Trinity College Dublin, The University of Dublin

Development of a core outcome set for third molar surgery

A thesis submitted in part fulfilment for the degree of D.Ch.Dent. in Oral Surgery

2024

Richard WF Carr

DECLARATION

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

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SUMMARY

Third molar surgery is one of the most common operations in the world and there is an extensive array of research carried out in the field to evaluate interventions that may improve patient outcomes.

Across surgery in general, there has been a tradition of decision making based on doctrine and the experience of experts.

As evidence-based medicine has developed, so too has the need for robust evidence in surgery, including third molar surgery.

Whilst many researchers do publish high quality evidence across various topics, there has been cross speciality recognition over recent decades of the importance of evidence synthesis and the need for standardisation of research design and reporting so that evidence synthesis can provide robust answers and recommendations for clinical questions.

Since the mid 1990s, core outcome sets have been one such innovation in the standardisation of reporting and it is now accepted that core outcome sets are needed in most fields.

There is evidence of heterogenous outcome reporting in third molar surgery and there have been initial efforts to explore outcome reporting, including by Irish oral surgery units. This inspired the author of this thesis to propose and lead on the instigation of a wider project to develop a core outcome set for third molar surgery (termed the ‘CORE8 Study’), using recognised and standardised methodology over four stages (CORE8.1 to CORE8.4).

Broadly split into pre-consensus (CORE8.1 and 8.2) and consensus stages (CORE8.3 and 8.4), the current body of work embodies a scoping review (CORE8.1), aiming to evaluate current outcome reporting in third molar surgery, and a qualitative study (CORE8.2), aiming to gain insight into outcomes of importance for patients. The scoping review utilised a systematic search and rigorous outcome extraction process whilst the qualitative study involved focus groups and framework analysis to identify new outcomes of importance, not otherwise seen in the current literature.

CORE8.1 has been able to showcase the wide range of research designs and topics as well as the countries of origin and journal of publication for 815 interventional studies in third molar surgery. This scoping review identified 82 outcomes, across four domains (physical, psychological, quality of life, practical) including six physical sub-domains (pain, swelling, function, healing, systemic response, complications). CORE8.1 highlights a dominance of physical outcomes in the current literature, in particular pain, swelling and mouth opening.

CORE8.2 has provided detailed insights on the perspectives of patients, crucially identifying two outcomes of importance not currently reported in the literature (time to normal diet, and appropriateness and accuracy of pre-op information in order to better manage patient expectations and forward planning).

Together, CORE8.1 and CORE8.2, as reported in this thesis, pave the way for future consensus stage work (CORE8.3 and CORE 8.4) to realise a core outcome set for third molar surgery.

ACKNOWLEGEMENTS

This thesis was supervised by Prof Alison Dougall and Mr Dermot Pierse. Without their support and guidance this would not have been possible.

I must also acknowledge the significant contribution of Prof Dr Branislav Bajkin, University of Novi Sad, Serbia, for his input on the steering group and as a co-reviewer during CORE8.1. I would also like to acknowledge my second reviewer in CORE8.1 at the extraction stage, Dr Robert Hardy.

As part of the project steering group, and in addition to those named above, the advice and support of the following people must also be acknowledged:

Dr Sasha Scambler – King's College London (qualitative research advice)

Prof Hal Duncan – Trinity College Dublin (core outcome set research advice)

Ms Isabel Fleishmann – Trinity College Dublin (search strategy advice/development)

I would also like to acknowledge the input of Trinity College Dublin medical librarian Mr David Mockler who acted as an independent search strategy peer reviewer.

Finally, I would like to acknowledge the unwavering support of my family and friends who have supported me throughout the challenges of dental, medical and specialist training, culminating in this degree.

CONTENTS

Chapter 1 – Introduction 1-4

1.2 - Contribution to Field 5
1.3 - Aim & Objectives 6

Chapter 2 - Literature Review

2.1 - Surgery, evidence and the need for core outcome sets
2.1.1 - A Brief History of Surgery and Surgery as a Craft 7-8
2.1.2 - Eminence above Evidence 8-10
2.1.3 - Evidence Based Medicine 10-12
2.1.4 - Challenges for Surgical Research 13-15
2.1.5 - Evidence Synthesis 15-18
2.1.5.1 - Meta-analysis 18-21
2.1.6 - The Standardisation of Evidence 21-22
2.1.7 - Core Outcome Sets – Definitions and Context 23-24
2.1.8 - Core Outcome Sets – The Justification 24-25
2.1.9 - Core Outcome Sets – Added Benefits 25-26
2.1.10 - The History of Core Outcome Sets – From OMERACT to COMET 27-29
2.1.11 - Core Outcome Set Development - Methodology 30-34
2.1.12 - Oral Health Related Core Outcome Sets 34-39
2.1.13 - Third Molar Surgery 39-43
2.1.14 - A Core Outcome Set for Third Molar Surgery 43-45
2.1.15 - Current Outcome Reporting in Third Molar Surgery 45-48
2.1.16 - Current Outcome Reporting and the CORE8 Study 48-49
2.1.17 – Conclusion from the Review of the Literature 49-50

Chapter 3 - Methods

3.1 - Methods – CORE8.1 Outcome Reporting in Third Molar Surgery – A Scoping Review 51
3.1.1 - Steering Group 51-52
3.1.2 - Objective of the Review 52
3.1.3 - Protocol & Registration 52
3.1.4 - Identifying the Research Question 53
3.1.5 - Eligibility Criteria – Inclusion Criteria 53

3.1.6 - Information Sources and the Search – Identifying Relevant Studies 53-57
3.1.7 - Study Selection 57-60
3.1.8 - Data Extraction Charting and Data Items 60-62
3.1.9 – Synthesis of Results - Collating and Summarising the Results 62-63

3.2 - Methods – CORE8.2 Qualitative Focus Groups
3.2.1 - Objective 64
3.2.2 - Inclusion Criteria 64
3.2.3 - Exclusion Criteria 64
3.2.4 - Ethical Approval 65
3.2.5 - Recruitment 65-66
3.2.6 - Topic Guide 67
3.2.7 - Data Collection 67-68
3.2.8 - Analysis 68
3.2.9 - Using the Qualitative Information from CORE8.2 to Complement CORE8.1 68

Chapter 4 - Results

4.1 - Results - CORE8.1 Outcome Reporting in Third Molar Surgery – A Scoping Review
4.1.1 - Identification of Studies 69-70
4.1.2 - Study Selection 70-72
4.1.3 - Data Extraction – Study Information - Journals 73-74
4.1.4 - Data Extraction – Study Information - Countries 75-76
4.1.5 - Data Extraction – Study Information – Study Type 76-77
4.1.6 - Data Extraction – Study Information – Study Topics 77-78
4.1.7 - Data Extraction – Study Information – Numbers of Participants 79
4.1.8 - Data Extraction – Study Information – Primary & Secondary Outcome Reporting 79
4.1.9 - Data Extraction – Outcomes 79-82
4.1.10 - Domains 83-84
4.1.11 - Sub-Group Analysis (110 Studies): Interventions, Outcome Measures and Study Intervention Positivity 85-86
4.1.11.1 - Interventions 86-89
4.1.11.2 - Positivity of Results 89
4.1.11.3 - Outcome Measures 89-90

4.2 - Results – CORE8.2 Qualitative Focus Groups 91
4.2.1 - Participant Demographics 91-93
4.2.2 - Analysis 93
4.2.2.1 - Familiarisation 93
4.2.2.2 - Framework Development 94
4.2.2.3 - Applying the Framework 94-101
4.2.2.4 - Charting 101-102
4.2.2.5 - Interpretation 102-104
4.2.2.6 - Data Saturation 104-106
4.2.3 - Using the Qualitative Information from CORE8.2 to Complement CORE8.1 106-109

Chapter 5 – Discussion

5.1 - CORE8.1 – Design and The Search Strategy 110-114
5.2 - CORE8.1 – The Evidence Base 114-116
5.3 - CORE8.1 – Limitations 116-121
5.4 - CORE8.1 – Conclusions 122
5.5 - CORE8.2 – Recruitment and Online Focus Groups 122-124
5.6 - CORE8.2 – Sample Size and Setting 125-127
5.7 - CORE8.2 – Analysis and Results 127-129
5.8 - CORE8.2 – Reflexivity 129-131
5.9 - Combining Results – CORE8.1 and CORE8.2 – New Outcomes 131-132
5.10 - Future Work to Realise 'The CORE8' COS 132

Chapter 6 - Conclusions 133-134

References 135-144

Appendices

1 – Bibliography of Included Papers at CORE8.1 145-221
2 – Focus Groups – Ethical Approval 222
3 – Focus Groups – Patient Information Leaflet 223-224
4 – Focus Groups – Consent Form 225-227
5 – Focus Groups – Topic Guide 228-229
6 – PRISMA-ScR Checklist 230-232
7 – Tabular Presentation of Results Described in Chapter 4 233-244
7.1 – Journal 233-237

7.2 – Country 238-239
7.3 – Topic 240-242
7.4 - Outcome 243-244
8 – Bibliography of References for 100 Conflicted Studies Analysed 245-253
9 – Consolidated Criteria for Reporting of Qualitative Studies Checklist 254-257

LIST OF FIGURES AND TABLES

Figure	Title	Page
3.1	Example front screen from COVIDENCE software	58
3.2	Example of COVIDENCE Screening Platform	59
4.1	PRISMA Flowchart CORE8.1	72
4.2	Data Extraction – Study Information – Journals by Frequency (High to Low)	74
4.3	Data Extraction – Study Information – Countries by Frequency (High to Low)	76
4.4	Data Extraction – Study Information – Study Topics	78
4.5	Data Extraction – Outcomes – Frequency of Reporting (High to Low)	82

Table	Title	Page
4.1	Search strategy and output	70
4.2	Study Type	77
4.3	Numbers of Participants	79
4.4	Primary and Secondary Outcome Reporting	79
4.5	Domains and Outcomes	83
4.6	Physical Domain Sub-domains and Outcomes	83
4.7	Outcomes within the Physical Sub-domains	84
4.8	Outcomes/frequency within Psychological, QoL & Practical Domains	85
4.9	Topics (A-Z) with associated interventions (sub-group 110 papers)	86-89
4.10	Outcomes (A-Z) with Defined Outcome Measures (sub-group 110 studies)	90
4.11	Sampling Frame - Focus Group 1	92
4.12	Sampling Frame - Focus Group 2	93
4.13	Key Themes with Indexed Transcripts	95-101
4.14	Charting Key Points	101-102
4.15	CORE8.2 Key Points, Insights, Outcomes and Potential Outcome Measures	106-108

LIST OF ABBREVIATIONS

COMET	Core Outcome Measures in Effectiveness Trials
CONSORT	Consolidated Standards of Reporting Trials
CORE8	Core Outcomes for Third Molar Surgery
COREQ	Consolidated Criteria for Reporting Qualitative Studies
COS	Core Outcome Set/Sets
COS-STAD	Core Outcome Sets – Standards for Development
COS-STAP	Core Outcome Sets – Standards for Protocols
COS-STAR	Core Outcome Sets – Standards for Reporting
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
GIRFT	Getting It Right First Time
HOME	Harmonising Outcome Measures for Eczema
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
OMERACT	Outcome Measures in Rheumatology Collaboration
OMFS	Oral & Maxillofacial Surgery
OutMac	Outcomes in Trials for Management of Caries Lesions
PRISMA and PRISMA-ScR	Preferred Reporting Items for Systematic reviews and Meta-analyses And Scoping Review extension
PROMS	Patient Reported Outcome Measures
QoL	Quality of Life
QOMS	Quality Outcomes in Maxillofacial Surgery
RCT	Randomised Controlled Trial
TOTPAR	Total Pain Relief

CHAPTER 1 - INTRODUCTION

Surgical extraction of third molar teeth is amongst the most common surgical procedures worldwide (O'Sullivan and Ríordáin, 2022). Indeed, figures from the USA in 1999 show that approximately 10 million third molars are removed annually (Friedman, 2007) while UK figures for England show that 77,000 patients per annum underwent the procedure in 2009/10 (McArdle and Renton, 2012).

As an important and ubiquitous surgical intervention, clinical trials relating to third molar extraction are commonplace.

Whilst many researchers present findings from well designed randomised controlled trials, very often the overall weight of evidence is limited by a lack of consistency in outcome reporting which hampers cross study analysis and meta-analysis. Indeed, in a systematic review and meta-analysis looking at steroids and their effects on post-operative discomfort after third molar surgery by Chen in 2017, the authors noted difficulties in summating heterogenous outcomes meaning that only a qualitative summary was possible (Chen et al., 2017).

In the age of evidence-based medicine, the days of expert opinion, "it works in my hands", are over. Today's approach must be evidence above eminence; and to provide the robust evidence required, comprehensive evidence synthesis across studies is essential.

The Cochrane collaboration identified similar problems in relation to bariatric surgery and recommended the development of a core outcome set (COS) (Colquitt et al., 2014). This is an agreed minimum set of outcomes recommended for measurement and reporting in all studies of a particular disease, condition or intervention (Coulman et al., 2016). Core outcome sets are not restrictive; indeed, other outcomes can be reported but the COS must be included (Williamson et al., 2012). Core outcome sets have been developed in many specialities for various conditions and interventions. The group that developed the bariatric COS recommended by the Cochrane collaboration (Coulman et al., 2016) noted that use of a COS can reduce heterogeneity in outcome reporting. In addition, core outcome sets can reduce reporting bias, where certain outcomes not originally part of a study might be selectively published based on the results of a study. Use of a COS can thus improve the summation of data from trials to inform evidence-based practice.

Searching of the research literature in oral surgery reveals no publications on the development or use of a COS in Oral Surgery, although there are groups who have developed COS in related fields. Indeed, Yan *et al* 2020 have shown that there is a high level of heterogeneity in outcome reporting in randomised controlled trials in relation to oral lichen planus (Yan et al., 2020). Consequently, development of a lichen planus COS has recently been completed (López-Pintor et al., 2023) and is listed in the COMET database website (Core Outcome Measures in Effectiveness Trials) amongst 39 other oral

health related core outcome sets, none of which focus on oral surgery interventions (COMET, 2020a).

There is a need to develop a core outcome set for studies and trials in third molar surgery and the process to realise this involves multiple stages and multiple research methods. The objective methodology for COS development is well developed and there have been initiatives to standardise the process through protocols and guidance published by the COMET website (COMET, 2020b; Kirkham et al., 2017, 2019, 2016; Williamson et al., 2017), a registry for COS research projects.

The stages involved are (Kirkham et al., 2017):

1) Scoping Review. This is for identification of previously reported outcome measures.
2) Qualitative focus groups (patients). These are to identify outcomes of importance to patients.
3) Delphi surveys (patients and professionals). These are to identify outcomes of most importance to patients and professionals and systematically narrow down those important enough for the consensus meeting stage.
4) Consensus meeting. This prioritises only the most important outcomes for inclusion in the final outcome set.

The project described in this thesis comprises the completion of stages 1 and 2 (as above), the pre-consensus stages of COS development.

This work will facilitate future consensus stage research to realise a COS for third molar surgery.

This thesis comprises a summary of the contribution of the current body of work to the field of oral surgery, the aims and objectives of the project, followed by a literature review and chapters describing the methods and results. The final chapters of the work comprise a discussion, conclusions, a reference list and appendices which include the list of references for included studies in the scoping review ethical approval paperwork and copies of patient information sheets, consent forms and the topic guide for the qualitative stage.

1.2 CONTRIBUTION TO FIELD

This work represents a unique contribution to the field since there are no current published third molar, or indeed oral surgery related core outcome set related projects. This work is novel, in the application of core outcome set development methods to oral surgery.

1.3 AIM & OBJECTIVES

AIM:

To investigate the current reporting of outcomes in trials in third molar surgery as well as what outcomes are most important to patients.

OBJECTIVES:

1. To assess current outcome reporting in third molar surgery through a scoping review.
2. To identify what outcomes are important to patients who are undergoing lower third molar surgery through qualitative focus groups.

CHAPTER 2 - LITERATURE REVIEW

2.1 - Surgery, evidence and the need for core outcome sets

2.1.1 - A Brief History of Surgery and Surgery as a Craft

The history of surgery is long and spans millennia, indeed there is evidence dating back to prehistoric times, for example in cranial trepanation which dates back to at least 5000BC for the treatment of head injuries (Verano, 2016).

It is also known that the ancient Egyptians described suturing techniques and bone setting, amongst other innovations (Blomstedt, 2014; Mackenzie, 1973), whilst the 'Sushruta Samhita', one of the earliest surgical 'textbooks' dates back to ancient times in India (Loukas et al., 2010). The ancient Greeks and Romans were no exception, in particular with Hippocrates laying the foundations for medical ethics (Reiser, 2003).

As surgery developed, it was very much a craft, and formal medical education would have been very limited. Indeed, in Britain and other areas of Europe from medieval times, surgery was commonly performed by barber surgeons with many practices based on tradition rather than scientific knowledge and medical training (Dobson, 1974). Much is written about this in the history books and in the UK and Ireland, the history of the Royal Surgical Colleges is entwined with that of the Barber Surgeons and it remains the reason for modern surgeons dropping the title 'Doctor' upon membership of the colleges in homage

to their history (Neuhaus, 2018). Indeed, the use of Mr/Ms harks back to times where surgeons (unlike physicians) would not have held university qualifications and thus did not hold an academic title.

Gradually, the scientific basis of surgery crept in. In fact, during the Scottish enlightenment in the 1800's, John Hunter was one of the early modern promoters of scientific research in surgery (Pitchai, 2021); amongst many interests, contributing significantly to the development of understanding of inflammation. Another prominent figure in the 19th century was Joseph Lister who transformed the safety of surgery with the advent of antisepsis and other steps that quashed infection rates (Pitt and Aubin, 2012).

Fast forward to more modern times and surgery is no longer just a craft. Modern surgery is based in scientific medical education and all modern surgeons undergo rigorous academic qualifications alongside learning the practical elements of performing operations (Loudon, 2000). However, the history of surgery and the very nature of learning procedures does mean that 'apprenticeship' still plays a crucial part in training.

2.1.2 - Eminence above Evidence

In the past, surgical decisions were made based on observations only and sometimes the doctrine of 'experts' (Thoma and Eaves, 2015). Indeed according to sources, David Sackett, commonly seen as one of the founding figures in modern evidence-based medicine, would often tell the story of US founding father George Washington's demise

(Thoma and Eaves, 2015). Whilst his cause of death has been debated, it is thought that Washington died from a combination of hypovolaemic shock and epiglottitis which had been treated with blood-letting, a common practice of the time (Thoma and Eaves, 2015). Whilst one of his doctors did suggest a tracheostomy, the dogma of the other ‘eminent’ physicians persisted, and the former treatment was provided.

Whilst the practical nature of surgery will always set it apart from medical specialities in terms of learning by doing, to achieve the best outcomes for patients, unlike in Mr Washington’s case and countless other examples in history, traditional ego-centric practice must be set aside and a reversal of the status quo must be adopted with a focus on evidence rather than eminence.

Nevertheless, this is uniquely difficult in surgery. The nature of apprenticeship in surgery, combined with the conventions of surgical hierarchy in the traditional ‘master-student’ model epitomises ‘eminence-based medicine’ according to Professor Jane Blazeby and others from the Balliol Collaboration (now the IDEAL Collaboration) (Ergina et al., 2009). This is an international initiative to improve research in surgery (Ergina et al., 2009). The apprenticeship model is based on the ‘master’ possessing all of the knowledge and skill whilst the apprentice surgeon learns by observation and by emulating their senior. The disadvantage according to Blazeby and colleagues is the prevention of new techniques/practices or information from filtering through to independent practice. The authors note the failure of aggressive knowledge translation methods in surgery to lead to the

adoption of best practice guidelines without the involvement of ‘eminent’ leaders in surgery (Ergina et al., 2009; Davis, 2003; Wright et al., 2006).

2.1.3 - Evidence Based Medicine

Having seen that surgery has a rich and long history, and having considered the advent of modern, scientifically based surgery and the challenges of overcoming surgical dogma, “this works in my hands”; so too must the history of modern evidence-based medicine be considered.

According to Thoma and Eaves (Thoma and Eaves, 2015), the evidence-based medicine movement started in the early 1980s, where clinical epidemiologists at McMaster University (Hamilton, Ontario, Canada) published articles to advise clinicians on the appraisal of evidence. One of the leading figures in the group was David Sackett and an example of one of those articles is a paper by Sackett on why and how journal articles should be read critically (Sackett, 1981).

Whilst the philosophical origins of modern evidence-based medicine may extend back to mid-19th century Paris, according to Sackett *et al* (Sackett et al., 1996), the term ‘evidence-based medicine’ was first used by Gordon Guyatt in 1991 (Guyatt, 1991). Guyatt is a Canadian physician who had coined the term in an editorial for the journal ‘ACP Journal Club’.

Evidence-based medicine can be defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al., 1996).

Of course, this sounds like a positive modus operandi but there have been cynics along the way, for example citing the view that it represents the suppression of clinical freedom and mainly serves those wanting to cut costs (Sackett et al., 1996). However, it is important to highlight the words ‘judicious’ and the sense of decision making that this definition encompasses since this emphasises the significance of clinical expertise and experience in using evidence-based medicine clinically. Whilst evidence may represent the best treatments for populations, the clinician still needs to transform this into a patient centred approach.

Today, the concept of evidence-based medicine has come a long way, such that the title of that early paper by Sackett (Sackett, 1981), promoting why journal papers should even be read, seems quite archaic. Indeed, according to Thoma and Eaves, emphasising the swing in professional opinion on the role of evidence-based medicine, a British Medical Journal online poll in 2007 ranked evidence-based medicine amongst some of the most important landmark developments in modern medicine (Thoma and Eaves, 2015). These ‘milestones’ also included innovations such as antibiotics, immunisation, sanitation and radiology (Thoma and Eaves, 2015).

Despite advances in the uptake and popularity of evidence-based medicine, editorials in surgical fields relating to the approach to evidence-based surgery did not appear prominently until much later

than in medical fields. Indeed, the equivalent of Sackett and Guyatt's early articles in medicine did not appear until 2001 when Meakin's introduced the first 'users' guide for evidence-based surgery' (Ergina et al., 2009; Meakins, 2001).

Although things have moved on positively in recent decades, whilst clinical expertise can only be gained with training and experience, so too is the usefulness of the evidence-based approach which is also dependent on its inputs. That is to say, if there is no evidence or the evidence base is poor, then the evidence-based approach has no basis.

In considering this, again Canada was leading the way, as a system known as 'Levels of Evidence' was developed well before Guyatt's advent of the term evidence-based medicine (Thoma and Eaves, 2015; Canadian Task Force on the Periodic Health Examination, 1979). Over the years since, Sackett was instrumental in improving this and generating the basis of the systems researchers are more familiar with today, where evidence can be assigned a level (for example the Oxford Centre for Evidence Based Medicine 'Levels of Evidence'(OCEBM Levels of Evidence Working Group, 2024)) and a 'GRADE' (Burns et al., 2011; Siemieniuk and Guyatt, 2024) of recommendation (Thoma and Eaves, 2015).

The systematic appraisal of evidence and assigning of levels and grades is an essential aspect in the dissemination and uptake of evidence in the clinical practice of evidence-based medicine.

2.1.4 - Challenges for Surgical Research

With the rise of evidence-based medicine and the adoption of systematic grading and recommendations, it is important to note some of the challenges unique to surgery.

Providing high quality evidence does have unique challenges compared to medical fields, and as noted above, evidence-based surgery can only be useful if its inputs afford the evidence that is required.

In the past, surgical research has been seen as somewhat of a laughing matter, with one Lancet commentator calling it a ‘Comic Opera’ and suggesting that surgical research fails to provide many answers (Horton, 1996).

Well-designed randomised controlled trials (RCTs) can provide the highest levels of evidence to answer clinical questions (OCEBM Levels of Evidence Working Group, 2024). The highest levels of evidence are meta-analyses, systematic reviews and systematic reviews of systematic reviews.

The RCT was first popularised in the 1940s when the UK Medical Research Council utilised its methodology in a trial of streptomycin for pulmonary tuberculosis and Dutch researchers trialled the use of Paludrine for malaria (Craft and Editors, 1998; Medical Research Council, 1948). These trials were instrumental in setting the precedent for randomisation as a way of minimising the risk of various biases and the influences of differential biases across groups that can lead to confounding factors. These early RCTs also laid the foundations for control groups and objective outcome measurement. In modern RCT

methodology, much attention is paid to allocation concealment and blinding (Kendall, 2003).

Blencowe *et al* note that carrying out RCTs in surgery is notoriously difficult due to numerous methodological and cultural challenges (Blencowe et al., 2017). The culture of surgery has already been discussed. In terms of methods, the most obvious challenge in surgery is often blinding. In medical trials, drugs are often tested against 'placebo' drugs. Placebo surgery is much more contentious and fraught with ethical issues. Placebo medications do not come with risks of side effects, but almost all surgery has risks like bleeding, swelling, pain, scar and infection. Despite this, there are examples of 'sham surgery' based surgical RCTs. Indeed, Sihvonen *et al* published an RCT comparing arthroscopic partial meniscectomy with sham surgery, achieving a high level of evidence and publication in one of the highest impact factor journals in the world, the New England Journal of Medicine (Sihvonen et al., 2013). The authors justified the study on the basis that osteoarthritis and associated meniscal injury is increasing and 700,000 arthroscopic meniscectomies per year were being done in the USA alone at the time. Clearly there was genuine clinical equipoise and the evidence had potential for wide impact.

According to Ergina *et al* (Ergina et al., 2009), there are other challenges too including:

- Patients are often unwilling to participate in surgical trials where they may suffer for no benefit if they receive sham surgery. This is very different to receiving a placebo medication where you

may not benefit (if indeed the active drug has a benefit) but the placebo itself will do you no harm.

- Patients may be unwilling to participate if the comparative procedure is more invasive (such as an open versus closed approach).
- There can be poor compliance with the allocation.
- Randomisation can be difficult if patients need to know their procedure in advance.
- Difficulties in blinding (patients and surgeons/investigators) and allocation concealment.

There have been various initiatives to improve surgical trials, such as the establishing in the UK of surgical trials centres and surgical speciality leads as champions for RCTs in their field (Blencowe et al., 2017).

2.1.5 - Evidence Synthesis

Since surgical research has often failed to employ RCTs, or the RCTs that are done are of poor methodological quality due to some of the issues discussed, the analysis and synthesis of data using meta-analysis and systematic reviews is often difficult (Garas et al., 2012). The issue is frequently compounded by heterogeneity in design and specifically, outcome reporting, where lack of standardisation in outcome reporting hinders cross study analysis (Coulman et al., 2016).

Furthermore, poorly or inadequately performed RCTs and meta-analyses can even mislead the evidence base, failing to inform practice or influence policymakers (Garas et al., 2012).

Garas *et al* notes that surgery is a rapidly evolving field; it is innovative, and new techniques or refinements are always evolving (Garas et al., 2012). This necessitates the ability to design robust studies, identify new evidence and thoroughly and objectively appraise it. But probably more important is the ability to synthesise that evidence so that new techniques or novel developments in surgery can be promoted and adopted, improved or indeed rejected with a scientific basis.

Evidence synthesis, the ability to systematically combine data from multiple studies, ensures researchers can draw faster and more reliable conclusions on any particular research question. In terms of evidence-based practice, clearly the ability to digest the implications of many papers in one document can help clinicians and policymakers to make decisions about what treatments to provide or even to fund (Garas et al., 2012; Mulrow, 1994).

Evidence synthesis can also help to identify gaps, indeed, many Cochrane collaboration systematic reviews draw conclusions emphasising the need for better quality RCTs, for example when making guarded conclusions based on small numbers of RCTs of high enough quality for inclusion (Colquitt et al., 2014; Garas et al., 2012; Uman, 2011).

For example, a 2014 Cochrane systematic review (Colquitt et al., 2014) on weight loss surgery for adults concluded:

1) “From the information that was available to us about the studies, we were unable to assess how well designed they were”
2) “Adverse events and reoperation rates were not consistently reported in the publications of the studies”
3) “Most studies followed participants for only one or two years, therefore the long-term effects of surgery remain unclear”
4) “Few studies assessed the effects of bariatric surgery in treating comorbidities in participants with a lower BMI. There is therefore a lack of evidence for the use of bariatric surgery in treating comorbidities in people who are overweight or who do not meet standard criteria for bariatric surgery”

This example shows that evidence synthesis for bariatric surgery (which did also make some positive recommendations) demonstrated a need for better reported studies, studies reporting on certain important outcomes that were not considered, studies in patient groups that were not represented and longer follow-up periods.

There are other benefits of evidence synthesis that are important, such as minimising bias, for example through risk of bias assessments as part of evidence synthesis (Sterne et al., 2019); and being able to draw conclusions with wider generalisability than individual studies (Mulrow, 1994) (since a broader range of participants and populations are likely to be represented in meta-analyses of multiple studies).

It has been apparent so far, that surgery has a long and fruitful history of innovation and that there have been major leaps in the surgical scientific and evidence base over the last few decades. However, to realise the place of evidence above eminence, it is perhaps this idea of evidence synthesis that is most crucial.

2.1.5.1 – Meta-Analysis

Whilst the very first published meta-analysis is generally attributed to statistician Karl Pearson in a 1904 study on typhoid vaccines (Koricheva et al., 2013), formal systematic reviews and meta-analyses as they are known today really only began in the 1970s and 80s.

Indeed, the term ‘meta-analysis’ was coined by Gene Glass in 1976 who used it to describe statistical analysis of multiple study results in systematic review methodology (Glass, 1976, 2015).

In the late 1970s Thomas Chalmers published one of the earliest modern meta-analyses focussing on anticoagulants in myocardial infarction (Koricheva et al., 2013); he analysed 6 RCTs in this work, showing a reduction in mortality with anticoagulant treatment. Chalmers’ work is often cited as one of the earliest and landmark uses of evidence synthesis in this way.

Many landmark uses of evidence synthesis occurred in cardiology, and while there will be many examples in other fields, cardiology certainly

offers perhaps one of the most stark examples of the importance of evidence synthesis.

In 1992, the New England Journal Medicine published a cumulative meta-analysis on therapeutic trials for the treatment of myocardial infarction (Lau et al., 1992). In this paper, Lau *et al* demonstrate the use of evidence synthesis but also the importance of updating that evidence synthesis as new trials are added to the evidence base – 'cumulative meta-analysis'. This is because once the threshold of evidence to draw definitive conclusions is surpassed, the implications for patient care can be vital.

Indeed, in Lau's paper, when cumulative meta-analysis is applied, it is clear that from at least 1973 ('Frankfurt 2' trial), or even as early as 1971 ("European 2' trial), that there was strong evidence for the effectiveness of streptokinase in reducing mortality in myocardial infarction. It can be seen in the cumulative analysis that from those years onwards, both the point estimate mean odds ratio and the 95% confidence intervals fall well below the null value (odds ratio of 1) demonstrating a clear reduction of odds of mortality. Lau presents a forest plot. This is a graphical representation of the results of multiple studies highlighting point estimate effect sizes with confidence intervals, a null value line (which the confidence intervals must not overlap) and a summary measure (usually a diamond) showing the pooled estimate effect size from all studies combined.

Lau's forest plot shows the cumulative meta-analysis against a conventional meta-analysis, and although the latter is less clear,

treatment effect, confirmed with narrow confidence intervals, is seen in several of the largest individual trials (GISI-1 and ISIS-2) and the summary of effect plot, based on 36,974 patients. This favours a reduction of mortality with treatment.

The stark implication here, is that with these methods and with proper evidence synthesis, patients could have been treated with streptokinase from the early 1970s. The evidence was there! Instead, streptokinase was only licensed in the USA by the FDA (Food and Drug Administration) in 1982 for other indications and from 1987 for acute myocardial infarction (Burney and Walsh, 1988) and large scale uptake of the drug for this indication did not really happen until after the largest trial (17,182 cases, ISIS-2 (Baigent et al., 1998)) was published in 1988 (Committee Members et al., 1996; Stewart et al., 1989). Meanwhile, many thousands of patients may have suffered un-necessary mortality from acute myocardial infarction because the evidence that already existed was not synthesised to effect clinical and policy change.

As evidence synthesis became popularised, so too did organised groups who proposed standardised rigorous methodology and dissemination of the evidence. Indeed, in the UK, Sir Iain Chalmers instigated the ‘Oxford Database of Perinatal Trials’ in 1978 (Koricheva et al., 2013). The database is seen as a forerunner for well-known organisations today like the Cochrane Collaboration(Koricheva et al., 2013).

The forest plot itself was first developed in the 1980s and was adopted by the Cochrane Collaboration as their logo and in current times the collaboration is at the forefront of evidence synthesis and dissemination.

2.1.6 - The Standardisation of Evidence

With the advent of formalised evidence synthesis and the acceptance that it is crucial in order to best serve patients, as emphasised, it is important to state again that the synthesis of evidence and the worth of the resulting recommendations depends on good inputs. That is to say, that the whole process relies on high quality evidence, but also evidence that is designed and reported in a way that supports its ultimate meta-analysis.

This is difficult, as the sources of evidence are seen to be highly variable and assigning standardised scoring for quality and risk of bias is frequently problematic (Garas et al., 2012).

This has led to the development of guidelines on study design and reporting such as CONSORT (Schulz et al., 2010) for RCTs and PRISMA (Page et al., 2021) for systematic reviews and meta-analyses (Garas et al., 2012).

Another innovation has been the establishment of trial registries, such as the US National Libraries of Medicine ‘ClinicalTrials.gov’ registry. These can improve transparency and accountability, reducing biases

like publication bias, but they depend on the registration of all trials which is not necessarily compulsory in all jurisdictions.

Another piece of the jigsaw, however, is outcome reporting. Even if universal standards for study design and reporting were observed, the synthesis of evidence can still be compromised if research on the same topics dose not report on the same outcomes that can then be summated. Certainly, for example, a greater level of evidence for the effect of a drug on pain by synthesising two studies cannot be achieved if only one of them reported on pain related outcomes.

In the bariatric surgery Cochrane review quoted earlier, important outcomes like adverse events and reoperation rates were not consistently reported in the considered trials, so drawing conclusions on the best operations for weight loss was compromised (Colquitt et al., 2014).

That review called for the development of a core outcome set for bariatric surgery.

In addition to some of the innovations in standardisation discussed, core outcome sets are another novel weapon in the arsenal to improve evidence synthesis and facilitate the use of research faster to really benefit decision making and improve care for patients.

2.1.7 - Core Outcome Sets – Definitions and Context

A core outcome set (COS) is an agreed minimum set of outcomes that must be measured and reported on in all studies of a particular disease, condition or intervention (Colquitt et al., 2014; Coulman et al., 2016; Williamson et al., 2012, 2017; Clarke and Williamson, 2015). With consistent outcome reporting, evidence synthesis within a particular field is then enhanced.

It is important to highlight, that core outcome sets are not designed to be restrictive, indeed researchers can still report on other outcomes of interest, so long as the set of core outcomes is reported in any study with an existing COS (Williamson et al., 2012). Webbe *et al* describe this concept well: “Core Outcome Sets should not stifle innovation. Rather than prescribing outcome selection, they simply represent a minimum group of outcomes that should be reported” (Webbe et al., 2018, p.163).

Outcomes, in the context of clinical trials can be defined as a “measurement or observation used to capture and assess the effect of treatment such as assessment of side effects (risk) or effectiveness (benefits)” (Williamson et al., 2017, p.1). Outcomes, differ from outcome measures; indeed outcomes are a measurable change in patient status over time such as pain or healing, whilst outcome measures on the other hand refer to a specific tool or test that might be used to assess that change in the outcome, for example pain on visual analogue scale or assessing bone healing with radiographic follow-up (El-Karim et al., 2023).

Outcome measures can also be either clinician reported (for example, objective evidence of dry socket) or patient reported (for example, subjective effects of pain on function and quality of life, such as ability to eat comfortably) (El-Karim et al., 2023). The latter are not interpreted by the clinician.

Since clinical decisions about the care of patients are made based on the outcomes of evidence and evidence synthesis, the outcomes that are looked at in any trial need to be relevant to patients as well as clinicians and policymakers (Williamson et al., 2017). However, Williamson *et al* in the COMET (Core Outcome Measures in Effectiveness Trials) handbook (Williamson et al., 2017) highlight that a lack of attention to the choice of outcomes chosen in trials has led to "avoidable waste in both the production and reporting of research" and crucially point out that outcomes are very often not those that patients actually regard as most import or relevant.

So, core outcome sets that are objectively developed and that take account of the views of clinicians and patients are needed to define what should be the relevant core outcomes in any particular field.

2.1.8 - Core Outcome Sets – The Justification

Having highlighted one Cochrane review (Colquitt et al., 2014) which recommended COS development in bariatric surgery, the problem is hugely reinforced when considering the findings of Kirkham *et al* who examined Cochrane reviews for insight into how often the authors conclusions are limited by missing data; Kirkham found that in 102 of

143 reviews included, the authors had commented on issues around reporting of key outcomes in their included trials (Kirkham et al., 2013).

These issues can be further compounded when variability of outcome measures is thrown in, with one study (Miyar and Adams, 2013) looking at trials in schizophrenia showing that in 10,000 trials, there were 2194 different measures used for assessing the patients outcomes (Williamson et al., 2017).

2.1.9 - Core Outcome Sets – Added Benefits

In addition to ensuring that the right outcomes are included in a COS and that this set is used to standardise outcome reporting, core outcome sets do have other benefits.

Williamson *et al* in the COMET handbook point out that outcome reporting bias can be reduced by standardising outcome reporting using COS (Williamson et al., 2017). Williamson states that reporting bias is the selective reporting of outcomes for publishing on the basis of the results. COS address this (Coulman et al., 2016), since if an outcome is important enough to be a core outcome, it should be reported even if it does not support the hypotheses of the authors who might otherwise decide to not to highlight that outcome. This is a significant problem says Williamson (Williamson et al., 2017), as there is systematic review level evidence to show that results that are not statistically significant are less likely to be fully reported (Dwan et al., 2008).

Webbe *et al* (Webbe et al., 2018, p.163) summarise the benefits of COS as follows:

- “They reduce heterogeneity and facilitate meta-analysis”.
- “They reduce the risk of reporting bias, and thus ensure that all trials contribute outcome data to meta-analyses”.
- “By involving a wide range of stakeholders, such as patients, parents and health professionals, it is more likely that clinically relevant outcomes are identified”.

Webbe *et al* also highlight an outcome set for paediatric diarrhoea (Karas et al., 2015) and this simple COS is a good example of what COS development leads to. In this example, any study into treatments for paediatric diarrhoea should include these core outcomes so that the above benefits within that field can be realised:

- Diarrhoea duration
- Degree of dehydration
- Need for hospitalisation
- Proportion of patients recovered by 48 hours
- Adverse effects associated with therapy.

2.1.10 - The History of Core Outcome Sets – From OMERACT to COMET

Amongst the various innovations in research methodology discussed, the realisation that standardised outcome reporting was important is not new.

In fact, according to Williamson (Williamson et al., 2017), one of the earliest attempts to standardise outcome reporting was by the World Health Organisation in the field of cancer trials in the 1970s.

However, the most significant work on core outcome sets has been through the OMERACT (Outcome Measures in Rheumatology (originally Rheumatoid Arthritis Clinical Trials)) collaboration (Tugwell et al., 2007). OMERACT was initially an informal network who aimed to improve outcome measurement in rheumatology and it was established at the conference on rheumatoid arthritis in Maastricht in 1992 (Tugwell et al., 2007; Tugwell and Boers, 1993). Peter Tugwell and Maarten Boers had been discussing the outcomes of European and North American trials in the speciality and noted that differences in reporting was hindering meta-analysis (Williamson et al., 2017; Tugwell et al., 2007). Within the group there was expertise in consensus techniques in research and it was suggested that these techniques could be used to develop agreement on a set of core outcomes for trials in rheumatoid arthritis (Williamson et al., 2017; Tugwell et al., 2007).

Since then, OMERACT have held 8 conferences and have achieved consensus on core outcome sets for rheumatoid arthritis, osteoarthritis,

psoriatic arthritis, fibromyalgia, and other rheumatic diseases (Williamson et al., 2017; Tugwell et al., 2007).

OMERACT is said to be data driven and iterative with its consensus processes involving relevant stakeholder groups (Williamson et al., 2017).

However, patient involvement was not always the case and it was not until OMERACT 6 in 2002 that a patient workshop provided the insight that fatigue was an outcome of crucial importance for rheumatoid arthritis patients and so it subsequently emerged as an outcome for consideration as a core outcome (Williamson et al., 2017).

There are other COS groups who focus on COS for particular fields including (Williamson et al., 2017):

- Pain (IMMPACT, 2024)

  Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).
- Eczema (HOME, 2024)

  Harmonising Outcome Measures for Eczema (HOME)

As the uptake of COS has increased into many fields, there has been a need for a unifying initiative for all those involved in developing COS and this came about in 2010 when the ‘Core Outcome Measures in Effectiveness Trials’ (COMET) initiative was launched (Williamson et al., 2017). The initiative aimed to collate resources, encourage the

exchange of ideas and to stimulate research into methodological issues around COS development (Williamson et al., 2017). The stated (COMET, 2024b) specific objectives of COMET are available on their website (COMET, 2020a):

1. Raise awareness of current problems with outcomes in clinical trials
2. Encourage COS development and uptake
3. Promote Patient and Public Involvement (PPI) in COS development
4. Provide resources to facilitate these aims
5. Avoid unnecessary duplication of effort
6. Encourage evidence-based COS development

Point 5 is particularly prudent since the website provides a registry so that COS development projects can be registered and searched such that multiple groups in different places do not un-necessarily work on a COS for the same field. COS can be most effective where there is a single recognised COS for the field.

The website also provides the ability to upload links to published papers related to particular projects such that COS research and ultimately the COS for a particular field is accessible and visible.

2.1.11 - Core Outcome Set Development – Methodology

Once a decision is made to develop a core outcome set for a particular field, a simplified outlook on the methodology is that there are two steps involved (Webbe et al., 2018).

1) Identify potential outcomes
2) Rank the outcomes to determine which are the most important ‘core outcomes’.

Involvement of clinicians and patients is essential in modern COS development and in contrast to the early days of OMERACT, one 2016 study suggested that nearly 90% of COMET registered COS projects do involve patients (Gorst et al., 2016).

Step 1 can be considered the pre-consensus stage whilst the methods used to rank and narrow down outcomes to the ‘core’ set can be considered the consensus stages.

The pre-consensus stage commonly involves systematically reviewing clinical trials within the particular field in order to extract the outcomes used. This usually shows that outcome reporting is very heterogenous and supports the idea that a core outcome set is necessary (Webbe et al., 2018; El-Karim et al., 2023).

It is then necessary to consider what patients, and in some cases other stakeholders consider important and this can involve various methodologies but typically involves qualitative methods such as focus groups or interviews (Webbe et al., 2018). The involvement of patients

is crucial to identify outcomes of importance that are not otherwise considered by professionals.

Consensus stages can involve various methods. Indeed, in the early days of OMERACT, ‘Nominal Group Technique’ was used (Tugwell et al., 2007), however the commonly accepted methodology for modern COS development is the modified Delphi technique, involving successive rounds of outcome ranking surveys (Webbe et al., 2018; Williamson et al., 2017). Typically, the surveys are sent to all interested parties, including patients, but would include experts in the speciality field across a wide geographic area (Webbe et al., 2018). Delphi rounds gradually narrow down outcomes that meet a ‘consensus-in’ threshold using techniques like removing the worst performing outcomes in successive surveys and/or providing feedback to participants about how important an outcome was considered by others at a previous round. This drives the survey results towards a consensus over several rounds of surveys and the outcomes that are important (consensus-in) are then put to a consensus meeting which is the final stage.

According to the COMET handbook, typically 2-3 Delphi rounds are necessary for most COS projects but some have required up to 6 (Williamson et al., 2017).

Consensus meetings can take various forms but ultimately result in voting or scoring of outcomes by patients, experts and other stakeholders to identify the agreed outcomes of importance which are then termed the core outcome set in that field.

In terms of formalised advice on methodology, the COMET handbook (Williamson et al., 2017) is perhaps the bedrock of COS research design. In particular, the handbook provides extensive advice on many aspects of designing a Delphi process for a particular field's COS, with advice on everything from who and how many people should participate (a so-called Delphi panel), to how many rounds, how questions should be ordered, feedback between rounds and defining consensus. There is also advice on using the COMET designed 'DelphiManager' software.

In terms of the qualitative stages, the handbook highlights the importance of involving patients and not just bringing outcomes from previous trials alone into the consensus stages. Indeed, COMET highlight the example from earlier in this review, where OMERACT failed to realise the importance of 'fatigue' as an outcome in rheumatoid arthritis when the early core outcome development projects failed to involve patients. Importantly, Williamson *et al* highlight the added value that the qualitative stages bring in shedding light on not just what is important to patients but why (Williamson et al., 2017)? This can be helpful if at the later stages of consensus, there is divergence between stakeholders on what outcomes are important enough to be deemed core.

To ensure that COS reflect the wider community of patients that they ultimately serve, it is recommended that qualitative stages include patients from a broad spectrum of socioeconomic and other characteristics such as age or other health comorbidities. In this way,

whilst sampling for qualitative stages is usually purposive, it is not a simply a convenience sample (Williamson et al., 2017).

Framework analysis is recommended at qualitative stages (COMET handbook (Williamson et al., 2017) 2.9.3.4), but is not the only method for qualitative analysis. Framework analysis facilitates the systematic organisation of qualitative data through categorisation of data using a framework of key themes indexed to the data (Gale et al., 2013).

In addition to the extensive COMET Handbook, there are various other supporting documents to define the methodological considerations that are expected and the standards for published protocols and COS reporting including:

- Core Outcome Sets – Standards for Development (COS-STAD) (Kirkham et al., 2017)
- Core Outcome Sets – Standards for Protocol Items (COS-STAP) (Kirkham et al., 2019)
- Core Outcome Sets – Standards for Reporting (COS-STAR) (Kirkham et al., 2016)

Importantly, once a core outcome set has been agreed, the work does not end there. There is generally significant work to be done on how the core outcomes should best be measured. According to the COMET handbook (Williamson et al., 2017), this is best achieved by carrying out or using the results of systematic reviews of measurement instruments and there is a consensus standard for the selection of health measurement instruments (COSMIN). The COSMIN initiative (COSMIN,

2024) website collates systematic reviews of measurement instruments and provides guidelines on how to perform systematic reviews for instruments without current evidence. There is a checklist for studies evaluating patient reported outcome measures and COSMIN have been in the process of producing a similar checklist for non-patient reported outcome measures (Williamson et al., 2017). Furthermore, collaboration between COMET and COSMIN has resulted in a guideline on how to select outcome measures for outcomes included in a COS (Williamson et al., 2017; Prinsen et al., 2016). Interestingly, two of the authorship names on that guideline (Prinsen et al., 2016) are Peter Tugwell and Maarten Boers, the original leaders in the early days of OMERACT. This highlights the complexity of core outcome set methodology and the collaboration that has taken place over the decades since 1992.

2.1.12 - Oral Health Related Core Outcome Sets

At the time of writing, there are 40 registered COS projects on the COMET website relating to oral health. This includes the wider CORE8 (COMET, 2024a) (Core Outcomes in Third Molar Surgery) project to which this thesis relates.

There are COS development projects within several areas of oral medicine, including lichen planus (Yan et al., 2020) and also in endodontics (El-Karim et al., 2023) and dental anxiety to name but a few.

Interestingly, within the field of endodontics, there had been several initial COS development projects which have paved the way for the

wider project that is currently ongoing. Indeed, according to El-Karim *et al* (El-Karim et al., 2023) a focussed abbreviated set was developed as part of guideline development within the European Society of Endodontology and a literature based synthesis of outcomes for some aspects of endodontics has been published; however, the latter work did not include some newer endodontic techniques and crucially, these studies did not use consensus methodology which is the standardised approach recommended by the COMET initiative. As such, there is a large project currently ongoing within endodontics and registered on the COMET website.

In Oral Medicine, a 2011 Cochrane systematic review into interventions for the treatment of lichen planus commented that included studies used a range of outcome measures which resulted in difficulties evaluating treatment and meta-analysing (Thongprasom et al., 2011). The authors also cited the work of Martin and Murrell to emphasise that the issue was not unique to lichen planus. Indeed, Martin reviewed trials in pemphigus revealing 116 outcomes within only 96 papers in the 25 years the review considered (Martin and Murrell, 2008). The Cochrane review recommended that “future RCTs should measure symptoms and clinical features by means of the same standardised outcome” (Thongprasom et al., 2011).

In 2020, a subsequent Cochrane systematic review focussed on steroid treatments for lichen planus but continued to highlight how outcome heterogeneity was hampering the analysis (Lodi et al., 2020). Lodi *et al* (Lodi et al., 2020) stated that they had been able to meta-analyse

studies comparing clobetasol and triamcinolone versus tacrolimus where the outcomes were:

- Pain resolution
- Clinical resolution
- Adverse effects

However, regarding wider outcomes, they commented that “the methods adopted to measure such outcomes were different and often difficult to compare, representing another obstacle to summarising their effects and to meta-analysing data”. Again, a recommendation was made for the standardisation of outcomes in lichen planus.

This has led Yan *et al* to formally assess the heterogeneity of outcome reporting in RCTs for lichen planus and this paper is one of the key pre-consensus stage reviews providing information on lichen planus outcome reporting to feed into a consensus process towards a core outcome set for lichen planus (Yan et al., 2020). Yan and colleagues searched PubMed, Embase and the Cochrane databases to identify RCTs over a 14 year period and went on to extract 119 outcomes from 88 included RCTs demonstrating a high degree of heterogeneity (Yan et al., 2020).

The lichen planus COS was registered with COMET in 2020 and in 2023 the final consensus stages were completed with Delphi style ‘clicker sessions’ and an interactive consensus stage at the World Workshop in Oral Medicine VIII and the American Academy of Oral Medicine Annual Conference (López-Pintor et al., 2023). Their final

COS included 15 items for inclusion in all future trials in oral lichen planus:

- Appearance of lesions
- Severity of lesions
- Symptoms
- Function
- Social impact
- Psychological impact
- Patient support from family and friends
- Compliance and tolerability
- Overall patient satisfaction
- Adverse events
- Economic impact
- Timelines
- Need for rescue medication
- Biomarkers post-treatment initiation
- Histopathology post-treatment initiation

Within the area of caries prevention and management, Lamont *et al* published an editorial in 2015 calling for a COS in this field (Lamont et al., 2015). Lamont were particularly concerned with the influence of reporting bias and emphasised, like the authors of the Cochrane bariatric COS previously discussed (Coulman et al., 2016), that one of the significant benefits in their field would be to reduce the non-publication of negative results. Indeed, they cite evidence that reporting

bias is a problem in oral health related trials, highlighting an assessment of oral health group Cochrane reviews that noted downgrading of primary outcomes to secondary outcomes in 11% of studies and non-reporting of primary outcomes in 10%; crucially 19% of papers reported new outcomes at the write up stage and thus exhibiting the nature of reporting bias (Pandis et al., 2015). Lamont also commented that part of the problem here probably lies in inadequate care at the design stage of trials when it comes to selecting the outcomes of importance to include, citing interviews (Smyth et al., 2015) with trialists highlighting that outcomes were often chosen on the basis of the researchers own experiences and knowledge rather than through a ”rational and systematic” methodology. The ‘Outcomes in Trials for Management of Caries Lesions’ (OuTMaC) COS project has been ongoing since and is registered on COMET (Schwendicke et al., 2024).

In orthodontics, a scoping review was published in 2018 demonstrating a high degree of heterogeneity in outcome reporting and a need for uniformity (Tsichlaki et al., 2018). The authors screened 1267 abstracts and included 164 studies for outcome extraction leading to 54 outcomes which were categorised into 14 domains. This scoping review along with outcomes from qualitative interviews and focus groups, went on to inform the consensus stages (Tsichlaki et al., 2017) which included Delphi surveys and a consensus meeting in a large and multi-centre study.

Ultimately, an orthodontic COS was finalised and published including 7 core outcomes (Tsichlaki et al., 2020):

- Breakages
- Adverse effects on teeth or tooth-supporting structures
- Skeletal relationship
- Alignment and/or occlusion
- Stability (intra-arch and/or inter-arch)
- Patient-related adherence
- Impact of self-perceived aesthetics

So, it is clear that the development of COS is an innovation that is crucial for evidence synthesis and ideally, COS should be developed across all specialities and fields.

Within oral health, there has been much progress towards COS development in several fields and the pre-consensus work across many wider and oral health fields has provided a wealth of evidence that outcome heterogeneity is widespread across health related research.

2.1.13 - Third Molar Surgery

In third molar surgery, many authors of systematic reviews struggle to synthesise the evidence to give clear recommendations.

Indeed, in a systematic review and meta-analysis evaluating the role of platelet-rich fibrin (PRF) on healing after third molar surgery, Al-Hamed *et al* commented on the “considerable heterogeneity” in outcome

reporting that meant meta-analysis was not possible for many outcome variables (Al-Hamed et al., 2017, p.1124). This severely limited the ability to draw firm conclusions and the study could only really recommend future standardised RCTs to address these issues.

Similarly to the reporting issues with primary outcomes in caries trials, Cochrane reviews have commented on the issue of incomplete outcome data and the poor level of reporting of important outcomes like those related to quality of life (Ghaeminia et al., 2020). Indeed, a review around the removal versus the retention of symptom free teeth could not identify any papers reporting on quality of life outcomes and found that incomplete outcome reporting led to a downgrading of the evidence from the small numbers of studies that did exist addressing this topic (Ghaeminia et al., 2017).

There has been positivity in terms of trials in analgesia, with one Cochrane review commenting that they were able to calculate the total pain relief (TOTPAR) at various relevant time points in all included trials evaluating paracetamol for analgesia after third molar surgery (Weil et al., 2007). This may be in part, because third molar surgery is frequently used as a pain model for the testing of analgesic medications by pharmaceutical companies and studies are often well funded and designed. That being said, the same authors did note issues around risk of bias in many included studies but this related mainly to allocation concealment rather than outcome reporting.

In terms of trials evaluating different techniques in third molar surgery, there is a Cochrane systematic review from 2020 which tried to address the evidence for a range of interventions including (Bailey et al., 2020):

- Flap type
- Use of lingual nerve protection
- Bone removal techniques
- Wound irrigation
- Primary versus secondary closure
- Suture techniques
- Drain use
- Autologous platelet concentrates like PRP (platelet rich plasma) or PRF (platelet rich fibrin).
- Root retention techniques

The authors considered the most important primary outcomes to be dry socket, wound infection, permanent neurosensory deficits and adverse events like fracture of the jaw. Wider secondary outcomes were also defined including pain, swelling and mouth opening.

However, in some areas like suture technique and drain use, no trials reported on the primary outcomes (Bailey et al., 2020). Furthermore, in trials evaluating lingual nerve retraction, whilst the outcome of main interest was reported (neurosensory deficits), there was a failure to report on any other primary outcomes. Again, in trials evaluating lingual spit technique, wound infection was frequently reported but other crucial

primary outcomes like dry socket or other important outcomes like adverse events including fractured jaw were not. In fact, this outcome (fracture of jaw) was not reported in any of the 62 included trials.

These patterns continued across the intervention areas considered.

There were also issues around incomplete outcome reporting with implications for assessing risk of bias properly. This included not reporting the numbers of participants included in outcome assessments rendering assessment of attrition bias impossible; there were also examples of selective outcome reporting or incomplete outcome reporting due to outcome measures that were not reproducibly measurable. Further, the authors found that many studies were un-useable for meta-analysis due to poor or poorly standardised outcome reporting around pain, swelling and mouth opening.

Whilst not only owing to issues around outcome reporting, indeed there were multiple other methodological criticisms for many trials, the review concluded that the quality of the evidence was poor across the board, and they were unable to make any firm recommendations on any of the topic areas included.

This is highly unfortunate, since this review probably constitutes one of the most comprehensive assessments of the evidence for a wide range of questions in third molar surgery.

These issues have an impact on major clinical guidelines. The 2020 Royal College of Surgeons document ‘Parameters of care for patients undergoing mandibular third molar surgery’ is a good example. This guideline provides up to date recommendations on where the evidence

lies across a number of clinical questions in third molar surgery; covering assessment, risk, indications and timing of surgery as well as various interventions such as whether or not to use antibiotics, steroids, drains or PRF to name but a few. It is notable that much of the evidence is classified as lower level ('B' or 'C') and this has led to many of the recommendations being graded 'O', meaning open recommendation, and suggesting that the evidence is not strong enough to make clear grade 'A' strong recommendations.

2.1.14 - A Core Outcome Set for Third Molar Surgery

It is clear from individual systematic reviews, wide ranging major Cochrane reviews and from the professional guidelines that they support, that the evidence base in third molar surgery is often not sufficient and that standardising outcome reporting must play a part in changing this.

This is important because third molar surgery is one of, if not the most common operation in the world. Indeed, around 10 million third molars are removed annually in the USA alone (Friedman, 2007). However, the implications of a poor evidence base have wider public health and societal impact when it is considered that public health systems are involved in the funding and delivery of these surgeries, with the NHS in England carrying out around 77,000 procedures a year (McArdle and Renton, 2012).

Despite this, at the time of commencing this project, there were no COMET registered COS projects in third molar surgery and there are no published core outcome sets in the literature otherwise.

This has led to a drive to work towards a COS for third molar surgery and the formation of a group within Trinity College Dublin School of Dental Science that has proposed the CORE8 study standing for ‘Core Outcomes in Third Molar Surgery’. The protocol for the overall study has been developed in conjunction with the COMET handbook (Williamson et al., 2017) and following the development standards document COS-STAD (Kirkham et al., 2017). The author of the present work has led on the CORE8 study and the two critical preliminary studies were undertaken by the author as part of his D Ch Dent in Oral Surgery thesis.

The stages for CORE8 are divided into pre-consensus stages:

1) CORE8.1

   Scoping Review – to identify outcomes already reported in the literature.

2) CORE8.2

   Qualitative research – to identify and understand the outcomes of importance to patients.

These stages will provide the basis on which to define outcomes and outcome domains for use in the later consensus stages:

3) CORE8.3

   Delphi surveys – to narrow down outcomes of the greatest importance to patients, professionals and other stakeholders and detail ‘consensus-in’ outcomes for consideration at stage 4.

4) CORE8.4

   Consensus meeting – to decide the core outcomes with input from patients, professionals and other stakeholders.

CORE8 is registered on the COMET website (COMET, 2024a).

2.1.15 - Current Outcome Reporting in Third Molar Surgery

With regards the initial stages in COS development, there has been some work to date on outcome reporting in third molar surgery.

Indeed, O’Sullivan and Ní Ríordáin carried out a focussed review published in 2021 (online) looking at the reporting of clinician-reported outcomes (O’Sullivan and Ríordáin, 2022). In particular, the authors highlighted the importance of these types of outcomes in the commissioning of health services since when these outcomes are recorded in a systematic way in clinical practice, they are increasingly used in quality assurance and the comparison of hospital performance and case mix. In particular, O’Sullivan cites several UK initiatives on

clinical outcome reporting in hospitals with regards to quality assurance including 2018 Oral and Maxillofacial Surgery (OMFS) ‘GIRFT’ (Getting It Right First Time) report that recommended standardisation of clinical outcomes as a priority (Morton, 2018). O’Sullivan highlights that OMFS lags behind other specialities and despite efforts including the ’Quality Outcomes in Maxillofacial Surgery’ (QOMS) project very few outcomes focussing on third molar surgery are collected even in the context of the ‘National Third Molar Audit’.

Whilst highlighting the implications for outcome reporting in clinical practice in terms of quality assurance and commissioning, particularly in hospital systems, O’Sullivan and Ní Ríordáin also emphasise the advantages of defining core outcomes for research. Indeed, they too recognise the limitations that outcome reporting is having on high level evidence, also quoting the Cochrane review (Bailey et al., 2020) on third molar techniques that failed to draw form conclusions in most areas as already discussed.

To look at the current situation, O’Sullivan and Ní Ríordáin searched PubMed and EMBASE, following recommendations from the PRISMA statement to identify RCTs within a 5 year period. They extracted details of trial design and clinically reported outcome measures from 20 included studies. They found split mouth design was common (12/20), with six studies focussing on analgesia, four studies on autologous platelet concentrates, four studies on local steroid use, two studies on collagen sponges and the remainder looking at local anaesthesia, acupuncture, novel intra-operative irrigants, ozone use and pre-operative dietary supplements. Swelling and mouth opening were the

most commonly reported outcomes followed by soft tissue healing, bone healing, dry socket and periodontal probing depth.

Following on from this study, the same authors have also looked at patient reported outcome measures (PROMs), publishing a scoping review in 2022 (O'Sullivan and Ní Ríordáin, 2022). They again highlight the use of PROMs within health service quality assurance and policymaking, pointing to the mandatory collection and analysis of PROMs in the NHS in England for certain surgical procedures and the Royal College of Surgeons of England policies on the recording of PROMs data within cosmetic surgery.

Within oral surgery, it is clear that PROMs have been considered for many decades, with Savin and Ogden reporting on quality of life after third molar surgery back in 1997 (Savin and Ogden, 1997). O'Sullivan and Ní Ríordáin state that this study was important because it led the way to a disease specific third molar quality of life instrument, the 'Post-Operative Symptom Severity" (PoSSe) scale which was developed in 2000 (O'Sullivan and Ní Ríordáin, 2022; Ruta et al., 2000).

Other commonly used PROMs in oral surgery include the 14-item oral health impact profile (OHIP-14) (O'Sullivan and Ní Ríordáin, 2022).

Recognising the need for standardisation of outcomes and realising the commonplace of third molar surgery and the impact that studies in the field have, in particular when its use as a pain model for analgesic studies is considered, O'Sullivan and Ní Ríordáin felt that more information was needed on PROMs to complement their review on clinically reported outcomes. Their 'scoping' review goes on to

summarise the different PROMs used in oral surgery. These included the following outcome measures:

Pain:

Numeric rating scale, visual analogue scale, verbal reasoning scale and McGill pain questionnaire and it's short form variation.

General Quality of Life:

'EQ-5D-3L' (a standardised instrument developed by the 'EuroQoL' group (EuroQoL, 1990), 'SF-36' and 'SF-12' (Ware and Sherbourne, 1992; Ware et al., 1996).

Oral Health Quality of Life:

OHIP-14 (Slade, 1997) and OHQoL-UK (McGrath and Bedi, 2001).

Post-operative Quality of Life:

PoSSe (Ruta et al., 2000).

Psychological:

HADS (Zigmond and Snaith, 1983).

2.1.16 - Current Outcome Reporting and the CORE8 Study

Whilst the evidence on clinical outcome reporting from O'Sullivan and Ní Ríordáin is certainly useful to feed into COS development, the study was quite small, extracting outcomes from only 20 RCTs (O'Sullivan and Ríordáin, 2022). Furthermore, the scoping review by the same authors on PROMs serves as an excellent summary of the actual

outcome measures used, but it does not provide significant insight into whether patient reported outcomes are actually being reported on sufficiently in the extensive literature around third molar surgery.

As a result, a wider scoping review of the literature is needed to identify what outcome measures are being reported.

In line with methodological guidelines in the COMET handbook and the COS-STAD, COS-STAP and COS-STAR statements, such a scoping review alongside qualitative data would pave the way to consensus stage projects to bring to fruition a COS for third molar surgery; ‘The CORE8’.

2.1.17 – Conclusions from the Review of the Literature

This literature review has considered the impact of the history and the nature of surgery on the traditional approach to evidence; or eminence! It has explored the origins and development of evidence-based medicine and the challenges in applying this to surgery. To this goal, the importance of the quality of evidence has been highlighted, and the huge impact that the effective synthesis of evidence can have for patients has been considered. In reviewing some of the innovations that have aided evidence synthesis, the importance of standardisation in research and the role that core outcome sets have in this can be seen. Finally, it has been shown that whilst several other surgical and oral health fields have made strides in this regard, there is no core outcome set for third molar surgery, yet the field suffers just like many others

from outcome heterogeneity and problematic outcome reporting such that effective evidence synthesis is severely hampered.

A core outcome set for third molar surgery is an important goal and the aims of this project in fulfilling CORE8.1 and CORE8.2 are the next necessary steps to inform future consensus stage research to realise the CORE8 outcome set.

CHAPTER 3 – METHODS & MATERIALS

3.1 - Methods - CORE8.1 Outcome Reporting in Third Molar Surgery – A Scoping Review

The scoping review was designed in line with the principles of the 'Joanna Briggs Institute' (JBI) 'Manual for Evidence Synthesis' (Aromataris et al., 2024) and also the 'Preferred Reporting Items for Systematic reviews and Meta-analyses' (PRISMA) extension for scoping reviews checklist (PRISMA-ScR) (Tricco et al., 2018).

3.1.1 - Steering Group

At the commencement of the project, a research proposal was submitted to the supervisors (Prof AD and Mr DP) at Trinity College Dublin and this was accepted. A steering group for the project was then appointed and consisted of the following members:

- Prof Alison Dougall (Trinity College Dublin, Ireland)

  Project Supervisor.

- Mr Dermot Pierse (Trinity College Dublin, Ireland)

  Project Supervisor and Oral Surgery speciality expert (Consultant in OMFS).

- Prof Dr Branislav Bajkin (University of Novi Sad, Serbia)

  Oral Surgery speciality expert (Professor of Oral Surgery) and co-reviewer.

- Dr Sasha Scambler (King's College London, UK)

  Qualitative research advice.

- Prof Hal Duncan (Trinity College Dublin, Ireland)

  Core outcome set research advice.

- Ms Isabel Fleishmann (Trinity College Dublin, Ireland)

  Search strategy advice/development (medical librarian).

Whilst not part of the steering group at the outset, Dr Robert Hardy joined the study subsequently as an independent investigator for the full text-review/outcome extraction stage of the review. Dr Hardy is a dental surgeon with prior experience leading a systematic review at the University of Edinburgh and was independent to Trinity College Dublin

3.1.2 - Objective of the Review

To assess current outcome reporting in third molar surgery through a scoping review.

3.1.3 - Protocol & Registration

The protocol for the review was not published but the CORE8 project, including details of the stages (CORE8.1, CORE8.2, CORE8.3 and CORE8.4), which include the scoping review (CORE8.1) was registered on the COMET website prior to commencement (COMET, 2024a).

3.1.4 - Identifying the Research Question

On the basis of an initial literature review, the research question was formulated: What are the currently reported outcomes in interventional studies in third molar surgery?

3.1.5 - Eligibility Criteria - Inclusion Criteria

In line with JBI guidelines, the inclusion criteria were formulated using the participants/concept/context (PCC) model (Aromataris et al., 2024), which is similar to the participants, interventions, comparators, outcomes (PICO) concept (Santos et al., 2007).

The criteria were designed to be inclusive, in order that the studies included and the extracted outcomes would represent patients of all types.

Population: Adults ≥ 18 years of age

Concept: Interventional clinical trials and clinical studies being carried out in third molar surgery with a view to changing the outcome. For example, a new drug or technique.

Context: All adult patient groups, in all settings, in all cultures.

3.1.6 - Information Sources and the Search - Identifying Relevant Studies

Once the question and the inclusion criteria were defined, a meeting of the steering group took place and advice on search terms and

databases was sought through the medical librarian in the group (IF). Guidance documents on the development and appraisal of the search strategy for core outcome set development reviews were followed (Gargon et al., 2015).

Based on other similar core outcome sets, the current projects methodology involved examining the preceding 12 years of evidence. This period was chosen after the search strategy was trialled with several time period limits as well as a ‘no-limits’ period and it was felt that the additional results beyond 12 years were insignificant. Furthermore, it was considered that all relevant outcomes were likely to have been reported within the last 12 years.

The following databases were chosen and the searches were limited to human only and English language only:

- Medline (Ovid)
- EMBASE
- Web of science core collection

Limiting the search to English language only was accepted due to the practical implications of including other languages within the context of the CORE8.1 research team and resources available.

The following databases were also considered but not chosen for the final searches.

- The Cochrane library – relevant articles would already be included through the selected databases (Gargon et al., 2015).

- Clinical trial registries – this scoping review was specifically looking for published outcomes.
- Scopus – The three chosen databases were felt to be sufficient following advice from the medical librarian (IF).

The following websites of key organisations were also searched for relevant guidelines whose reference lists could be screened to ensure all relevant papers were included:

- NICE - National Institute for Clinical Excellence
- Royal College of Surgeons of England Faculty of Dental Surgery
- Scottish Intercollegiate Guidance Network
- American Association of Oral and Maxillofacial Surgeons
- American Dental Association
- Royal Australasian College of Dental Surgeons

The search strategy was tested and refined and the final search strategy, with limits to English language, human only and years 2010-2023 (search date: 30/06/2022) was as follows:

Medline (Ovid)

1. Exp Molar, Third/
2. ((3rd OR third) adj3 molar*).mp.
3. (wisdom adj3 (tooth OR teeth)).mp
4. M3M.mp

5. OR/1-4
6. Exp Tooth extraction/
7. Su.fs
8. (Surger* or surgical or surgeon).mp
9. (Extraction* or removal* or retention).mp
10. (Coronectom* OR odontectom*).mp
11. OR/6-10
12. 5 AND 11
13. 12 not (exp animals/ not humans.sh.)

Embase

1. ‘third molar’/exp
2. ((3rd OR third) NEAR/3 molar*):ti,ab,kw
3. (wisdom NEAR/3 (tooth or teeth)):ti,ab,kw
4. (M3M):ti,ab,kw
5. OR/1-4
6. ‘tooth extraction’/exp
7. Su/lnk
8. (Surger* or surgical or surgeon):ti,ab,kw
9. (extraction* or removal* or retention):ti,ab,kw
10. (Coronectom* OR odontectom*):ti,ab,kw
11. OR/6-10
12. 5 AND 11
13. #12 NOT ([animals]/lim NOT [humans]/lim)

Web of Science (Core Collection)

1. TS=((3rd OR third) NEAR/3 molar*)
2. TS=(wisdom NEAR/3 (tooth OR teeth))
3. TS=M3M
4. OR/1-3
5. TS=(Surger* or surgical or surgeon)
6. TS=(Extraction* or removal* or retention)
7. TS=(Coronectom* OR odontectom*)
8. OR/5-7
9. #4 AND #8

The search was not limited to mandibular only and specific terms that were considered but added no additional results included ‘lower eights’. *In-vitro* studies were excluded in the search strategy.

In addition, prior to finalising the search, the strategy was sent for peer review with an independent medical librarian, Mr David Mockler (Trinity College Dublin). This was a useful process as initial search terms were slightly adjusted rendering more results before the final strategy was agreed.

3.1.7 - Study Selection

After the search strategy was finalised, the references were collated and imported into the ‘Covidence’ programme, an online software tool for managing systematic review references and data extraction (Covidence, 2024).

The programme helps manage the flow of each study through abstract screening, full text review acceptance or rejection and ultimately data extraction. Figure 3.1, below, is an example of the front screen of the application where studies are categorised in terms of their place in the process:

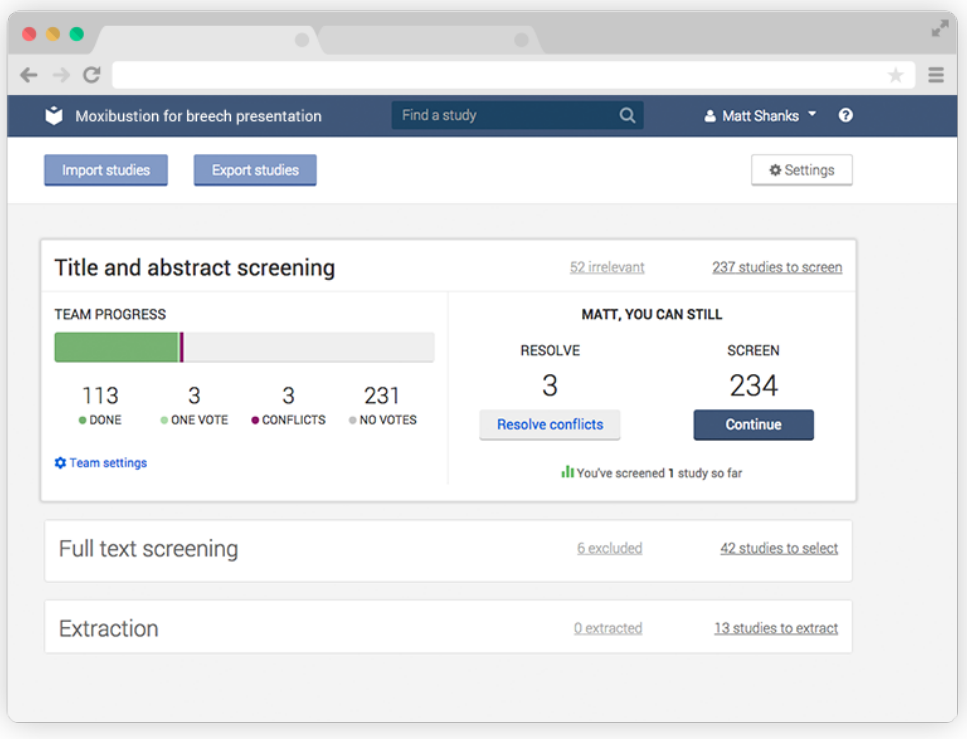


Figure 3.1: Example front screen from COVIDENCE software

Figure 3.2, below, is an example of how the platform presents papers for screening:

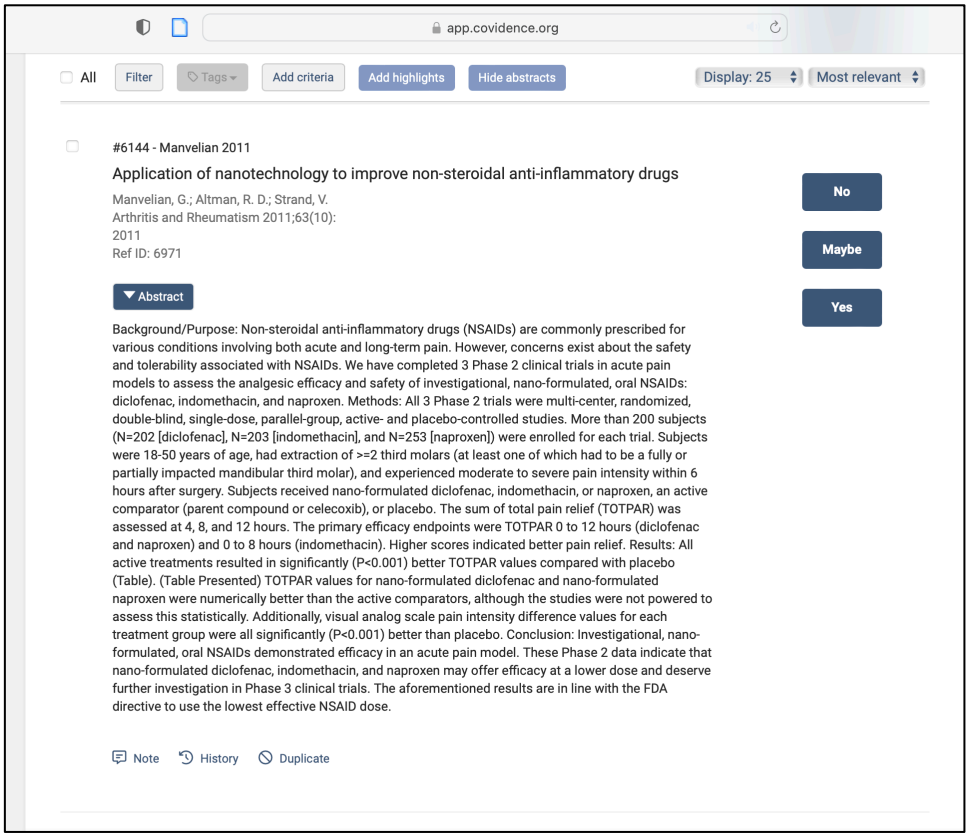


Figure 3.2: Example of COVIDENCE screening platform

As the three databases used would identify some of the same papers, a deduplication process was carried out after import of the complete reference list.

Title and abstract review was then carried out independently by two reviewers (R Carr and B Bajkin) such that every single abstract was independently co-reviewed.

Conflicts were initially intended to be resolved through reviewer discussion and agreement, but it was subsequently decided to assess a proportion (100 studies) of the conflicted studies for any additional outcomes they might add and this process led to full extraction from only the mutually agreed included studies. This can represent a

limitation and will be discussed further in the results and discussion sections.

Once a study was included, it moved to the full text review stage and at this point a single reviewer (R Carr) reviewed the full text article. Some exclusions were expected at that stage because of the number of studies included and the potential for misleading titles and abstracts.

This generated a list of studies for data extraction (Appendix 1).

3.1.8 - Data Extraction Charting and Data Items

Data extraction was carried out using a data extraction sheet using Microsoft Excel (Microsoft, 2024).

The extraction sheet was trialled on 110 studies and adjustments made before continuing the extraction on the remaining studies for extraction.

Extraction was by a single reviewer but 50% of the studies were then subjected to second review and extraction by an independent reviewer, Dr Robert Hardy. Dr Hardy was invited to join the team in this role because he was known to the author of this thesis and is an experienced dental surgeon with published systematic review first author experience (University of Edinburgh). Dr Hardy was briefed on the CORE8.1 methodology and the process for data extraction by Dr Carr. Dr Hardy then independently extracted outcomes and any additional outcomes or queries were discussed with Dr Carr and the data extraction sheets updated accordingly.

The fields for the final data extraction form were as follows and were selected in line with the JBI Manual guidelines for scoping reviews (Aromataris et al., 2024):

- Journal Title
- Country of Study
- Digital Object Identifier (DOI)
- Pub-Med ID (PMID)
- Study Type
- Topic
- Additional Topics
- Number of Participants
- Reported Outcomes
- Whether or not primary and secondary outcomes were clearly defined

It was decided not to record article title as this was an additional step, made the form less easy to use and was not beneficial for analysis since any article title could easily be retrieved as necessary using the DOI or the PMID.

In addition, included studies were imported into referencing software as they were extracted, so that the DOI and PMID were checked and no omissions made.

Papers without a PMID or DOI had their journal volume, issue and page numbers recorded in the DOI field and were imported by hand into the referencing software (Zotero (Zotero, 2024)).

The original data recording sheet trialled on 110 studies as above, collected additional data on the actual outcome measures as well as the broad outcome reported (e.g. pain or swelling). Examples would include measures like pain by visual analogue scale or quality of life using 14-item oral health impact profile (OHIP14). Furthermore, the study intervention and comparator were recorded as well as whether the authors overall conclusions in a study were positive in respect of the relevant intervention, i.e. did the intervention improve outcomes? The reasons why these fields were not used in the final extraction sheet will be discussed later. However, the 110 studies that were subject to extraction of this data still provided useful information on these aspects of the included studies. Indeed, this data was analysed to provide data on intervention types, outcome measures and study intervention positivity.

3.1.9 – Synthesis of Results - Collating and Summarising the Results

The extracted data was analysed using excel to produce simple descriptive statistics for the proportions of studies per journal and country as well as study type, topic, whether or not primary and secondary outcomes were defined and average numbers of participants. The latter was split into studies including pain model studies and excluding pain model studies since the high numbers of participants in many industry funded pain model studies would skew the average numbers of participants in other topic areas.

The outcomes were standardised on the data collection sheet where any slightly different descriptions of similar outcomes were merged. This allowed the generation of simple descriptive statistics on the frequency of reporting of each outcome.

Finally, outcomes were organised and listed against representative outcome domains.

3.2 - Methods - CORE8.2 Qualitative Focus Groups

3.2.1 - Objective

To identify what outcomes are important to patients who are undergoing lower third molar surgery through qualitative focus groups.

Focus groups, rather than interviews, were the chosen methodology, as recommended by the COMET handbook because they allow the exchange of ideas and views between participants and can result in dynamic group interaction and iterative exploration on what is important and why (Williamson et al., 2017).

3.2.2 - Inclusion Criteria

All adult patients who were planned for or had undergone third molar surgery of any type.

The aim was for an inclusive sampling framework, ensuring patients of differing ages, socioeconomic groups and medical histories were not excluded from the conversations around preferences and priorities around outcomes.

3.2.3 - Exclusion Criteria

This was kept to a minimum to protect the aim of an inclusive sample. The only exclusion criteria were patients who did not want to take part or those who would or could not consent to take part.

3.2.4 - Ethical Approval

Ethical approval was required for CORE8.2 since the study involved patients and required collection of their personal data in order to contact them and offer them dates and times to take part in a focus group. Ethical approval was sought through the Trinity College Dublin 'Research Ethics Application Management System'. This involved an application form and submission of supporting documents including copies of the patient information leaflet and consent form for the focus groups as well as the topic guide.

GDPR training was completed by the principal investigator R Carr and supervisor D Pierse and submitted with the application. Online research integrity training ('Epigeum') at both core (8 modules) and specialist level (5 modules) was completed by the principal investigator R Carr.

The study was assessed at school level (Dental School Research Ethics Committee) and ethical approval was granted, ref: DSREC2024-02 (Appendix 2).

3.2.5 - Recruitment

Recruitment was purposive from oral surgery clinics at Dublin Dental University Hospital. All senior clinicians who were running clinics were informed about the study and acted as gatekeepers. This was approved by the ethics committee because although the clinicians had direct

involvement in the patients care, they did not have any involvement in CORE8.2.

The role of the clinicians was to identify any patient seen in their clinic during the recruitment period who fitted the inclusion criteria and to ask them if they would consider taking part. If a patient was interested in taking part, the clinician would explain more about the focus group study and provide the patient with a patient information leaflet (Appendix 3). Patients who were happy to take part would then sign a consent form (Appendix 4), on which they also provided their contact number and email address.

After a period of at least a week, the patients were emailed to invite them to suggest their availability dates and times so that a time suiting multiple participants could be identified. This was followed up with a phone call several days later to confirm suitable times once responses suggested there was a mutually convenient time.

A ‘zoom’ (Zoom, 2024) link was then provided to participants by email and SMS text message so that they could log-in to the focus group at the designated time. An SMS text message reminder of the group time was sent on the day of each focus group.

It was emphasised from the outset and at contact and at the start of the actual focus group that participants had the right to withdraw at any time.

Whilst looking for diversity in the included participants, all agreeable patients were included in the offered focus group times.

3.2.6 - Topic Guide

Following principles taught by the 'Social Research Association', a topic guide was prepared based on the outcomes and domains generated from CORE8.1 (Appendix 5). The aim was not to stifle discussion with very specific questions, like an interview, but rather to stimulate and guide discussion to ensure the group discussed and exchanged ideas and views that at minimum covered the domains generated by the scoping review. At the start of the focus group, the topic guide required the investigator (R Carr) to explain the aims of CORE8.2 in the context of the wider CORE8 study, which involved information previously provided through the patient information leaflet. The guide then required an explanation of the right to withdraw followed by 'ice-breaker' questions to build rapport and get the participants talking. Following this, participants were asked what came to mind when they thought of wisdom teeth and the guide otherwise supported the investigator to facilitate the exchange of ideas whilst providing prompts to ensure all domains from CORE8.1 were covered.

3.2.7 - Data Collection

Focus groups were carried out via Zoom and were not recorded.

At focus groups, the investigator R Carr ran the focus group whilst transcription in real time was carried out by R Hardy, ensuring thorough and contemporaneous transcription and allowing the investigator to

focus only on facilitating the focus group. The transcripts were not returned to the participants for feedback.

3.2.8 - Analysis

Data was analysed, identifying themes in each group, based on the topic guide with additions based on what participants talked about from the transcript data.

The themes were compared to identify commonality versus unique insights from each group with the aim of determining data saturation once present such that no further groups were necessary. Saturation was identified when no further themes emerged.

The focus group data was then analysed using framework analysis, as recommended by COMET (Williamson et al., 2017). Participants were not asked for feedback on the findings.

3.2.9 - Using the Qualitative Information from CORE8.2 to Complement CORE8.1

Finally, the insights from the framework analysis were equated to measurable outcomes in order to enhance the outcome and outcome domains from CORE8.1. With the addition of the qualitative data, a comprehensive pre-consensus outcome and domain list to inform future consensus stage studies was drawn up.

CHAPTER 4 - RESULTS

4.1 - Results – CORE8.1 Outcome Reporting in Third Molar Surgery – A Scoping Review

4.1.1 - Identification of Studies

The searches using the search strategy previously defined were run on 30/06/2022.

This rendered a total of 10,714 results broken down into 3,497, 3,772 and 3,361 references in Medline, EMBASE and Web of Science (Core Collection) respectively and the search strategy and these numbers are summarised below in table 4.1:

Medline (Ovid)	EMBASE	Web of Science (Core Collection)
1. Exp Molar, Third/ 2. ((3rd OR third) adj3 molar*).mp. 3. (wisdom adj3 (tooth OR teeth)).mp 4. M3M.mp 5. OR/1-4 6. Exp Tooth extraction/ 7. Su.fs 8. (Surger* or surgical or surgeon).mp 9. (Extraction* or removal* or retention).mp 10. (Coronectom* OR odontectom*).mp 11. OR/6-10 12. 5 AND 11 13. 12 not (exp animals/ not humans.sh.)	1. 'third molar'/exp 2. ((3rd OR third) NEAR/3 molar*):ti,ab,kw 3. (wisdom NEAR/3 (tooth or teeth)):ti,ab,kw 4. (M3M):ti,ab,kw 5. OR/1-4 6. 'tooth extraction'/exp 7. Su/lnk 8. (Surger* or surgical or surgeon):ti,ab,kw 9. (extraction* or removal* or retention):ti,ab,kw 10. (Coronectom* OR odontectom*):ti,ab,kw 11. OR/6-10 12. 5 AND 11 13. #12 NOT ([animals]/lim NOT [humans]/lim)	1. TS=((3rd OR third) NEAR/3 molar*) 2. TS=(wisdom NEAR/3 (tooth OR teeth)) 3. TS=M3M 4. OR/1-3 5. TS=(Surger* or surgical or surgeon) 6. TS=(Extraction* or removal* or retention) 7. TS=(Coronectom* OR odontectom*) 8. OR/5-7 9. #4 AND #8
Limited to English and 2010-2023: **3,557 Results**	Limited to English and 2010-2023: **3,784 Results**	Limited to English and 2010-2023: **3,373 Results**

Table 4.1: Search strategy and output

The searches of the websites and guidelines of key organisations did not render any additional references.

4.1.2 - Study Selection

Electronic deduplication identified 5,101 duplicates resulting in 5,613 references entering the abstract screen stage.

After double reviewer abstract screening, 3944 studies were excluded and there were 616 reviewer conflicts. These were not carried forward to full text review but 100 of the conflicted studies (Appendix 8) were subjected to analysis to ensure that the conflicted studies were not any

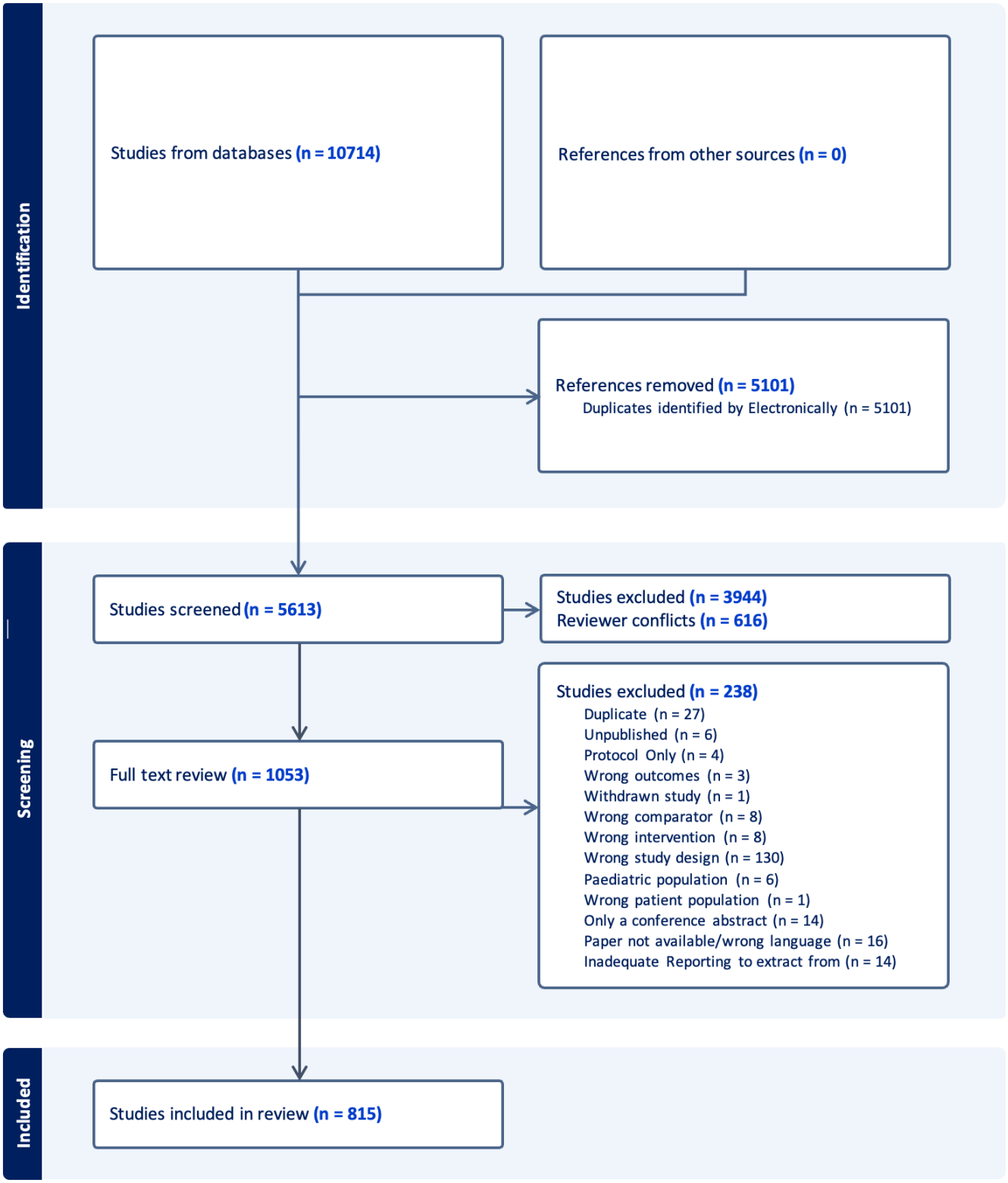
particular type of study that required discussion and possible inclusion. Furthermore, the outcomes reported were screened to make sure that resolution of the conflicts and potential inclusion of these studies was not going to add additional outcomes that had not already come up.

This analysis was carried out after the co-reviewer agreed studies had been full text screened and been through data extraction and no additional topics or outcomes that added to the existing outcome list were identified.

This left 1053 studies for full text review of which 238 were excluded for reasons detailed in the following PRISMA flowchart (Figure 4.1).

The final number of included studies was therefore 815.

Figure 4.1: PRISMA Flowchart CORE8.1



4.1.3 - Data Extraction – Study Information – Journals

By far the most common journal of publication was the ‘Journal of Oral and Maxillofacial Surgery’, comprising 103 of the 815 studies. This was followed by the ‘International Journal of Oral and Maxillofacial Surgery’ at 61 publications.

Figure 4.2, shows the journals and the number of publications in order of frequency highest to lowest. A tabular summary of the same results is presented in Appendix 7.1.

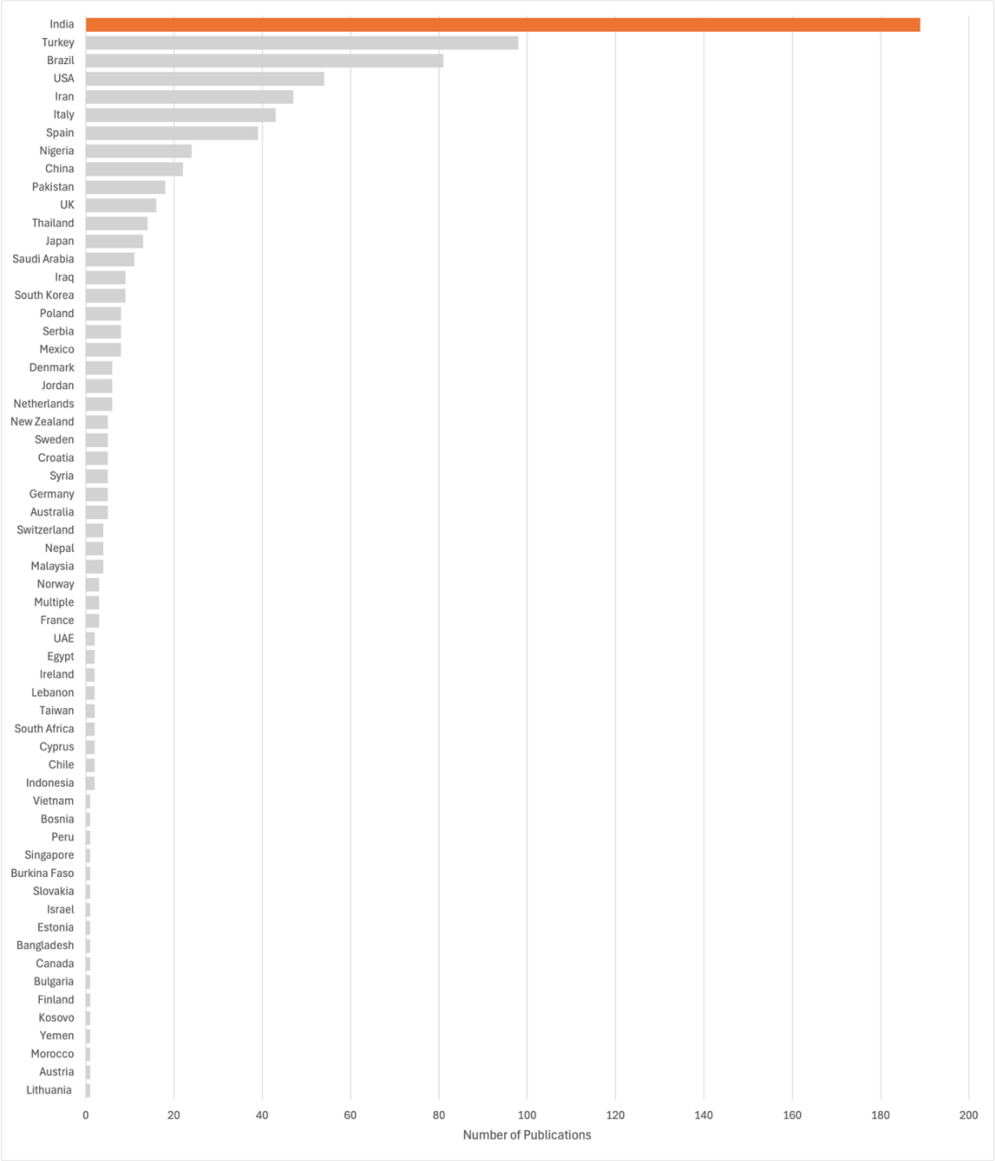
Figure 4.2: Data Extraction – Study Information – Journals by Frequency (High to Low)

4.1.4 - Data Extraction – Study Information – Countries

By far the most common country of study was India. Note, country of study represented the actual country where the study was carried out, not simply the country listed against the authors. This data was frequently mixed, with authors listed from various countries contributing. Where data was collected across sites in multiple countries, the country was defined as ‘Multiple’.

Figure 4.3 shows the countries and the number of publications in order of frequency highest to lowest. A tabular summary of the same results is presented in Appendix 7.2.

Figure 4.3: Data Extraction – Study Information – Countries by Frequency (High to Low)



4.1.5 - Data Extraction – Study Information – Study Type

The majority of studies were randomised controlled trials, a sizable proportion of which were split mouth studies.

Table 4.2, below, shows the study type and the number of publications in order of frequency highest to lowest.

Table 4.2: Study Type	No
RCT (including randomised split mouth, n142)	724
NRCT	56
Cohort	12
Retrospective Cohort	8
NR Split Mouth	3
Prospective Clinical Trial	3
Retrospective Cohort (Chart Review)	2
Case-Control	2
Prospective Comparative Study	2
Retrospective Comparative Study	2
Case Series	1
TOTAL:	**815**

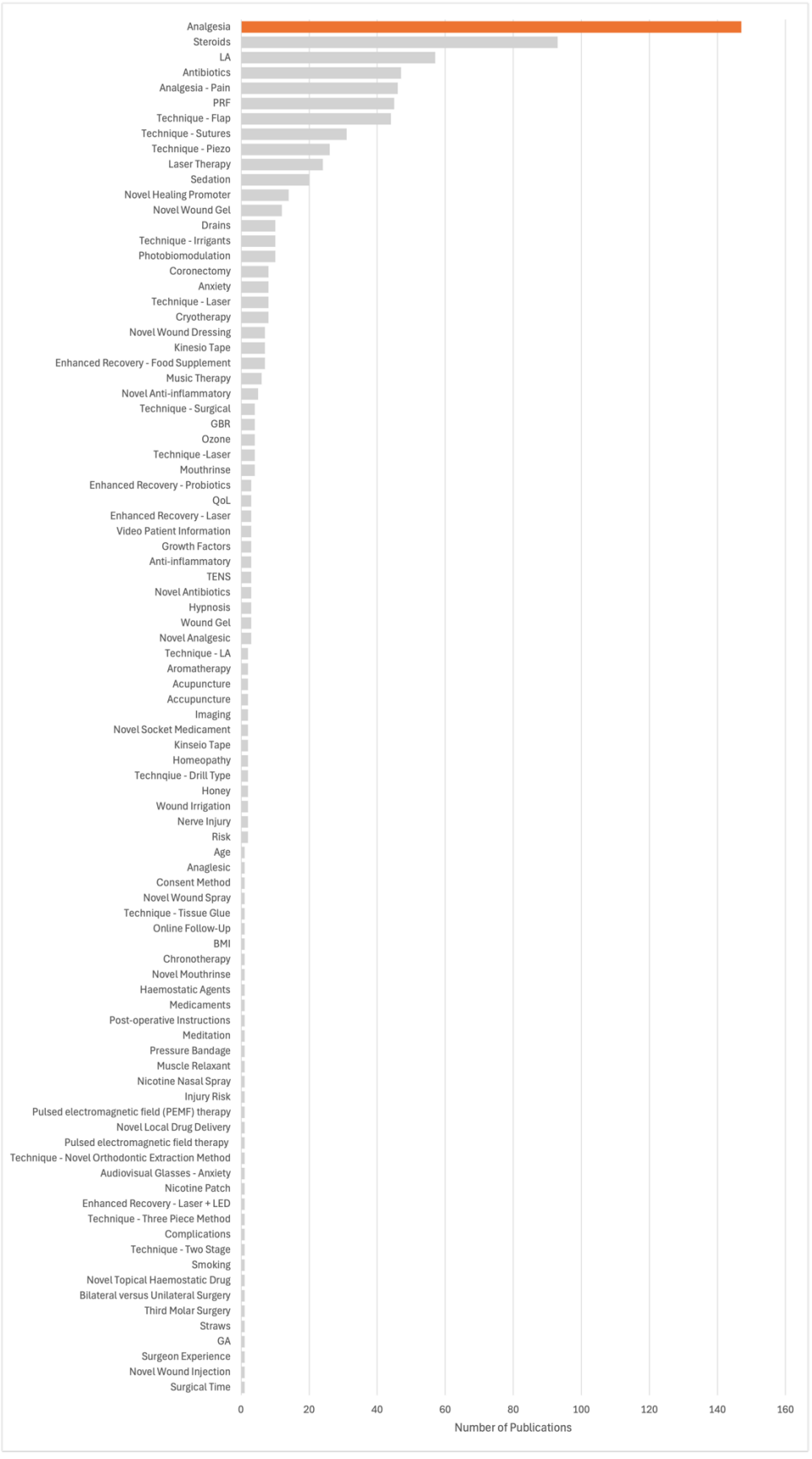
Table 4.2: Study Type (Key: RCT = Randomised Controlled Trial, NRCT – Non-Randomised Controlled Trial, NR Split Mouth = Non-Randomised Split Mouth).

4.1.6 - Data Extraction – Study Information – Study Topics

The most common topic was analgesia with the second most common topic being steroid use. Analgesia was counted separately from analgesia studies that were primary analgesia studies using third molar surgery as a pain model which was coded as ‘Analgesia – Pain’. This delineation enabled analysis of how many studies were on analgesia primarily for the purpose of analgesia in third molar surgery rather than simply the testing of analgesics using third molar surgery as a model.

Figure 4.4 details the numbers of studies per topic from highest to lowest. A tabular summary of the same results is presented in Appendix 7.3.

Figure 4.4: Data Extraction – Study Information – Study Topics



4.1.7 - Data Extraction – Study Information – Numbers of Participants

Table 4.3 shows the average number of participants in the included studies overall and in RCT and split mouth studies; the averages for studies overall when analgesia studies utilising third molar surgery as a pain model were discounted are also presented.

Average number of participants across all studies	102
Average number of participants across all studies when analgesia studies that primarily used third molar surgery as a pain model were excluded	91
Average number of participants in RCTs and split mouth studies (randomised or non-randomised)	90

Table 4.3: Numbers of Participants

4.1.8 - Data Extraction – Study Information – Primary & Secondary Outcome Reporting

Primary and secondary outcome reporting was only clearly defined in a small number of the included studies, as seen in Table 4.4.

Clearly Defined Primary & Secondary Outcomes	
Yes	88
No	727

Table 4.4: Primary and Secondary Outcome Reporting

4.1.9 - Data Extraction - Outcomes

There were 82 different outcomes reported across the 815 studies.

The number of outcomes reported per study was quite variable, with some studies reporting many outcomes whilst some only reporting one or two. A total of 2,638 outcomes were reported across the 815 studies.

Pain, swelling and mouth opening were the most commonly reported outcomes, being reported in 664, 400 and 354 studies respectively.

Quality of life outcomes were reported in 49 studies.

Time off work, an outcome of potential importance to patient, was reported in just 3 studies.

‘Global pain scale’ and ‘TOTPAR’ were recorded as specific outcomes separately to ‘Pain’ as these were frequently utilised in analgesia studies using third molar surgery as a pain model and were reported more specifically to studies where pain was measured through visual analogue scale or other less specific metrics.

Where a study was carrying out specific or detailed monitoring of patient’s physiological parameters this was recorded as ‘Haemodynamic’, whilst papers reporting specifically on single measures such as blood pressure or oxygen saturation were recorded under those outcomes.

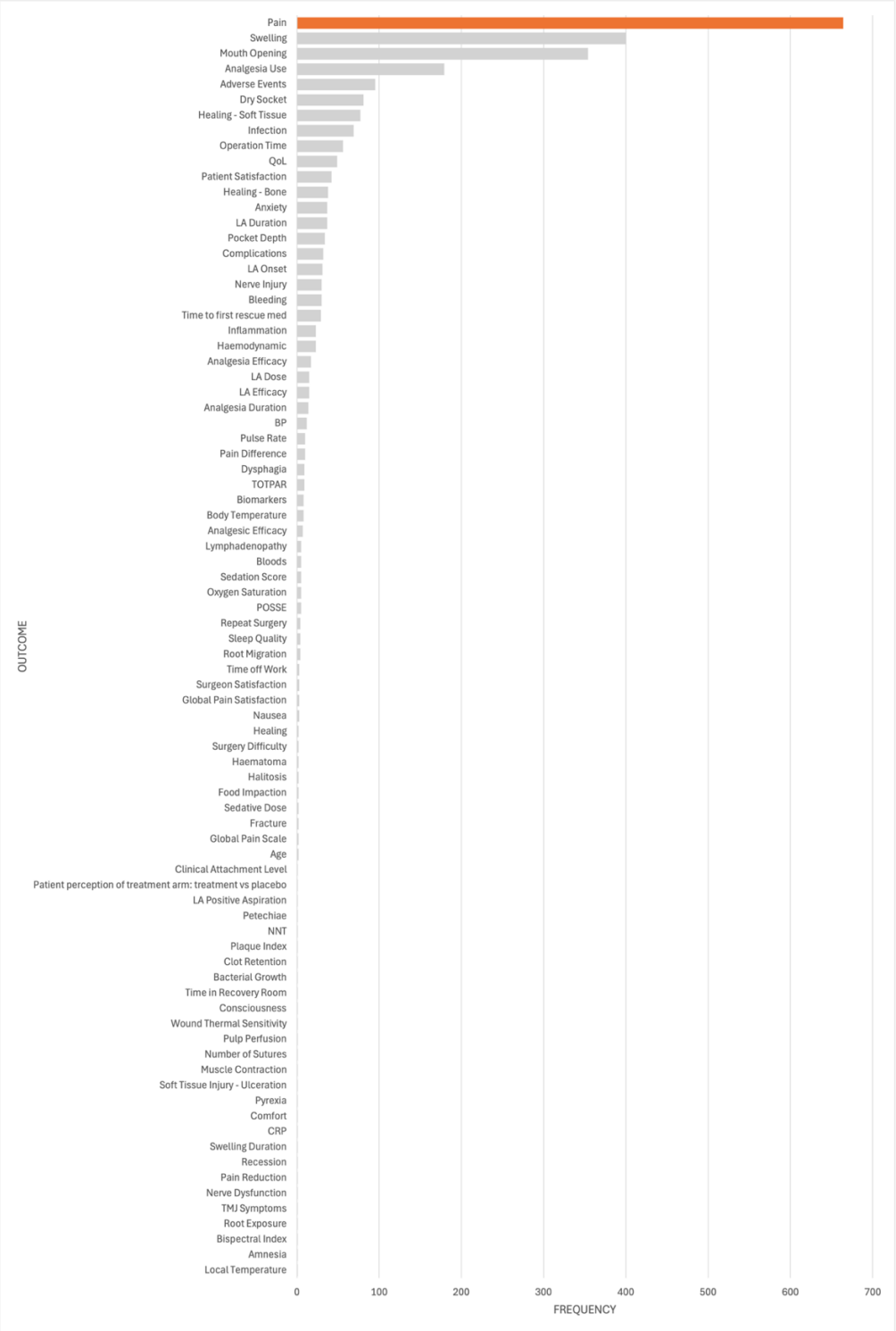
Operation time was extracted as an outcome when it was specifically recorded as an outcome in a study. For example, if a study investigated a new technique where the operating time may be reduced or lengthened by that technique, then operating time would be considered an outcome and extracted. Where operation time was recorded only as baseline information, and was not an outcome that would have been

influenced by the intervention, it was not recorded as an outcome. An example of this is where a study recorded the operating time in order to ensure it was not a confounding variable that would introduce a differential bias across groups in terms of an outcome; for example, if a new technique caused more swelling but this was related to additional operating time rather than the intervention itself. In this example, the outcome is swelling, unless the study was also interested in the operating time as an outcome of the different techniques.

The outcome of ‘biomarkers’ was recorded to encompass blood tests or other biochemical markers such as salivary biomarkers. The exception to this was if a study was specifically investigating a particular biomarker, such as CRP, in relation to an intervention, in which case the specific biomarker was recorded as the outcome.

Figure 4.5 details the outcomes in order of frequency of reporting from highest to lowest. A tabular summary of the same results is presented in Appendix 7.4.

Figure 4.5: Data Extraction – Outcomes – Frequency of Reporting (High to Low)



4.1.10 - Domains

Using the outcome list, domains were developed in order the categorise the outcomes and these are summarised below in table 4.5 against the number of outcomes falling within each domain:

Domain	**Number of Outcomes in Domain**
Physical	63
Psychological	6
Quality of Life	6
Practical	7
	Total Outcomes: 82

Table 4.5: Domains and Outcomes

The physical domain was split into 6 sub-domains as presented in table 4.6 below:

Physical Sub-Domain	**Number of Outcomes in Domain**
Pain	16
Swelling	2
Function	5
Healing	8
Systemic Response	11
Complications	21
	Total Outcomes: 63

Table 4.6: Physical Domain Sub-domains and Outcomes

The breakdown of the 63 outcomes within the 6 physical sub-domains is presented below in table 4.7:

Table 4.7: Outcomes within the Physical Sub-domains (Key: LA = Local anaesthetic, TOTPAR = Total pain relief)

Pain	No	Swelling	No	Function	No
Pain	664	Swelling	400	Mouth Opening	354
Analgesia Use	179	Swelling Duration	1	Dysphagia	9
LA Duration	37			Food Impaction	2
LA Onset	31			Muscle Contraction	1
Time to first rescue med	29			TMJ Symptoms	1
Analgesia Efficacy	17				
LA Dose	15				
LA Efficacy	15				
Analgesia Duration	14				
Pain Difference	10				
TOTPAR	9				
Analgesic Efficacy	7				
Global Pain Satisfaction	3				
Global Pain Scale	2				
Pain Reduction	1				
Wound Thermal Sensitivity	1				
Healing	**No**	**Systemic Response**	**No**	**Complications**	**No**
Healing - Soft Tissue	77	Haemodynamic	23	Adverse Events	95
Healing - Bone	38	BP	12	Dry Socket	81
Pocket Depth	34	Pulse Rate	10	Infection	69
Inflammation	23	Biomarkers	8	Complications	32
Healing	2	Body Temperature	8	Bleeding	30
Clinical Attachment Level	1	Bloods	5	Nerve Injury	30
Clot Retention	1	Oxygen Saturation	5	Lymphadenopathy	5
Plaque Index	1	Sedation Score	5	Repeat Surgery	4
		CRP	1	Root Migration	4
		Local Temperature	1	Nausea	3
		Pyrexia	1	Fracture	2
				Haematoma	2
				Halitosis	2
				Bacterial Growth	1
				LA Positive Aspiration	1
				Nerve Dysfunction	1
				Petechiae	1
				Pulp Perfusion	1
				Recession	1
				Root Exposure	1
				Soft Tissue Injury - Ulceration	1

The breakdown of the 19 outcomes within the remaining domains is presented below in table 4.8:

PSYCHOLOGICAL	No	QoL	No	PRACTICAL	No
Anxiety	37	QoL	49	Operation Time	56
Sedative Dose	2	Patient Satisfaction	42	Time off Work	3
Amnesia	1	POSSE	5	Age	2
Bispectral Index	1	Sleep Quality	4	Surgery Difficulty	2
Consciousness	1	Surgeon Satisfaction	3	NNT	1
Patient perception of treatment arm: treatment vs placebo	1	Comfort	1	Number of Sutures	1
				Time in Recovery Room	1

Table 4.8: Outcomes/frequency within Psychological, QoL & Practical Domains (Key: PoSSe = Post-operative symptom severity score)

4.1.11 - Sub-Group Analysis (110 Studies): Interventions, Outcome Measures and Study Intervention Positivity

The original data recording sheet trialled on 110 studies as above, collected additional data on the actual outcome measures as well as the broad outcome reported (e.g. pain or swelling). Examples would include measures like pain by visual analogue scale or quality of life using 14-item oral health impact profile (OHIP14).

Furthermore, the study intervention and comparator were recorded as well as whether the authors overall conclusions in a study were positive in respect of the relevant intervention, i.e. did the intervention improve outcomes? The reasons why these fields were not used in the final extraction sheet will be discussed in the discussion but the 110 studies that were subject to extraction of this data still provided useful

information on these aspects of the included studies and this was analysed to provide data on intervention types, outcome measures and study intervention positivity as follows:

4.1.11.1 - Interventions:

Table 4.9, below, lists the interventions extracted from the sub-group of 110 papers, highlighting the range of interventions being investigated across a range of topics. This information is useful, as it demonstrated a range of interventions ranging from the conventional to the more novel. For example, within the topic of analgesia, interventions included conventional interventions like ibuprofen as well as more novel interventions like novel nano analgesics.

Table 4.9: Topics (A-Z) with associated interventions (sub-group 110 papers)

TOPIC	INTERVENTION
Age	40 and over
Analgesia	Benzydamine hydrocloride mouthwash
Analgesia	Etoricoxib Pre-op
Analgesia	Rofecoxib Pre-op
Analgesia	Naproxen
Analgesia	Ketorolac, Tramadol or Placebo Pre-Op
Analgesia	Pre-op Ibuprofen
Analgesia	Sub-mucosal tramadol
Analgesia	Flurbiprofen
Analgesia	Piroxicam Sublingual
Analgesia	Lornoxicam IV Pre-op
Analgesia	Sub-cutaneous Tramadol + Oral Analgesia
Analgesia	Pre-op Dexketoprofen
Analgesia	Stilpane (paracetamol/codeine/meprobamate)
Analgesia	Ketoprofen Pre-op
Analgesia	Ibuprofen
Analgesia	Oral Paracetamol

Analgesia	Celecoxib
Analgesia	Tramadol
Analgesia	Diclofenac Sodium
Analgesia - Pain	Nano-Analgesic (iclofenac, indomethacin, naproxen)
Analgesia - Pain	Novel Drug (oral SCIO-469)
Analgesia - Pain	Paracetamol 1000mg
Analgesia - Pain	Three doses ibuprofen/paracetamol compound drug
Analgesia - Pain	Low Dose Etoricoxib
Analgesia - Pain	Combination ibuprofen & paracetamol
Analgesia - Pain	Aceclofenac
Antibiotics	Co-amoxiclav
Antibiotics	Antibiotics + Standard Management
Antibiotics	Oral antibiotics
Antibiotics	Local Antibiotic with PRF
Antibiotics	Amoxicillin / Clavulanic Acid
Antibiotics	Amoxicillin / Clavulanic Acid
Bilateral versus Unilateral Surgery	Bilateral third molar surgery
Complications	Poor oral hygiene or smoking
Cooling	Ice Packs
Coronectomy	Coronectomy
Coronectomy	Coronectomy
Drains	Tube Drain
Drains	Drain
Enhanced Recovery - Probiotics	Probiotic
Growth Factors	Concentrated Growth Factors
Imaging	Intimate Signs Nerve Compression
Kinesio Tape	Kinesio Tape
Kinesio Tape	Kinesio Tape
LA	Articaine high dose
LA	Lidocaine with clonidine
LA	Twin-mix (same as control but with 4mg dexamethasone)
LA	Articaine
LA	Ropivacaine
LA	Levobupivacaine
LA	4% Articaine with adrenalin
LA	4% Articaine
LA	0.5% Ropivacaine with Dexamethasone
LA	0.75% ropivacaine
LA	ID block with Lidocaine
LA	Bupivacaine and Ropivacaine
Medicaments	Chlorhexidine gel
Music Therapy	Music - different types
Novel Anti-inflammatory	Novel Drug (trypsin +chymotrypsin + bromelain)
Novel Anti-inflammatory	Serratiopeptidase + Paracetamol

Novel anti-inflammatory	Bromelain
Novel Gelatine Sponge	Novel Gelatine Sponge
Novel Wound Dressing	Absorbable Collagen Sponge
Novel Wound Gel	Wound gel (chitosan, 0.2% chlorhexidine, allantoin, dexpanthenol)
Novel Wound Gel	Wound gel (chitosan, 0.2% chlorhexidine, allantoin, dexpanthenol)
Photobiomodulation Therapy	Photobiomodulation Therapy
PRF	Socket PRF
PRF	PRF
PRF	PRF
PRF	PRF
PRF	PRF
PRF	PRF
PRF	PRF
PRF	PRF
PRF	PRF
Sedation	IV dexmedetomidine
Sedation	Sedation + LA
Sedation	Midazolam + Ketamine
Sedation	Promethazine and pentazocine sedation
Sedation	Diazepam
Steroids	Pre-op Dexamethasone
Steroids	Post-op Dex or Cool Wrap
Steroids	Sub-mucosal Dexamethasone
Steroids	Dexamethasone PO 4mg - Pre-op
Steroids	Submucosal Steroid (Dexamethasone or Methylprednisolone)
Steroids	Intraosseous Dexamethasone 4mg
Steroids	IV dexmedetomidine
Steroids	Dexamethasone 4mg
Surgical Time	Short Surgical Time
Technique - Flap	Cogswell Classic
Technique - Flap	Modified Envelope Flap
Technique - Flap	Envelope Flap
Technique - Flap	Vertical Flap
Technique - Irrigants	1% Metronidazole Saline
Technique - Laser	Laser
Technique - Laser	Extra-oral laser
Technique - Laser	Laser (various doses and extra vs intraoral)
Technique - Laser	Laser
Technique - Laser	Post-op Laser
Technique - Piezo	Piezo
Technique - Piezo	Piezo
Technique - Piezo	Piezo Surgery
Technique - Sutures	No Sutures

Technique - Sutures	No Sutures
Technique - Sutures	Knotless sutures
Technique - Sutures	Suture
Technique - Sutures	Primary closure
Technique - Piezo	Piezo Surgery
TENS	Electro-neuro Feedback (TENS)

4.1.11.2 - Positivity of Results:

Out of the 110 studies in the sub-analysis, 89 (80.8%) concluded that the intervention or interventions in question had a positive effect on outcome measures of interest. In this sense, benefits to the patient or a reduction in risk were felt to be achieved by the study intervention in a majority of the 110 studies.

4.1.11.3 - Outcome Measures:

For the sub-analysis of 110 studies, table 4.10, below, lists the outcome measures recorded where the outcome was not only recorded but either a named measure was given or a full description of the measure was provided.

Note the abbreviations in the table:

PGE2 = Prostaglandin E2

LA = Local Anaesthesia

VAS = Visual Analogue Scale
CRP = C-Reactive Protein
ESR = Eosinophil Sedimentation Rate
OHIP-14 = Oral Health Impact Profile-14
PoSSe = Post-operative symptom severity score
QoL = Quality of Life
GOHAI = Geriatric Oral Health Assessment Index

Table 4.10: Outcomes (A-Z) with Defined Outcome Measures (sub-group 110 studies)

Analgesia Efficacy	**Analgesia Use**	**Anxiety**
Time to meaningful analgesia	Patient Recorded	Gatchel's anxiety scale (GAS)
		Corah Dental Anxiety Scale (CDAS)
		Beck Anxiety Questionnaire
		Modified Dental Anxiety Scale (MDAS) Spielberger State-Trait Anxiety Inventory
Biomarkers	**Bispectral Index**	**Comfort**
Salivary and Urinary PGE2	Measured - Objectively	Measured - Subjective
Complications	**Dry Socket**	**Healing - Bone**
Chart Review – Specific	Blum's Criteria	X-ray
Healing - Soft Tissue		**Inflammatory Response**
Measured - Objectively		CRP
Measured - Subjective		ESR
		Cytokines
LA Duration	**LA Onset**	**Mouth Opening**
Measured - Objectively	Measured - Subjective	Measured - Objectively
	Measured - Objectively	
Nerve Injury	**Pain**	**Patient Satisfaction**
Chart Review	VAS	Interviews
Quantitative Sensory Testing	Numeric Questionnaire	Modified verbal scale
	Patient Recorded	5-Point Likert Scales
	Time to first rescue med	
	Pain Scale	
	Verbal Rating Scale Time weighted sum of pain relief	
	Pain Intensity Difference	
	Likert Scale	
	Total Pain Relief	
	Global Pain Scale	
	Full Cup Test	
Pocket Depth	**QoL**	**Sedation Score**
Measured - Objectively	OHIP-14	Ramsey sedation score (RSS)
	PoSSe	
	Questionnaire	
	12 Item GOHAI	
	Global QoL Scale	
Swelling		
Measured - Objectively	Laskins Method	Numeric Score
3D Scan		

4.2 - RESULTS - CORE8.2 Qualitative Focus Groups

The qualitative study is reported in line with the 'Consolidated Criteria for Reporting Qualitative Studies' and the associated check-list is included in Appendix 9 (Tong et al., 2007).

Two online focus groups were held during June 2024 lasting over 1 hour each.

Thirteen patients had agreed to participate during a recruitment period in May 2024. Whilst all eligible patients were approached when attending oral surgery clinics during the period, it was not recorded if a patient did not want to participate.

The attendance was 5 participants in each group.

One participant in group 1 attempted to join the group but had connection issues and was unable to connect on Zoom.

Two participants (one in each group) who had agreed to take part did not log-in to the group at the agreed time. One of those participants subsequently made contact to apologise and offered to take part in a future group should there be further focus groups.

4.2.1 - Participant Demographics

The sampling frame for the two focus groups is presented in tables 4.11 and 4.12 below.

A range of ages representing third molar patients took part. Whilst typical third molar surgery patients are young, often aged in their twenties and thirties (Vranckx et al., 2021), the participants in the present study included patients in their sixties as well, ensuring a diverse sample.

There was also an equal spread of male and female identifying participants over the course of the two groups.

Two participants had responsibilities for dependants and whilst most participants were medically fit and well, two participants did have other health problems; one of whom had significant medical problems with directly relevant medical history to healing after third molar surgery. All but one patient underwent full extraction procedures and four out of the ten had sedation and would likely represent the views of more anxious patients.

There was a range in socioeconomic status as can be seen in the occupation data but also in the inclusion of several patients with medical cards.

Table 4.11: Sampling Frame - Focus Group 1

Participant	Age	Sex	Occupation	Dependants	Health	Medical Card	Treatment	Sedation
1 (1.1)	66	M	Chef	Nil	Zolendronic acid MRONJ risk Prostate Ca	YES	Coronectomy	YES
2 (1.2)	45	M	Truck Driver	Child of 15 to look after	Fibromyalgia	YES	Removal	NO
3 (1.3)	35	F	Shop worker			No	Removal	NO
4 (1.4)	25	M	Student			No	Removal	YES
5 (1.5)	28	F	Secretary			No	Removal	NO

Table 4.12: Sampling Frame - Focus Group 2

Participant	Age	Sex	Occupation	Dependants	Health	Medical Card	Treatment	Sedation
1 (2.1)	28	F	Medical Secretary	Nil		No	Removal	YES
2 (2.2)	62	M	Procurement	Nil		No	Removal	YES
3 (2.3)	22	F	HCA	Nil		Yes	Removal	NO
4 (2.4)	30	F	Business	1 Child		No	Removal	NO
5 (2.5)	26	M	Accounts	Nil		No	Removal	NO

4.2.2 – Analysis

Framework analysis was used to explore patients' perspectives and identify key themes that could inform the process for later consensus research to identify the most relevant CORE outcomes. The analytic approach was thematic and inductive, rather than deductive, in order to facilitate an open exploration of what was important to patients.

4.2.2.1 - Familiarisation

The transcripts from the two focus groups highlighted a range of experiences and patient concerns surrounding third molar surgery.

In particular, the participants provided insights into physical symptoms in the post-operative period and the practical challenges of getting on with life during the healing phase.

The participants raised the importance of psychological impacts before, during and after surgery.

4.2.2.2 - Framework Development

The transcripts were examined, and items were identified and grouped into key themes which emerged.

Across the two groups, the key identified themes were:

- Perceptions/thoughts on wisdom teeth (i.e. what patients think or feel at the mention of third molar surgery).
- The surgical experience (before, during and after)
- Pain and numbness (this was linked because one participant complained of altered sensation but felt this had led to less pain)
- Dietary adjustments
- Swelling and infection
- Post-operative care and the practical implications
- Psychological issues
- Quality of life
- The overall experience of taking part in the focus groups

4.2.2.3 - Applying the Framework

The themes above were indexed to particular points raised and specific quotes from participants which are detailed in table 4.13 below:

Table 4.13: Key Themes with Indexed Transcripts

Theme	Transcript
Perceptions/thoughts on wisdom teeth	• **Problems, usually in younger life.** *"Problems, having to have something done, why do we have them?"* *"I felt like wisdom teeth were something younger people have to have done. Younger people than me."* • **Anxiety about the procedure and the aftermath, including stories about swelling and pain.** *"I just felt very anxious before the procedure"* *"You hear lots of stories about the swelling"* • **Positive and negative expectations based on stories heard.** ***"****I suppose you hear lots of stories about the swelling and things like that, so I was worried about the procedure and pain"* *"I had spoken to a few people who'd had theirs done. They had said you know it's not very pleasant but it's not that bad"* *"I had colleagues in who worked in the dental field, so they helped reassure me a few times. Probably stopped me looking at doctor google too much, so that stopped me getting to anxious from that"*
The surgical experience (before, during and after)	• **Concerns about sedation and its importance.** *"I didn't have the sedation…but I wasn't too anxious. I felt I was in the right place and once I was numbed I didn't have any pain during"* *Sedation "definitely helped make me feel a lot more relaxed"* *Music "once I was relaxed on the sedation I didn't really feel that aware of it"* *"I lay down as I was drowsy after the sedation"…which increased swelling.* • **Detailed experiences of pain management during and after surgery.** *"I would want to be numb for longer as for me it was pain" (What was important before/during/after)* *"Might not have gone through with it if I'd known how painful it would be afterwards"*

	"The pain killers did work, but once they started wearing off after a few hours, you'd have pain for 30 mins or so before the next load kicked in" • **Practical challenges with sedation due to family responsibilities.** *For afterwards "yes it would be good if sedation wore off quicker"* *"I felt anxious but I had decided not to have sedation because I have kids and I didn't want to be too out of it afterwards".*
Pain and numbness (this was linked because one participant complained of initial altered sensation leading to a painful tongue injury)	• **Significant post-operative pain; varying experiences with painkillers.** *"I didn't feel a thing, I didn't even know they'd done it…the operation…but it was afterwards, the pain. Once the numbness wore off. The few hours after that were horrendous"* *"Pain was definitely a big part of getting through it. I think I got solpadeine and ibuprofen"* *"If I did feel the pain killer dipping off then I'd get a bit irritable"* *Patient who had lingual nerve injury: "I was told about the risk of numbness and it's no one's fault, but I bit my tongue… I obviously took a chunk of it off. I was not aware of it. I did not feel it and can't remember doing it. That has been very sore as the nerve came back. More sore than the tooth itself"* • **Discussion on the effectiveness of alternating painkillers.** *"I found that if I alternated the hours for the painkillers, it kinda covered the hours off at the end of one painkiller"* *"Solpadeine would wear off around the 4 hour mark, but the ibuprofen would then be kicking in if I'd taken that just a few hours before"* *"I did something similar but I found that really it wasn't until the second day that I had the hang of it"* • **Managing pain through various methods, including noting times of medication intake.** *"I found it hard to remember which ones I had taken. So I was writing a note in my phone with the times. If there was a way of helping the*

	patients with what they've taken, or tips on the best way"
Dietary adjustments	• **Difficulty with liquid and soft diets.** *"would be helpful to be told more about it and to be given suggestions for it"* *"A suggested menu card would be good. Suggestions on soft foods"* *"it's no one's fault that I bit the tongue, but if I'd been given more advice on liquid diet that might have helped prevent me biting it"* *"Yeah, I don't think I would want to look at soup for a while. For me it was the stitches, that affected diet, the tugging"* • **Adjustments needed for cooking for family members.** *"Because I'm a chef, I do most of the cooking, so my family had to accept my diet… they'd probably want me back on normal diet quicker as it affected what they were eating too"* *"I was cooking for the kids, but then I was having to make something different, or modify it, for me so that I had softer food"* • **Suggestions for quicker return to normal diet and pre-prepared soft food menus.** *"If there was some way of getting back to normal diet quicker then that would have helped"* *"If you were more pre-warned as well, you could kinda prepare them, because you might not always feel like cooking, when recovering"*
Swelling and infection	• **Swelling duration and management, including use of ice packs.** *"I got some swelling, but it only really hit on day 3-4. I was told not to use ice straight away, because it could hinder the healing time. But to be honest I did use it straight away, not a cold pack, but like a cold damp towel just held kinda around my face. That kinda helped"* *"I did use some cold packs, I think they helped. I didn't seem to get too much swelling"* • **Pre-surgery infection management and its impact on post-op swelling.**

	"I'd had to be started on antibiotics by my dentist a few days before the surgery. So I don't know if that helped. Dunno if that's something you could do with all patients, start antibiotics may be the day before" *"My face was like the elephant man beforehand because of the flare of infection I had. So hard to know if I really got any more afterwards. I didn't use any cold packs after"* • **Infection concerns and hygiene practices post-surgery.** *"I have needed an extra course of antibiotics at follow-up as I still had some swelling and pain and there was a concern for infection"* *"I liked the kin mouthwash. And the salt rinsing. I know from previous ulcers and things that salt rinses clear thing up"* *"I was a bit nervous brushing the teeth around the area. Should you or shouldn't you. You know. You're afraid of upsetting it and damaging it"*
Post-operative care and the practical implications	• **Managing responsibilities such as work and childcare during recovery.** *"It was better to have the days off work. The first day, you're really getting your head around the pain killers etc.* *"I work from home, so no major practical issues. Because I knew beforehand what to expect"* *"Went back to work the following day – I probably shouldn't have done. I had only started in the job a week before. So I didn't want to be off"* • **Financial concerns and clarity about costs.** *On time off: "Because of my job, I'm able to do some extra shifts to make up for it so the financial aspect wasn't really the issue"* *"For me one of the biggest things was paying for it. I would have liked more information up front on the costs"* *"They're a lot less than it would be in a private setting. So I was just kinda happy to be getting it at the dental hospital"* • **Experiences with follow-up care and check-ups.** *"If there was a lot of follow up then that would be tedious, getting the time off work for that. I just had one follow up"*

	"I have a follow-up coming up, I had dissolving stitches, so I didn't have to have them taken out. But I would still rather have a follow up"
Psychological issues	• **Anxiety before surgery and varying psychological impacts post-surgery.** *"I just felt very anxious just before the procedure"* *"I wasn't really that anxious until it was coming up to the minutes of it, like when I was about to go along for the procedure, but yeah, the sedation was important for me. You can feel it taking the nerves off. You can drift to sleep if you want"* *"I was anxious. But I think that's just my own personal disposition. The poor taxi driver on the way in got an earful"* *"I felt silly afterwards because it was actually very easy, I didn't feel a thing"* • **Feelings of relief and satisfaction after the procedure.** *"I can confidently say that I've received very good care. They're out, I'm happy out"* *"They got it out without any damage so I'm very happy with that"* • **Support from family, friends, and healthcare professionals.** *On professional support/pre-op information: "they concentrated most on the procedure and the recovery, which I found the worst bit, was kind of forgotten about"* *"Until I read up on it, I thought the same. Did I need that much time off. Like I had had teeth taken out before and I just thought you know, it will be grand. But when they explained what they have to do. Then I realised. It was well explained before"* *"I just thought, it's getting a tooth out. But yeah, I would agree it's good to know you have some time off. It was more than I thought it was. It's a surgery"* *"The consultation can be a bit overwhelming, but the information pack that they give you if very helpful, you can read through it at your leisure and get a but more information. It's hard to retain all of that at the consultation"* *"I had colleagues in who worked in the dental field, so they helped reassure me a few times"*

Quality of life	• **Impact on sleep, social activities, and daily routines.** *"I tried to sleep a bit sat up the first day but that was a bit awkward"* *"I tried to sleep on my back to avoid lying on the sore side of the face, but then I would snore and my wife was giving out to me"* *"I found it quite awkward, I was sleeping on my left side, lying on my jaw, and with the swelling as well"* *"I had the surgery on the Tuesday, and I managed to go to a concert on the Saturday. Like I was there a few hours and then I felt my head was spinning and went home, but I was out, socialising, it was ok"* *"I think I woke up a few times and needed to use pain killers. But it was ok. During the day, I felt a bit lethargic, low energy levels. By the Saturday I went to a family do, a family get together. I played golf too"* • **Strategies to manage discomfort and return to normal activities.** *"I had to be normal as possible for my kids"* *"I had to get on with things so I was probably kind of distracted, with my kids etc. I did have pain, and I'd agree with the others that it was better after that first day, but I suppose I wasn't sitting thinking about it"*
The overall experience of taking part in the focus groups	• **Positive feedback on the care received and the importance of participating in the focus group discussion.** *"I can confidently say that I've received very good care"* *"It was a positive experience. To be honest. The care was excellent"* *"The whole thing was really a very good experience. All the staff were very professional. Service was second to none so I couldn't fault it at all. I was very impressed.* *"I was slightly worried that it's a training hospital. But then when I was there I realised it's all fully qualified surgeons working on you"* *"Any health studies, if I'm approached, I will always say yeah. I've seen first hand how much work goes into a lot of medical studies. So if I'm approached, I will always take part"*

	"It was a quid pro quo really, you were doing something useful for me so I wanted to do something useful for you. That's the least I could do" *"I knew, from the leaflet, this would help others in the future. So I suppose I just thought once asked that I should take part. It's been interesting to see how others found this. We're all in a similar boat"* *"Thanks for asking me to take part. Very interesting. It was actually nice to be asked for feedback like this"* *"Well there will always be something that comes up when you ask patients that's new to the table. Like research has shown that it's good to ask patients. So I think you're onto a good thing here. You can't go wrong. Fair play to ye!"* *"I just thought you never know what would come out of it, and I thought I would be a complex case because of my zometa, so I was happy to take part"* • **Suggestions for improving future patient experiences and recovery processes.** *"Would have liked to know more about how difficult the recovery would be"*

4.2.2.4 - Charting

The data from the framework was summarised into a theme chart recording key points and this is presented in table 4.14 below:

Table 4.14: Charting Key Points

Theme	**Key Points**
Perceptions of wisdom teeth	Positive and negative expectations Anxiety Concerns about pain and swelling
The surgical experience	Importance of sedation Pain management

	Practical challenges during recovery
Pain and numbness	Significant post-op pain Painkiller management Experiences with numbness
Dietary adjustments	Difficulty with liquid diets Need for quicker return to normal diet Impact on family meal prep and planning
Swelling and infection	Swelling management and duration Pre-surgery infection management Preventing infection and oral hygiene after surgery
Post-operative care/practicalities	Managing work and family responsibilities Financial concerns Follow-up care
Psychological impact	Anxiety before surgery Relief post-surgery Psychological issues during recovery
Quality of life	Impact on sleep Impact on social activities and daily routines Strategies for managing discomfort and getting back to normal
Overall experience	Positive feedback on care Importance of participating in this research Suggestions for improvement – enhanced pre-op information (recovery, diet).

4.2.2.5 - Interpretation

The focus groups have highlighted that patients concerns around third molar surgery are complex, and multifaceted and that many of the outcomes of importance to them are interlinked. For example, pain and

swelling caused sleep issues for one participant which led to him sleeping on his back and cause him to snore which caused interpersonal problems with his wife who was also then affected.

Key findings included:

Physical symptoms:

Pain and swelling were of high concern, as were effective analgesic regimens.

Function was of high importance, with several participants highlighting the impact of liquid diet and being prepared for this during the recovery period.

Practical:

Challenges with diet and maintaining work and family life around this.

Patients were concerned with parental responsibilities during recovery.

Some patients raised concerns over costs of treatment and time off work.

Psychological:

Many patients cited concerns around anxiety peri-operatively and found sedation helpful.

Quality of Life:

Patients cited concerns around their expectations of recovery and its reality. They wished they had been better prepared for this.

Recovery impacted on sleep, social activities and disturbance of daily routines.

In summary, the focus groups suggested the need for better pre-operative information that focuses not just on the procedure but also the recovery and they would value outcomes that enable them to get them back to normal diet and day to day activities earlier.

4.2.2.6 - Data Saturation

In order to assess data saturation, thematic saturation was analysed by first identifying the common themes across the two focus groups:

1. Pain Management: Both groups put significant emphasis on discussion of pain, pain management and the impact on daily life.
2. Anxiety and Psychological Impact: This was consistently noted before and after surgery.
3. Dietary Adjustments: Both groups noted challenges with diet post-surgery. Some participants noted the impact on being prepared for this and the impact in family meal preparation.
4. Swelling and Infection: Common experiences with swelling.

5. Practical and Financial Concerns: Similar concerns about managing responsibilities (e.g. to children) and clarity on costs.
6. Positive and Negative Experiences: Overall satisfaction with the care received was common to both groups. Both groups suggested improvements to pre-operative information, in particular the realities of the recovery period, getting back to work and the dietary implications.

Unique insights were then considered:

- Group 2 placed additional emphasis on the practical aspects of diet management compared to group 1, with suggestions like pre-prepped meals or meal plans. The theme and key points around diet were unchanged.
- Group 2 also gave more detailed feedback on cost issues and the need for more clear information. This seemed to represent the case of one participant who felt they had not been told the costs clearly.

Overall, the themes were consistent between the groups with the second group largely reinforcing the view of the first. Whilst the additional detail on issues around cost and diet management were certainly valuable, it was considered that they did not add to the key points from group 1 and in the context of the wider CORE8 study, they would be unlikely to add additional outcome measures for consideration at the CORE8.3 or CORE8.4 consensus stages.

In conclusion, data saturation was declared, and the data was considered to complement the scoping data from CORE8.1.

4.2.3 - Using the Qualitative Information from CORE8.2 to Complement CORE8.1

The qualitative data provides valuable insights into why certain aspects of third molar surgery and recovery are important. This can help understand the importance of outcomes at later consensus stages.

However, additional analysis was required in order to use the focus group data to complement CORE8.1. This was necessary to identify outcomes that either did not emerge from the scoping study or did emerge but were infrequently reported in the literature.

To do this, the key points raised by participants were aligned with measurable outcomes.

Table 4.15, below, presents the key points and relevant outcomes:

Table 4.15: CORE8.2 Key Points, Insights, Outcomes and Potential Outcome Measures

Key Point	Insight	Outcomes	Outcome Measures e.g.
Anxiety & Psychological	Participants raised anxiety as an issue.	Anxiety Patient Satisfaction	Modified dental anxiety scale;

			Patient satisfaction surveys.
Pain Management	Pain, in particular effectiveness of analgesia and issues around breakthrough pain were raised.	Pain	VAS score; Numeric Rating Scale; Analgesic Use
Sedation	Concerns about recovery after sedation were raised.	Sedation satisfaction	Questionnaires; Recovery Time
Swelling	Participants highlighted using ice packs.	Swelling	Objective measurement; Facial 3D scanning
Infection & Hygiene Issues	Particular concerns raised on how to keep the mouth clean post-operatively	Infection	Infection rates; oral hygiene scores
Dietary Implications and Recovery	Emphasised in both focus groups.	Function – Time to normal diet	Time to normal diet

Financial Concerns	Inadequate pre-op information.	Cost Transparency	Patient satisfaction surveys including cost satisfaction
Practical Issues	The impact on daily activities and getting back to work were emphasised.	Time off work QoL	Questionnaires on date of return to work; QoL indices like OHIP-14
Follow-up	Patients felt follow up was important	Follow-up	Follow-up attendance rates
Information and Communication	The need for better pre-operative information was emphasised.	Information re-call Patient satisfaction Helpfulness/Appropriateness of pre-op patient information	Questionnaires

The outcomes generated were considered against the outcomes already identified in CORE8.1, identifying several outcomes not considered or poorly represented in the literature from CORE8.1.

The following outcomes emerged, requiring consideration alongside CORE8.1 at any future consensus stages:

Time to normal diet: This is a new outcome highlighted by CORE8.2.

Time off work: This is currently infrequently reported as per CORE8.1.

Appropriateness and accuracy of pre-operative information: This is a new outcome highlighted by CORE8.2.

It was also noted that participants in CORE8.2 confirmed the importance of many CORE8.1 outcomes, including the most commonly reported outcomes of pain, swelling and function in terms of mouth opening. The participants were also highly concerned with issues around pain and anxiety control.

CHAPTER 5 - DISCUSSION

5.1 - CORE8.1 – Design and The Search Strategy

The scoping review has been successful in identifying 82 outcomes across 4 domains, including 6 physical sub-domains.

Whilst outcome extraction was the primary aim of the study, it has also provided insight on the types of study that are carried out and their topics, as well as additional information on which countries are producing this research and which journals are publishing it.

As a result of the design of CORE8.1, it is likely that all relevant studies within the review period were included, that the review is comprehensive and that the results are representative of the outcomes that are currently reported in third molar surgery.

Whilst perhaps the most common and well-known form of systematic evidence synthesis is the systematic review, methodological researchers have defined up to 25 “knowledge synthesis” (Aromataris et al., 2024) methods (Aromataris et al., 2024; Tricco et al., 2016).

The methodology at CORE8.1 was to carry out a scoping review, also known as a “mapping review” (Aromataris et al., 2024). According to the Joanna Briggs Institute (JBI) ‘Manual for Evidence Synthesis’ (Aromataris et al., 2024), scoping review methodology has been defined under published frameworks since 2005 (Arksey and O’Malley (Arksey and O’Malley, 2005)) and 2010 (Levac *et al* (Levac et al., 2010)). The JBI itself subsequently refined the guidance on scoping reviews, emphasising the need for rigorous, transparent and trustworthy

methods (Aromataris et al., 2024). Whilst the word ‘systematic’ was used at one stage (Aromataris et al., 2024; Peters et al., 2015), this was dropped, recognising the need for all forms of evidence synthesis to be systematic and the term scoping review is now favoured across multiple organisations. Indeed, the ‘Preferred Reporting Items for Systematic Reviews’ (PRISMA) statement provided a scoping review extension (PRISMA-ScR) (Tricco et al., 2018).

The reasoning a scoping review was chosen, is that unlike a systematic review, which would usually address a specific question, such as the effectiveness of an intervention; a scoping review can be used to “map the key concepts that underpin a field of research, as well as to clarify working definitions, and/or the conceptual boundaries of a topic” (Aromataris et al., 2024). In the context of CORE8.1, the purpose of the review was to explore the breadth of the literature in terms of current outcome reporting. Munn *et al* have defined the indications for scoping reviews and core 8.1 aligns with two of their six indications (Munn et al., 2018):

- “To identify the types of available evidence in a given field”
- “To examine how research is conducted on a certain topic or field”

Scoping reviews do not synthesise evidence with methodological appraisal and quality assessment; rather, they provide an overview of the evidence.

Scoping reviews are systematic, with an *a priori* protocol and inclusion and exclusion criteria. These criteria are typically less restrictive than in

systematic reviews and the ‘population, concept, context’ (PCC (Aromataris et al., 2024)) structure for scoping review research questions reflects this, being broader and slightly less specific than the ‘Patient, Intervention, Comparison, Outcome’ (PICO (Santos et al., 2007; Schardt et al., 2007)) model.

The other defining systematic characteristics for scoping reviews, which are common to systematic reviews are (Aromataris et al., 2024):

- Explicit, transparent, peer reviewed search strategy
- Standardized data extraction forms

The CORE8.1 scoping review fulfils these characteristics and peer review of the search strategy was implemented and led to changes that rendered additional references when the search strategy was tested.

Peer review of the search strategy is not always seen in scoping reviews but is essential in order to fully comply with the recommendations of the JBI Manual (Aromataris et al., 2024) and in fitting with guidelines published by McGowan *et al* (McGowan et al., 2016) on ‘Peer Review of Electronic Search Strategies’ (PRESS) who recommend the involvement of a librarian and independent librarian peer review, as per CORE8.1 methodology.

The inclusive approach to the research question and the systematic search strategy resulted in a very large return of references (10,714 and 5,613 prior to and after deduplication respectively), in fitting with the ethos of a scoping review.

Extending the search limits to a 20 year period was considered at strategy testing stage. At that point, the search strategy was being tested in Medline (OVID) only. It was found that no limits searches returned circa5000 references while a 10 year limit returned circa2700. It was felt that a 20 year limit was unlikely to return a significant number of additional references given the relatively small difference between a no limits search and a 10 year search and it was also considered that the proposed 12 year period should contain sufficient references to cover all relevant outcomes.

The subsequent high exclusion level indicates that the scoping search strategy is likely to have identified all relevant papers. If the screening process had led to inclusion of most of the returned references then it would be questionable as to whether there was a body of additional relevant research that had not been identified.

Furthermore, the broad range of journals and the wide range of countries of origin of the research studies included demonstrates that the scoping review has identified relevant research from a wide range of settings and geographical locations and is likely to be representative of the outcomes that researchers are including around the world.

This was reassuring, because at the design stage, the scoping study steering group had questioned whether or not to include ‘SciELO’, the South American Web of Science database. It was felt that there was a risk of missing South American papers of relevance to the topic without this database, but it was recognised that inclusion of this database would result in additional barriers to data extraction since much of the

literature would not be in English. Whilst the involvement of Spanish speaking colleagues was considered, it was decided not to pursue this database due to the practicalities of organising this within the constraints of the time and resources available for CORE8.1. Reassuringly, it can be seen from the results that many studies from Brazil were included as well as Mexico, Chile and Peru.

5.2 - CORE8.1 – The Evidence Base

In terms of the type of evidence, the results have shown a large number of study designs are randomised controlled trials or randomised split mouth studies. This is encouraging, since the literature review has emphasised the importance of high-quality evidence inputs to ensure useful recommendations can be made upon evidence synthesis. However, it was apparent during data extraction that a large number of studies were not following reporting guidelines such as CONSORT (Schulz et al., 2010) and that there were frequently obvious design flaws such as poor blinding or allocation concealment. In addition, CORE8.1 analysis did consider whether primary and secondary outcomes were clearly defined, and this was unfortunately a frequent omission with only 88 of the 815 studies reporting this clearly. As discussed in the literature review, this is important since setting clear primary and secondary outcomes ensures outcome reporting in line with that protocol and failure to do so can lead to reporting bias. This being said, it must be highlighted that CORE8.1 was a scoping review and as such did not critically appraise the evidence or assess bias so

conclusions on the quality of study design and the strength of the evidence are not possible and were not the aim here. Nonetheless, it is encouraging that a lot of research in the field of third molar surgery utilised designs that minimise differential biases and confounding factors across intervention and comparator groups.

The study did identify a large range of topic areas, demonstrating the range of research that is done within the field; from obvious topics like analgesic, steroid and antibiotic use, to more obscure and novel innovations like the use of photobiomodulation, probiotics in enhanced recovery regimens or music therapy.

Many of these topics would have wide application not just within third molar surgery but also within surgery and medicine in general. This is certainly true of analgesic studies utilising third molar surgery as a pain model, but also where interventions might confer benefits in other fields, for example in wound healing, which is not necessarily third molar surgery specific (e.g. the aforementioned enhanced recovery interventions). The range of topics and the potential wider applications therefore emphasis the importance of future consensus stage research to realise a COS.

One concerning feature that was noted during CORE8.1, was that some of the included studies highlighted ethical issues. For example, some studies randomised participants with high-risk inferior alveolar nerve

injury signs to coronectomy or complete extraction. It was questionable whether this was acceptable, since at the time these papers were published, it would have been difficult to argue that there was clinical equipoise in terms of the ability of coronectomy to reduce the risk of nerve injury given that this has been shown at least as far back as 2005 (Renton et al., 2005). CORE8.1 has not analysed this formally, but it was noticeable that India, Turkey and Brazil produced overwhelmingly the most research in the field, with western European states like the UK and Ireland contributing much less. One would have to wonder why this is? It may be simply the large populations of these states and the resultant number of interested investigators and institutions, or there may be other factors at play including lower research ethics thresholds in some instances. Indeed, it was recognised in the literature review that the ethics involved in surgical research can be difficult, in particular in trials involving 'sham' surgery control groups (Ergina et al., 2009). With respect to the above, it must be noted that the USA was the fourth highest location of included studies, but this is likely because many third molar pain model analgesia studies originated in the USA, since this is frequently the location of major pharmaceutical companies who typically fund these studies.

5.3 - CORE8.1 - Limitations

Two methodological limitations must be highlighted when considering the results of CORE8.1.

Firstly, there were 616 references that were co-reviewer screened which were in conflict and were not included in the final extraction. A conflict arose when one reviewer felt a study should be included but the other reviewer felt it should not and the 'COVIDENCE' platform (Covidence, 2024) highlighted these papers for conflict resolution.

Originally, resolution of conflicts in these papers was planned to be by discussion between the co-reviewers followed by agreed exclusion or inclusion. However, before this was carried out, full text review and data extraction commenced on already agreed included studies. It was soon apparent that outcome extraction took a considerable enough amount of time. Within the time and resource constraints of the project, where one reviewer (R Carr) was extracting outcomes, it was decided that only those papers (815) that met the threshold of co-reviewer first time agreement would be included fully. This was felt to be acceptable for several reasons:

1. With 815 included studies, it was recognised that CORE8.1 was a very comprehensive review with respect to other COS scoping reviews. Indeed, the previous scoping work by O'Sullivan and Ní Ríordáin on both clinician reported (published in 2021) and patient reported outcomes (published in 2022) in third molar surgery included analysis of only 20 papers in their initial paper with the second review very much being a narrative review without a systematic search or analysis of any substantial body of individual papers (O'Sullivan and Ríordáin, 2022; O'Sullivan and Ní Ríordáin, 2022). Furthermore, the well-regarded scoping

review (Tsichlaki et al., 2018) that informed the Orthodontic COS (Tsichlaki et al., 2020) dealt with a fraction of the number of included studies that CORE8.1 has considered. Indeed, Tsichlaki *et al* identified 1,267 studies, reducing to 675 after deduplication, with only 164 studies making it to final inclusion (Tsichlaki et al., 2018). Likewise, the review (Yan et al., 2020) that informed the oral lichen planus COS (López-Pintor et al., 2023) identified 1,087 articles, deduplicating to 843 and included 88 studies. This is a stark comparison to CORE8.1 where 10,714 studies deduplicated to 5,613 studies, all of which had to be screened and the resulting number of included studies was 815.

2. An analysis of 100 of the 616 studies in conflict was carried out. This sample was random and an involved an abstract screen to see if the conflicted studies raised any significantly different topic areas, study designs or outcomes. This was necessary because whilst the first reason above was supportive of the approach here, it could have been that the included studies in the other fields were simply the limit of the evidence that is in the research literature in those fields; so, it does not transpose simply in view of the numbers of studies, that CORE8.1 had reached a sufficient inclusion. There was still a risk that the conflicted 616 studies may contain additional studies that should be included and that would add additional insights into topic areas, study types and reported outcomes. Thankfully, the analysis of 100 of these studies indicated that this was not the case (Appendix 8).

When it came to the data extraction from the 815 included studies, a strength of the CORE8.1 methodology was that whilst full text review and data extraction was done by a single reviewer (R Carr), 50% of the papers were subjected to co-review (R Hardy) to check the extracted data.

The second major limitation of CORE8.1 was related to extracting additional data from the studies which would have provided more insight into outcome measures alongside the primary data on the actual outcomes reported.

The data extraction sheet did originally contain fields to collect data on outcome measures, for example alongside the outcome of ‘Anxiety’, data would be collected on measures used, such as ‘Modified Dental Anxiety Scale’. Data was also collected on the actual interventions (e.g. IV Dexamethasone), not just the broad topic (i.e. Steroids), and whether the authors made positive or negative conclusions on the effectiveness of the intervention of interest to alter the outcomes.

This data collection was discontinued after the first 110 studies because it was rendering the data extraction stage un-achievable within the limits of the time and manpower resources for CORE8.1.

For several reasons, the time taken to extract this data was considerable, not least the very variable reporting of outcomes and outcome measures; but also, because on a practical level, the data extraction form became long, overly complicated to look at and difficult to navigate on a computer screen.

Whilst initially ambitious to extract this additional data, the extraction form was simplified to concentrate more on the primary objectives of the study which were to identify the outcomes currently reported.

Indeed, as discussed in the literature review, COS development does not stop once a COS has been agreed (Williamson et al., 2017; Prinsen et al., 2016) since there is subsequently considerable work involved in attempts to standardise the actual outcome measures; with the 'Consensus Standards for the selection of health Measurement Instruments' initiative (COSMIN, 2024) (COSMIN) existing to advise on and help to standardise the methodology involved in these processes. This is really a post-consensus COS stage and whilst it would have been interesting to collect some of this data as part of CORE8.1, the practicality of achieving this was a limitation.

Nevertheless, this data was extracted from 110 studies and this enabled a sub-analysis of these papers to shed light on the topics, outcome measures used and conclusion positivity from these papers.

The papers were extracted in random order so the 110 studies analysed for this additional data may be representative of the complete sample rendering this data useful.

As previously discussed regarding topics, the actual interventions were wide ranging, from obvious interventions like common antibiotics to novel anti-inflammatory drugs like Bromelain or novel wound medicaments like chitosan or application of concentrated growth factors. The outcome measures were also wide ranging, for example,

anxiety was measured using 5 different anxiety scales in the 110 analysed papers. The table in the results section breaks the measures down against the outcomes they measure and is informative, enhancing some of the information from the similar table focussing on patient reported outcomes published in the scoping review by O'Sullivan and Ní Ríordáin (O'Sullivan and Ní Ríordáin, 2022).

Regarding the authors reporting positive or negative effects of their intervention, 89 of 110 reported that the intervention of interest improved outcomes. This is interesting, however potentially not very useable data. As discussed above, the CORE8.1 scoping review did not critically appraise or bias assess the included studies so the authors conclusions are only that.

In terms of the limitations, the resources in terms of time and manpower have been cited. Indeed, data extraction was by a single reviewer. For a review with the numbers of studies included in CORE8.1, based on the time taken for full text review and outcome extraction, fully extracting all outcome measures and more detailed intervention information as above would require a team of perhaps 10-20 reviewers extracting 50-100 studies each. Whilst it is not clear how many people were involved in data extraction in other scoping reviews, it is notable that the much smaller lichen planus scoping review (Yan et al., 2020) had 6 named authors whilst the orthodontic scoping review had 4 (Tsichlaki et al., 2018).

5.4 - CORE8.1 – Conclusions

Despite limitations, CORE8.1 has identified 82 outcome measures across 4 domains with 6 physical sub-domains. It was notable that there was a high degree of repetition, with very many studies reporting on the outcomes of pain, swelling and mouth opening. It was also clear that investigators tend to focus on physical outcomes much more than those in the psychological, practical or quality of life domains. This was emphasised by the need for 6 physical sub-domains.

5.5 - CORE8.2 – Recruitment and Online Focus Groups

Holding the online focus groups was a positive experience. The author had undergone training in holding focus groups and focus group analysis prior to this stage through the social research association, and had accessed advice on the topic guide through that training; this utilised the approach by Braun and Clarke (Braun and Clarke, 2013).

Very few patients declined to be involved when approached by the gatekeeping clinicians in clinics they were attending. Although this could represent positive bias (such as selection bias), the gatekeeping clinicians were not otherwise involved in the CORE8.2 study at all so they did not hold a vested interest in this recruitment process. Subsequently, a high turnout rate at the focus groups was also noted and patients were very positive about the groups taking place via Zoom.

This was probably because it afforded accessibility, allowing them to take part from home and they were not particularly inconvenienced by the process. Furthermore, it allowed the investigator to run the groups in the evening, at times that would easily suit the participants, as the only equipment required was a computer with webcam. This may help to explain the high turnout rate and it might be hypothesised that this is likely to have supported a more inclusive sample, with people with co-morbidities and/or carer responsibilities being able to take part.

In terms of limitations, one limitation was that the focus groups only included patients who had undergone mandibular third molar surgery. However, the most significant impacts after third molar surgery do relate to lower surgery, with upper third molar surgery frequently being straightforward.

Another potential limitation was in the use of the online format via Zoom (Zoom, 2024). Whilst this had advantages in terms of attendance as discussed, there are recognised potential challenges with online groups compared to in person groups (Falter et al., 2022).

Technical difficulties can affect some and may even put off some cohorts from participating, such as those who are less computer literate, which often includes the elderly. In CORE8.2 there was one participant who did not have a computer and initially thought he could not take part; however, it was explained that Zoom works with a mobile smart phone and the participant managed to log-in via his phone without issue. One potential participant however did have technical issues and could not log-in due to connection issues.

It can also be difficult to pick up on non-verbal cues such as body language and nuances like facial expression. Participants can be less engaged because of distractions in their own environment (Falter et al., 2022), and it can be difficult to build rapport because the online format is relatively impersonal. Participants can multi-task during the session so they might not give the focus group their full attention which can affect authenticity and there can be challenges in some circumstances around data security and time zone issues which did not really affect CORE8.2.

One of the challenges that could have affected CORE8.2 was the challenge of moderating a screen of people. Indeed, reflectively, the numbers who attended in the CORE8.2 groups were ideal, since a screen split into 6 (moderator + 5 participants) is relatively easy to look at. If there had been even a few more participants in each group, it would have been difficult to look at all of the participants and some of the challenges mentioned above, such as nuances of facial expression and body language, would have been compounded.

The COVID-19 pandemic forced a lot of qualitative work to move to online platforms and much research has been done over that time showing that despite the challenges, online focus groups can be valid and comparable to in person focus groups (Falter et al., 2022); and can be valid even for sensitive topics (Wettergren et al., 2016).

5.6 - CORE8.2 – Sample Size and Setting

It had been anticipated that two to four groups of 6-8 patients would be required to reach a point of data saturation, as per the literature for similar studies. Data saturation can be defined as the circumstance when the collected data is sufficient in breadth and depth to adequately answer the research question, with no new themes emerging from data analysis (O'Reilly and Parker, 2013). However, for this surgery, no new themes emerged in the second of two focus groups and following this, saturation analysis was carried out and the CORE8.2 team determined that saturation could safely be declared. This was similar to the experience in other oral health related COS projects. Indeed, the patient perspective on oral lichen planus treatments was investigated with two groups of 5 patients each in Cork, Ireland, as part of the pre-consensus research that led to the consensus stages of the oral lichen planus COS (Diniz-Freitas et al., 2023). Those same 10 patients went on in that study to contribute to the consensus stage, voting on 15 domains using 9-point Likert scales (López-Pintor et al., 2023).

However, a limitation in CORE8.2, and arguably the Cork study, was that the focus groups were carried out using participants from one institution, in a single city in one country. Whilst a range of participant ages, genders, medical statuses and socioeconomic backgrounds were included; it would have been ideal to run focus groups in different settings and ideally different countries. It cannot be known from CORE8.2 whether patients in private practice settings might have focussed more on financial outcomes for example. Indeed, it is notable

that the orthodontic COS aimed for 35 participants, and they achieved this through seven focus groups and 16 qualitative interviews which were carried out across two primary care and three secondary care sites (Tsichlaki et al., 2020). Whilst this data was all from England, it clearly would have achieved a broader data set. Although data saturation was reached in one setting within the practical constraints and methodology of CORE8.2, it can't be known that more focus groups in these additional settings would not have enhanced the data. Indeed, it could be that with further qualitative work, outside of the scope of the current project but more akin to the wide settings in the orthodontic COS, that the conclusion of having reached saturation is overly optimistic.

Following CORE8.1 and CORE8.2, in addition to previous work in Cork, Irish investigators have an opportunity to work together at the core of this to achieve a COS for third molar surgery (CORE8). Given the experience and interest of the Cork based researchers (O'Sullivan and Ní Ríordáin) in third molar outcome reporting and COS (O'Sullivan and Ríordáin, 2022; O'Sullivan and Ní Ríordáin, 2022), in addition to the lichen planus COS work under Ní Ríordáin (López-Pintor et al., 2023; Diniz-Freitas et al., 2023), it is notable that there is interest and expertise within Ireland in COS development for third molar surgery. This offers future opportunities to address the possibility of further qualitative data Ireland-wide, as well as to propagate this collective synergy towards realising consensus research (CORE8.3 and CORE8.4) with international buy-in and applicability. Innovative collaborative work is needed to explore financial and other culturally

important outcomes that may be outliers that were not identified by this single centre sample.

5.7 - CORE8.2 – Analysis and Results

Qualitative analysis followed the principles of framework analysis which was developed by Ritchie and Spencer in the 1980s (Gale et al., 2013). This is recommended by the COMET handbook for COS development (Williamson et al., 2017) and is particularly useful in focus group analysis as its focus is not on categorization and quantification of qualitative data (as content analysis can be (Hsieh and Shannon, 2005)), but provides a systematic approach to, and can allow comparison of data across different focus groups. The step-by-step process also helps in interpretation as it identifies key themes and points from the transcripts and produces thematic insights to the qualitative raw data.

Crucially, the focus groups provided a lot of insight into why particular outcomes are important to patients and the resultant data was equitable in many areas to measurable outcomes which could be considered alongside the outcomes defined by CORE8.1.

Whilst CORE8.1 highlighted the heavy emphasis of existing research on physical outcome measures, CORE8.2 identified that patients placed high importance on quality of life and functional outcomes.

Patients were particularly concerned with their recovery and getting back to normal diet and to work. They also raised issues around the quality of pre-operative counselling on what the recovery period would be like.

Despite the emphasis of investigators on physical outcomes, it should be of no surprise that patients raise quality of life and functional issues as their prime concern.

Indeed, in a 2023 paper by McGrath *et al*, quality of life measures were used to evaluate changes in quality of life in the post-operative period following third molar surgery (McGrath et al., 2003). The measures are not new, with the investigators utilising well developed oral health quality of life measures including OHIP-14 and the UK oral health related quality of life (OHQoLUK) which does assess eating and work related information. The investigators found that quality of life does not return to normal until post-op day 6. It is common to explain to patients that there is a recovery period but clinicians often just inform patients that a week to recovery might be expected. CORE8.2 revealed that patients tend to underplay that advice, believing that they are just having a tooth out and it can't be that bad:

- *"I had had teeth taken out before and I just thought you know, it will be grand. But when they explained what they have to do. Then I realised"*
- *"It's good to know you have some time off. It was more than I thought it was. It's a surgery"*

The work of McGrath, alongside the CORE8.2 evidence for the importance of things like diet and pre-operative information, suggests clinicians really should be doing more to help patients understand and prepare for what the recovery will be like. Further work might explore the advice given by surgeons who may downplay the post-operative quality of life outcomes, being more concerned and focussed on the risks that involve litigation.

5.8 - CORE8.2 – Reflexivity

Reflexivity, in the context of qualitative focus groups, refers to considering the researchers influence on the research process and the influence of the research process itself on the participants and the researcher (Reid et al., 2018).

In this respect, the potential for a surgeon running focus groups about surgery, to shape the data that is collected must be acknowledged.

An independent qualitative researcher, not necessarily qualified in surgery or aware of the outcomes from CORE8.1, would potentially remove this influence. However, within the constraints of this work, as a clinician researcher, it was crucial to be prepared prior to the focus groups by being introspective. That is, to be aware of the perspectives and assumptions that I would bring to the table and how they could influence the data.

To ensure no undue influence, neutral facilitation of the focus groups was essential, and the use of a topic guide developed systematically from CORE8.1 combined with open lines of questioning using the guide prompts should have minimised any potential undue influence on the results. Techniques such as silences were used to encourage the group to keep discussing topics naturally, without undue influence from the facilitating researcher at CORE8.2. Active listening and probing questions, like “why is that important to you?” were utilised and topic guide prompts were asked very much as open prompts rather than specific or closed questions so that the CORE8.1 domains were covered but the focus was not so specific as to simply influence the participants to raise the same key points as CORE8.1.

Although the participants did know the researcher was a surgeon, the line of questioning from topic guide prompts, which was not technically worded, ensured participants spoke freely and were not ‘performing’ in order to ‘impress the doctor’. There was also an open opportunity to add any other comments and to feedback on the experience of taking part at the end of the focus groups. Patients were very positive in this regard, feeling they had enjoyed the opportunity to contribute to make things better in the future, and thus highlighting that they felt their views had been brought out and listened to and were unlikely to have consciously felt unduly led by the influence of the researcher.

In the analysis, the use of structured framework analysis aided objectivity but of course there was again potential for the influence of a surgeon researcher developing themes on a surgical topic. However,

the emergence of outcomes related to pre-operative information and function (time to normal diet) is reassuring since surgeons would tend to focus on very physical outcomes like pain and swelling. In further reassurance, the emergence of such outcomes of importance in CORE8.2 echo's the experience of other groups once patients were involved, such as OMERACT, as previously discussed and highlighted again below.

5.9 - Combining Results - CORE8.1 and CORE8.2 - New Outcomes

In equating the information from CORE8.2 to measurable outcomes, the focus groups have confirmed the importance of clinician based outcome priorities from CORE8.1, particularly pain, swelling, mouth opening and anxiety. Crucially however, CORE8.2 identified the following outcomes, not otherwise identified or adequately reported from CORE8.1:

- Time to normal diet.
- Appropriateness and accuracy of pre-operative information.
- Time off work (reported infrequently in CORE8.1).

Looking to other specialities, the experience of the OMERACT investigators can be recalled, who failed to recognise the importance of 'fatigue' as an outcome in the early days of reaching consensus on core outcomes for rheumatoid arthritis. As discussed in the literature review, the OMERACT investigators only recognised this outcome after the

involvement of the patient perspective at OMERACT 6 (Williamson et al., 2017).

5.10 – Future Work to realise 'The CORE8' COS

The author intends to submit papers for CORE8.1 and CORE8.2 for publication in peer reviewed medical journals and subsequently to link these publications to the COMET entry for the CORE8 study.

CORE8.1 and CORE8.2 have provided the critical pre-consensus data to support the movement of the wider CORE8 study into the consensus phase. Instigated and led by the author, CORE8 has now become a research theme within Dublin Dental University Hospital and it is envisaged that the consensus stages could form the basis of a research project for a future oral surgery specialist trainee. It is recognised that collaborative work will be required to achieve an international Delphi panel and consensus meeting, and this thesis has highlighted that there is interest in this theme in Cork, with opportunities for collaborative inter-institutional working. The author intends to remain a key member of the CORE8 steering group to ensure the realisation of 'The CORE8' outcome set as the single COS for third molar surgery.

CHAPTER 6 - CONCLUSIONS

CORE8.1 represents a significant step to understanding the current state of outcome reporting in third molar surgery and alongside CORE8.2, paves the way for consensus research towards a COS for third molar surgery.

The scoping review has identified the range of outcomes reported and delineated them into clear domains but has demonstrated the repetitive and heavy focus on physical outcomes.

CORE8.2 has provided qualitative insights which will be important for future consensus research and has highlighted the importance of quality-of-life outcomes, in particular getting back to normal diet and getting back to work, as well as knowing what to expect and being prepared for the recovery period.

CORE8.2 has been successful in identifying new outcomes including ‘time to normal diet’ and ‘appropriateness and accuracy of pre-operative information’.

Together CORE8.1 and CORE8.2 complement previous work on patient and clinician reported outcomes by colleagues in Cork.

Work must now begin on publishing this work and uploading it to the COMET registry for the wider CORE8 study.

Given the size of the challenge, future consensus research must be carried out collaboratively in order to progress towards the CORE8 COS for third molar surgery; Irish investigators are well placed to lead

this given the work to date both in this project and by colleagues in Cork.

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APPENDIX 1

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APPENDIX 2

Focus Groups – Ethical Approval

DUBLIN DENTAL UNIVERSITY HOSPITAL
OSPIDÉAL DÉADACH OLLSCOILE ÁTHA CLIATH

Research Ethics Committee
School of Dental Science &
Dublin Dental University Hospital
Lincoln Place
Dublin 2
Ireland

23rd May 2024

RE: "*Development of a core outcome set for trials in lower third molar surgery*"

REC Reference: DSREC2024-02

Dear Dr Carr,

Thank you for your recent application to the Dental School Research Ethics Committee (DSREC). Your application has been granted ethical approval. Please quote the above reference in all future correspondence.

Yours sincerely,

Prof. Gary Moran
Associate Professor in Microbiology
Chair DSREC
School of Dental Science and
Dublin Dental University Hospital,

Dublin Dental University Hospital
T : +353 1 612 7245
Ospidéal Déadach Ollscoile Átha Cliath
E : gpmoran@dental.tcd.ie

APPENDIX 3

Focus Groups – Patient Information Leaflet

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

CORE8 STUDY

Core Outcomes in Lower Third Molar Surgery

Participant Information Leaflet - Focus Groups

INTRODUCTION:

Thank you for considering taking part in this study.

The study aims to look into what the most important outcomes that should be measured when research is done to look at lower third molar (wisdom tooth) surgery. For example, if a study was comparing how effective two pain killers are, then clearly a crucial outcome is the amount of pain that patients suffer following surgery.

Many types of studies are done every year evaluating various different aspects of lower wisdom tooth surgery, such as what pain killers are best, whether antibiotics are necessary or what techniques or equipment should be used.

Often, studies help us understand what might work better, but individual researchers are often only reporting in small projects meaning that we are often still unsure as to what works best. A way to help build a bigger picture is to get all researchers reporting on similar outcome measures so that studies on similar topics can be compared to increase the amount of evidence that can be used to answer a question, such as what pain killers work best.

This study aims to work out what the most important outcomes are.

This takes into account looking at what is currently reported on in studies, as well as asking patients and professionals what factors they think are important.

FOCUS GROUPS:

You are being asked to participate in a focus group where you will be able to share your views on what you think is important when having lower wisdom tooth surgery. For example, you might be concerned with obvious things like pain, or you may be concerned about wider factors like time off work after surgery. The focus group means that you would be part of a group with a researcher and other participants discussing with each other what is important. The other participants will be able to see you. The researcher may ask questions to stimulate discussion but the idea of the group is to generate discussion to help us identify and understand why you may feel that certain outcomes are important.

WHAT TO EXPECT:

If you agree to take part in a focus group, you will be asked to sign a consent form on which your contact details and hospital number are recorded. You will then be contacted by phone or email by a researcher about the possible dates/times to take part. The groups would take part online, via zoom, and if you agree

to a particular date/time, the researcher will email you a link for the focus group as well as reminder of the time/date. You would then log-in to the group using the link.

You will need a computer with a webcam to take part.

The focus group will last up to an hour but may be shorter.

WHAT HAPPENS TO MY INFORMATON?

Your personal details will be recorded on the consent form and will only be used to contact you as detailed above.

A record of your details and hospital number will be kept securely in the dental hospital (by keeping your consent form on file) so that it is possible to show that you took part in the study. The only people with access to your consent form (and thus your personal details) are the researchers involved in the study.

The focus groups are NOT being recorded. During the groups, you will be assigned a number which will be recorded on your consent form and your comments will be transcribed (written down) separately under that number only. As such, in the transcribed records of the focus group and in the analysis later, what you contribute will not be traceable back to you other than by the researchers who have access to your consent form and the transcribed comments. These transcribed comments will be kept separately from your consent form indefinitely as they form part of the raw data for the study. The record of your personal details on the physical consent form will be destroyed 7 years after the study ends. This period is a standard period for health related research.

If you later wish to see a copy of what was transcribed for you, we will provide this to you with the other participants comments removed from the transcript. To access this, you will contact the researcher delivering the group who will provide their name and email address during the group.

CONSENT AND WITHDRAWAL:

If you are happy to take part, we will ask you to sign a consent form and provide your email address and phone number to contact you as above. You are free to withdraw from the study at any time and if you withdraw or do not log-in to take part (assumed withdrawal) then your consent form will be destroyed and thus your personal data will not be held at all.

WHY TAKE PART?

Whilst the study will not benefit you directly, you will be contributing to a study that aims to improve the research base in this field and help us to make better decisions for future patients to improve their experience of lower wisdom tooth surgery.

APPENDIX 4

Focus Groups – Consent Form

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

STUDY NAME: CORE8 FOCUS GROUPS
Centre ID: DDUH
Identification Number for study:

Consent Form

There are X sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researchers to complete. **Please ask <u>any</u> questions you may have when reading each of the statements.** **Thank you for participating.** **Please <u>Initial</u> the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.**	
General	**Tick box**
I confirm I have read and understood the **Information Leaflet** for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study **is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason**. I understand that deciding not to take part will not affect my future medical care.	
I understand that my **dental notes and records** may be looked at by my study Doctor/Dentist and his/her study team at Dublin Dental University Hospital where it is relevant to the research. I agree that these individuals can access my records. I understand that all information will be kept private and confidential and that my name will not be disclosed.	
I understand that I **will not be paid for taking part in this study**[1].	

I know how to contact the research team if I need to.	
I agree to take part in this research study having been fully informed of the **risks, benefits and alternatives** which are set out in full in the information leaflet which I have been provided with.	
[I agree to being contacted by researchers by email and/or phone[2] as part of this research study][3].	
Data processing	**Tick box**
I understand that personal information about me, including the transfer of this personal information about me outside of the EU, will be protected in accordance with the General Data Protection Regulation.	
I understand that there are **no direct benefits to me** from participating in this study. I understand that **results from analysis of my personal information will not be given to me**.	
I understand that **I can stop taking part in this study** at any time without giving a reason and this will not affect my future medical care.	

---------- ----------

Patient Name (Block Capitals) Patient Signature Date

---------- ----------

Witness Name (Block Capitals) Witness Signature Date

Patient DDUH Number:
Participant Email Address:
Participant Phone Number:

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.
I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date

| | |

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.

APPENDIX 5

Focus Groups – Topic Guide

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

CORE8 STUDY

Core Outcomes in Third Molar Surgery

FOCUS GROUPS – TOPIC GUIDE

Introductions

- Contact email address for researcher (if patient wants to request a copy of their transcript).
- Explanation of transcript.
- Explanation of focus group.
- Explanation of right to withdraw.

Icebreakers

Starting questions:

What's the first thing that comes to mind when I mention wisdom tooth removal?

What do you think is important to look at if we were trying to improve the experience of third molar surgery?

CUES:

Pain and discomfort

- Is this important? Why? (may lead to lifestyle/practical considerations naturally in discussion)
- Better to know? Would it affect your choice to have surgery or not?

Swelling

- Similar questions to above

Infection

- Accept risks of preventative measures even if they also had risks?

Sensory deficit

- Risk vs risk no treatment vs risk of interventions (CBCT/coronectomy) that might alter nerve risk.
- Alternatives – coronectomy – what do you think about leaving some of the tooth even if there's a risk of future problems/need to remove it.

Dry socket

- Occurs up to a third of lower third molars – any thoughts on this?

Mouth opening

Ability eat

Ability to swallow

Affects on adjacent teeth health

Length of healing

Psychological – anxiety

Quality of life – sleep, ability to do normal life? (exercise etc)

Practical issues

- Time off work important?
- Costs
- Follow up requirements

Any thoughts around taking medications, medication side effects?

CLOSE:

Any other thoughts to share?

Why did you decide to take part?

What was it like to participate in the group?

Final comments?

APPENDIX 6

PRISMA-ScR Checklist (Tricco et al., 2018; PRISMA, 2024):

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	51
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	Thesis Summary Pages
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	48-49, 110-112
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	52-53
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	52
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	53
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	53-55
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	55-57
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	54-55

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	60-63
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	61
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	62-63
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	72
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	74-90
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	74-90
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	74-90
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	110-116
Limitations	20	Discuss the limitations of the scoping review process.	116-121
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	122
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping	N/A

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		review. Describe the role of the funders of the scoping review.	

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

APPENDIX 7

Tabular Presentation of Results Described in Chapter 4

7.1 - Appendix Table 7.1: JOURNAL

Appendix Table 7.1: JOURNAL	No
Journal of oral and maxillofacial surgery	103
International journal of oral and maxillofacial surgery	61
Medicina Oral Patologia Oral Y Cirugia Bucal	47
Journal of Maxillofacial & Oral Surgery	41
Oral and maxillofacial surgery	30
Clinical oral investigations	20
British Journal of Oral & Maxillofacial Surgery	19
Oral surgery, oral medicine, oral pathology and oral radiology	18
Annals of maxillofacial surgery	15
Journal of Dental Anaesthesia and Pain Medicine	15
Nigerian journal of clinical practice	13
The journal of contemporary dental practice	13
Journal of Stomatology Oral and Maxillofacial Surgery	12
National journal of maxillofacial surgery	12
Journal of clinical and diagnostic research	11
Journal of Craniofacial Surgery	11
Quintessence international	11
BMC oral health	10
Journal of Cranio-Maxillofacial Surgery	10
Journal of clinical and experimental dentistry	8
Journal of oral biology and craniofacial research	7
Journal of Pharmaceutical Research International	7
Journal of Research in Medical and Dental Science	7
Journal of Clinical Medicine	6
Journal of Pharmacy and Bioallied Sciences	6
Lasers in medical science	6
Pakistan Journal of Medical & Health Sciences	6
Clinical Journal of Pain	5
Head & face medicine	5
Journal of family medicine and primary care	5
Journal of Oral and Maxillofacial Surgery Medicine and Pathology	5
Journal of Pain	5
General dentistry	4
International journal of dentistry	4
International journal of environmental research and public health	4
Journal of dental research, dental clinics, dental prospects	4

Journal of the Korean Association of Oral and Maxillofacial Surgeons	4
Pain	4
Pesquisa Brasileira em Odontopediatria e Clinica Integrada	4
Anesthesia progress	3
British dental journal	3
Clinical Therapeutics	3
Contemporary clinical dentistry	3
Current Medical Research and Opinion	3
European Journal of Dentistry	3
Indian journal of dental research	3
Indian Journal of Public Health Research and Development	3
International Journal of Research in Pharmaceutical Sciences	3
Journal of Ayub Medical College	3
Journal of Evolution of Medical and Dental Sciences	3
Journal of Oral Rehabilitation	3
Maxillofacial plastic and reconstructive surgery	3
Minerva stomatologica	3
Osteoarthritis and Cartilage	3
Photomedicine and laser surgery	3
Beneficial microbes	2
BioMed research international	2
British journal of anaesthesia	2
Cranio-Maxillo-Facial Surgery	2
Drug Invention Today	2
Drugs in R&D	2
European journal of clinical pharmacology	2
European journal of pain	2
Evidence-based complementary and alternative medicine	2
Indo American Journal of Pharmaceutical Sciences	2
International Journal of Pharmaceutical Research	2
Journal of applied oral science	2
Journal of clinical medicine research	2
Journal of dental research	2
Journal of dental sciences	2
Journal of international oral health	2
Journal of International Society of Preventive & Community Dentistry	2
Journal of oral & maxillofacial research	2
Journal of Pharmacology and Toxicology	2
Journal of Taibah University Medical Sciences	2
Journal of the College of Physicians and Surgeons - Pakistan	2
Journal of the Pakistan Medical Association	2
Laser therapy	2
Medical Forum Monthly	2
Medical principles and practice	2

Nigerian journal of surgery	2
ORAL & implantology	2
Oral diseases	2
Pain and therapy	2
Pain research & management	2
Photobiomodulation, photomedicine, and laser surgery	2
PloS one	2
Scandinavian journal of pain	2
The Nigerian postgraduate medical journal	2
Trials	2
Turkish journal of medical sciences	2
Vojnosanitetski pregled	2
World Family Medicine	2
Acta clinica Croatica	1
Acta Odontologica Latin Americana	1
Acta stomatologica Croatica	1
Advances in therapy	1
Agri : Agri (Algoloji) Dernegi'nin Yayin organidir = The journal of the Turkish Society of Algology	1
Ain Shams Journal of Anesthesiology	1
Anesthesia, essays and researches	1
Annali italiani di chirurgia	1
Annals of Dental Specialty	1
Annals of Nutrition and Metabolism	1
Annals of the Rheumatic Disease	1
Annals of Tropical Medicine and Public Health	1
Antibiotics	1
Applied Sciences-Basel	1
Archives of Pharmacy Practice	1
Australian dental journal	1
BMJ open	1
Brazilian dental journal	1
Brazilian Oral Research	1
Clinical nutrition	1
Clinical pharmacology in drug development	1
Collegium antropologicum	1
Cukurova Medical Journal	1
Daru : journal of Faculty of Pharmacy, Tehran University of Medical Sciences	1
Dental and medical problems	1
Dental research journal	1
Dentistry journal	1
European Journal of Inflammation	1
European Journal of Molecular and Clinical Medicine	1
European Journal of Pain Supplements	1
Experimental and therapeutic medicine	1

Frontiers in oral health	1
Gazzetta Medica Italiana Archivio per le Scienze Mediche	1
Homeopathy	1
Indian journal of dentistry	1
Indian Journal of Forensic Medicine and Toxicology	1
Inflammation Research	1
International Journal of Advanced Biotechnology and Research	1
International journal of clinical pharmacology and therapeutics	1
International Journal of Current Pharmaceutical Research	1
International Journal of Immunopathology and Pharmacology	1
International journal of medical sciences	1
International Journal of Pharmaceutical Investigation	1
International Journal of Pharmaceutical Research and Allied Sciences	1
International journal of surgery	1
ISRN surgery	1
JMIR research protocols	1
Jordan Journal of Pharmaceutical Sciences	1
Journal International Medical Sciences Academy	1
Journal of Acupuncture and Meridian Studies	1
Journal of applied oral science : revista	1
Journal of biological regulators and homeostatic agents	1
Journal of Biomedical Materials Research	1
Journal of clinical pharmacology	1
Journal of dentistry (Shiraz, Iran)	1
Journal of Evidence-Based Dental Practice	1
Journal of Experimental and Clinical Medicine	1
Journal of IMAB	1
Journal of infection and chemotherapy	1
Journal of investigative and clinical dentistry	1
Journal of Istanbul University Faculty of Dentistry	1
Journal of lasers in medical sciences	1
Journal of medicine and life	1
Journal of oral & facial pain and headache	1
Journal of oral and maxillofacial pathology	1
Journal of oral science	1
Journal of orofacial pain	1
Journal of Population Therapeutics and Clinical Pharmacology	1
Journal of the American Dental Association	1
Journal of the American Pharmacists Association	1
Journal of the Formosan Medical Association	1
Journal of the Michigan Dental Association	1
Journal of the Nepal Medical Association	1
Kathmandu University medical journal (KUMJ)	1
Konuralp Tip Dergisi	1

La Clinica terapeutica	1
Lasers in surgery and medicine	1
Medical Science	1
Medical science monitor	1
Medicina	1
Medicine (United States)	1
Medicinski glasnik	1
Medico-Legal Update	1
Minerva anestesiologica	1
New Armenian Medical Journal	1
Nigerian medical journal	1
Odontology	1
Open Access Macedonian Journal of Medical Sciences	1
Oral Science International	1
Pain Medicine	1
Pain practice	1
Photochemistry and photobiology	1
Physiology & behavior	1
Phytotherapy research	1
Postgraduate medicine	1
Research Journal of Pharmaceutical, Biological and Chemical Sciences	1
Revista Brasileira de Anestesiologia	1
Revista Portuguesa De Estomatologia Medicina Dentaria E Cirurgia Maxilofacial	1
SADJ	1
Shiraz E Medical Journal	1
Singapore medical journal	1
Southern African Journal of Anaesthesia and Analgesia	1
Stomatologija	1
The International journal of clinical and experimental hypnosis	1
The journal of evidence-based dental practice	1
The journal of headache and pain	1
The Journal of oral implantology	1
The Pan African medical journal	1
The Saudi dental journal	1
The Scientific World Journal	1
Turkish journal of anaesthesiology and reanimation	1
West African journal of medicine	1
West China journal of stomatology	1
TOTAL	**815**

7.2 - Appendix Table 7.2: COUNTRY

Appendix Table 7.2: Country	No
India	189
Turkey	98
Brazil	81
USA	54
Iran	47
Italy	43
Spain	39
Nigeria	24
China	22
Pakistan	18
UK	16
Thailand	14
Japan	13
Saudi Arabia	11
South Korea	9
Iraq	9
Serbia	8
Mexico	8
Poland	8
Jordan	6
Denmark	6
Netherlands	6
Germany	5
Australia	5
Sweden	5
Croatia	5
New Zealand	5
Syria	5
Nepal	4
Switzerland	4
Malaysia	4
France	3
Norway	3
Multiple	3
Egypt	2
Lebanon	2
Ireland	2
South Africa	2
UAE	2
Cyprus	2
Chile	2

Indonesia	2
Taiwan	2
Austria	1
Finland	1
Kosovo	1
Estonia	1
Slovakia	1
Bangladesh	1
Bosnia	1
Lithuania	1
Burkina Faso	1
Yemen	1
Israel	1
Canada	1
Bulgaria	1
Vietnam	1
Singapore	1
Morocco	1
Peru	1
TOTAL:	**815**

7.3 - Appendix Table 7.3: TOPIC

Appendix Table 7.3: TOPIC	No
Analgesia	148
Steroids	93
LA	57
Antibiotics	47
Analgesia - Pain	46
PRF	45
Technique - Flap	44
Technique - Sutures	31
Technique - Piezo	26
Laser Therapy	24
Sedation	20
Novel Healing Promoter	14
Novel Wound Gel	12
Technique - Irrigants	10
Drains	10
Photobiomodulation	10
Technique - Laser	8
Anxiety	8
Coronectomy	8
Cryotherapy	8
Kinesio Tape	7
Novel Wound Dressing	7
Enhanced Recovery - Food Supplement	7
Music Therapy	6
Novel Anti-inflammatory	5
Technique - Surgical	4
GBR	4
Technique -Laser	4
Mouthrinse	4
Ozone	4
Hypnosis	3
Novel Analgesic	3
Enhanced Recovery - Probiotics	3
TENS	3
Novel Antibiotics	3
Wound Gel	3
Enhanced Recovery - Laser	3
Video Patient Information	3
QoL	3
Anti-inflammatory	3
Growth Factors	3

Imaging	2
Wound Irrigation	2
Novel Socket Medicament	2
Honey	2
Risk	2
Acupuncture	2
Technique - Drill Type	2
Nerve Injury	2
Aromatherapy	2
Technique - LA	2
Kinesio Tape	2
Homeopathy	2
Acupuncture	2
Meditation	1
Technique - Novel Orthodontic Extraction Method	1
Nicotine Patch	1
Online Follow-Up	1
Technique - Three Piece Method	1
Haemostatic Agents	1
Consent Method	1
Muscle Relaxant	1
Bilateral versus Unilateral Surgery	1
Chronotherapy	1
Post-operative Instructions	1
Novel Local Drug Delivery	1
Pressure Bandage	1
Third Molar Surgery	1
Age	1
Novel Wound Spray	1
Pulsed electromagnetic field (PEMF) therapy	1
Audiovisual Glasses - Anxiety	1
Pulsed electromagnetic field therapy	1
Enhanced Recovery - Laser + LED	1
BMI	1
Medicaments	1
Injury Risk	1
GA	1
Nicotine Nasal Spray	1
Technique - Two Stage	1
Smoking	1
Novel Mouthrinse	1
Novel Topical Haemostatic Drug	1
Straws	1
Complications	1

Surgeon Experience	1
Novel Wound Injection	1
Surgical Time	1
Technique - Tissue Glue	1
TOTAL	**815**

7.4 - Appendix Table 7.4: OUTCOME

Appendix Table 7.4: OUTCOME	No
Pain	664
Swelling	400
Mouth Opening	354
Analgesia Use	179
Adverse Events	95
Dry Socket	81
Healing - Soft Tissue	77
Infection	69
Operation Time	56
QoL	49
Patient Satisfaction	42
Healing - Bone	38
Anxiety	37
LA Duration	37
Pocket Depth	34
Complications	32
LA Onset	31
Bleeding	30
Nerve Injury	30
Time to first rescue med	29
Haemodynamic	23
Inflammation	23
Analgesia Efficacy	17
LA Dose	15
LA Efficacy	15
Analgesia Duration	14
BP	12
Pain Difference	10
Pulse Rate	10
Dysphagia	9
TOTPAR	9
Biomarkers	8
Body Temperature	8
Analgesic Efficacy	7
Bloods	5
Lymphadenopathy	5
Oxygen Saturation	5
POSSE	5
Sedation Score	5
Repeat Surgery	4
Root Migration	4

Sleep Quality	4
Global Pain Satisfaction	3
Nausea	3
Surgeon Satisfaction	3
Time off Work	3
Age	2
Food Impaction	2
Fracture	2
Global Pain Scale	2
Haematoma	2
Halitosis	2
Healing	2
Sedative Dose	2
Surgery Difficulty	2
Amnesia	1
Bacterial Growth	1
Bispectral Index	1
Clinical Attachment Level	1
Clot Retention	1
Comfort	1
Consciousness	1
CRP	1
LA Positive Aspiration	1
Local Temperature	1
Muscle Contraction	1
Nerve Dysfunction	1
NNT	1
Number of Sutures	1
Pain Reduction	1
Patient perception of treatment arm: treatment vs placebo	1
Petechiae	1
Plaque Index	1
Pulp Perfusion	1
Pyrexia	1
Recession	1
Root Exposure	1
Soft Tissue Injury - Ulceration	1
Swelling Duration	1
Time in Recovery Room	1
TMJ Symptoms	1
Wound Thermal Sensitivity	1
TOTAL DIFFERENT OUTCOMES	**82**
TOTAL OUTCOMES REPORTED	**2,638**

APPENDIX 8

Bibliography of References for 100 Conflicted Studies Analysed:

Albuquerque, A. F. M. et al. (2017) Effect of pre-emptive analgesia on clinical parameters and tissue levels of TNF-α and IL-1β in third molar surgery: a triple-blind, randomized, placebo-controlled study. *International Journal of Oral and Maxillofacial Surgery*. [Online] 46 (12), 1615–1625.

Albyati, M. & Bede, S. (2020) The Effect of the Difficulty of Surgical Extraction of Impacted Mandibular Third Molars on the Postoperative Inflammatory Response. *Journal of Research in Medical and Dental Science*. 8 (1), 107–111.

Ali, H. T. et al. (2018) Variables predictive of the intensity of postoperative pain following mandibular third molar surgery: a prospective study. *Minerva Stomatologica*. [Online] 67 (3), 111–116.

Aliabadi, E. & Tavanafar, S. (2019) Effect of 4% articaine and 2% lidocaine both with 1:100,000 epinephrine on hemodynamic changes in impacted mandibular third molar surgery: Prospective, double-blinded, randomized clinical trial. *Revista Latinoamericana de Hipertension*. 14 (6), 682–687.

Alissa, R. et al. (2010) The influence of platelet-rich plasma on the healing of extraction sockets: an explorative randomised clinical trial. *European Journal of Oral Implantology*. 3 (2), 121–134.

Almeida, P.-C. et al. (2020) Volume and effectiveness assessment of articain 4% versus mepivacaine 2% used in third molar surgery: randomized, double-blind, split-mouth controlled clinical trial. *Medicina Oral, Patologia Oral Y Cirugia Bucal*. [Online] 25 (6), e762–e768.

Al-Saadi, T. S. & Al-Quisi, A. F. (2023) The Influence of the Hyaluronic Acid Gel on the Postoperative Sequelae following Surgical Removal of the Impacted Mandibular Third Molar in Comparison with the A-PRF: A Randomized Controlled Trial. *International Journal of Biomaterials*. [Online] 20231883460.

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APPENDIX 9

Consolidated Criteria for Reporting of Qualitative Studies

Checklist (adapted from Tong *et al* (Tong et al., 2007)):

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	67
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Project title page – Specialist Trainee in Oral Surgery
3. Occupation	What was their occupation at the time of the study?	Project title page – Doctoral Research Student
4. Gender	Was the researcher male or female?	Project title page - Male
5. Experience and training	What experience or training did the researcher have?	65, 122
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	65-66
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	67
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions,	129-131

	reasons and interests in the research topic	
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	93
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	65-66
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	65-66
12. Sample size	How many participants were in the study?	91-93
13. Non-participation	How many people refused to participate or dropped out? Reasons?	91
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	91
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	67
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	92-93
Data collection		

17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	67, Appendix 5
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	No. N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	67
20. Field notes	Were field notes made during and/or after the inter view or focus group?	No. Transcripts were written. Page 67
21. Duration	What was the duration of the inter views or focus group?	91
22. Data saturation	Was data saturation discussed?	68, 104-106
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	68
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	One.
25. Description of the coding tree	Did authors provide a description of the coding tree?	Thematic. 94.
26. Derivation of themes	Were themes identified in advance or derived from the data?	Induced. 93.
27. Software	What software, if applicable, was used to manage the data?	No. Manual.
28. Participant checking	Did participants provide feedback on the	68

	findings?	
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	95-101
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes. 103-104
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	N/A