the pain diary, 64% of patients stated they had pain on POD 7.

Daily Activities were unaffected by pain in 16% of patients, while 25% of patient's daily activities continued to be affected 7 days post-surgery. 5% of patients complained of pain which began affecting daily life between days 4-7. All of these patients visited a GDP/GP during this time period. Symptoms of morbidity were recorded by 77% of patients of which 66% complained of difficulty eating. Inability to work, attend school/college and speak normally were the most common complaints reported.

Of those who returned their pain diary, 32% visited a health care professional during the 7 days post-surgery, 70% of these were between days 3-5. Two of these patients were smokers, with a third patient having ceased smoking 1 month prior to surgery.

Patients were asked to record analgesic consumption during the post-operative period, *Table 29*. The recommended prescription of paracetamol, dexketoprofen and oxynorm on day was followed by 41% of patients. This reduced to 8% by day 7. Unprescribed analgesics rose from 4% on day 1 to 19% on day 7. Analgesics continued to be consumed by 82% of patients on day 7.

Table 29 Analgesic consumption during 7 days post- surgery

DAY	1	2	3	4	5	6	7
PARACETAMOL + DEXKETOPROFEN + OXYNORM	41%	43%	41%	31%	15%	12%	8%
PARACETAMOL ± DEXKETOPROFEN ± OXYNORM	52%	49%	50%	54%	66%	60%	55%
TOTAL PRESC	**93%**	**92%**	**91%**	**85%**	**81%**	**72%**	**63%**
OTHER MEDS	4%	5%	6%	12%	14%	23%	19%
NIL MEDS	3%	3%	3%	3%	5%	5%	18%

5.0 DISCUSSION

5.1 Study Design

This study was designed as a split-mouth randomised clinical trial. The patient acted as their own control. Both anaesthetic agents were used on the same patient at the same time under the same operating conditions. This study design has the advantage of limiting inter-individual variability and greatly enhances the statistical power. A study sample of 80 was required to detect a difference of 10mm in VAS between bupivacaine and lidocaine ensuring 90% power at the 5% level of significance and allowing for non-compliance rate of 30%.

While split-mouth trials have been criticised due to "spill over" effects of the treatment and treatments being carried out at different times, this study was designed to prevent these flaws (23). The prerequisites for successful use of this study design were met as the treatments were double blinded, localised and short lived (195).

Giving due consideration to the effect of general anaesthesia on motor and cognitive ability, all questionnaires and VASs were simply presented avoiding use of technical or medical jargon.

5.2 Sample Characteristics

There were 85 patients included in the study. Age ranged from 16 to 44 with median age of 20.3. 95% of patients were less than 30 years. This corresponds with similar studies and reflects the fact that wisdom teeth generally cause problems during eruption between ages

18-25 (196). In our department, patients undergoing orthognathic surgery require prophylactic removal of third molars which contributed to the proportion of 16-20 year olds (54%) having third molars removed.

Females accounted for 70% of the study participants. Females are believed to have a greater discernment of physical disharmony and are more likely to seek treatment compared to their male counterparts (197). There was no difference in post-operative pain between males and females in this study.

This study was limited to ASA I and II patients. 91% of participants were ASA grade I which reflects the young population captured. There was no correlation between age and ASA grade. Smoking rates for this group of participants were low and therefore no definitive conclusions could be drawn between the association of smoking and ASA grade.

There was a high response rate for the seven day pain diary with 86% of patients returning the diary via post. This may have been due to patients being supplied with a stamped addressed envelope at discharge and contacted during their recovery. Studies have shown a higher response rate when postal mail with monetary incentives / stamped addressed envelopes are used and follow-up contact is made (198, 199). As 95% of study participants in this study were <30 years, a web survey may have yielded similar response rates with less financial implications (200).

5.3 Psychological variables

Non-surgical factors including individual and demographic factors have been shown to impact on pain experience(24). Individual factors include psychological variables such as a predisposition to catastrophize, as well as baseline levels of anxiety and depression. These were recorded in this study to assess if they had an influence on pain levels.

In 1976, Beck et al. discussed catastrophizing in terms of "dwelling on the worst possible outcome of any situation in which there is a possibility for an unpleasant outcome" (201). Catastrophizing is thought to comprise of elements of rumination, magnification and helplessness. These components constitute the 13 items of the PCS, developed by O Sullivan in 1995 which continues to demonstrate adequate internal consistency and validity(202). The PCS has been shown to be a predictor of pain in many settings including acute, chronic, diagnostic and experimental pain studies(203). The PCS was used pre- and post-operatively in this study to detect if increased scores were associated with higher pain scores in the immediate post-operative period. A total score of ≥30 is thought to be clinically relevant(119). High PCS scores were not associated with greater Phase I VAS scores in this study.

Any surgery, including third molar removal can be stressful for a patient. The association between anxiety and pain is not a new one with several studies showing a positive correlation between greater levels of anxiety and post-operative pain (25-27). It is important that anxiety prior to third molar surgery is addressed in order to foresee potential difficulties in the intra and post-operative period. The Hospital Anxiety and Depression Scale

is a valid tool(112) which aims to identify patients experiencing greater levels of anxiety and depression. A score of 0-7 is considered normal. 8-10 is considered borderline, with a score > 11 representing psychological morbidity.

Patients in this study completed a HADS pre- and post-operatively. Six patients were considered borderline for an anxiety trait, with seven borderline for depression. Two patients scored >11 for depression. When repeated prior to discharge, a statistically significant reduction in anxiety scores was seen. This is likely to be due to patients feeling less anxious on completion of the surgery. There was no statistical difference in depression scores.

This study did not reveal an association between greater pain scores and HADS anxiety and depression scores. The sample size when considering psychological variables does not compare to large studies to detect such an association(112). Some post-surgical studies continue to monitor anxiety and depression for a longer duration than here(27). Continuing to do so may have demonstrated changes as pain decreased or increased for the first post-operative week.

Use of the PCS and HADS did not yield any unexpected results and may suggest their application in relatively small studies such as this may not be advantageous. Completion of these questionnaires prior to discharge is challenging for patients recovering from surgery and a general anaesthetic.

5.4 Pre-operative pain assessment

Third molars can cause pain due to the same reasons that warrant their extraction; caries, associated pathology and pericoronitis. As previously mentioned pain is multifaceted with patient age and gender as well as surgery type impacting on the level of post-operative pain experienced (204). Baseline pain levels were taken to assess if greater pre-operative pain was associated with greater post-operative pain. The short-form McGill Pain Questionnaire (SF-MPQ) was used in this study. This version is less arduous than the original which has 78 pain descriptors. The SF-MPQ takes on average 2-5 minutes to complete(205) and its validity has been repeatedly proven for different disciplines (160, 206). It consists of 15 descriptors of pain which are rated on an intensity scale. 11 of these are sensory descriptors while the remaining 4 are affective terms. Each question was scored from 0-3 with a maximum score of 33 for the sensory subset, and a maximum of 12 for the affective subset. A majority of patients reported an absence of pre-operative pain.

5.5 Assessment of difficulty and technique of third molar surgery

All 85 patients included in this study had bilateral similarly impacted lower third molars. Not all were symmetrical according to Winter's classification. 16 cases were asymmetrical. The confounding factor of multiple operators was removed by this study design. Surgical duration which has been shown to impact on post-operative pain (207) was less variable by having a single experienced maxillofacial surgeon complete all extractions.

No significant difference was seen in the mean surgery time for removal of right and left molars for the total group. Statistical analysis was also performed to compare surgical

duration (minutes) of the bupivacaine versus lidocaine side. No statistical difference was found between the two groups.

5.6 Post-operative pain assessment

The SF-MPQ was repeated prior to discharge. Statistically significant differences were found between pre- and post-operative MPQ scores for sensory and affective pain. Third molar surgery is associated with post-operative pain despite a combination of analgesics and local anaesthetics. The difference in pain was expected as most patients reported an absence of pain pre-operatively. “Mild” pain (total sum sensory and affective) was reported by 95.2% of patients. This differs from similar research where “moderate” or “severe” pain is frequently reported (104).

The visual analogue scale (VAS), the verbal rating scale (VRS) and numeric pain scale (NPS) are the most commonly used scales to assess pain intensity. Each have their own advantages and disadvantages. The VAS while more technically challenging compared to the VRS and NPS, can be analysed using parametric tests and is therefore the preferred method in many scientific papers (208). In this study, pain intensity for both left and right sides was assessed using a VAS on three occasions prior to discharge. It was reassessed on four further occasions post discharge. No significant difference in pain intensity was found between the sides prior to discharge (phase I). A significant difference in pain was found during phase II (3-8hrs), when pain was significantly less on the side treated with bupivacaine. Maximum differences between the groups was seen three- four hours post-op. This finding supports similar studies (18) (92) demonstrating that longer periods of analgesia can be achieved with

longer acting anaesthetics such as bupivacaine. This supports its use for oral surgical procedures generally associated with significant persistent postoperative pain.

Bupivacaine is widely available as a plain solution or with adrenaline (1:200 000) in 10ml glass ampoules. Its unopened shelf life is two years. Bupivacaine with epinephrine is available in 1.8mL cartridges. The average dose of 1.8 mL (9 mg) per injection site will usually suffice; an occasional second dose of 1.8 mL (9 mg) may be used if necessary to produce adequate anaesthesia after making allowance for 2 to 10 minutes onset time. It is recommended that the total dose for all injection sites, *spread out* over a single dental sitting, should not ordinarily exceed 90 mg for a healthy adult patient (ten 1.8 mL injections of 0.5% bupivacaine HCL with epinephrine).

A VAS for right and left sides was completed by each patient once daily for seven days. Figure 2 illustrates that pain on the bupivacaine and lidocaine sides peaked on day 2. This conflicts with other studies which found post-operative pain peaked during the first 24 hours (56, 209). Pain was identical on both sides on POD 3.

Median pain scores for either group did not exceed 30mm at any stage during the post-operative recovery period and could therefore be considered “mild” (210, 211). Analysis of returned pain diaries revealed 64% of patients continued to have pain on POD 7. Median VAS scores for POD 7 revealed Scores <10mm for both sides which is considered none/mild (212). This concurs with similar third molar studies where pain on POD 7 is considered “very weak” or “none”(28, 56). Interestingly, 82% of patients continued to take analgesics on POD 7. This would suggest that 18% of patients either had no pain due to the continued consumption of analgesics or patients continue to take analgesics if it has been prescribed

for one week despite an absence of pain. A longer follow-up time may be warranted in future studies to capture a longer period of patient reported outcomes.

Symptoms of morbidity were reported by three quarters of patients, of which difficulty eating was the main complaint. The median number of days that daily activities were affected was 4. Similar studies have found that daily activities are affected and return to work delayed for an average of 3 days (29, 30, 213).

5.7 Post-operative Complications

Almost a third of patients visited a health care professional during the first post-operative week as result of pain +/- infection. The incidence of alveolar osteitis following third molar removal varies greatly with a wide range between 1-40% reported in the literature (72). Transient paraesthesia affecting the lip/tongue was reported by 3 patients representing 3.5% of the overall number of research patients. Similar findings were identified in comparable studies (72, 74). No further significant post-operative complications occurred.

5.8 Satisfaction Measures

Satisfaction in this study was assessed using the Dental Visit Satisfaction Scale at discharge and on POD 7. This scale assesses satisfaction using three subscales; information/communication, understanding/acceptance and technical competence. Patients rate their response to standardised statements on a 5 point scale, each of which is allocated a score that can then be analysed. “The dentist was too rough when he worked on me” was omitted as patients were not awake during the procedure. In this study a

maximum score of 45 reflected complete satisfaction, with a score of 25 regarded as a neutral point showing neither satisfaction nor dissatisfaction. All patients scored above this neutral point on both occasions. No difference was found between satisfaction scores for males and females in this study.

There was a statistically significant drop in satisfaction scores between discharge and POD 7. This is likely due to the deterioration in oral health related quality of life during the immediate postoperative period (169). A significant number of patients required medical intervention during the first week as a result of pain and infection. Dissatisfaction with the explanation of pain expectation and empathy of the dentist in relation to pain were also key factors in lower scores on POD 7.

Studies have shown that thorough explanation regarding post-operative recovery is associated with significantly greater inability to work (213), but can improve patient satisfaction (170). This issue should be addressed in order to adequately prepare patients in our department.

Patients were given the opportunity to leave a free comment at discharge and POD 7. A greater proportion of comments left at discharge were of a positive nature. This may have been due to the effectiveness of the analgesics and local anaesthetics at the time. Negative comments on POD 7 were in relation the presence of pain or infection, issues with analgesics and a longer than expected recovery time. Patients may have felt more able to express dissatisfaction when they were no longer in the company of the research/theatre staff. Positive comments related to the standard of care and pre-operative information received and the absence of pain.

5.9 Patient preference

Although there has been a vast amount of research using the third molar pain model to compare local anaesthetics, patient satisfaction relating to local anaesthetics remains equivocal (21, 96, 214, 215). As mentioned previously, the sensation of numbness may not be considered pleasant. Some patients may prefer to experience pain rather than have a prolonged loss of sensation (96).

In this study, bupivacaine was the preferred local anaesthetic of choice at discharge, end of day of surgery and on POD 7. Preference on POD 7 provides a more conclusive result as patients have had adequate time for reflection. When asked "if you were having your wisdom teeth removed again, which freeze would you prefer to be used on both sides, Short lasting or Long lasting?", patients were twice as likely to choose a long lasting anaesthetic (bupivacaine).

An equal number of positive and negative comments were left regarding the longer lasting numbness. Some expressed a preference for pain over numbness while others preferred to be numb rather than experience pain. Two patients commented that the shorter acting anaesthetic was preferred due to persistent paraesthesia in the lip/tongue.

5.10 Limitations and Suggestions for Further Study

Sample size was calculated using an estimate of the standard deviation of the difference between the two groups, lidocaine and bupivacaine. This standard deviation was based on unpublished research which compared lidocaine to a control (no LA) and hence was not a

directly comparable. For phase II of the study the standard deviation of the difference was smaller than the estimated used to compute sample size (13.9 vs 22). Using a smaller standard deviation would not have required as many study participants for analysing VAS score but would have affected the estimates of other outcome variables.

In order to achieve a sufficient sample size, bilateral impacted third molars of similar difficulty were included in this study. Due to a greater than expected response rate, these unsymmetrical third molars could have been omitted. Statistical analysis however did not show significant differences in surgical duration, Winter's classification or surgical type between the groups and therefore all cases were included. Inclusion of unsymmetrical third molars added an additional level of complexity to the analysis of results.

Due to the lack of a research nurse, it was not possible to be in the operating theatre to record the time and therefore this was the joint responsibility of the surgeon and assistant. Likewise having a research nurse solely responsible to ensure questionnaires and VASs were thoroughly completed would have been beneficial.

6.0 Conclusion

A vast amount of research has been carried out on the topic of local anaesthetics for third molar surgery. To the best of our knowledge none have directly compared lidocaine to plain bupivacaine on the same patient, at the same time under the same operating conditions. Patient and operator variabilities are hence minimised by this split mouth design using a single operator.

This research demonstrates that plain 0.5% bupivacaine provides longer analgesia than 2% lidocaine with adrenaline. Its use in an out-patient setting would be of particular value where pain is often central to delayed discharge. This longer period of analgesia does not have a prolonged impact on pain experience during the seven days following surgery.

Emphasis has been placed on identifying indicators of anxiety, depression and potential to catastrophize in pre-surgical patients in order to predict those who may be more susceptible to complain of greater pain. These questionnaires did not detect a correlation between higher pain scores and pre-operative anxiety/depression and potential to catastrophize. This may be a result of the young patient population captured or the relatively small study size.

Patient satisfaction is key to successful healthcare systems and was central to this study through the use of validated questionnaires and free comment sections. A realistic depiction of recovery is important to adequately prepare patients for surgery and its aftermath. Assessing patient reported outcomes has allowed insight into a patient's recovery and its analysis has the potential to benefit future patients.

Following a period of reflection, bupivacaine was the anaesthetic of choice for a greater percentage of patients. Some preferred bupivacaine due to the longer period of anaesthesia it provided, while others expressed their dislike for the persistent numbness.

This study supports patient choice with regards to different local anaesthetic agents. Selection should be based on the perceived difficulty of surgery, patient variables and preference.

8.0 Appendices

Appendix I

CONSENT FORM

CONSENT BY SUBJECT FOR PARTICIPATION IN RESEARCH PROJECT

Protocol Number: _____ Subject Name: _____

Title of Research Project:

Comparison between lidocaine and bupivacaine in patients undergoing third molar extraction in terms of patient satisfaction

Investigators:

Dr. Caroline McCarthy, UCC Dental Hospital, Dept of Oral Surgery

Prof. Duncan Sleeman, UCC Dental Hospital, Dept of Oral Surgery

Dr. Paul Brady, UCC Dental Hospital, Dept Of Oral Surgery

You are being asked to participate in a research study. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

Nature and Duration of the procedure:

The aim of this research is to look at the relationship between the type of local anesthetic used and the amount of pain experienced by the patient. You will receive a local anesthetic on one side of your mouth that lasts on average 2-3 hours. The anesthetic on the other side will last on average 5-8 hours. Both of these are commonly used in dentistry.

Some pain is expected after wisdom tooth extraction despite being numb. We want to look at how satisfied you are with the feeling of numbness for the post-operative period.

The surgery will be carried out by Prof. D Sleeman.

Potential Risks and Benefits:

There are no additional risks associated with taking part in this study, other than those already associated with wisdom tooth removal. You will feel numb on one side of your mouth for up to 8 hours and for this reason hot food and drinks should be avoided until normal feeling returns. (Standard advice given after extraction(s) is to avoid hot food and drink for 24 hours)

AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. I have had the opportunity to ask questions concerning any and all aspects of the Research Project and any related matters or issues of concern. I am aware that my participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me.

I, the undersigned, hereby consent to participate as a subject in the above described Research Project conducted at Cork University Hospital. I have received a copy of this Consent Form and Research Subject Information Sheet for my records. I understand that if I have any questions concerning this research, I can contact the investigators listed above.

Date:

Signed:

[Research Subject's Name]

Witnessed:

[Chief Investigator/Co-Investigator]

Witnessed:

[Parent/Guardian for Minor Research Subject or Next of Kin for Elderly Patient]

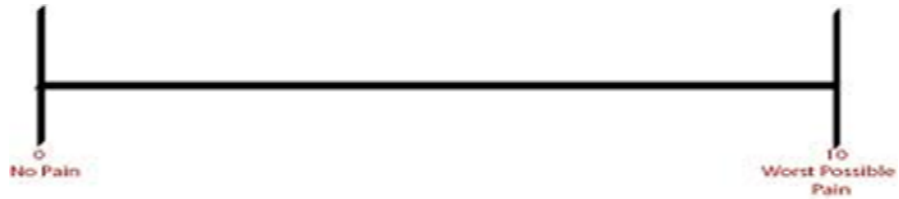
Appendix II

PT NAME: _____ PATIENT NO.: _____ PATIENT REF: _____ DATE: _____

- PLEASE INDICATE HOW BAD YOUR PAIN IS ON EACH SIDE OF YOUR MOUTH
- PLEASE TICK WHICH SIDE OF YOUR MOUTH YOU PREFER. TICK BOTH IF YOU HAVE NO PREFERENCE.

Immediate

LEFT ☐



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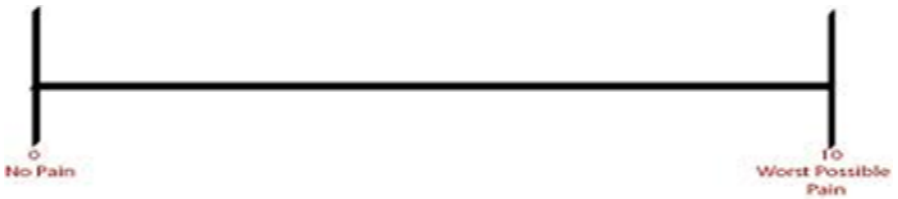

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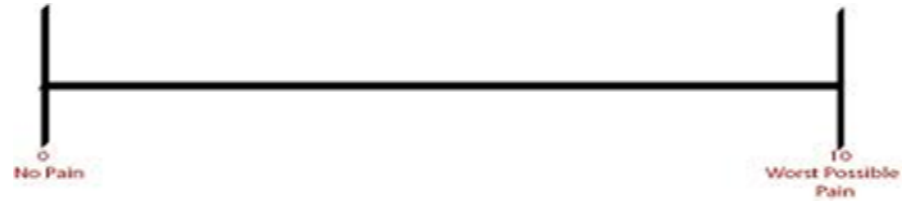

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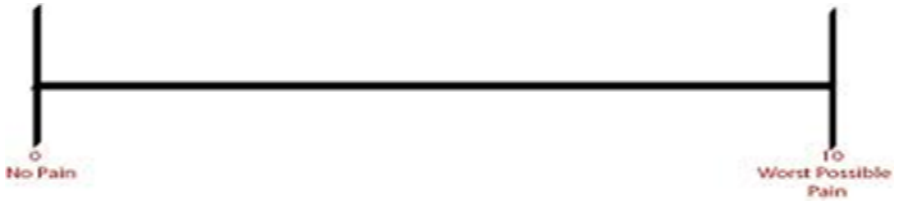

1 Hr

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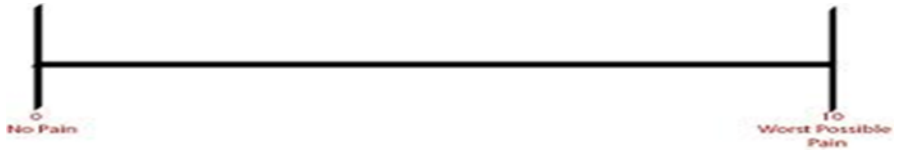

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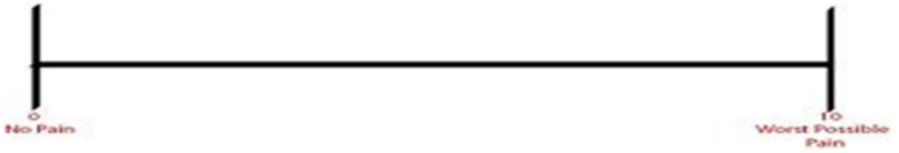


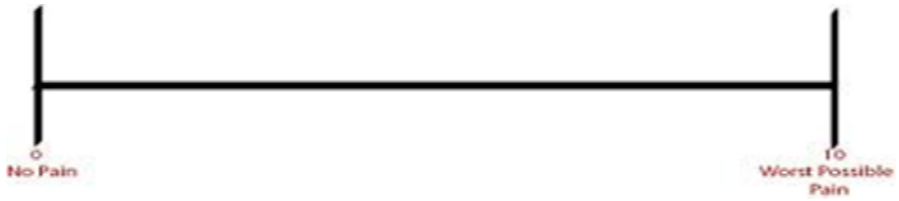
Appendix III

PT NAME: _____ PATIENT NO.: _____ PATIENT REF: _____ DATE: _____

- PLEASE INDICATE HOW BAD YOUR PAIN IS ON EACH SIDE OF YOUR MOUTH
- PLEASE TICK WHICH SIDE OF YOUR MOUTH YOU PREFER. TICK BOTH IF YOU HAVE NO PREFERENCE.

1 Hr

LEFT ☐



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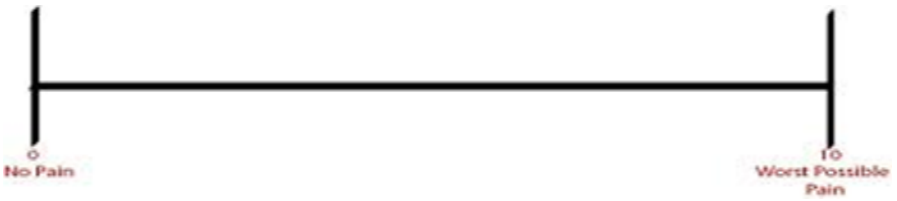

3 Hrs

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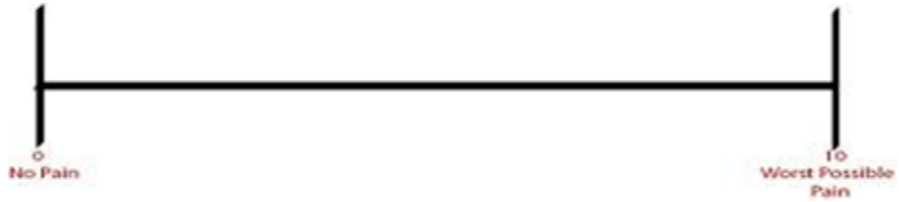

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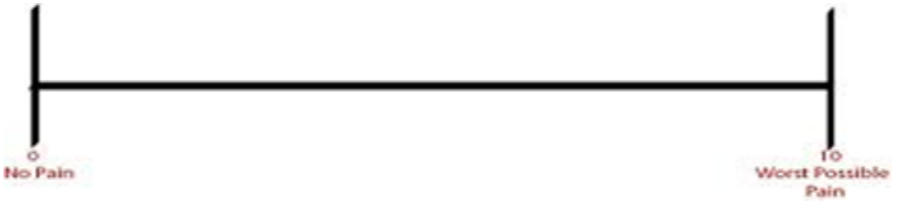

4 Hrs

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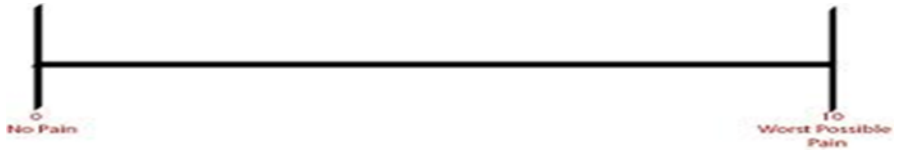

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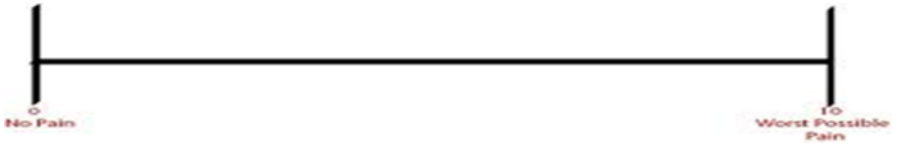

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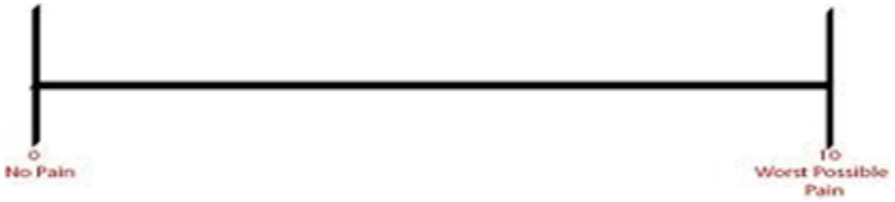

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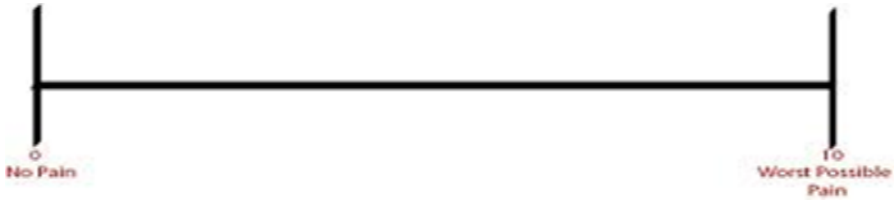

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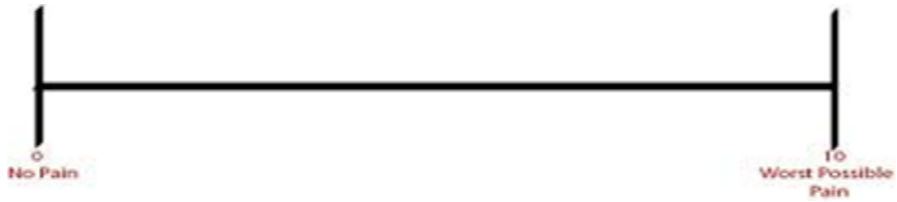

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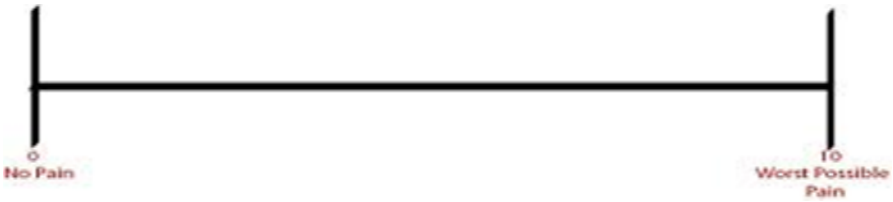


1. Did you take painkillers today, to treat pain from your dental surgery? (Please √)

   Yes ☐ No ☐

   Paracetamol ___ Tablets Time(s) taken eg 2.30pm _____ _____ _____ _____ _____ _____ _____
   Keral ___ Tablets Time(s) taken _____ _____ _____ _____ _____ _____ _____
   Oxynorm ___ Tablets Time(s) taken _____ _____ _____ _____ _____ _____ _____

2. If you were having your wisdom teeth removed again, which freeze would you prefer to be used on **both** sides, the anaesthetic used on the

   Left side ☐ **OR** Right side ☐ (Please √)

   Please give a reason for your choice_____

Appendix IV

PAIN CATASTROPHIZING SCALE

PATIENT REF: ☐

PT NO.: ☐

DATE: ☐

Everyone experiences painful situations at some point in their lives. We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which youhave these thoughts and feelings when you are experiencing pain.

0= not at all 1=to a slight degree 2=to a moderate degree 3=to a great degree 4=all the time

When I'm in pain …

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.
7. ☐ I keep thinking of other painful events.
8. ☐ I anxiously want the pain to go away.
9. ☐ I can't seem to keep it out of my mind.
10. ☐ I keep thinking about how much it hurts.
11. ☐ I keep thinking about how badly I want the pain to stop.
12. ☐ There's nothing I can do to reduce the intensity of the pain.
13. ☐ I wonder whether something serious may happen.

Appendix V

HOSPITAL ANXIETY and DEPRESSION SCALE

NAME:

PATIENT NO.:

Date:

PATIENT REF:

Tick (√) the box of the answer that is most appropriate to you:

	Yes definitely	Yes sometimes	No, not much	No, not at all
1. I wake early then sleep badly for the rest of the night				
2. I get very frightened or have panic feelings for apparently no reason at all				
3. I feel miserable and sad				
4. I feel anxious when I go out of the house on my own				
5. I have lost interest in things				
6. I get palpitations, or sensations of “butterflies” in my stomach or chest				
7. I have a good appatite				
8. I feel scared or frightened				
9. I feel life is not worth living				
10. I still enjoy the things I used to				
11. I am restless and can’t keep still				
12. I am more irritable than usual				
13. I feel as if I have slowed down				
14. Worrying thoughts constantly go through my mind				

Appendix VI

Short Form McGill Pain Questionnaire

PATIENT NAME: _____

PATIENT REF: _____ DATE: _____

PT NO.: _____

Please tick (√) the circle for the amount of pain you are experiencing in relation to your mouth

	None	Mild	Moderate	Severe
Throbbing	○	○	○	○
Shooting	○	○	○	○
Stabbing	○	○	○	○
Sharp	○	○	○	○
Cramping	○	○	○	○
Gnawing	○	○	○	○
Hot-burning	○	○	○	○
Aching	○	○	○	○
Heavy	○	○	○	○
Tender	○	○	○	○
Splitting	○	○	○	○
Exhausting	○	○	○	○
Sickening	○	○	○	○
Fearful	○	○	○	○
Punishing	○	○	○	○

Appendix VII

DENTAL VISIT SATISFACTION SCALE (1 week)

NAME:

PATIENT NO.:

PATIENT REF:

DATE:

Please **circle** the most appropriate score for the statements below, using the following scale;

1- Strongly disagree

2- Disagree

3- Neither agree or disagree

4- Agree

5- Strongly agree

1. After talking with the dentist, I know what the purpose of my procedure is.

1 2 3 4 5

2. After talking with the dentist, I have a good idea what to expect in the next few weeks.

1 2 3 4 5

3. The dentist told me all I wanted to know about the procedure.

1 2 3 4 5

4. I felt understood by the dentist.

1 2 3 4 5

5. I felt that the dentist really knew how upset I was about the possibility of pain.

1 2 3 4 5

P.T.O

6. I felt the dentist accepted me as a person.

1 2 3 4 5

7. The dentist was thorough in doing the procedure.

1 2 3 4 5

8. The dentist was too rough when he worked on me.

1 2 3 4 5

9. I was satisfied with what the dentist did.

1 2 3 4 5

10. The dentist seemed to know what he was doing during my visit.

1 2 3 4 5

11. If you were having your wisdom teeth removed again, which freeze would you prefer to be used on <u>both</u> sides

Short lasting ☐ OR Longer lasting ☐ (Please √)

Please indicate any further comments on matters associated with your procedure in the box below.

Appendix VIII

PAIN DIARY

Day __

1. Did you have pain that you associate with your dental surgery today (please tick)

   Yes ☐ No ☐

2. Did pain associated with your dental surgery affect what you could or could not do today?

   Yes ☐ No ☐

   If yes, in what way?

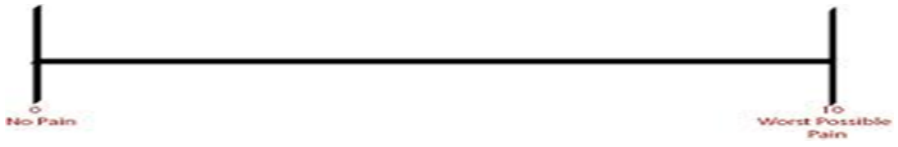
   _____

3. Did you take painkillers today, to treat pain from your dental surgery?
   Paracetamol ___ Tablets
   Keral ___ Tablets
   Oxynorm ___ Tablets

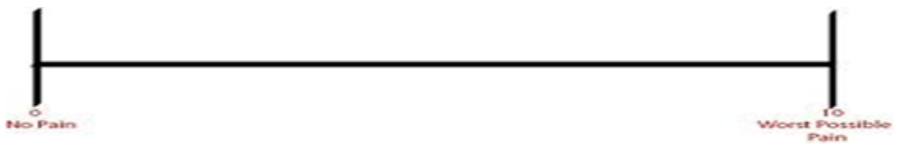
4. Did you need to see a dentist today for complications associated with the surgery?

   Yes ☐ No ☐

5. Indicate how bad your pain is on the LEFT side of your mouth



6. Indicate how bad your pain is on the RIGHT side of your mouth



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