IS DIGITAL PHOTOGRAPHY A MORE COMMUNICABLE APPROACH FOR STUMP SHADE SELECTION, WHEN TREATMENT PLANNING ALL-CERAMIC RESTORATIONS FOR DISCOLOURED TEETH?

A dissertation submitted to the University of Manchester for the degree of Masters of Restorative and Aesthetic Dentistry in the Faculty of Medical and Human Sciences

2019-2020

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Abstract

Is digital photography a more communicable approach for stump shade selection, when treatment planning all-ceramic restorations for discoloured teeth?
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Background and Aim Multicoloured teeth pose a challenge to many clinicians when it comes to shade. It has been suggested that the way in which tooth discoloration is communicated to the lab has an effect on the accuracy of the colour match of an all-ceramic restoration. The aim of this study is to determine whether digital photography provides a more communicable approach for stump shade selection than stump shade guides, when fabricating all-ceramic restorations for discolored teeth.

Methods The proposed study design for this work is an analytic, experimental, non-randomised controlled trial. The population will consist of twenty-five adult participants, who have chosen to undergo all-ceramic restorations on discoloured anterior teeth in a primary care setting. The suggested intervention is to use high definition digital images to convey the correct stump shade to the lab, vs. using a traditional stump shade value from a shade guide. The primary outcome is the crown that the patient prefers in situ. The secondary outcome is the crown the clinicians prefer, as per photographic images of the crowns in situ. To minimise bias, the dentist and the patient will be blind to the type of crown being cemented, as will the clinicians, whose questionnaires will be filled in anonymously.

Discussion The significance of the detail that digital photography provides when compared to a single stump shade, particularly when treating multi-coloured darkened teeth, will be presented and discussed. It will then be suggested to the dental community that a superior method of shade selection and communication with the lab technician exists, in order to resolve noticeable shade differences.

Keywords digital photography, tooth substrate, stump shade, all-ceramic

Declaration

No portion of the work referred to in the dissertation has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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The author

Alexandra obtained her DMD (Doctor of Medical Dentistry), from the University of Pécs, Hungary in 2013. That Winter, she returned to her roots, where she spent the next four years working in several mixed NHS and private practices in South Wales. In order to develop her new skill set, Alexandra enrolled in Tipton Training postgraduate courses. In early 2017 she completed the restorative course, and before that the phantom head course, which helped her excel in the restoration of more complex treatment cases. In order to help nervous patients, or those requiring a more holistic approach, Alexandra also studied dental acupuncture.

Alexandra has committed to and is currently studying a part-time MSc at the University of Manchester in restorative and aesthetic dentistry. When she returned from maternity leave to her associate position in April 2018, she continued to collect cases and document them; Alexandra then decided to broaden her skill set further, by completing Invisalign Go training and starting her qualifications in facial aesthetics.

In May 2019 Alexandra took a position in Oxfordshire, where she focused on holistic cosmetic approaches to her patients' needs. Her extensive training portfolio also gained two further facial aesthetic qualifications in Sunekos and BioRePeel. In September, the final stage of Alexandra's MSc began with her dissertation.

Dedication

This dissertation is dedicated to my husband, Corporal Rhydian Davies Eng Tech MIMechE, for without his continued support, this MSc would not have been possible.

Overview

- Introduction, PICO, aims and objectives: These headings briefly introduce the reader to the thought process behind the research question, the population, intervention, control and outcomes proposed for the study, the aim of the study and its related objectives.
- Literature review: A detailed look at the background of the issue, previous research into the topic, and an in-depth appraisal of several relevant papers. The structure and type of study is also discussed.
- Study design and methodology: This chapter is a manual for the planned study. It explains to the very last detail, who, what, where, when and how the research, the research team, the participants and the data will be conducted.
- Data management, quality assurance and statistical analysis: Due to the new European GDPR guidelines (2018) a well thought out and structured data management process needed to be created in order to ensure patients' autonomy and confidentiality.
- Ethical considerations: As this type of research requires human participation, a guide for the REC has been typed up to ensure their ethical concerns have been addressed.
- Study budget, collaboration: A brief explanation of an unorthodox approach to budget control.
- Reflection: The principal investigators account of the journey undertaken in order to create this piece of work.
- References and Appendices: A comprehensive list of references and noted appendices.

Introduction and PICO

Introduction

The subject of this research proposal was decided upon when the principal investigator took a problem-based approach to both a restorative and an aesthetic issue that was coming up in self-reflection of previous cases, as well as patient concern in a primary care setting.

Whether it be due to an injury or decay, a fair percentage of patients require or already have existing anterior indirect restorations. The most common complaints are firstly, that the restorations are not the same colour as the adjacent teeth. Secondly, the material used to fabricate the crowns has a poor aesthetic appearance, due to the majority of older restorations being porcelain fused to non-precious metal.

This aesthetic issue has been partially solved with the introduction of Zirconium and Lithium Dioxide restorations, which don't contain dark metal cores, however, the final shade of a restoration is still affected by the underlying colour of a tooth preparation.

This study proposal aims to solve this problem by suggesting to the dental community that a superior method of shade selection and communication with the lab technician exists, in order to resolve noticeable shade differences.

PICO

What population group do you intend to study (P)?*	Adult patients undergoing all-ceramic restorations on discolored anterior teeth in a primary care setting.
What intervention do you intend to examine (I)?*	Using high definition digital images to convey the correct stump shade to the lab.
What comparator do you intend to use (C)?*	Traditional stump shade guide values.
What is/are your outcome measure/s (O)?*/**	1. The crown the patient prefers in situ. 2. The crown the dentists prefer as per photographic images of the crowns in situ.

Aim and objectives

Aim

To determine whether digital photography provides a more communicable approach for stump shade selection than stump shade guides, when fabricating all-ceramic restorations for discolored teeth.

Objectives

- To conduct an analytic, experimental, non-randomized controlled trial in a primary care setting to investigate whether the way in which tooth discoloration is communicated to the lab has an effect on the accuracy of the colour match of an all-ceramic restoration to the adjacent teeth.
- To assess whether the patients can determine a difference between the two crowns and evaluate their preferences with regards to the shade matches made using digital photography and stump shade guides.
- To record and evaluate the dentists preferred crown, based on digital images of the two crowns in situ.
- To present and discuss the significance of the detail that digital photography provides when compared to a single stump shade, particularly when treating multi-coloured darkened teeth.

Literature review

Introduction

The purpose of this review is to emphasize the need for continued study into effective laboratory communication when conveying substrate colour and the shade required for a final restoration.

The aesthetic and restorative dentist of today needs to have a sound understanding on the subject of colour and how the variables that govern the final shade of the restored tooth impact the treatment planning of the case (Azer et al., 2011). Clinical considerations arise, such as tooth conservation, ceramic thickness and optical properties (Czigola et al., 2019). In 2017, Perroni et al., highlighted the fact that reproducing a natural tooth colour with ceramic restorations is a complex clinical task; it is mainly affected by darker tooth substrates, along with ceramic translucency. Both of these variables determine the final aesthetics and acceptability of the restoration (Sari et al., 2018).

Tooth substrate hue and value, or stump shade as it is more commonly known, is at the epicentre of colour variation when using all-ceramic restorations (Basegio et al., 2019). Phelan (2002) identified that conveying the final shade of the restoration to the lab is not sufficient to produce an accurate match for the final restoration because many substrates are comprised of more than a single shade or material, which can also limit the biomechanical properties (Ahmad, 2008).

Background

A stump shade is the colour of the prepared tooth structure, upon which an indirect restoration will be placed (Vivadent, 2019). Currently, a stump shade guide (see Figure 1) is used to select the nearest matching shade and the code is recorded on the lab docket, which is sent to the technician, so that he may apply a stain on the die cast which will mimic the stump shade. This then allows the technician to work upon a colour base so that the final ceramic restoration will appear the same shade when it is placed over the prepared tooth (PDA Colorado, 2017).

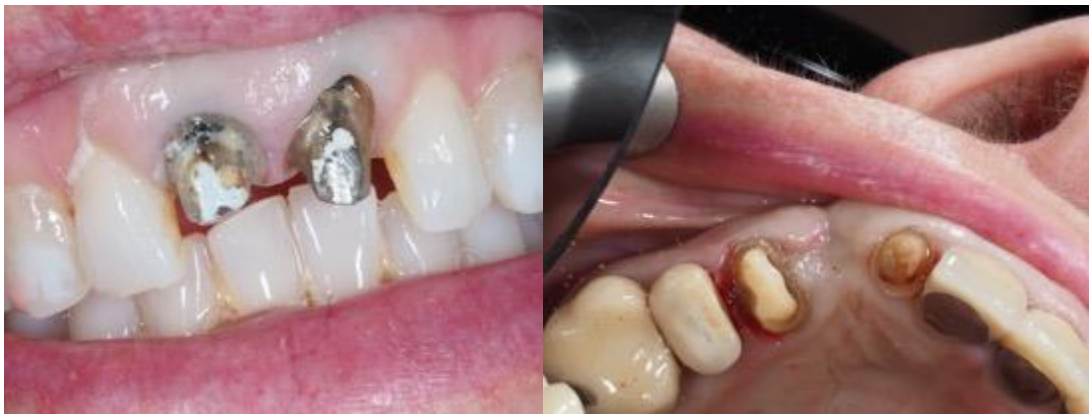
Laboratories advise that stump shades are always taken for ceramic restorations (Bayshore Dental Studio, 2019). However, in primary care settings, this is not always the case; a study undertaken in 2017 by Tulbah et al., showed that communication over details of tooth colour, material selection and restoration design were particularly lacking.

Figure 1: Stump shade guide (Austin, 2016).

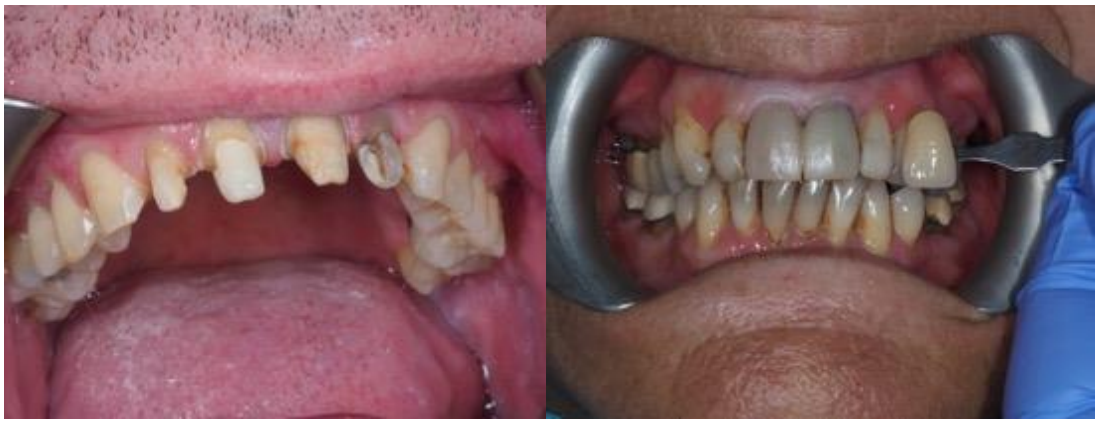
For the purposes of the proposed study, the focus will be on communicating the correct stump shade for all-ceramic restorations. However, to understand the variations in the underlying substrate shade, firstly an understanding of the aetiology of tooth discoloration must be reached.

In 2005, Sulieman categorized different types of staining. Firstly, extrinsic staining, which is due to various materials coming into contact with the teeth and leaving direct or indirect stains. Secondly, intrinsic staining, which is due to metabolism, genetics, iatrogenic intervention, trauma, idiopathic causes and aging. Lastly, discoloration may be internalized, due to carious lesions and restorations which causes the tooth to deposit secondary or tertiary dentin (Walmsley, 2008).

The list of clinical examples for the categorization above is extensive (Baharvand, 2014); furthermore, the variation in colour for each tooth substrate is just as capacious (see Figure 2 and Figure 4). None of these prepared teeth have an exact match on the stump shade guide as each individual substrate is more than one color.



Above, from the left, **Figure 2**: Aesthetic crown replacement, discoloured tooth substrates with a metal core. **Figure 3**: Bridge replacement after extraction, discolored tooth substrates with a composite core (Images – author's own).



Above, from the left, **Figure 4**: Tooth reconstruction after trauma, non-vital teeth with a composite core. **Figure 5**: Temporary composite crowns that appear grey as discolored tooth substrate shines through the thin, translucent material, despite it being the same shade as the adjacent teeth (Images – authors' own).

In combination, tooth discoloration is seen as a frequent dental problem (Hattab, Qudeimat and Al-Rimawi, 1999). In 2014, 43.5% of college students at a university in the UAE self-reported tooth discolouration (Mohsin Hasan et al., 2014). A year later, a clinic in Nigeria reported that during a three-year period, 136 patients presented at the clinic with the sole complaint of tooth discolouration and 86.6% of those cases were due to pulpal necrosis (O Gbadebo and Mojirade Ajayi, 2015). Furthermore, in 2017, Ibiyemi, Ibiyemi and Taiwo

found that 44% of their study population had tooth discolouration (not just extrinsic staining), whilst an additional 33% perceived that their teeth were discoloured.

The results above clearly show that patients' perceptions make tooth discoloration just as much an aesthetic problem as a clinical one, hence the need for a reliable, reproducible protocol, that is accessible to all dentists, cheap and quick to use, to be validated for use in dental primary care.

Previous clinical attempts include whitening the substrate before cementation, using stump shade guides of a single colour (Chu and Mieleszko, 2015) and using spectrophotometers to analyse tooth colour within an area of the substrate (Ishikawa-Nagai et al., 2010). These methods fail to communicate the detail of the substrate color to the lab. Also, spectrophotometers and whitening treatments are costly to both the dentist and the patients respectively.

Current accepted methods of shade taking are either subject to the observer's perceptibility or fail to communicate the full extent of the complexity of the tooth substrate to the laboratory. In 2017, Kalantari, Ghoraishian and Mohaghegh found that only 7.6% of crowns fabricated via conventional shade taking were seen as a satisfactory colour match in situ, compared to the 73% that utilised a spectrophotometric calibration. With such a low success rate whilst using traditional shade guides alone, clinicians face wasted clinical time, higher lab bills and dissatisfied patients.

In 2018, Matani et al., briefed the dental community on the complexity of shade matching and how to effectively convey the underlying discoloured tooth substrate to the laboratory. "A definitive cast that replicates the shade of the prepared tooth helps the ceramist to fabricate a restoration that masks the discoloration appropriately and still achieves the desired optical properties". None of the previously mentioned methods account for the substrate being covered in enamel, or dentin, or both, or having intact filling materials of varying colours, or having glass fibre or metal cores. Digital imaging, however, is a way to communicate the exact position and colour variation of these imperfections (Joseph et al., 2018).

In his recent book 'Dental Digital Photography', Feng Liu (2019), describes the rationale behind medical photography. He states that the images must be 'objective, opportunity

related, comparative, informative and artistic'. For example, when photographs are provided during indirect restorative procedures, a lab technician can fully visualize the detail of the substrate upon which he must create an aesthetic, natural restoration, that effectively masks a multi-coloured substrate, whilst maintaining as much of the translucency exhibited by a natural tooth as possible (Kahng, 2019).

Digital photography has been around for decades but has become increasingly popular in the last two. Dianne Rekow stated in her publication in 2019, that digital radiography was first used in the late 1980's and since the early 2000's the use of digital technology has risen by as much as 1125%. These findings are consistent with the UK based study Burke et al. publicized in early 2019, which states that between 2002 and 2008, the use of digital intraoral cameras increased by 45%. This then dropped slightly by 2015; the authors rationalize this change in statistics due to the introduction of intra-oral scanners, cameras and smart phones and their integral role in everyday practice.

Clinical photography has become most popular among younger dentists, as aside from record keeping, there is also competition over sought after job vacancies. It is now seen as a necessity to form a personal portfolio which includes detailed photographic evidence of cases, in order to prove clinical competence and impress prospective principals with exceptional aesthetic skills (Khan, 2019). Also, with an increasing 'climate of fear' (Fox, 2019) and the survey findings which point to a clinical mindset of defensive dentistry (Dental Protection, 2018), there is a growing need for documentary evidence to form a robust defence during litigative procedures (Wander, 2014).

Search Strategy

A structured search of the literature was undertaken (see Appendix 1) and run in three databases. This was utilized, to determine the search terms that were entered into Science Direct, Pub Med and the University of Manchester Library advanced searches.

Three searches were carried out in each database with the following terms:

- Discolored tooth OR discoloured tooth AND Stump shade

- Ceramic restorations AND Shade match
- Digital photography AND Shade match

Each search used the same limitations, which were a 10-year span from 2009-2019 and articles only in English. As per Burke et al. (2019), which was mentioned previously, smart phones and HD cameras have been used with increasing frequency since 2009, hence the specificity in age of the papers selected.

The first set of search terms reveals the lowest results, which in some databases was zero. In contrast, search C yielded 408 results, all of which were research articles. When hundreds of papers were found through the key terms, the research article box was selected so that the best scientific literature could be inspected or the term 'AND Dentistry' was added to the search. This was not the case in all searches as in some instances it reduced the results to zero (see appendix 1 – individual search screen shots which contain search result numbers). Titles were inspected for relevance and then further reading was done into the abstracts of each paper.

Four articles were selected for an in-depth appraisal. Two were comparative studies in an in vivo setting, which were subjected to a Diagnostic CASP Checklist (Miyajiwala et al., 2017 and Vivek et al., 2013) and two were examining feasible techniques for shade selection in an in vitro setting (Tam, 2017 and Schropp, 2009).

Critical Appraisal

Of the four studies, only one had no participants or observers (Tam, 2017); the other three had a range of 12-50 participants and 1-10 observers. The range in both categories is large and in the instance where there is only one observer (Miyajiwala et al., 2017), the results may be questionable. A large patient cohort with a maximum number of observers would provide diversity in tooth substrate colours as well as greater reassurance in the results if a majority agree on the same outcome.

The upper right maxillary incisor was the tooth of focus in each experiment, with which the observers must make a shade match. As the largest and most prominent tooth, it creates a

focal point for the observers, however a randomly selected anterior tooth with some pathology would further test the viability of the method. It has been noted in all four publications that human shade selection is subjective due to color perception, however the observer groups contained both sexes and only in the article by Miyajiwala et al., (2017), was the single observer tested for color blindness. Digital photographs of the substrate can be subjectively assessed by a human observer or processed through computer software multiple times without a change of variables. The use of shade tabs placed adjacent to the matching areas of the prepared tooth indicate the clinicians shade choices, which if impaired, will be clear to a lab technician.

Tam (2017) and Schropp (2009) focused on the development of feasible shade selection protocol in vitro. The first study concentrated on photography, specifically with a smart phone camera. In contrast, Schropp (2009) conducted a set of parallel experiments, that attempted to compensate for a variation in operator competency, by using well-exposed, over-exposed and under-exposed photographs. The vast amounts of data that the first study collected and analysed greatly promote the viability of digital imaging, whereas the second article showed that despite less accuracy in shade matching with incorrectly exposed images, the errors were not completely detrimental to the results and easily rectifiable in a clinical setting.

In contrast, Miyajiwala et al., (2017) and Vivek et al., (2013), used patients' teeth for conventional shade matching. The later of the studies highlighted the difference in available lighting, as well as a marked difference in accuracy with digital photography and shade matching computer software. The former study included a spectrophotometer as a comparative method. The results in this study are the least reliable, as the photographic results do not produce a chosen shade, so the author has had to improvise with a range of color variation.

Although the methodology varied, in every single study the viability of digital photography as a shade matching method was tested. The collective result was that digital photography is a superior method of shade taking, based on the percentage of correct shade selections via computer software and direct human observation, although each author had their own individual take on how this protocol should work. Perhaps this is because the focus was on chairside or simulated chairside shade taking. This is very important, as it is the basis for the entire exercise. The dentist wants their restoration to look real and match the adjacent teeth

and the lab technician needs to work upon the appropriate substrate shade. The dentist is a chairside observer, whereas the lab technician is a simulated chairside observer. He receives the casts that simulate the patient's dentition but must make shade-based decisions by relying on the information presented to him in clinical images. The proposed study will focus on the information required by the technician in order to create an acceptable restoration, hence, the studies that focus on simulated chairside shade taking, are of the greatest interest.

Laboratory communication and its importance were mentioned in every paper, as well as further study into restoration fabrication as a result of the shade matching method. The outcome measure was a collective one and that was to find the percentage of accuracy that a single method provided in shade taking. This was achieved by calculating how many times the human, or the computer, correctly identified the most appropriate shade.

Each paper found in favour of digital photography as a viable protocol in shade selection. The authors seem aware of their limitations, which included perceptibility among their observers and the fact that some of their shade taking technology was limited to a small area on the tooth. All four papers mentioned that it is only through digital imaging, that the shape, anatomy and enamel details can be fully portrayed to a technician.

The weakest paper was that of Miyajiwala et al., (2017), as the results are based on the percentage of times that two single shade selection methods yielded the same choice of shade and not a precise shade match. However, the question of how the correct shades were initially decided upon arose, especially where human subjects were used (this point was not made clear in any of the papers). All known shade matching methods were being tested; therefore, they couldn't be used for initial shade confirmation, which then leaves the study vulnerable to perceptibility. This unanswered question highlights the fact that this is still an under researched area of restorative dentistry, despite the crucial role shade taking plays in the success of the final restoration.

In order to replicate any of the study outcomes in a primary care setting, the chosen methodology must be quick, economical and accurate. Tam (2017) used a smart phone and computer software. A phone camera is readily available, but professionalism and GDPR guidelines are called into question with this type of camera. Also, an associate's clinical time is limited, which would rule out equilibrating a computer program. Miyajiwala et al., (2017)

and Schropp (2009) used more than one shade taking method in order to compare their efficacy, however the proposed study aims to focus on clinical photography. Therefore, the methodology which exhibits the greater suitability for the proposed study is that of Vivek et al., (2013), whose focus is on conventional shade taking and digital photography. DSLR cameras are costly but readily available to dental associates, as are VITA shade guides. Once manual settings have been implemented, standardised photographs with satisfactory chair lighting can be replicated over and over with no added cost and minimal additional appointment time.

In summary, digital photography according to current literature, appears to be a viable method to aid a clinician in shade selection in a primary care setting. The VITA Master Shade Guide and the standardised camera settings (ISO 200, F22 and a distance of 20-40cm) have been taken into consideration for future study design.

Discussion

Color was first written about by Aristotle, over 2000 years ago, who named the primary colours and suggested that they related to the elements (McManus, 2008). This theory was disparaged by Isaac Newton in 1666, who documented his prism experiment in his well-known publication, Optiks. His efforts resulted in the current colour spectrum that is visible to the human eye (Handley, 2019). In 1810, Johann Wolfgang von Goethe challenged the science of colour with his own 'theory of colours' (Kalamaras, 2014). His view was that 'color was not simply a scientific measurement, but a subjective experience perceived differently by each viewer' (Library.si.edu, n.d.).

Today, in dentistry, Goethe's theory takes precedence, as colour variation is now scientifically measured through perceptibility and acceptability when human participants are involved (Alghazali et al., 2012). Taking this into consideration, the chosen outcomes of the proposed study must account for the perceptions of the dentist, the lab technician and the patient. Hence, the dentist will suggest shades that will appear in the photographic images and the lab technician will fabricate the crowns according to their own perception of the images and instructions. This is very much dependant on image quality and detailed specifications. Lastly, the patient will have the final say as to which crown they feel matches best; their

opinion and satisfaction is essentially the most important. If the crowns are fabricated through digital photography to both the patient and the dentists agreed specifications, the technique should be considered viable.

The study design must clearly show that digital photography is an accurate way in which reproducible results are achieved with all-ceramic restorations, despite the variables that can cause a restoration to be clinically unacceptable. By testing the communicability of a simple technique such as digital photographs of prepared discoloured substrates with the necessary shade tabs in comparison to a written single stump shade guide choice, the quality and accuracy of the crowns produced by the laboratory technician can be evaluated. Both the clinicians trained eye and the perceivability of each individual patient, will influence more clinicians to adapt their clinical practice.

DSLR cameras are multifunctional in dentistry. They can record videos of patients facial and oral movements and provide portrait photos of patients for profile evaluations and smile designs. The various lenses also allow for macro imaging, which captures high resolution pictures of pre-, mid- and post-treatment dentition (Joseph et al., 2018). All of these functions are references for the treating clinician, the patient and the laboratory technician. By further investigating the communicative abilities of digital imaging in restorative procedures, an improvement in the outcome of more complex treatments may be achieved.

In 2010, Chu, Trushkowsky and Paravina stated that a successful all-ceramic restoration is based upon the correct management of the tooth substrate and restorative material. The final shade of the product will not match the initial shade that was taken by the dentist, unless the substrate shade is successfully communicated to the ceramist. They also concluded that ‘color communication is best performed using reference photography with reference shade tabs.’

In previous studies, the focus has been on correctly shade matching a crown to the adjacent natural teeth, using the upper right maxillary incisor as a reference, as it is the most mesial and the largest of the anterior teeth. However, the final restoration must effectively mask the underlying tooth substrate, whilst also appearing life-like, in order for the shade selection of the final value to have proved successful. Hence, the proposed shift in focus, from the adjacent teeth, to the tooth substrate. A satisfactory result will only occur through effective laboratory colour communication. Hence, this study aims to further develop the shade taking

process and see it through to the final clinical appointment, so that a full protocol can be written up, in order to improve the success that clinicians have with aesthetic restorations.

This study proposal will compare two different methods for communicating the shade of the stump of the tooth that is being restored. The laboratory will receive two different sets of data, so that two crowns will be made based on the allocated communicative form. The patients will not have to accept an inferior product, they will have the choice of which crown they have cemented, and their choice will be documented and compared with the clinician's choice of restoration. The outcome measures are based on patients and clinician's preference. It has been noted that individual perceivability and acceptability will play a role in the decision making.

As a result of the study design being a non-randomised controlled trial, the outcome measure statistics may be called in question. Any trial that isn't randomized is extremely vulnerable to both selection bias, information bias and confounding (Tanaka, Tanaka and Kawakami, 2015). However, it would not be appropriate from a clinical, ethical or legal point of view to deprive the participants of a superior clinical outcome, if they were to be randomized into two groups. Due to these concerns around trial conduction, a statement and checklist was published in 2004 by the Trend Group (Des Jarlais, Lyles and Crepaz, 2004). This set of documents acknowledges the pitfalls of non-randomization and seeks to highlight the advantages of making non-randomized trial results part of the evidence-based approach. This way of thinking brought experienced researchers together to formulate a type-specific checklist for those looking to study certain protocols where randomization was not an option. By utilizing this material in finalizing the methodology of the proposed trial, the risk of unwanted bias will be minimalized, and the quality of trial reporting will be satisfactory.

Conclusion

In summary, both patients' growing perception and the clinical presentation of tooth discolouration, are enough of an issue to warrant a dental clinician's attention. Evidence-based dentistry is now widely accepted and encouraged by both dental regulators and educators; therefore, once the weaknesses of a particular protocol have been established, it makes sense to either try to modify or completely change it.

Consequently, after appraising the studies mentioned earlier, the idea that digital imaging not only provides a more accurate shade match than a traditional shade guide, but also communicates the final shade as well as the complex stump shade simultaneously to the lab, means that the potential of this new protocol is worth investigating.

Selecting participants from a population in a primary care setting and integrating the study into day-to-day NHS care, means that the protocol that is produced by this study will be economical and time sensitive. Most importantly though, this adaptation of shade selection can be adopted by both national health and private dentists.

Study design and methodology

Trial Design

The CONSORT 2010 Checklist of information to include when reporting a randomised trial was used to create a comprehensive study design and a detailed but achievable and applicable methodology (Consort-statement.org, 2010). This chapter was further refined by The TREND Statement, which aids in the transparent reporting of evaluations with nonrandomized trial designs (Cdc.gov, 2018).

The classification of the study design is an experimental, non-randomised trial. Each patient will have two crowns fabricated for them, one aided by digital photography and the other by a stump shade guide shade; hence, the study group and the control group consist of the same patients, who are given a choice as to which crown they prefer in situ.

This quasi-experimental design was selected, as it would not have been clinically appropriate or ethical to prevent patients from having the choice of certain treatment options. Non-randomised clinical trials are often conducted when the efficacy of a protocol or a treatment is being tested. The medical community have long since established the opinion that randomized controlled trials give the most reliable, evidence-based results upon which clinical decision making is founded. This is largely due to their limited bias when compared to other study designs. Whilst this is a concern when randomisation cannot be implemented, the advantages in this proposed approach outweigh the disadvantages. By staging a non-randomized clinical trial, a control measure can be included, which strengthens the primary outcome statistics (Axelrod and Hayward, 2006). More recently, a review was published by Tanaka, Tanaka and Kawakami (2015), which stated that if a strict management protocol was followed in order to minimize bias, study designs such as this one could effectively confirm the efficacy of a protocol and evaluate its post-marketing safety.

Study Setting

The practice where the patients will be recruited and the clinicians will be asked to choose between the fabricated crowns is situated in Carterton, Oxfordshire. It is a mixed primary care practice, with two NHS dentists, five private dentists and three hygienists.

Two laboratories will be used to fabricate the crowns (see appendix 6), despite the practice being in a primary care setting, as NHS patients are routinely offered both NHS and private options. By using a private lab and a mixed lab, several technicians working to various standards with different levels of experience, to further test the reproducibility and reliability of the methods. This approach eliminates bias and reflects the general situation in mixed practices across the UK. The first is Swift Dental in Bolton, who will be sent NHS work. It is the largest dental laboratory in the UK with over 300 employed technicians across 4 departments. The second lab is Jon Davies' Dental Laboratory in Newbury. This establishment is privately owned by Jon Davies himself, who still works as the head technician. The lab will only work on a private basis, but Jon and his team are very experienced and take an interest in minute details.

Study Staff

- Principle investigator: head of the trial, responsible for checking participant eligibility, recruitment, clinical work and overseeing the ethical and safety measures during the trial.
- Principle Investigator's Administrators'/Nurses: two nurses that work in the primary care setting with the primary investigator and will be responsible for handling the laboratory work, collecting the consent forms and appointment booking.
- Randomly allocated dental technicians in both laboratories: responsible for fabricating their allocated crown(s) in accordance with the principle investigators instructions.
- One primary care dentist (NHS based) and five private dentists, with backgrounds in oral surgery, endodontics, implantology, sedation and general dentistry: anonymous participants in the secondary outcome questionnaire.

Sampling frame

The proposed study population is the NHS patient list presided over by the primary investigator at Burford Road Dental Practice. Currently there are 4427 patients in total on this list. Any patients who are seen by the primary investigators' colleagues at the practice, who meet the eligibility criteria and are willing to be internally referred for the purpose of the trial, must also be considered within the sampling frame. The combined number of potentially

eligible patients from the performers lists is 6001. This number was obtained by asking the dental software company to run a custom search with the following criteria:

- Patients aged 18-99 years old
- Excluding pregnant or breast-feeding mothers

It has been previously mentioned in the literature review that an exact figure in a specified timescale wasn't readily available and an approximation of 1-2 patients per week was made. In order to further validate the suggested figures, another search was also carried out on the NHS contract periods (April-March) for the last three years. From 2016-2018 a mean number of 59 crowns were placed per year, which approximates to one crown a week. A list of patients was then drawn up so that the justification of crown placement could be divulged. Of the 157 patients listed, an extremely high percentage appear to have suffered from substrate discolouration, just as they did in the O Gbadebo and Mojirade Ajayi study (2015).
A sample of 10% (16 crowns) from the list of patients was randomly selected and the PI checked the history of each individual tooth. In total, 69% of teeth were non-vital and 94% of teeth had previously been filled more than once before being crowned. In light of this, it would be reasonable to say that the vast majority of patients presenting at the practice with a clinical reason for crown placement would also present with a discoloured substrate.

Based on these figures, the sample size calculation requires the study to recruit 25 participants to the trial (calculation provided in sample size section). On average the PI sees 4 patients each month who might be eligible for the trial. Of those patients, it is anticipated that 75% will consent to participate. Therefore, it will take approximately 8-9 months to recruit sufficient participants to the trial.

Participant recruitment

For clarity on the timeline and appointment schedule of the proposed study, please see Table 1-2. The appointments have been ordered from v0-v5 and throughout this chapter the numbers are used to aid the reader in understanding the process of the study.

v0: Patients attending routine appointments and who have one or more anterior teeth that are discoloured or multicoloured and require an indirect restoration will be given the clinically

appropriate treatment options. If they decide to have all-ceramic restorations, they will then be approached by any one of the trial clinicians and informed about the trial. If a patient is eligible to participate (tested against criteria described below) and they have consented to the proposed treatment plan after receiving the various treatment options, they will be informed of that the practice is recruiting for the trial by either the PI or one of the trial administrators. If the patient is interested they will be invited to discuss the participant information sheet (PIS) and consent form (see Appendix 3-4). The patient will have time to ask questions and to take the PIS home to review and decide.

v1: A signed copy of the consent form will be obtained at the next appointment before any treatment is undertaken. This second appointment is a short one, but it is a vital part of the informed consent process. Although the patient may have already voiced their chosen treatment options and verbally shown interest in the trial, they must be allowed a cooling-off period, as well as time to reflect on the financial implications of their choice. They may also return with further questions about the treatment which could potentially sway their choice completely and render them ineligible. This confirmation appointment will minimize the amount of trial dropouts and ensure the patients have fully understood their role as well as their treatment options.

Eligibility criteria

The eligibility criteria for recruitment of participants are listed below:

- the participant is not currently enrolled in any other study that may affect the outcome of the proposed study
- the participant is above 18 years of age
- the participant is not classed as a vulnerable adult and is not known to lack the capacity to make an informed decision
- the participant is a regular attender at the dental practice
- the participant does not have active periodontal disease at the time of recruitment
- the participant has one or more anterior teeth that are discoloured or multicoloured and require an indirect restoration
- Teeth adjacent to the restorations(s) are healthy and an acceptable colour to the patient (whitening is not required to reach a different shade before treatment commences)

- the participant is not currently undergoing dental treatment such as orthodontics or tooth whitening

Withdrawal criteria

The following withdrawal criteria will ensure that ethical considerations for the patients remain a priority:

- If the patient becomes ill during the trial and cannot attend during the specified data collection period.
- If a restoration is found to be clinically unacceptable: the completely wrong colour, poor margins, poor aesthetics that aren't related to the colour, poor occlusion, poor anatomy, poor seating upon the tooth substrate or missing in the post.
- The patient wishes to withdraw from the trial.

	STUDY PERIOD					
	v0: Examination	**v1: Recruitment**	**v2: Shade Selection**	**v3: 1st Outcome**	**v4: 2nd Outcome**	**v5: Data Analysis**
TIMELINE	***01-09/2020***	**01-09/2020**	***02-10/2020***	***02-10/2020***	***10/2020***	***10-11/2020***
ENROLMENT:						
Treatment Options	X					
Eligibility	X					
PIS & Consent Forms	X					
Treatment Selection & Signed Forms		X				
INTERVENTIONS:						
Digital Images			X			
Stump Shade Guide			X			
OUTCOMES:						
Patients' Crown Choice				X		
Clinicians' Crown Choice					X	
Results						X

Table 1: Spirit Statement Figure (example dates) (Spirit-statement.org, 2013)

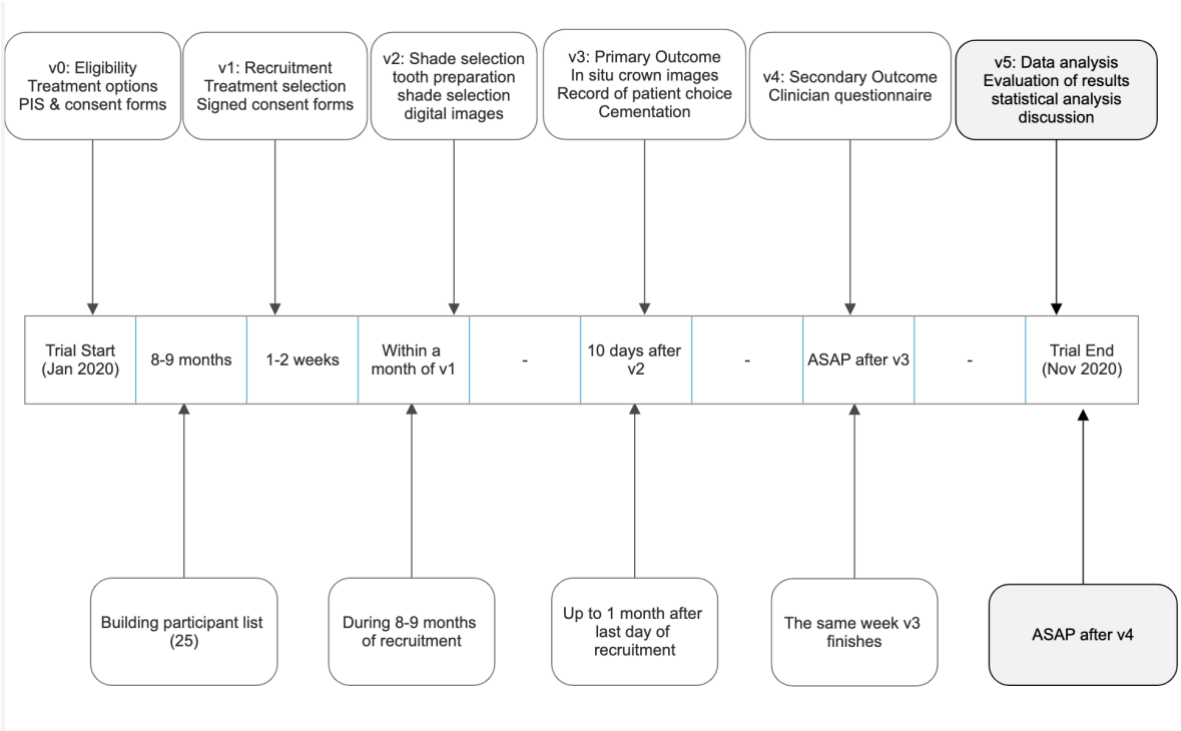


Table 2: Study timeline diagram (example dates)

Interventions

Treatment options:

1. Crown fabrication using shade matching with 1-3 shade tabs and detailed digital photographs each prepared tooth along with the adjacent teeth
2. Crown fabrication using a traditional stump shade guide shade

Intervention Protocol

Pre-intervention Protocol

V2: As the first part of the trial (V0), patients presenting with discoloured or multicoloured anterior tooth substrates that require crowns are asked to participate in the trial. Photographic consent and trial participation forms are signed after the patients have read and understood the patient information sheet (V1) (see appendix 2-4). Preoperative photographs are taken on an OLYMPUS OM-D EM10 Mark II Camera with an OLYMPUS M.ZUIKO 60mm f/2.8 Macro Lens and an OLYMPUS STF-8 Macro Flash. The flash is set at 1:1, the exposure at F22, the shutter speed at 1/200 and the ISO at 100 and the distance from the

patients' teeth was between 20-40cm (Sharland and Mackenzie, 2015). The previous restorations are then removed (if the teeth have had previous indirect restorations) or fresh tooth substrate is prepared.

Digital Image Protocol

v2: Further detailed photographs are taken of each stump with 1-3 matching shade tabs for both the stump shades and the final shade (Ivoclar shade guide which both labs use). Silicone impressions of the upper and lower tooth arches, along with a silicone bite are taken. In the postal parcel, one set of impressions, along with laboratory instructions of an accompanying email with digital images are sent to the corresponding laboratory (private or NHS).

Stump Shade Guide Protocol

v2: During the same tooth preparation appointment, a single stump shade from the shade guide (one per tooth) and a final shade from the Ivoclar shade guide are taken and recorded on the lab docket (see appendices 8-9). A second set of silicone impressions are sent to the lab, completely separate from the those related to the digital images, with a different patient code and in a different box, to ensure a separate technician will work on them.

Lab Protocol

The technicians are asked to fabricate single or multiple all-ceramic crowns to a final shade, with the information provided. A lab docket will be filled in (see appendix 8) with the patient's code and their required restoration (all-ceramic crown). The following individual information will also be recorded:

- The photographic crown lab dockets will state the final shade required and a note to look out for an accompanying email containing the digital images. The email will be labelled as the patients' code so there is no confusion.
- The stump shade crown lab dockets will state the final shade required and the stump shade.

Fit appointment

Participants return to the practice for appointment v3. The crowns will have been sent back to the practice and each set of crowns is tried in one after the other and photographed. The nurse will randomly open one of the lab bags and document whether it is PC or SC. The crown will be given to the dentist to try in and photograph using the camera settings mentioned above. The patient will choose the restoration(s) they prefer, and those that are selected will be cemented.

Outcomes

v3: Primary Outcome: The patients' choice of crown when viewed in situ pre-cementation.
v4: Secondary Outcome: The clinicians' choice of crown pre-cementation when compared side-by-side through digital photography.

Outcome measurement

v3-v4: Every patient's choice of crown will be recorded in a case report document (see appendix 7), just as each clinicians' questionnaire shall be collected and the type of crown that gets the most votes by the patients, by the clinicians and collectively shall be calculated.

v3: The main outcome is the patient's choice of crown. As the patient will be able to try-in both the photographic crown and the stump shade crown and view them both in the mirror and on a screen (iPad) after digital photographs have been taken. They will be allowed to decide which one they keep, and have it cemented in. As patient satisfaction is the highest priority, this has been listed as the primary outcome. In order to avoid bias, the crowns will be randomly presented to the patients and only the trial nurse will be aware of which crown she is handing the dentist to try-in and photograph. The results will be recorded in the case report file by the nurse as the cementation takes place and the PI will be informed after each treatment has been completed.

v4: As a secondary outcome, six trained clinicians will be asked which of the fabrication methods has better shade matching ability, as per photographic images of the crowns in situ.

This stage of the trial will be conducted once all the participants have completed their treatments. The practice clinicians will be asked one-by-one, to take the questionnaire on an iPad, during practice hours, in a well-lit surgery. They will be shown the photos of the pairs of crowns in a slide show and will be asked whether they prefer Crown A or Crown B for the shade match (see appendix 5).

Randomisation

A sequence of randomisation is not applicable in this study as there is only one study group. This does put the study at risk of bias; hence the following steps have been taken to ensure that the risk is minimal:

- The lab work will be labelled so that the principal investigator and the two nurses involved can identify the work as follows:
  Patient Initials - Patient date of birth - Photographic crown(PC)/stump shade crown(SC). For example: AD - 27061989 - PC
  (The code was taken from the idea presented by the University of Manchester, on how to keep case study patients anonymous).
- The participants are to be recruited and enrolled by the principal investigator. At this time, each participant will be allocated a code which will be modified into two sub codes (PC/S2) during the preparation phase.
- The lab technicians will not be aware of the significance of the code and neither will the patients. It will not be visible at any time to the clinicians who are to take part in the questionnaire.
- The code will be written only on the lab docket and won't be visible to the patients, as the lab dockets get folded inwards, to ensure anonymity.
- During the try-in process, the nurse present will be responsible for opening the lab work and making sure the crowns are not mixed up.
- The nurse will be asked to randomly offer the dentist a crown to try in and photograph and will only tell the dentist which crown the patient chose once the protocol is completed and the patient has left the room.

- Immediately after the fit appointment, the dentist will upload the photos to a cloud-based storage system into files labelled with the sub codes. This will prevent any mix up with the photos of the specifically fabricated crowns.
- The principal investigator will then take the best photo from each file and pair it with a photo from its opposing sub coded file. In the top right-hand corner of each individual crown image, the letter A or B will be printed.
- These comparative digital image files will form a slide show that the clinicians will utilize for the questionnaire.

Blinding

- Participants: will be blinded to the fabrication method of their crowns during the try-in and which crown they selected for cementation. The crowns will be kept in their individual lab bags and taken out and replaced one by one so that there is no mix up between the photographic crowns and the stump shade crowns.
- Laboratory Technicians: will be blinded to the fact that another crown is going to be made using different information.

  Where the laboratory is concerned, the protocol must be maintained, so that the lab technicians remain blinded and do not have access to both sets of instructions that could aid them in their crown fabrication.

  As the one of the labs is based in Bolton and the practice is based in Carterton, observing the laboratory technicians won't be possible. However, by sending one parcel of impression and an email with photos in one parcel and a separate parcel with the stump shade, the lab should allocate the work to different technicians, who will be none the wiser.
- Clinicians: will be blinded by not revealing which method was used to fabricate which crown. The crowns in the photos (in situ) will be placed side-by-side and labelled A & B. They will be asked to tick A OR B as their preferred crown in the questionnaire paper. The papers are to be completed anonymously.
- Principal Investigator: Initially, the Principal investigator will be blind to which crown they are placing and photographing, until after the chosen crown has been cemented and the patient has left the surgery. Immediately after, the nurse will make the dentist

aware of which crown is which in order to record the patients and choices, but they will not be aware who filled in which questionnaire with regards to the clinicians.

- Nurses: The nurses are responsible for labelling, sending, receiving and documenting laboratory work. They will be aware of which crown is which so that they are not mixed up and will inform the dentist after the protocol has finished. They will be asked to give out the crowns in no particular order, so that there is no bias in the order that the patients see their work in situ.

Safety considerations

The proposed trial is classed as Non-CTIMP (Clinical Trial involving an Investigational Medicinal Product) (Assets.publishing.service.gov.uk, 2006). However, as the trial involves human subjects, as well as questionnaires for quantative analysis (see appendix 5), it is subject to the Good Clinical Practice (GCP) Guidelines, developed by the NHS Health Research Authority (HRA) (Maurice and Lepay, 2002).

A data monitoring committee (DMC) will not be appointed, as the trial does not involve subjects who are mentally incapacitated or those with life-threatening diseases. The protocol does not pose a significant risk to the participants and there are no significant unknown or uncertain outcomes.

In line with Good Clinical Practice, any situation which is seen to compromise the safety of anyone involved in the trial, will be reported immediately to the trial sponsor, as well as the local health board (LHB). The document lays out the classification of a serious adverse event (SAE) in paragraph 1.50 and further guidance on safety reporting protocols are found in paragraph 4.11 (Maurice and Lepay, 2002).

Safety reporting guidance has also been published by the Health Research Authority (HRA), specifically on Non-CTIMP trials, stating that only related and unexpected SAE's are to be reported to the Research Ethics Council (REC) (Health Research Authority, n.d.). This means that safety concerns that may arise during the restoration process, such as material allergies or devitalisation of the prepared tooth, which are possible treatment complications, do not need to be reported. However, such situations would render the patient unable to continue as a trial

participant and they would need to be withdrawn. An appropriate assessment of their condition and a new treatment plan would be drawn up and their care would be continued, adjacent to the trial.

A risk management strategy created by the NHS Foundation Trust will be used to risk assess the proposed procedures, before the trial commences, in order to appropriately safeguard the research team (Ouh.nhs.uk, 2015).

Lastly, during the trial, the appropriate quality checks must be carried out, so that the fabricated restorations are not only successful in colour match, but also in fit and function. Despite the fact that the focus is on shade match, a high standard of patient care must be ensured, so no crowns will be included in the trial that aren't fit for purpose.

Data management, quality assurance and statistical analysis

Data Collection

The data that will be collected for the primary and secondary outcomes of the proposed trial is qualitative and nominal in nature.

v0-v1: Data will initially be collected from patients once they have satisfied the eligibility criteria and signed the appropriate consent forms. This will consist of a case report form (see appendix 7) filled in by the PI or the trial administrator that is present. The form will firstly have the codes used for laboratory work clearly labelled at the top for identification purposes. The initial data collection will comprise of the patients' age and ethnicity, followed by the dates that they have booked in for treatment (see appendix 7).

v2: The second stage of data collection will be during the tooth preparation appointment. The codes and subsequent labs shall be recorded on the case report form and the trial administrator shall update the document as work is sent and received.

v3: At the crown fit appointment, further data shall be collected on the patients crown preference and shall be recorded by the trial administrator, as they alone will know which crown is which, until after the appointment has ended.

v4: The final data collection will take place when the clinicians are asked to complete a questionnaire, based on a constructed slideshow. All six questionnaires shall be collected in a separate case file, as they formulate the secondary outcome and relate to all patients, rather than a single individual.

Each patient shall have one case report form, which will be a paper copy until their treatment is complete, at which point it will be converted to an electronic file and placed in the Dropbox. The paper copy will then be shredded. Their digital images, which will be taken during the two treatment appointments, will be stored digitally and the case report form will be scanned into the same file once it has been completed.

Data Management

A Dropbox account will be opened specifically for the trial. Dropbox is a secure online storage company, which allows for password protected access on any computer with an internet connection.

Each patient will be allocated a file using their code. The file will comprise of their consent forms, their pre- and post-operative photographs and their completed case report file. A separate file labelled 'Clinicians' will contain the completed clinicians' questionnaires. Only the PI and the trial administrators will have access to the account password.

The PI has previously used the software and will show both the trial administrators how to access the files so that information may be added as per the data collection timeline.

A back up of the files will be kept on the practice hard drive, as they contain patient information that is relevant to the practice. Each participants Dropbox file will be added to their dental records, once the trial is complete. Adult dental records are stored for 11 years, as per the guidelines set out by the Department of Health (Dentalprotection.org, 2017).

Data Entry

The participants' photographs will be uploaded to the computer from the camera immediately after the appointment with the participant by the trial administrator, in order to avoid any mix up of patients. Each photo will be labelled with the participant's code, followed by a subsequent number (1,2,3…) if more than one photo is taken. Within the participants Dropbox file, the files 'Pre-operative' and 'Post-operative' will be created. In the postoperative file, two further files will be made, labelled with the lab work codes of both photographic and stump-shade crowns. The photos, once labelled, will be saved into their appropriate files.

Microsoft Excel will be used to log the incoming data. A file will be opened, and each participant will be allocated a tab, which will be labelled with their patient code. Each time data is added to the patients file it will be logged on the Excel sheet and the trial

administrators' initials will be added next to each entry, so the PI is aware of who has done what.

Checking Data

At the end of each working week where participants have been seen, a trial administrator will be asked to go through the relevant files and check that the data collected has been labelled and stored appropriately. Any errors that cannot be corrected, for example, if photos have gone missing or been mixed up, the participant(s) will need to be withdrawn from the trial, in order to maintain the integrity of the collected data.

In order to prevent unnecessary withdrawals, the trial administrators will be asked to log the changes made to the data. When photographs are transferred and labelled, the initials of the administrator, the date and the file where they were saved will be logged on an excel file, which will be saved in the trial dropbox folder. This log can then be used to audit the historical processing of data.

As all data will be stored digitally, source verification is swiftly done by clicking on the document info and accessing the metadata.

Photo quality is also something that will be reviewed, both before the photos are stored and during auditing. An image may be deemed unacceptable, as it may affect the choices made by the participants or the clinicians if it is of poor quality. This could also have an effect on the outcome of the crowns, as the technician may not be able to determine the exact shade from an over or under exposed image. In such a situation, photographs will either need to be repeated, or the participant will need to be withdrawn from the trial.

Data storage and disposal

Once the trial is complete, each patients file will be transferred from Dropbox to their subsequent practice file. The same will occur with the clinician's questionnaires, as they each

have a patient file at the practice. Once this process is complete, the Dropbox account will be closed.
Individual patient case report forms will be filled in during the recruitment phase and kept in a storage file (the practice still has some secure paper filling cabinets), until their treatment is complete. The case report form, one digitalised, will be destroyed. In summary, all consent forms, case reports, photographs and lab dockets will be digitally uploaded to each participants notes.

Sample Size Calculations

Based on the studies used for critical appraisal in the literature review, it became apparent that a small sample size (<50 participants) would be sufficient, as each study was concluded with significant results with regards to digital imaging. However, as none of these studies relate directly to the methodology of the proposed research, further reading to find a similar methodology and sample size calculation was undertaken.

In 2012, Öngül, Şermet and Balkaya, conducted a similar study where two crowns were fabricated using two different shade guides to determine which was more precise in shade matching. Their sample size calculation was performed using a power analysis, which gave them the number of participants required in order to detect a significant difference between the colour variation of the two shade guides. Since the primary outcome of the trial is the choice the patients' make about the shade match of the photographic and stump-shade crowns, it is logical that the type I and II error probabilities would be the same.

In light of this, a two-sided significance level of 95 and a power of 80 was entered into the sample size calculator. The suggested sample size in order to see 70% of participants choose the photographic crown over the stump-shade crown for a clinically significant result is 25 (see Table 3). It should be noted that as this is a non-randomised trial with only one group of participants, the sample size is halved, as the patients will be asked to choose between the exposed method (digital imaging) and the control method (stump-shade guide). Therefore, in total, 50 crowns will be fabricated as per the sample size calculation, but only 25 participants are required.

The percentage of choice was set so that there would be no doubt clinically that this protocol is one that should be implemented in daily practice. Upon reflection of the statistically analysed findings from the articles chosen for appraisal in the literature review, this percentage is slightly higher, since none of these articles have caused a significant change to the implementation of such protocols in primary dental care. In 2017, Miyajiwala et al., found a frequency of agreement between spectrophotometer readings and digital photographic images in 66% of cases. This finding is coherent with those of Schropp (2009), who on average found that observers could also correctly identify the shade from digital images 66% of the time. The highest percentage came from well-exposed photographs (70%) and the lowest from under-exposed photographs (59%). Lastly, in 2013, Vivek et al., found a mean of 58% when observers were asked to identify various shade from digital imaging.

Providing that the digital images that are taken in the proposed study are well-exposed, the added detail they provide should enable the lab technician to create a superior product, which will lead to a vast majority of patients and clinicians finding the photographic crowns preferable.

Sample Size:X-Sectional, Cohort, & Randomized Clinical Trials	
Two-sided significance level(1-alpha):	95
Power(1-beta, % chance of detecting):	80
Ratio of sample size, Unexposed/Exposed:	1
Percent of Unexposed with Outcome:	30
Percent of Exposed with Outcome:	70
Odds Ratio:	5.4
Risk/Prevalence Ratio:	2.3
Risk/Prevalence difference:	40

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	25	24	29
Sample Size-Nonexposed	25	24	29
Total sample size:	50	48	58

References

Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15
Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19
CC = continuity correction
Results are rounded up to the nearest integer.
Print from the browser menu or select, copy, and paste to other programs.

Results from OpenEpi, Version 3, open source calculator--SSCohort
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Table 3: Sample Size Calculation (Dean, Sullivan and Soe, 2013)

Null and Alternative Hypotheses

Null Hypotheses (H0): There is no statistically significant difference between the shade selection method of the crown that the patient prefers in situ.

Alternative Hypotheses: (H1): There is a statistically significant difference between the shade selection method of the crown that the patient prefers in situ.

Statistical Analysis

The primary outcome will be examined first, followed by the secondary outcome. Once these data sets have been analysed through their chosen tests and the results have been scrutinised, they will then be further compared to see whether there is a significant difference in the crown choices made by the patients and the clinicians. This last test, if proved statistically significant, would also be of great clinical importance; daily practice protocol would certainly need amending in order to compensate for such different views.

Baseline Characteristics

Data to be collected during the trial is listed in table 3.

Variable	Data Type	Data Categories
Gender	Nominal	Male or Female
Age	Continuous	18-99
Ethnicity	Nominal	White, Mixed, Asian, Black, Other
Participant Crown Choice	Nominal	A or B
Clinician Crown Choice	Nominal	A or B

Table 4: Data collection variables

The central tendency for nominal data is the mode. In this instance, the mode would be the letter A or B. However, as the letters are randomly allocated to the two crowns based on the order which they were presented to the patient by the trial administrator and not so that PC=A and SC=B (this is also continued in the slide show for the clinicians), the mode is not relevant. If, however, the mode was observed by converting A and B into their subsequent crown code PC vs. SC, then the mode would be a qualitative analysis, resulting in the most selected crown, either photographic or stump-shade, respectively. Hence, when reviewing both the patient and clinicians' choices, the type of crown that is predominantly selected, is the mode.

With regards to the dispersion of the data, the frequency distribution is appropriate, in order to record the frequency in which each crown was selected. The following table illustrates how the data may be grouped:

Crown	Frequency	Percent
PC	18.0	70%
SC	7.0	30%

Table 5: Frequency Distribution Example

The proportion of the chosen crowns can also be calculated. Based on the frequency (see Table 4 – target results used as an example), it can be approximated that 70% of patient's prefer a PC crown, which results in a proportion fraction of 7/10 (see Table 5).

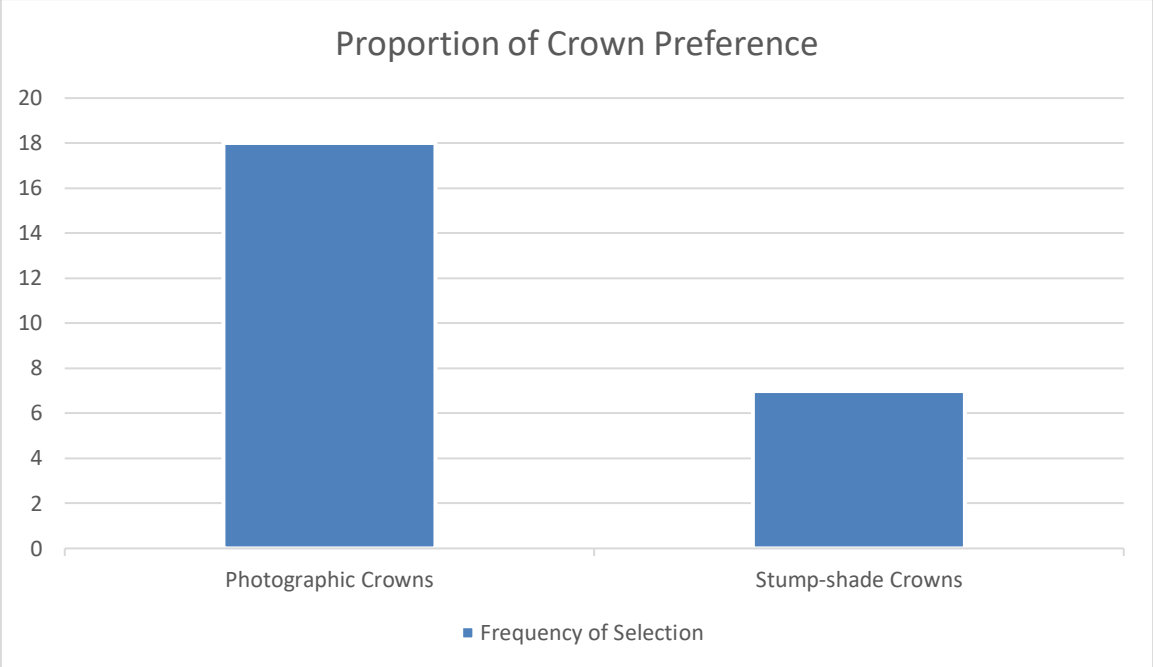


Table 6: Proportion of Crown Preference

Lastly, the crown choices will be presented against the patients' gender, age and ethnicity to see if there is a marked difference in preference (see tables 7-9). Chi square tests will also be used to determine the significance of these variables (see table 10).

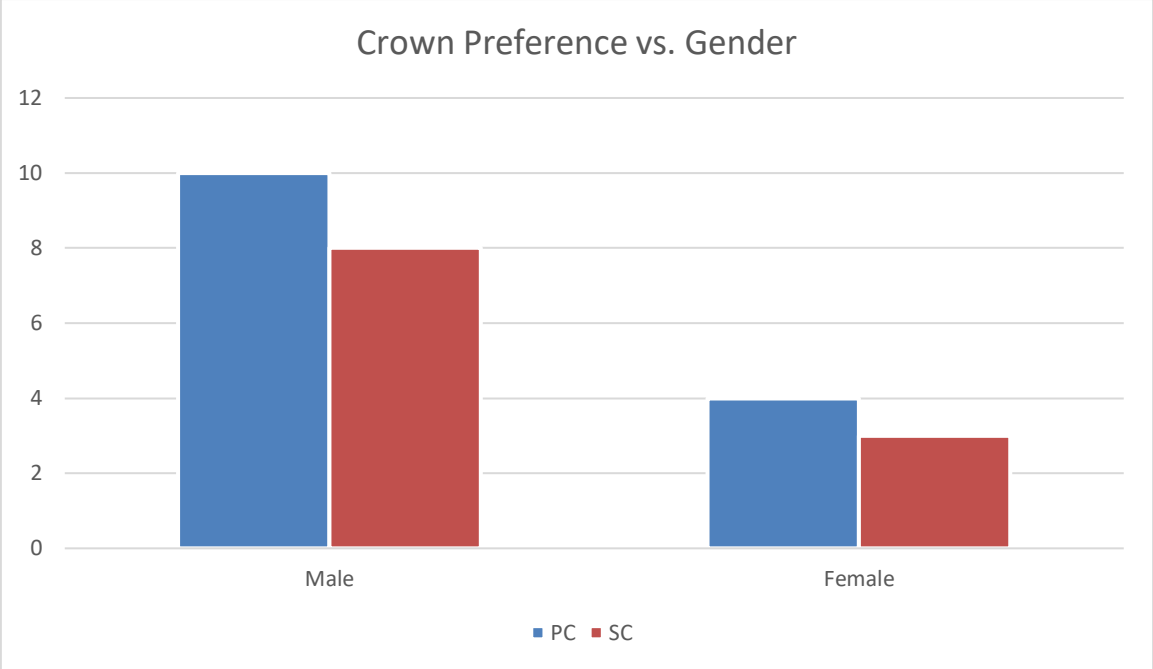


Table 7: Crown Preference vs. Gender (Example Figures)

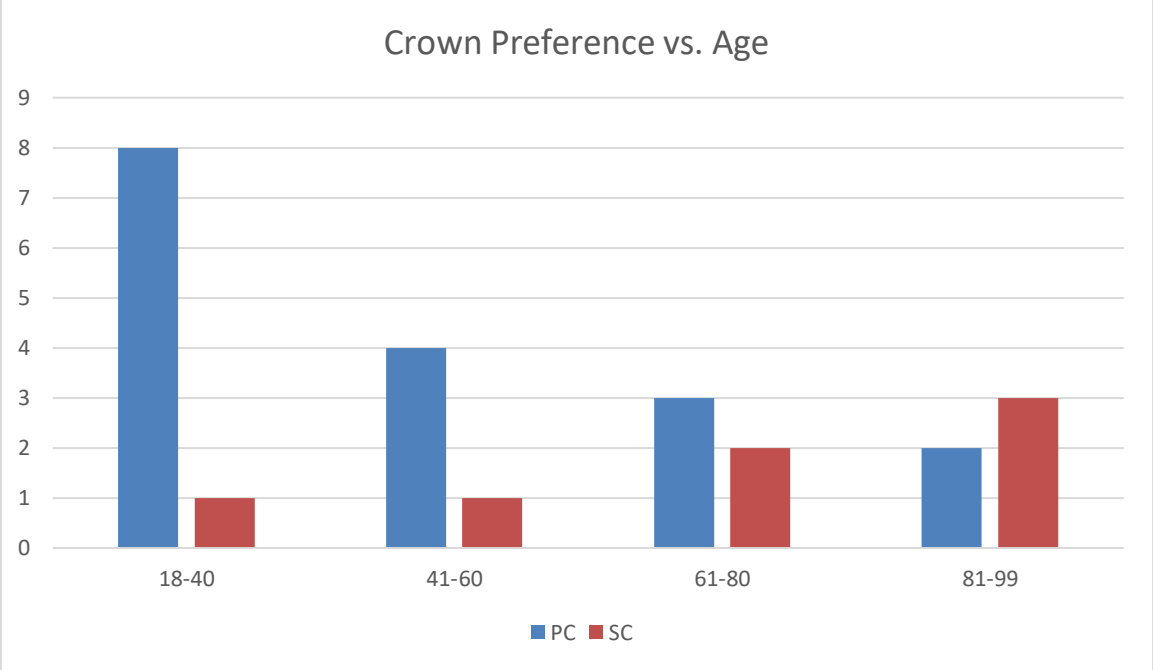


Table 8: Crown Preference vs. Age (Example Figures)

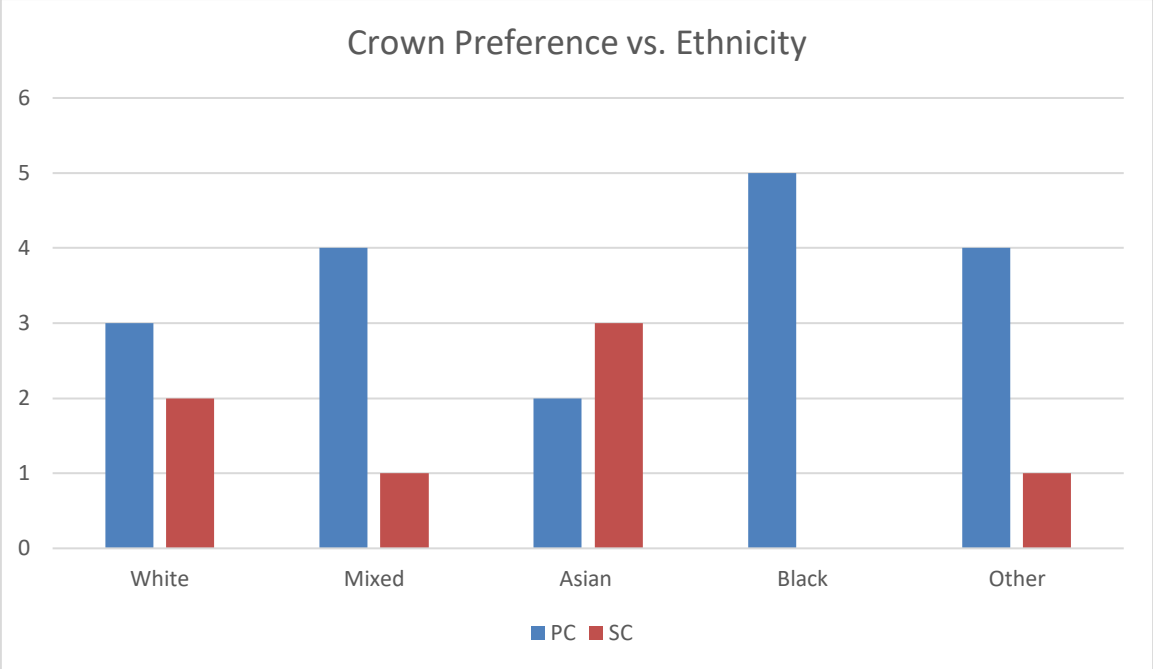


Table 9: Crown Preference vs. Ethnicity (Example Figures)

Analysis of primary outcome

The proposed study is looking for differences in crown selection based on shade matching protocols. The patients' choice of crown is classed as a single nominal dependant variable. The patients' choice is a single independent variable with two conditions (a photographic crown and a stump-shade crown). Each of the participants is asked to choose a crown which renders the data collected as an independent measure. In this instance, either the Chi-squared test or the Fischer's exact test could be used. Upon further examination, the Chi-squared test appears to calculate the significant difference between the expected frequency of choice of a particular crown and the actual selection frequency (En.m.wikipedia.org, n.d.).

PC

	Observed N	Expected N	Residual
.00	8	15.5	-7.5
1.00	23	15.5	7.5
Total	31		

SC

	Observed N	Expected N	Residual
.00	23	15.5	7.5
1.00	8	15.5	-7.5
Total	31		

Test Statistics

	PC	SC
Chi-Square	7.258[a]	7.258[a]
df	1	1
Asymp. Sig.	.007	.007

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 15.5.

Table 10: Chi-squared test (Example Figures)

Analysis of secondary outcome

The tests required to analyse the results from the clinician's questionnaires are the same ones that will be used for the analysis of the primary outcome. This is due to the fact that the clinicians are still a group of individual participants who are being asked to choose between the same crowns (albeit through a digital slide show) (See Table 10).

Comparison of primary and secondary outcome

When comparing the primary and secondary outcome data, which is considered as ordered categorical data (Crown A or Crown B), the Boxplot or a Cross-tabulation of ordered categories and the Mann-Whitney U test were suggested. Of the three tests, a Cross-tabulation is able to compare the choices of the clinicians and the participants (Ibm.com, n.d.).

	Crown Choice		Total
	PC	SC	
Participants	X	Y	25
Expected Count	18	7	25
Clinicians	X	Y	6
Expected Count	5	1	6
Total	XX	YY	31
Expected Count	23	8	31

Table 11: Cross-tabulation of results (Example Figures)

Clinical Implications

The reliability of shade-selection whilst utilizing digital imaging is not in question in this study. Its focus is the development of a superior shade selection protocol that is simple and quick enough to use in a primary care setting. As many more dentists today invest in DSLR cameras and smart phones, if the null hypothesis is rejected, a statistically significant majority of photographic crown selection, would render such a protocol as a necessity. With this in mind, further research would need to be done into the effect of cementation and the potential shade alteration that some dental cements may cause.

Having said this, if the colour variation between the two final crowns is not perceivable by the majority of patients; regardless of whether it is or not with the clinicians, the practice of sending photographic images to the lab still holds clinical significance. Whilst the colour match may be acceptable despite a slight difference, the details of the soft tissues, the buccal surfaces of the teeth and their anatomical outlines are far clearer than on a gypsum cast.

As a final note on this particular topic, it is possible that the clinicians crown choices may significantly differ from those of the patients due to the fact that the clinicians are seeing the crown from a different perspective with a trained eye. If such a scenario was to occur, further research into the difference of opinion could optimize clinical efficiency and patient satisfaction. In the meantime, ethically and professionally, patients are entitled to their autonomy, hence their choice of crown has become the primary outcome. In light of this, a

discussion before cementation should ensue, especially if there is a difference of opinion, albeit in a way that doesn't undermine the patient or their wishes.

If the null hypothesis is accepted, photography will still continue to play a major role in dentistry. Today's youth, including newly qualified dentists, are a generation of social media users. Communication, personal/professional expression and verification through publicized photography is what captivates young people.

Ethical considerations

In order to conduct the study in a way that aligns with modern scientific moral principles, the concordat to support research integrity (Hale et al., 2012), Best Practice (Health Research Authority, 2016) and ICH Guidelines (Ich.org, 1996) were used to design the study and to create patient information sheets and consent forms.

Ethical Approval

The study proposal will be submitted to the Research Ethics Committee for approval before any part of the study is undertaken. This will ensure that the principal investigator's endeavours to cover all legal and ethical aspects of the trial have been successful. It has been deemed necessary that ethical approval is required, as per the Health Research Authority guidelines (Health Research Authority, n.d.). Each stage of the process has been examined against the relevant guidelines, to make sure that all considerations with regards to safety, ethics, the law and bias have been addressed.

Study Justification

The proposed research will improve the protocol of shade selection, which in turn will improve the quality of the aesthetics of anterior all-ceramic restorations within a primary care setting. The benefit is that patients will receive a natural looking crown that blends into their dentition, regardless of the colour of their underlying tooth substrate.

The Research Team

The principal investigator is currently progressing through the final module of the MSc and has passed the relevant courses needed in order to undertake such study (see Appendix 10). The trial administrators are both qualified dental nurses that are used to the procedures used for crown preparation. Adequate training in the trial protocol will be given before the actual trial commences.

Participant Selection

Patients between the ages of 18-99, who are not pregnant or breast feeding and who do not lack mental capacity have been chosen to form the participant group. These particular criteria were selected so that the consent process would be the same for each individual, with no added considerations, such as being underage or needing a guardian's signature. Also, the primary outcome would be subject to bias if there was any doubt about the decision-making skills of the participants. With regards to the clinicians selected for the secondary outcome, they also fit the eligibility criteria for participant recruitment (see eligibility criteria – methodology chapter).

Safety

Participant safety is paramount. In this study, the risk to participants is minimal. Crown preparation is a routine procedure, as is shade selection. The only risks to the patients are those that already exist and are exclusively related to crown preparation, such as loss of vitality, for example. These risks will be explained to the patients before they consent to the treatment and are indeed recruited to the trial (see appendix 4). Where researchers are concerned, there is no added risk to the trial administrators or the principal investigator.

Recruitment

Recruitment of participants will occur in a clinical setting after a patient has agreed upon a treatment plan that is relevant to the proposed research. The patient's eligibility must be cross-checked against each of the criteria, with particular attention being paid to their mental capacity. Other ethical considerations include patient privacy, voluntary participation, clear and accurate information, avoidance of therapeutic misconception and unbiased presentation of the study.

Once full eligibility had been established, the principal investigator will give the patient a verbal explanation of the trial and its importance, whilst also giving the patient the PIS and

consent forms to review in their own time (see appendix 3-4). The patient will then be given a period of time at home to consider their options. If the patient decides to become a trial participant, or has further questions with regards to participation, they can meet with the principal investigator again, before the forms are signed. Only once this has happened will appointments be scheduled, in order to allocate the appropriate amount of time needed in order to complete each stage of the protocol.

Consent

The principle of informed consent is to allow the participant to make an autonomous decision, once they have had ample explanation of their diagnosis and their treatment options, with subsequent risks and benefits. This decision-making process is bilateral, as the clinician must be satisfied that the patient has both the capacity to consent, as well as the understanding to consent.

The principal investigator will be the only research member who will be obtaining informed consent, since the trial administrators do not have sufficient training. As a dentist, the PI is qualified to examine, diagnose and offer treatment options to the patient. Once the patient has made an informed decision about their treatment and subsequently signed off on it, the dentist can then explain about the trial and answer any questions the patient may have. The PI can then obtain further consent for participation in the trial.

At each appointment, the PI will also explain what will occur and obtain further verbal consent, with another member of staff present, to ensure that ongoing consent is provided. This shall be recorded in the clinical notes, just as it is when normal clinical work is undertaken, outside of a research setting. If the trial is subject to changes that may affect the patient, this will need to be discussed, as well ask asking the patient to sign a new consent form, confirming their acknowledgement and acceptance of these changes.

During the initial examination process, the capacity of the patient to consent will be assessed. Their medical history will be reviewed and updated. Patients taking antidepressants, antipsychotics, those suffering from ailments that present with memory loss and those that have difficulty understanding their treatment options will be excluded. Only those who do not

fall into the medical categories mentioned above and who have a sound understanding of their chosen treatment and its implications will be asked to participate.

Data Protection and Publication

Anonymity and confidentiality are vital in dentistry in both research-based and clinical practice. Patients clinical notes are stored securely on cloud-based software, managed by the practice. The PI will also use password protected, cloud-based storage for the trial, as well as the practice software as a back-up. The patient's individual clinical notes will be supplemented with their trial notes, so that if they ever requested a copy, the notes would be comprehensive. During the trial, codes will be used rather than the patient's names, in order to protect their identity.

Auditing will take place weekly to ensure that patient data is being stored accordingly. This task will be undertaken by both the PI and the trial administrators.

The results of the trial, once carried out and completed, would be written up into a research article and sent to various dental publications. Magazines such as the British Dental Journal, may accept it as content in one of their issues, which would circulate the results among the dental community, with the intention of improving daily clinical practice.

Study budget

The study will be undertaken in a primary care setting, where clinical work is paid by the NHS via the Units of Dental Activity (UDA's). The trial protocol will only differ from normal clinical practice with regards to shade taking and the fact that two crowns will be simultaneously fabricated. With these facts in mind, the PI has proposed that the patients pay the standard NHS fee for a crown (band 3 - £269.30) and the dentist receive the UDA value for a band 3 treatment (12 UDA's).

If this suggestion is accepted, the PI will not need to receive an additional research salary, as their primary care income will not be affected. In addition, the practice will continue to pay the two trial administrators an hourly rate (£10.50), which would only need to be supplemented for additional trial work. As a result, the practice itself wouldn't be affected and the NHS contract will continue to run during the course of the trial. Lastly, this approach will mean that equipment, running costs and overheads are already provided for through the contractual agreement the PI has with the practice owners.

Additional considerations that may affect the length of the trial or the time spent with participants, are also covered by the NHS contract. For example, unscheduled patient visits that take up NHS clinical time without increasing the overall profit margin or perhaps render the patient ineligible to participate, are all set out in the claiming rules and regulations.

In summary, this method of conducting the trial is beneficial to the practice, the research team and the patients who attend the practice. The trial administrators would need to be compensated approximately £2200 per annum, for 4 hours trial work per week. The laboratory fees per patient would double to a total of £60 (£200 in the case of private crowns), but as these are absorbed equally by the practice and the dentist, the PI would agree to take responsibility for the lab bills of the 25 proposed participants. The profit margin once the lab bill is deducted, is still over 50% of the allocated UDA value.

Collaboration

- Thames Valley Primary Care Trust: Acknowledgement and acceptance of the trial being held at Burford Road Dental Practice.
- Burford Road Dental Practice: Acknowledgement, acceptance and support of the trial being held at the premises; the acceptance of data being added to the patient's files and the acceptance of staff participation (trial administrators).
- John Davies Dental Laboratory: Agreement to work alongside the principal investigator and fabricate the lab work according to the trial guidelines and instructions.
- Swift Dental Laboratory: Agreement to work alongside the principal investigator and fabricate the lab work according to the trial guidelines and instructions.
- NIHR Involve: To work alongside the INVOLVE team, so that members of the public can be involved in any way possible and the information is accessible to all who show an interest.

Reflection

Conceiving, formulating and finally expressing the proposed research idea for the dissertation module of this MSc has been one of the most challenging, yet enjoyable academic experiences. In order to fulfil the modular requirements, many professional and personal attributes were called upon. Organisational skills, discipline, focus and punctuality were required to deliver the chapters within their allocated time slots. Creativity, patience and perseverance helped cultivate the content.

The experience itself was at times overwhelming, due to the time required to find and process an adequate amount of high-quality information. The literature review was the most difficult chapter in this respect. On the other hand, due to multiple professional and personal commitments, the workload was made a priority and a structured schedule was adhered to. This resulted in feelings of accomplishment and personal satisfaction.

Explaining the rationale behind the trial idea wasn't difficult, however finding similar studies upon which to build a robust case in favour of this experiment was time consuming and at some points, unyielding. Accomplishing this task nurtured several skills such as populating database searches, attempting critical appraisal of previous papers and the ability to observe patterns between trial designs.

Completing this trial proposal has brought about a personal understanding of new limits and abilities. Academic research is not 'rocket science', but a logical and well executed approach to solving a question.

In conclusion, the chosen topic is clinically relevant, and the trial is feasible within a primary care setting. Specifically, the application of knowledge and considerations for a viable protocol, despite the time and budget constraints of the NHS, mean that this study could alter the way all dentists practice, not just those working privately.

Although not all clinical issues need to be resolved in such a rigorous and academic way, this problem-based approach which encompasses safety, ethics and a reproducible methodology, is a crucial exercise for those wishing reach an end result which considers all possible outcomes, any associated risks or benefits and allows for reflection and professional growth.

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Appendices

Appendix 1: Structured Search

<table>
<tr><td colspan="2">1. What is the clinical question?
‘Is digital photography a more communicable approach for stump shade selection, when treatment planning all-ceramic restorations for discolored teeth?’</td></tr>
<tr><td>Population of Interest</td><td>Adult patients undergoing all-ceramic restorations on discolored anterior teeth in a primary care setting.</td></tr>
<tr><td>Intervention of Interest</td><td>Using high definition digital images to convey the correct stump shade to the lab.</td></tr>
<tr><td>Comparison of Interest</td><td>Traditional stump shade guide values.</td></tr>
<tr><td>Outcome of Interest</td><td>A. The crown the patient prefers in situ.
B. The crown the dentists prefer as per photographic images of the crowns in situ.</td></tr>
<tr><td colspan="2">2. Which databases are relevant to your question?
A. Manchester University Library
B. PubMed
C. Science direct</td></tr>
<tr><td colspan="2">3. What search terms will be used?</td></tr>
<tr><td>Population</td><td>Discolored tooth OR discoloured tooth</td></tr>
</table>

AND	
Intervention	Digital Photography
AND	
Comparison	Stump shade
AND	
Outcome	Shade match

4. Are there any limitations?

A. English Language

B. 2009-2019

C. With excessive results the term “AND Dentistry” was added to make sure the articles were relevant or the ‘research article’ box was ticked in order to find the highest quality literature.

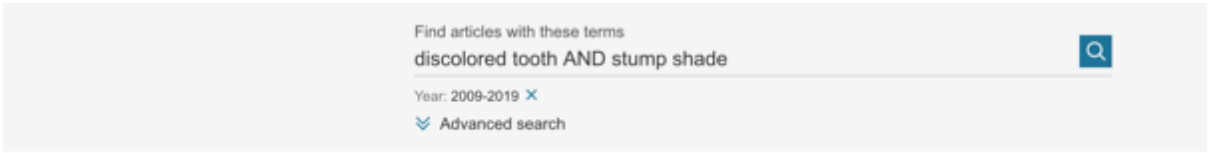
5. Searches (please see screen shots of individual databases below)

A. Discoloured tooth AND stump shade

B. Ceramic restorations AND shade match

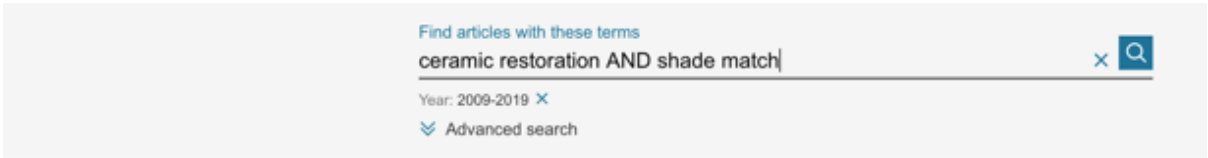
C. Digital photography AND shade match

Science Direct



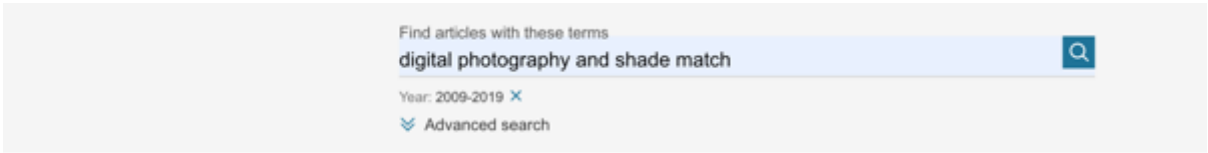
23 results

Download selected articles Export



426 results

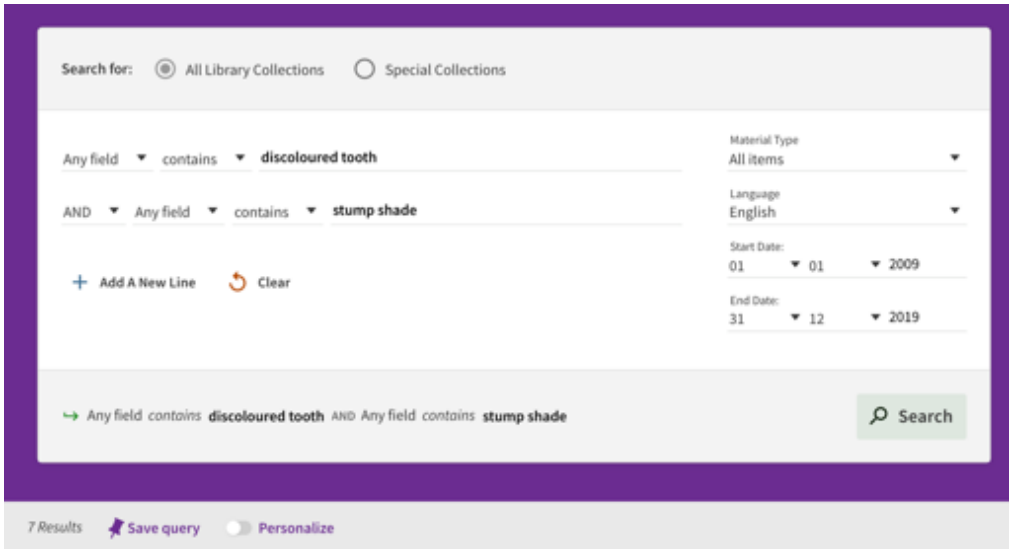
Download selected articles Export

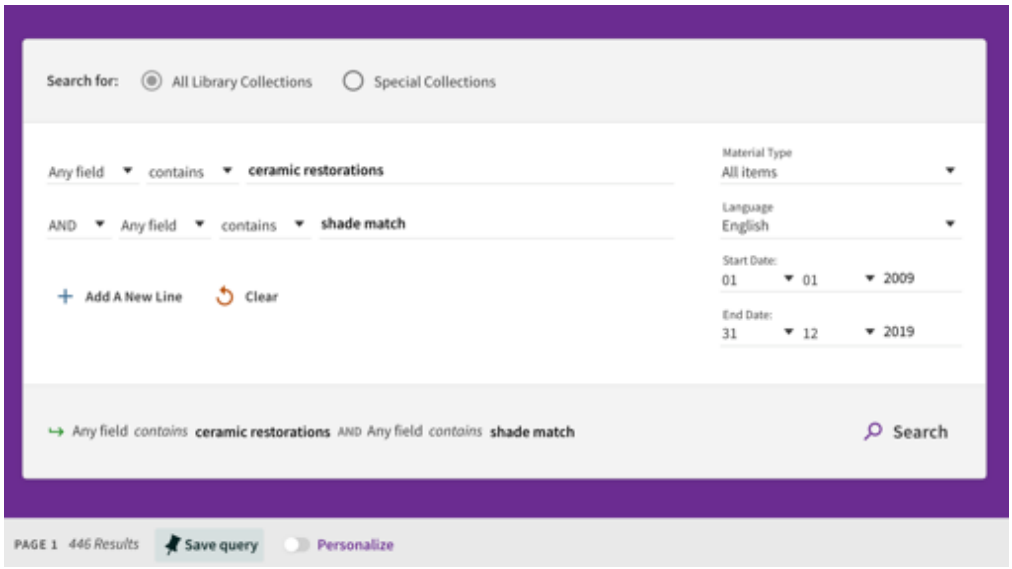


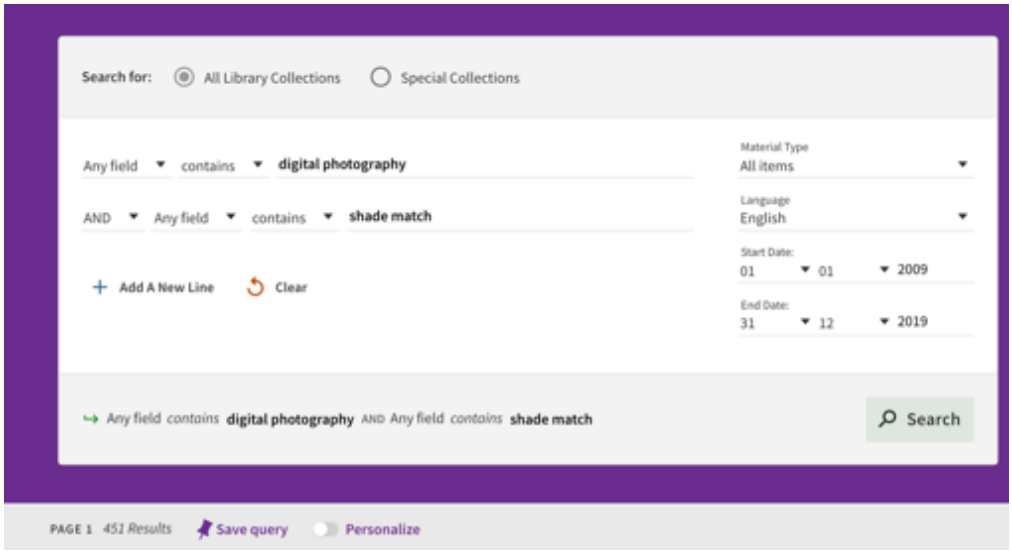
785 results

Download selected articles Export

Manchester University Library







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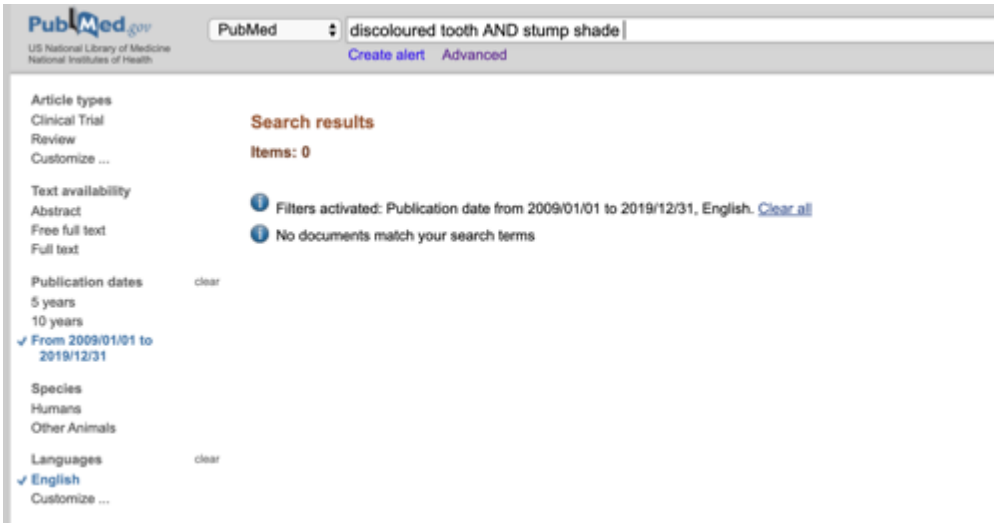
PubMed.gov
US National Library of Medicine
National Institutes of Health
PubMed
discoloured tooth AND stump shade
Create alert
Advanced
Article types
Clinical Trial
Review
Customize ...
Text availability
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Free full text
Full text
Publication dates
clear
5 years
10 years
From 2009/01/01 to 2019/12/31
Species
Humans
Other Animals
Languages
clear
English
Customize ...
Search results
Items: 0
Filters activated: Publication date from 2009/01/01 to 2019/12/31, English. Clear all
No documents match your search terms


Filters activated: Publication date from 2009/01/01 to 2019/12/31, English. Clear all
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27
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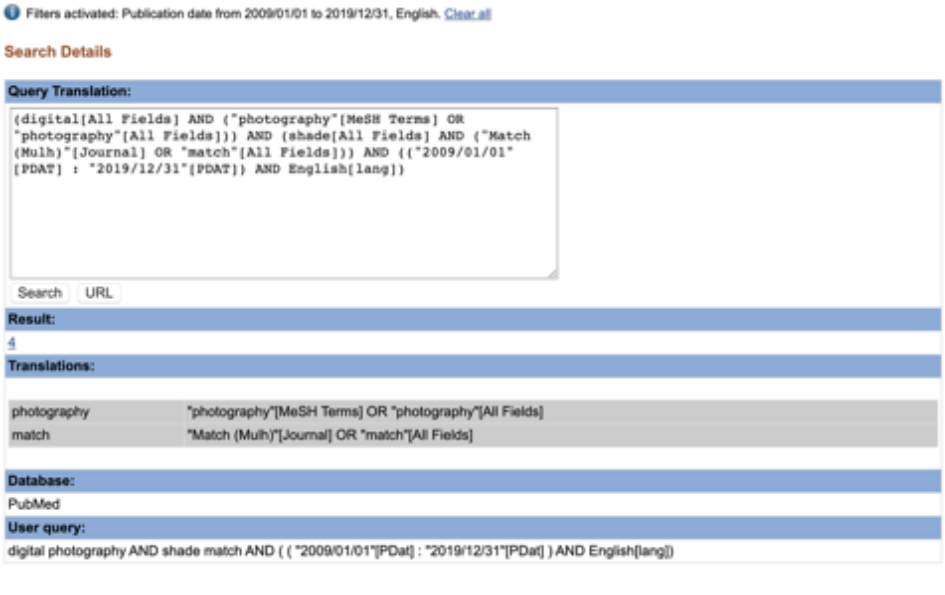
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match "Match (Mulh)"[Journal] OR "match"[All Fields]
Database:
PubMed
User query:
digital photography AND shade match AND (("2009/01/01"[PDat] : "2019/12/31"[PDat]) AND English[lang])

Appendix 2: Digital Image Consent Form

Consent Form

The University of Manchester School of Dentistry and Healthcare Learning Company (Smile-on) Ltd. handles all candidate and patient information in accordance with the Data Protection Act 1998.

PATIENT'S CONSENT

I,_____, understand that _____ is enrolled in the University of Manchester and Healthcare Learning Company (Smile-on) Ltd., Master of science degree in Restorative & Aesthetic Dentistry.

I consent that the anonymised records of my dental treatment, including photographs, radiographs (X-rays) and models of my teeth and jaws will be used for educational purposes.

I consent that in addition to educational purposes, photographic and radiographic images may also be used for publication in a journal, textbook, as part of a display or information leaflet or on a restricted or open access website which may be seen by members of the general public as well as clinical professionals. I understand that it may not be possible for me subsequently to withdraw this consent.

I understand that I am entitled in accordance with current legislation to scrutinise these records, including the case presentations transcribed from the records, and may ask for copies for which the candidate may seek reimbursement of reasonable expenses.

I am over 18 years of age and have been given a copy of this consent form.

Name (print):

Signature:

Date:

Appendix 3: Trial Consent Form

Burford Road Dental Practice

50 Burford Road, Carterton, Oxfordshire, OX18 3AD

01993 842534, Reception@burfordroad.co.uk

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: Is digital photography a more communicable approach for stump shade selection, when treatment planning all-ceramic restorations for discolored teeth?

Name of Researcher: Dr Alexandra Davies

Please initial box

1. I confirm that I have read the information sheet dated XX/XX/20XX (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [Burford Road Dental Practice], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers. ☐
5. I understand that the information held and maintained by Burford Road Dental Practice may be used to help contact me or provide information about my health status. ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Appendix 4: Patient Information Leaflet (PIS)

Burford Road Dental Practice

50 Burford Road, Carterton, Oxfordshire, OX18 3AD

01993 842534, Reception@burfordroad.co.uk

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

PATIENT INFORMATION SHEET v.1

Title of Project: Is digital photography a more communicable approach for stump shade selection, when treatment planning all-ceramic restorations for discolored teeth?

Trial Summary

On behalf of Burford Road Dental Practice, you are invited to participate in a clinical trial that aims to improve the colour match of all-ceramic crowns to a patient's adjacent teeth, through the use of digital photography. If this protocol is successful, it will help other patients who have discoloured teeth and wish to restore them in a natural and aesthetic way.

What's involved?

The dentist will take photographs and analyse the natural colour of your teeth with shade swatches. They will then prepare your teeth for your chosen restorations. During the final appointment, you will be asked to select one of two crowns made for each tooth and your chosen restoration will be cemented in.

Considerations

This study is not suitable for participants that are trying to conceive, are currently pregnant and those who are breast feeding.

Benefits and risks of taking part

The benefit of participation is that you will be allowed to choose which crown you prefer, an offer which is not routinely given to patients, as normally only one crown is fabricated.

There are no added risks to the protocols involved in this trial, only those related to the usual procedures during tooth preparation and placing indirect restorations.

FAQ

- What if something goes wrong?

  Please inform the practice and your dentist will be in contact with you as soon as possible.

- What will happen if I don't want to carry on with the study?

  You may withdraw your consent at any time during the trial.

- How will my information be kept confidential?

  The practice adheres to all current GDPR guidelines and none of your personal data will be passed on to 3rd parties or published.

- What will happen to the results of this study?

  This study may be published in professional dental journals.

- Who is organising and funding this study?

  The study is organised and funded by the principal investigator, Dr Alexandra Davies.

- How have patients and the public been involved in this study?

  The public are not involved in the study, the patients are recruited through the dental practice by the principal investigator.

- Who has reviewed this study?

The University of Manchester have reviewed and approved the study, as it has been written up for the purpose of a master's degree.

- Further information and contact details

  Please contact the practice; the details can be found on page 1 of this information sheet in the top right-hand corner.

- What to expect during the consent process?

  This information sheet as well as a photographic consent form and a trial consent form will be given to you to review. Dr Alexandra Davies will be available for further questions if required and you will be asked to sign both consent forms before any clinical work begins.

- What if relevant new information becomes available?

  You will be informed at the earliest possible convenience and your options will be discussed with you.

- Informing General Practitioner / other healthcare practitioner

  If you are NOT happy for your GP to be informed that you are participating in this trial and for the practice to update them with any necessary information, please let the principal investigator know at your earliest convenience.

- How do I make a complaint?

  If you are unhappy with any of the care that you have received during your participation in this trial, please speak to the principal investigator or contact the practice for a copy of the complaint's procedure.

Appendix 5: Clinicians Questionnaire

Please select the crown that presents a better colour match.

Only put a CROSS in ONE box, A OR B.

Crown Pair	A	B
Example	X	
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		

Appendix 6: Laboratory Participation Sheet

Burford Road Dental Practice

50 Burford Road, Carterton, Oxfordshire, OX18 3AD

01993 842534, Reception@burfordroad.co.uk

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

LABORATORY PARTICIPATION SHEET

Title of Project: Is digital photography a more communicable approach for stump shade selection, when treatment planning all-ceramic restorations for discolored teeth?

To whom it may concern,

I, Dr Alexandra Davies, the principal investigator in the proposed clinical trial mentioned above, wish to inform you that I would like to send work to your laboratory which will be used during the clinical trial.

My focus is on all-ceramic crowns. I will require some crowns to be fabricated with instructions that include the stump shade and the final shade of the crown. Others will include digital photographs of the tooth substrate(s) with adjacent shade tabs and a final shade.

The work will be allocated an ID number to ensure anonymity.

I respectfully ask that your laboratory agree to participate in the trial and allocate these pieces of work randomly, rather than to the same technician.

Yours Sincerely,

Dr Alexandra Davies

Please indicate below with your signature that you agree to participate in the trial:

_____	_____	_____
Name of Participant	Date	Signature

Appendix 7: Case Report Form

Burford Road Dental Practice

50 Burford Road, Carterton, Oxfordshire, OX18 3AD

01993 842534, Reception@burfordroad.co.uk

IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial (PIN):

PATIENT CASE REPORT FORM

Age:

Ethnicity:

Appointment Dates:

Crown of Choice:

Appendix 8: Swift NHS Lab Docket

Crown & Bridge

Lakeside House | Smiths Road | Bolton | BL3 2QJ | 01204 323 323

PORCELAIN BONDED RESTORATION

Dentist & Practice Details

Alexandra Davies
Burford road Dental
50 Burford Road
Camarthen
OX183AD

01993842354

Account No. **DP15797**

Job No.

1867084

1 Details

Patient Name CROWN LAB. CODE

Date Sent

Practice Delivery Date

Note: Work will be delivered between 9:00am and 5:00pm on delivery date

2 Service Level (NHS)

Private | Independent | Standard ✓

Please Note failure to complete steps 1 - 6 will prevent the work from being started. This may cause delays to you.

3 Restoration Type

ZIRCONIA RESTORATIONS
- ✓ Full Form Zirconia Crown / Bridge
- Layered Zirconia Crown / Bridge

PORCELAIN BONDED RESTORATIONS
- Bonded Crown (non precious)
- Bonded Crown (precious)
- Bonded Bridge (non precious)
- Bonded Bridge (precious)
- Maryland (1 pontic 2 wing)
- Maryland (1 pontic 1 wing)

METAL ONLY RESTORATIONS
- Full Shell Crown / Inlay / Onlay (60%)
- Full Shell Crown / Inlay / Onlay (33%)
- Full Shell Crown / Inlay / Onlay (non precious)
- Post & Core (non precious)
- Post & Core (precious)

Precious metal is charged extra

METAL FREE RESTORATIONS
- Composite Inlay / Onlay
- Composite Crown
- Composite Veneer
- Porcelain Veneer
- Porcelain Inlay / Onlay
- Dentine Bonded

PRIVATE ONLY METAL FREE RESTORATIONS
- EMAX Crown / Bridge
- EMAX Inlay / Onlay
- EMAX Veneer

TEMPORARY RESTORATION
- PMMA Crown / Bridge
- Metal Composite Crown / Bridge

4 Shade

FINAL SHADE

ONLY FILLED IN FOR PHOTO. CROWNS SUBSTRATE CROWNS!

5 Instructions

FOR PHOTOGRAPHIC CROWNS:

* PLEASE SEE EMAIL - CROWN LAB CODE USED AS SUBJECT - PHOTOS ATTACHED *

FOR STUMP-SHADE CROWNS:

ONLY STUMP SHADE VALUE IF FINAL SHADE VALUE WILL BE FILLED IN.

18 17 16 15 14 13 12 11 | 21 22 23 24 25 26 27 28
48 47 46 45 44 43 42 41 | 31 32 33 34 35 36 37 38

Stump Shade

Lab Use Only

DR

CR

QC

Promotion ☐

Order Lab Tickets ☐

6 Enclosed qty.

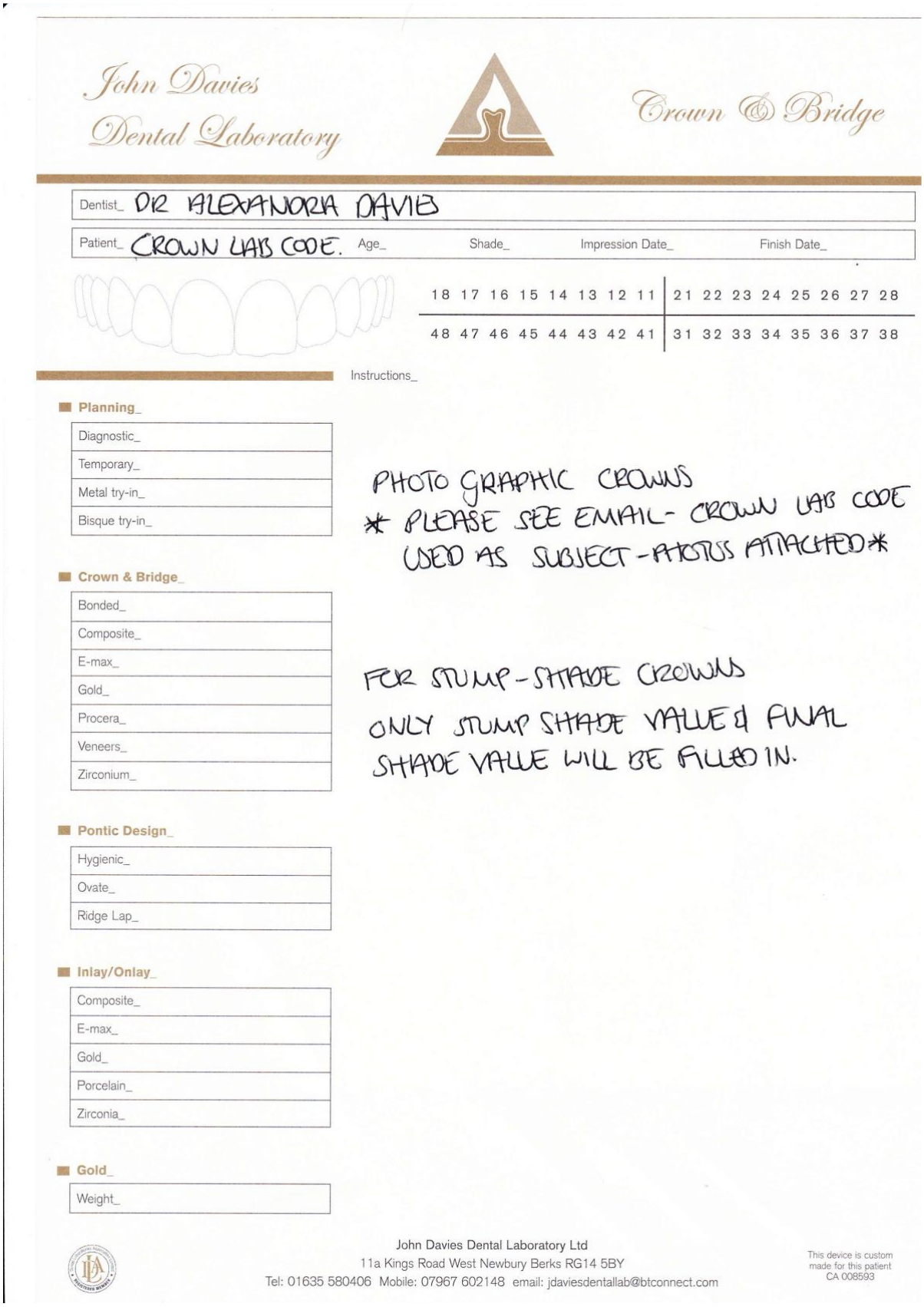
Model ☐ Imps ✓ Bites ✓ Jigs ☐ CD/USB ☐

Other

Please note : Patients should not be booked in on delivery date

This is a custom made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.

Appendix 9: Jon Davies Private Lab Docket



John Davies Dental Laboratory

Crown & Bridge

Dentist_ DR ALEXANDRA DAVIES

Patient_ CROWN LAB CODE. Age_ Shade_ Impression Date_ Finish Date_

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

Instructions_

PHOTO GRAPHIC CROWNS
* PLEASE SEE EMAIL - CROWN LAB CODE USED AS SUBJECT - PHOTOS ATTACHED *

FOR STUMP-SHADE CROWNS
ONLY STUMP SHADE VALUE & FINAL SHADE VALUE WILL BE FILLED IN.

Planning_

- Diagnostic_
- Temporary_
- Metal try-in_
- Bisque try-in_

Crown & Bridge_

- Bonded_
- Composite_
- E-max_
- Gold_
- Procera_
- Veneers_
- Zirconium_

Pontic Design_

- Hygienic_
- Ovate_
- Ridge Lap_

Inlay/Onlay_

- Composite_
- E-max_
- Gold_
- Porcelain_
- Zirconia_

Gold_

- Weight_

John Davies Dental Laboratory Ltd
11a Kings Road West Newbury Berks RG14 5BY
Tel: 01635 580406 Mobile: 07967 602148 email: jdaviesdentallab@btconnect.com

This device is custom made for this patient
CA 008593

Appendix 10: Curriculum Vitae

CURRICULUM VITAE

Name: Dr Alexandra Davies	
Present appointment: *(Job title, department, and organisation.)*	
Associate Dentist (NHS Contract), Burford Road Dental Practice	
Address: *(Full work address.)*	
Burford Road Dental Practice, 50 Burford Road, Carterton, Oxon, OX18 3AD	
Telephone number:	**Email address:**
01993 842534	admin@burfordroad.co.uk
Qualifications:	
DMD (Doctor of Medical Dentistry) – University of Pecs Medical School, 2013 MSc in Restorative and Aesthetic Dentistry – University of Manchester, 2020	
Professional registration: *(Name of body, registration number and date of registration.)*	
General Dental Council, UK 246597, 2013	
Previous and other appointments: *(Include previous appointments in the last 5 years and other current appointments.)*	
Associate Dentist 2019 – Long Hanborough dental Practice, Wootton Dental Centre 2018 – Crendon Dental Centre 2017 – Crescent Dental Centre, Townhill Dental Practice 2016 – Kee Dental Care	
Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*	
2012 – 2013: Dissertation for undergraduate degree (Principal Investigator) 2007 – 2013: Assisted my professors as a native speaker in editing their research so that it would be accepted in various publications	
Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, consent or other training appropriate to non-clinical research. Give the date of the training.)*	
2008 - 2009: Statistics courses during my undergraduate degree in preparation for undertaking a dissertation 2019: Research methods course in preparation for the current dissertation	
Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*	
N/A	
Signature:	**Date:**
Alexandra Davies	3.12.19

Template CV for research applicants
Version 2, January 2007